National Committee on Vital and Health Statistics

Comments Received in Response to Draft Considerations for Review & Discussion for the NCVHS Standards Subcommittee Hearing January 18-19, 2023

Federal Register Notice: 87 FR 65782

Input on Proposals for Updated and New Standards and Operating Rules from X12 and CAQH CORE

Received as of January 26, 2023*

#	Organization	Signatory
1	ADA	Dr. Stacey Gardner Chair, Dental Content Committee
2	AdvaMed	Richard Price, Senior Vice President Payment & Health Care Delivery Policy and Head of Research
3	Advocate Aurora Health	Katie Akemann Director, Revenue Cycle Business Support
4	AHA	Michael Schiller, CMRP Senior Director, Supply Chain
5	AHA	Terrence Cunningham Director, Administrative Simplification Policy
6	AHIP	Danielle A. Lloyd Senior Vice President, Private Market Innovations & Quality Initiatives
7	AIDC Members	Mike and Jeff Nolan AIDC100 members LUC members
8	Alaska Neurology Center, LLC	Amberly Hobbs, MBA Practice Manager
9	AMA	James L. Madara, MD CEO and Executive Vice President
10	Aspen Dental Management, Inc	Margaret Schuler Senior Vice President, Practice Support Operations and Revenue Cycle Management
11	Athenahealth	Nora Iluri Vice President, Revenue Cycle & Practice Management
12	Austin Palliative Care, Austin TX	Desiree Tyrpak Director of Provider Services
13	BCBS of Michigan	
14	BCBS of North Carolina	Emily Brannen, Vice President Digital Strategy
15	Beesleys Point Familty Practice	Jerry A. Horowitz, D.O.
16	Borough of Runnemede, NJ	Shelley Streahle, CFO
17	Boston Hernia - 1	Lauren Ott, PA-C
18	Boston Hernia - 2	Lauren Ott, PA-C
19	Boston Hernia-3	Michael Reinhorn MD, MBA, FACS Associate Clinical Professor in Surgery Tufts University

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20	Centene Corporation	Anika Gardenhire Chief Digital Officer
21	Coalition of State Rheumatology Organizations	Gary R. Feldman, MD, FACR, President Madelaine A. Feldman, MD, FACR Past President and Vice President, Advocacy & Government Affairs
22	Colon-Rectal Surgery Associates, PC, Aiken SC	Domingo D. Price Practice Administator
23	Cooperative Exchange-1	Pam Grosze, Board Chair, Cooperative Exchange, Vice President, Senior Product Manager, PNC Healthcare
24	Cooperative Exchange-2	Mike Denison Industry Affairs Committee Chair, Cooperative Exchange
25	EMG Laboratory Lawrence, MA	Dr. Drasko Simovic EMG Laboratory
26	ENTACC of Chester County-PennMedicine	Deanna DiMascio, MBA Practice Administrator
27	Fire Department City of Wildwood, NJ	Ernie Troiano, III
28	Geisinger	Jove Graham, PhD Associate Professor
29	Geisinger Health Plan	Bret Yarczower MD, MBA Senior Medical Director Chair of Technology Assessment
30	Geneva Eye Clinic, Geneva IL	Jojy Schless, MSW, MSM Director of Operations
31	Hampton Roads ENT-Allergy	Sharon Marcum, COPM Practice Manager
32	HHS Food and Drug Administration	The FDA UDI Team On behalf of Center for Devices and Radiological Health
33	HL7 International	Charles Jaffe, MD, PhD, Chief Executive Officer Andrew Truscott, Chair, Board of Directors
34	Jopari Solutions	Sherry Wilson Executive Vice President and Chief Compliance Officer
35	Joseph Drozda, MD	Joseph P. Drozda, Jr., M.D. Researcher Emeritus, Mercy, Chesterfield, MO
36	Kidney Specialist, Inc	Sarah Coffmon, CMPE, CPC-A Practice Manager
37	Kidney Specialists of South Texas, PA	Monica Hansen, BBA, CMPE Administrator
38	Krupka-Weissman	Dan C. Krupka, PhD, Managing Principal, Twin Peaks Group, LLC Joel S. Weissman, PhD, Deputy Director and Chief Scientific Officer of the Center for Surgery and Public Health at Brigham and Women's Hospital in Boston, and Professor of Surgery in Health Policy at Harvard Medical School

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40	Labcorp	Gheisha-Ly Rosario Díaz, Esq. RCM HealthCare Standards Compliance Program Administrator
41	Loren Wissner Green, MD	Loren Wissner Green, MD
42	Maine Comprehensive Pain Management, PC	Dr. Terence K. Gray President and Founder
43	Medical Society of the County of Kings The Academy of Medicine of Brooklyn	Jagdish K. Gupta, MD, President Sherman Dunn, DO, Chairman, Board of Trustees
44	Medtronic	Christine M. Jackson, J.D. Vice President, Global Health Policy
45	Michael Reinhorn, MD	Michael Reinhorn MD
46	Midland Inpatient Medical Associates, Midland TX	Steve Olive, Executive Director Midland Health Group Management Premier Family Care 1, Inc
47	Midwest Ear Nose & Throat LLC	Rhonda Wild Medical Office Administrator
48	Ming Lei	Ming Lei
49	Montefiore Care Management	John Williford Vice President Population Health Vice President and Chief Operating Officer
50	Nachimson Advisors LLC	Stanley Nachimson, Principal, Nachimson Advisors LLC
51	National Association of Health Data Organizations (NAHDO)	Norman K Thurston, Ph.D. Executive Director
52	National Council for Prescription Drug Programs, Inc. (NCPDP)	Lee Ann C. Stember President & CEO
53	National Uniform Billing Committee	Terrence Cunningham Chair, NUBC
54	National Uniform Claim Committee	Nancy Spector Chair, NUCC
55	New York Urology Specialists	Alex Shteynshlyuger MD Director of Urology
56	NewLife OBGYN	Lisa Eng, DO, FACOG
57	Peerless Pediatrics	Stephanie Sanderson MD
58	Peerless Pediatrics Cleveland TN	Cathy Faulkner, FACMPE Administrator
59	Pinnacle ENT Associates, LLC Wayne, PA - Penn Medicine	Kim Steffenhagen, CPC, CEMC, COPM Central Billing Liaison

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60	Point32Health	Michael S. Sherman, MD, MBA, MS Chief Medical Officer
61	Premier, Inc.	Soumi Saha, PharmD, JD Senior Vice President of Government Affairs
62	Quail Creek ENT, Amarillo TX	Roger Puckett, CPA Administrator, Quail Creek ENT
63	Rajesh Kakani, MD	Rajesh S. Kakani, MD, FACS President, Long Island Society of Otolaryngology-Head and Neck Surgery Fellow, American Academy of Otolaryngology- Head and Neck Surgery Fellow, American Academy of Otolaryngic Allergy
64	Robert Weiser, MD	Robert Weiser, MD
65	Rogue Valley Physicians, PC	Alicia Myrick Administrator
66	San San Wynn, MD	San San Wynn, MD Hematologist/Oncologist
67	St. Joseph Health New Jersey	Linda Reed, RN, MBA, CHCIO, FCHIME Sr. Vice President and Chief Information Officer
68	Stephen Danziger	Stephen Danziger
69	Sunrise Urology, PC, Gilbert, AZ	John C. Lin, MD
70	Symmetric Health Solutions, LLC	Terrie L. Reed, MSc Chief Strategy Officer
71	Texas Medical Association	Gary W. Floyd, MD President
72	U.S. Congress	Elizabeth Warren, United State Senator Charles E. Grassley, United State Senator Bill Pascrell, Jr., Member of Congress
73	United Health Group	Christopher Carlson Senior Vice President – Provider Digital Transformation UnitedHealthcare
74	United Medical Care, LLC Pemroke, MA	Jean-Pierre M. Geagea, MD, FACC Interventional and General Cardiology
75	WEDI	Nancy Spector Chair, Board of Directors
76	Women's Care of Wisconsin	Natasha Frahm Director of Operations
77	Yuehuei An, MD	Yuehuei An, MD Orthopaedic Surgeon (Board Certified) and Hand Surgeon Yuehuei An Orthopaedics PC Associate Professor of Orthopaedic Surgery Zucker School of Medicine, Hofstra University
78	Zhang Medical Associates, Foxboro, MA	Jie Zhang
79	Template Submission #1	# identical responses submitted using this template
80	Template Submission #2	# identical responses submitted using this template
81	Template Submission #3	# identical responses submitted using this template
Newly Added Submissions		

#	Organization	Signatory
82	HL7 International	Charles Jaffe, MD, PhD, Chief Executive Officer Andrew Truscott, Chair, Board of Directors
83	Aetna	Scott Waller Vice President, Information Technology
84	Symmetric Health Solutions, LLC	Terrie L. Reed, MSc Chief Strategy Officer

*** This compilation includes 3 new additional submissions since the January 3rd version previously posted**

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December 15, 2022

Jacki Monson, JD
Chair, National Committee on Vital and Health Statistics
c/o Rebecca Hines
NCVHS Executive Secretary
3311 Toledo Road
Hyattsville, MD 20782

Via: NCVHSmail@cdc.org

RE: Request for Public Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules

Dear Ms. Monson,

The Dental Content Committee of the American Dental Association (DeCC), a named Designated Standards Maintenance Organization under the Health insurance Portability and Accountability Act (HIPAA) in § 162.910(a) welcomes this opportunity to provide feedback on the NCHVS Request for Comment Proposals for Updates to X12 Transactions and New and Updated and CORE Operating Rules.

The individual organizations represented on the Dental Content Committee have not pursued analysis of the cost impact of the X12 version 8020 claims and remittance advice transactions, nor conducted an operation assessment or workflow analysis. However, there is consensus that the updated version will offer a net positive value.

DeCC members have actively participated in X12 meetings and contributed to the development of the updated versions and are supportive of its adoption.

We strongly support concurrent use of the version 5010 and version 8020. We recognize that concurrent versions will increase implementation costs and demands on operations however, the DeCC believes this to be an essential period of transition and the benefit outweighs the cost. The DeCC supports a two-year time frame for the transition upon publication of the Final Rule. Should this occur we ask X12 work with DeCC to address the administrative burden that the 5010 version continues to create for all dental stakeholders and their patients for payment, treatment, and healthcare operations. Dental implementers are eager to work with X12 to improve the adoption of X12 transactions across provider-to-payer HIPAA transactions for dental covered entities and their business associates. This would include recommendations from work that is currently progressing within our standards community.

We would encourage NCVHS to consider avoiding a January 1 go live date, as it would create even greater burden on the payers as a significant portion of the dental contracts, including Federal and State sponsored programs, are on a calendar benefit year. The months leading into and following January are equally as difficult and suggest adjusting the go live date to June/July.

Furthermore, we support efforts to allow access to the materials for review (via X12 Glass) through federal funding. There is precedence for this type of financial support as it was offered during the adoption of version 5010.

The DeCC appreciates the opportunity to participate in these hearings and present our recommendations on the current change request process and ways to improve its efficiency and effectiveness. The introduction of operating rules into the administrative requirements will be a significant change for the industry. We are pleased to see NCVHS playing a central role in the development of processes to coordinate the development of standards and operating rules. I will be happy to answer your questions now and the DeCC looks forward to continuing to be a part of this conversation in the future.

The DeCC appreciated the opportunity to comment on this request for public comment. If you have any questions, please contact Rebekah Fiehn, Director, Coding and Dental Data Exchange, at fiehnr@ada.org.

Sincerely,

/s/
Dr. Stacey Gardner
Chair, Dental Content Committee

cc: Dental Content Committee

AdvaMed
Advanced Medical Technology Association

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December 15, 2022

National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Via email: NCVHSmail@cdc.gov

Re: RFC on X12 and CAQH CORE Proposals

Dear Committee Members:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am writing to express our opposition to a recommendation from X12 to add the Device Identifier (DI) portion of a medical device's Unique Device Identification (UDI) to the proposed new version 8020 claim transaction. While we strongly support efforts to reduce existing obstacles to the adequate identification of medical devices, we do not support adding this information to the claims submissions. We believe a superior alternative exists for enhancing patient safety in the use of high-risk medical devices through the inclusion of UDI in electronic health records (EHRs).

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies.

There are many positive benefits of a UDI system once fully implemented, including:

- Facilitating more accurate reporting, reviewing, and analyzing of post-market device data by providing a standard and clear way to document device use in electronic health records, clinical information systems, and registries;
- Generating post-market data that could be used to support premarket approval or clearance of new devices and new uses of currently marketed devices;
- Providing a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion, and prepare for medical emergencies; and
- Aiding in the development of an internationally harmonized medical device identification system.

AdvaMed has worked extensively with the Food and Drug Administration (FDA) to help maximize the usefulness and value of the UDI system as a post-market tool and to lessen the implementation burdens on industry and the broader healthcare ecosystem. AdvaMed remains committed to working with FDA, hospitals, physicians, and other stakeholders to move forward

in implementing an effective UDI system that takes into account the diversity of medical devices and provides information useful to understanding their post-market performance.

Adding devices' UDI or DI to claims submissions ignores existing tracking, registry, and other post-market data collection requirements already in place for implants. FDA's rules, for example, require implant manufacturers to track devices through the chain of distribution and to the patient to enable manufacturers to promptly locate devices in commercial distribution. Tracking information may be used to facilitate notifications and recalls ordered by FDA in the case of serious risks to health presented by the devices. Similarly, many implantables are subject to a device registry. If the stated goal of adding DI to claims submissions is to improve post-market surveillance, other avenues exist to do this, which would not open the door for purposes beyond the scope of patient safety. These approaches also are far superior to claims in that they can be real-time and allow for much faster identification and response. In addition, tracking information from claims will not be current, given delays of processing and reporting information from health plans. Claims tracking will be dated, incomplete, and a highly ineffective and costly tool for surveillance or tracking medical device safety.

We further note that the claims transactions are used for the express purpose of paying for health care services, and current coding systems provide sufficient information to identify procedures involving medical devices for the purposes of reimbursement under existing commercial and public health care payment systems. Adding UDI information to a claims form will not provide a complete understanding and evaluation of device performance.

Moreover, X12 has proposed to NCVHS that only the DI portion of the device's UDI be added to the institutional and professional claims submissions with the stated goal of improving post-market surveillance for certain medical devices. We, however, argue that the DI portion of a UDI represents an extremely limited data set of the underlying product. In particular, the DI represents only the manufacturer name and device model. More detailed information such as expiration date or serial number is contained in the production identifier (PI) portion of the UDI. We point out that FDA's medical device reporting requirements require both the DI and PI information for the device to ensure the data set can be fully evaluated and understood. Capturing only a device's DI would not provide sufficient information and could result in wrong conclusions about the nature of an emerging problem. Furthermore, DI information in the claims transaction would not provide a clear picture on the condition of the patient and ultimate benefit of a device to the patient's quality of life and whether the device is the source of a problem.

AdvaMed does believe, however, that adding UDI information in EHRs would facilitate more accurate reporting, review, and analysis of post-market data for medical devices. We support inclusion of UDI information in the EHR as a way to increase the availability of UDI information to health care providers involved in the treatment of a patient as well as to strengthen the reliability of the information for the patient's implantable device(s).

Capturing UDI within the EHR would overcome many of the limitations that would exist if this information is contained within a claims database that is not accessible to physicians and other health care providers caring for patients. Patients change commercial insurance plans relatively frequently and no legal obligation exists for a plan to maintain contact with a formerly insured individual. In contrast, the portability of a patient's EHR is key as it ensures that the information stays with the patient, regardless of any health plan enrollment changes. In the EHR, the information will provide a more complete and accurate understanding of a patient's clinical history to draw appropriate and objective conclusions about the impact of a device on care outcomes. In addition, it would serve as a more robust post-market surveillance tool and would improve coordination among doctors and support medical decision-making.

Beyond our concerns about the value of including DI in the version 8020 claims transaction, AdvaMed is also concerned about the cost impact, including provider burden, this recommendation will have on the health care system. We respectfully request that NCVHS explain to the public why these costs should be incurred, especially after CMS and HHS in the past have estimated that these will be very significant.

In 2015, then-CMS Administrator, Marilyn Tavenner, enumerated these in a letter to Senators Warren and Grassley:

- Including UDIs on claims would entail significant technological challenges, costs, and risks to normal claims processing for Medicare and other payers
- All HIPAA covered entities (e.g., health plans, health care providers, and clearinghouses use a standardized claim format adopted by the Secretary and known as the 837 and can only require information to be reported on claims that is consistent with that form. Altering the 837 would involve a lengthy multi-stepped process.
- Changing the claim format to include UDI would also require substantial, expensive, and time-consuming changes to claims process systems and claims warehouses for **all** health plans, providers, clearinghouses, and vendors and business associates.
- Retrofitting Medicare's legacy claims systems to accommodate UDI reporting would require extensive programming changes and claims edits that could negatively impact the processing time and adjudication of more than 1.2 billion claims that Medicare annually process.
- The claims form update from version 4010 to version 5010 took 5 years, at a total combined cost to CMS for Medicare and Medicaid of $700 million, with other payers bearing additional costs.
- Information reported on claims needs to be verified to ensure that it is valid. Collecting UDIs on claims would be prone to errors because there are an estimated 300,000 UDIs for high-risk implantable medical devices, multiple UDIs may need to be reported on a claim.
- Developing, applying, and continually updating claims edits for either UDI or DI would be expensed and challenging and will add substantial ongoing costs to all stakeholders.

A year later in a letter to the same Senators, the Secretary of HHS, Sylvia Burwell, provided another cost estimate for including the DI portion of the UDI on the claims form. She indicated that the initial cost for CMS to implement an updated claims form that collects the DI for implantable devices for Medicare fee-for service patients would be approximately $300 million. This estimate, however, would not include annual out-year Medicare costs or the costs to State governments to implement the updated claim transaction in their Medicaid claims processing systems. Nor did it include costs that would be incurred by private health plans and other stakeholders for including DI on claims. We should note, however, that the cost estimate did deter the Secretary from supporting the proposal to include DI on the version 8020 claims transaction. That is the principal reason for asking NCVHS to assess costs of the recommendation on DI and to share that information with stakeholders.

AdvaMed appreciates the opportunity to offer these comments to NCVHS as it considers proposed changes to the version 8020 claims transaction. As we explain above, we believe that the EHR is a more appropriate focus for collecting UDI information. To that end, we believe that the Office of the National Coordinator for Health Information Technology (ONC) and CMS should be working together with EHR vendors to create efficient mechanisms and tools for collecting and incorporating UDI into the EHR. We also believe that this strategy will minimize the significant new costs a revised claims system would incur by incorporating UDI or DI into the claims form.

If you have any questions, please contact Richard Price at rprice@advamed.org.

Sincerely yours,

Richard Price, Senior Vice President
Payment & Health Care Delivery Policy and Head of Research

From: Akemann, Katie
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Thursday, December 8, 2022 1:20:16 PM
Attachments: i

Advocate Aurora Health would like to provide feedback on the recommendations. We would ask that a three year timeline be implemented as our EHR, Epic, does not currently support the proposed framework changes/recommendations. This would allow time for any necessary development and implementation.

Thank you,

Katie Akemann
Director, Revenue Cycle Business Support

Assistant: Stacie Kaminski

From: Schiller, Mike
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Tuesday, December 13, 2022 11:05:55 AM

Response to:
National Committee on Vital and Health Statistics
Request for Public Comment on
Proposal for Updates to X-12 Transactions and New and Updated CORE Operating Rules

The American Hospital Association's professional membership group, Association for Health Care Resource & Materials Management (AHRMM), sponsors the Learning Unique Device Identifier (UDI) Community (LUC). The LUC is comprised of physicians, clinicians, hospital supply chain professionals, manufacturers, distributors, software application providers, health care consultants and representatives from Group Purchasing Organizations (GPOs), GS1, HIBCC, HIDA and the FDA. The mission of the LUC is to enhance patient safety and improve supply chain efficiency by developing recommended practices that speed the adoption and maximize the utilization of the UDI.

We appreciate the opportunity to provide the following comments related to NCVHS's question "**Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction."**

We strongly support the value inclusion of the UDI-DI in claims data makes to medical device research. Limiting analysis of medical devices to what information is captured in an individual health care organization's Electronic Health Record (EHR) does not provide a sufficient data pool or the comprehensive information necessary to do comparative research. Patients often seek treatment from multiple health care providers and information about real world device performance can only be obtained by including the UDI-DI for implantable devices in claims data.

Because drug and vaccine information are contained in claims data and have been used by medical researchers to create a robust objective pool of information, health care providers are better able to determine the optimal care for a specific patient's condition. Such research improves patient safety and outcomes as well as lowering medical costs. The lack of post-market research based on real world outcomes for medical devices leaves providers dependent upon marketing information and very limited clinical research to inform their decision making. The FDA requires manufactures to prove their devices are safe but does not necessarily require manufacturers to prove how they compare to other forms of treatment, e.g., answering the questions as to how coils, clips and stents compare when treating brain aneurysms. Including the UDI-DI for implantable devices in claims data would positively facilitate this type of research.

Including the UDI-DI for implantable devices in claims data is the next logical step in achieving the UDI's potential. The original vision was that a unique number (UDI) would allow a medical device to be tracked from production through utilization, that it would enhance patient safety by facilitating the recall process and improve patient outcomes by enabling post-market surveillance that incorporated real world evidence. Additionally, the UDI would improve supply chain efficacy and

reduce cost.

Significant progress has been made since the initial UDI regulations were implemented nearly a decade ago. Manufacturers have invested significant time and money to include the UDI on product labels and populate the Global UDI Database (GUDID) with key data attributes. Electronic Health Record (EHR) providers (large and small) have designed systems that meet ONC requirements including the ability to capture, parse and report the UDI. Hospital and manufacturer's business systems (Enterprise Resource Planning – ERP) can now capture, store, and conduct Electronic Data Interchange (EDI) transactions using the UDI. The ability for hospitals to scan barcoded UDI information directly into EHR systems at the point of care has expanded from a limited number of large health care systems to medium and in some cases small organizations. North Country Healthcare, a rural system in New Hampshire, is a good example of how health care providers are collaborating with their IT partners to maximize the use of the UDI.

The patient safety and economic return on the investments that have been made across the health care supply chain will be further enhanced by the information that will be gleaned from the inclusion of the UDI for implantable devices in claims data. *For these reasons, we strongly advocate for the addition of the UDI to claims data.*

Sincerely,

Michael Schiller, CMRP
Senior Director, Supply Chain
American Hospital Association
Association for Health Care Resource & Materials Management

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December 15, 2022

Jackie Monson, JD
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CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Dear Ms. Monson:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, the American Hospital Association (AHA) is writing to provide comments in response to the National Council for Vital and Health Statistics (NCVHS) Standards Subcommittee Request for Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules. The AHA appreciates NCVHS's efforts to solicit industry feedback and for the opportunity to provide comments.

The AHA commends NCVHS's efforts to collaborate with industry stakeholders to improve the standards and operating rules development, adoption, and implementation processes. Additionally, we appreciate the work of X12 and CAQH CORE in developing the recommended updated transactions and operating rules for industry consideration. We offer the following comments regarding each organization's recommendations:

X12 Version 8020 837I and 8020 835 Transactions

Costs and Operational Impact

To date, the AHA has not conducted a complete and thorough cost/benefit analysis on implementation of the updated X12 version 8020 claims transaction, as conducting such a test at this time would be resource intense, difficult, and potentially inaccurate or misinformed without additional information.

Gathering the granular, specific information to conduct a cost/benefit analysis requires a significant amount of resources. Stakeholders would need to project the specific ways in

which a new standard would require systematic changes and corresponding workflow adjustments. The effort requires significant time to identify all the changes necessary in each entity's systems, determine how to capture and handle the new data, and change business rules. Additionally, stakeholders would need to estimate the anticipated efficiencies and reduced burden that would be realized due to improved transactional capabilities. Stakeholders are unlikely to conduct such a thorough analysis at this stage, as the transaction has yet to be recommended to the Secretary and may be subject to change prior to its listing in a notice for proposed rulemaking (NPRM), particularly since X12 does not recommend implementation of the 8020 standard, but rather the version of the standard that has been most recently completed prior to the NPRM release date.

Prior to adoption of a new X12 version, the AHA urges X12 to conduct robust pilot testing to ensure that the updated transactions will function properly and that the proposed revisions will increase efficiencies and improve business functions. Such testing will help identify the potential return on investment for hospitals and other stakeholders, enable accurate cost analysis, and reveal the benefits of adopting the revised version. This undertaking of thorough testing should not be underestimated and must be balanced against the anticipated benefits of the new version.

We highlight that the transition from the 4010 to 5010 standard represented significant costs to all industry stakeholders when implementing an updated version of standards, and we have no reason to believe the transition from 5010 to 8020 would be any different. Concurrently, since the onset of the COVID-19 pandemic in March 2020, our hospitals and health systems have coped with intense staffing and financial pressures.[1] Since March 2020, hospital expenses have increased significantly. For example, 2022 expenses are projected to represent an increase of nearly $135 billion over 2021. Moreover, labor expenses are projected to increase by $86 billion. Undertaking a significant IT transition at this time without adequately delineating and quantifying its benefit and savings potential would likely have a profound financial toll on hospitals already struggling to care for their communities.

Further underscoring the need for robust cost benefit analysis and subsequent testing is the need to avoid claim and remittance transmission disruptions, especially at a time when many of the nation's largest health insurers are billions of dollars behind on payments to hospitals and providers.[2]

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[1] https://www.aha.org/system/files/media/file/2022/09/The-Current-State-of-Hospital-Finances-Fall-2022-Update-KaufmanHall.pdf

[2] https://khn.org/news/article/anthem-united-major-insurers-behind-on-payments-billions-owed-hospitals-doctors-covid/

Importantly, the AHA believes a significant unanswered factor in the cost analysis is whether more than one version of the standards will be allowable and/or required. Should stakeholders be required to support multiple versions simultaneously, tools and framework for supporting the versions will increase substantially even if the overlap is for an industry-defined short time period. Additionally, we note that requiring support for multiple versions at once would result in additional administrative costs on providers and would increase reliance on clearinghouses for claims payment.

XML Schema

The AHA recognizes that XML schema may offer a new flexibility to the exchange of claims and remittance information. However, because the infrastructure and operations currently in place utilize the EDI standard, and because XML schema carries higher storage and transportation costs, we believe that the EDI must remain the required syntax, with the XML being an optional additional functionality.

FHIR Crosswalks

The AHA is unclear on the utility of FHIR crosswalks for the claims and remittance advice transaction standards. The X12 materials fail to specifically delineate the manner in which the crosswalks would be used to supplement or support the transactions, making it difficult to project their specific benefits. Additionally, until the crosswalks are successfully built and tested, it is difficult to determine their usefulness.

We envision that, should multiple claim or remittance standards be allowable simultaneously, FHIR crosswalks may aid in efficient and accurate electronic communication between the standards. However, if multiple standards and versions are neither allowed nor required, the utility of FHIR crosswalks may be negligible.

Unique Device Identifier (UDI)

The AHA supports the improvement of medical device safety and recognizes that there has been a considerable amount of progress in medical device safety reporting since the notion was first introduced about a decade ago. At that time, the inclusion of UDI in claims was important because there were not yet sufficient means of tracking this information on a large scale. However, since then, as X12 mentions, significant work has been performed to insert this information into clinical records and EHRs. Moreover, since the reporting of the UDI information is preferable in the clinical context, as it allows a more complete picture as to the clinical circumstances related to device failure, the AHA is unsure that there is significant value in inserting UDI information into the claim at this time. We note that the FDA has not released a clear definition as to which devices are to be considered “high-risk” for the purposes of safety surveillance and reporting. As a result of these questions, we withhold a specific conclusion on adding UDI to these transactions until additional detail and an updated explanation are available that explain

how UDI claims reporting would enable improved safety surveillance to occur in ways not already accomplished through other means.

Alternative Payment Models (APM) and Value Based Purchasing (VBP)

The AHA supports the concept of APM and VBP arrangements as these novel methodologies have the capability of improving value of care and reducing some of the otherwise unnecessary costs from the care and payment processes. To date, however, there have not been widespread or consistent APM or VBP usage. These inconsistencies and varied utilization make it difficult to ascertain whether the updated standards are beneficial. Without additional detail about a specific VBP program and methodology, the AHA is unable to project the ways in which version 8020 may support VBP claims and remittance information. However, we note that, thus far, most APMs have been built on a fee-for-service architecture.

Implementation Time Frame

The AHA is generally in favor of maintaining a two year implementation window for health plans and providers after publication of a final rule. However, we highlight that, during the 5010 transition, testing delays coupled with limited staff and finite budgets strained hospital resources. During the 5010 transition, many hospitals expressed concern that testing delays encroached on their ability to implement necessary system changes. Accordingly, should the industry move forward in its adoption of version 8020, we underscore the need to create and maintain the least disruptive pathway to implementation. Health IT initiatives must be balanced with the need to acquire sufficient resources, educate the industry, and provide the time to adequately test with trading partners. Additionally, we suggest that any go-live date avoid simultaneous go-live dates with other health IT initiatives.

Implementation and Simultaneity

The AHA is uncertain of the benefits of allowing for the concurrent use of multiple versions of a standard and express significant concern with the potential need to support multiple versions simultaneously, which could result in additional administrative burden and cost. Overall, the value of standards to the healthcare environment is that stakeholders can implement a single approach to communicating information across all parties with whom they interact. Standards increase efficiency and drive down costs. Therefore, we question whether the allowance of more than one version furthers the goal of ensuring uniformity and predictability across the industry.

Should the industry move toward allowing multiple standards or versions of transactions, this would amplify the need for substantial testing to be performed. Robust cross-standard testing is critical to determine the impact of multiple standards and versions. Additionally, the NCVHS consideration of each HIPAA transaction

individually, rather than as part of a comprehensive transaction suite, furthers the need for additional testing. Were regulations to follow a similar process, the industry would be faced with implementing new versions of some standards while maintaining old versions of others. The use of such piecemeal approach should not be pursued without substantial testing that gives confidence that the versions are cross-compatible with one another. Ultimately, the AHA urges that NCVHS exercise caution in moving forward with recommending variation into the healthcare standards environment.

Good Faith Estimates and Advanced Explanation of Benefits

To aid the AHA in its cost/benefit analysis of updating the current health care claims standard from version 5010 to version 8020, we are particularly interested in how adopting the updated version could help implement the Advanced Explanation of Benefits (AEOB) price transparency provisions under the No Surprises Act. For example, the AHA strongly supports leveraging existing provider and health plan workflows, standards, and technology for claim submission and adjudication to support the creation of AEOBs for patients. To the extent that adoption of version 8020 is necessary to properly complete predetermination for an AEOB, we would consider this functionality to be extremely beneficial. However, we are not certain that utilization of the 8020 transaction would be necessary in this situation. The X12 5010 transaction set already includes the capability of completing predetermination of benefits. This functionality is spelled out in a separate implementation guide from the claim instead of being incorporated into the institutional and professional claims. As a result, we believe that CMS could theoretically name the 5010 version of the transaction for transmitting good faith estimates to health plans. As the industry awaits further information and regulation from CMS on the implementation of the AEOB provision, we would welcome additional insight from X12 into whether version 5010 in fact has claims pre-adjudication capabilities that could easily be leveraged for transmitting good faith estimates to health plans, as well as any additional functionality that could be realized from version 8020 for this process.

Virtual Credit Cards

X12 notes that one of the benefits of the 8020 835 remittance transaction is that it enables payers to send compliant remittance information for virtual credit card payments. The AHA observes that virtual credit cards are utilized by many payers throughout the industry, and we recognize the utility of ensuring that the standard remittance transaction supporting these payments. That said, the AHA has significant reservations about health plan implementation of virtual credit cards for the purposes of claims payments. Our members have consistently indicated that many health plans are switching to virtual credit card payments without provider authorization to receive reimbursement in this manner. Such unilateral payment changes frequently result in substantial processing fees and reduced payment receipts for providers, as well as

considerable administrative hassles in switching to an alternate payment method after discovering the switch to virtual cards.

The AHA is appreciative of the CMS guidance on electronic payments released earlier this year, which highlights some of the general protections given to providers relating to virtual credit cards, including the availability of the HIPAA standard electronic funds transfer transaction. However, this guidance does not prevent the opaque, problematic rollout process that many health plans are utilizing to introduce virtual card payments. In order to safeguard payment legitimacy, the administration should only proceed with further legitimization of the virtual credit card process if the agency takes proactive steps to ensure that plans are not inappropriately switching providers to costly virtual card payment methods without advanced agreement from the provider.

Conclusion

For reasons detailed above, the AHA is extremely concerned that the X12 transactions have not undergone adequate testing and piloting to ensure that the proposed updates to the standard will produce legitimate benefits and not have unintended consequences for the industry. At this time, the AHA recommends that X12 conduct pilots and tests demonstrating that that there will not be unforeseen technical issues, provide detail about the manner in which X12 envisions rollout occurring, and sufficiently articulate how the updated transaction's proposed benefits will improve the industry. Additionally, the AHA recommends that the NCVHS pursue additional clarification surrounding its recommendations that would allow multiple standards and versions to exist simultaneously, as adherence to such recommendation would significantly alter the impact of adopting new standards. As a result, the AHA does not support NCVHS recommending adoption of the proposed transactions at this time.

CORE Operating Rules

Efficiency Improvements. Infrastructure updates to the adopted Eligibility and Benefits and Claim Status Operating Rules

The AHA supports the infrastructure updates to the eligibility and benefits (270/271) and claim status (276/277) operating rules, particularly increasing system availability requirements from 86% to 90%. Hospitals provide care to patients 24 hours a day, 7 days a week. Since determining patient eligibility is such a crucial step in care planning and management, payer systems also need to be available at all times. By reducing the possibility of system downtime, this rule helps ensure that patients and providers are not left without access to important information when they need it.

We also note that timely completion of eligibility checks will be imperative to successful implementation of the No Surprises Act price transparency provisions, as providers

need to know the patient's coverage for particular services in order to comply with the law and properly provide timely and accurate cost estimates and potential discounts for their scheduled care.

Data Content updates for Eligibility and Benefits Operating Rule

The AHA recommends implementation of the data content updates for the eligibility and benefits operating rule. The update enables the reporting of important data related to telemedicine, remaining coverage benefits, tiered benefits, and procedure-level information. Of particular importance, the rule establishes a clear methodology that enables providers to determine whether a patient has telehealth benefits for a particular service, something that is not possible in prior versions. The need for this added functionality has been of particular importance to a number of our hospital members, who have reported difficulty in ascertaining patient telehealth benefits for the purposes of care planning.

New: Patient Attribution. Content rule within the new Eligibility and Benefits Operating Rule (vEB.1.0)

The AHA is supportive of efforts to streamline VBP data exchange, as these programs could help usher in significant benefits for the healthcare system. At this time, we remain cautious of creating operating rules for these processes, which vary substantially in programmatic design. While we support the enhanced capability to identify patients whose care falls under a VBP arrangement, we recognize that specific programs may necessitate the exchange of alternative or additional information. As a result, we recommend pilot testing this process and demonstrating that the exchange of this information will achieve its projected benefits prior to recommending the rules for adoption.

Companion Guide Template

The AHA supports operating rules that may help avoid unnecessary disruptions associated with transitioning to updated standards. In this manner, we believe version agnostic companion guides could be beneficial for the industry, as it does not make sense to render all companion guides automatically obsolete with new standards versions. We stress, however, that flexibility between standards transitions not invite expanded flexibility in content requirements and add to the inevitable variation created by plan specific companion guides.

Updated Connectivity Rule

The AHA remains supportive of the CAQH CORE Connectivity Operating Rules. As we indicated when the rule was first set forth in 2020, the AHA believes that enhancing

security of the current transactions is essential, particularly in today's healthcare environment.

Costs and Benefits

The AHA has not conducted a cost assessment of the CAQH CORE Operating Rules, and we believe additional testing and piloting are essential prior to implementation for the industry. As discussed above, the AHA recognizes the potential for substantial cost savings associated with the proposed enhancements to meet current needs, such as by implementing increasing telehealth benefit transparency and reflecting tiered benefit information.

Attachments Operating Rules

The AHA is unprepared to support either of the attachments rules at this time. Though we are supportive of the industry coalescing around common business practices in the absence of regulation, we believe it is likely premature to adopt controlling operating rules prior to naming a corresponding standard. While the industry has been long awaiting an attachments standard, we believe waiting for such a standard to be released would allow for the potential to advance the operating rules and the anticipated standard in tandem to allow the operating rules to fully compliment the standard.

Conclusion

The AHA appreciates the solutions to ongoing business issues that the CAQH CORE operating rules seek to address. In particular, the AHA strongly supports the added functionality and efficiencies created by the eligibility infrastructure and data content rules and the connectivity rule. As a result, the AHA supports adoption of these operating rules, which can help leverage the existing standards to solve current problems.

Additionally, the AHA supports CAQH CORE efforts to address the long-standing industry need to standardize the attachments processes. However, as a result of CMS's intention to release an attachment regulation in the coming months, we believe it is premature to adopt operating rules at this point, instead recommending that the operating rules be considered in conjunction with or following the approval of an attachment standard.

Thank you for the opportunity to comment on this important topic and for your attention to the concerns we have raised. Please contact me if you have any questions or feel free to have a member of your staff contact Terrence Cunningham, director of policy, at tcunningham@aha.org.

Sincerely,

/s/

Terrence Cunningham
Director, Administrative Simplification Policy

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December 15, 2022

Submitted Electronically to: *NCVHSmail@cdc.gov*

Richard Landen and Denise Love, Co-Chairs
National Committee on Vital and Health Statistics (NCVHS)
Subcommittee on Standards
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

RE: RFC on X12 and CAQH CORE Proposals

Dear Mr. Landen and Ms. Love:

Patients deserve high-quality, equitable, and affordable care, with everyone working together. This requires safe, efficient sharing of data that patients, their care teams, and their health insurance providers need to make informed health care decisions. AHIP[1] appreciates the opportunity to provide input to the Subcommittee as you discuss recommendations to the Department of Health and Human Services (HHS) on adopting proposed updated standards from X12 and proposed updated and new operating rules from the Committee on Operating Rules for Information Exchange (CAQH CORE).

Our member health insurance providers are committed to offering coverage for consumer-centric care that helps maintain wellness and improve health outcomes. Data and technology are integral to our members' offerings, allowing them to furnish patients and their doctors with the information they need to make informed health care decisions. Health Information Technology (HIT) is rapidly evolving, and we appreciate the need to ensure a lack of or outdated standards do not hamper efforts to improve the flow of data and reduce the burden of current processes on all stakeholders. However, we must also balance innovation with the value of standardization and the effort required to implement updated standards and rules. We urge the Subcommittee to preserve what is working in the current standards while allowing stakeholders the flexibility needed to innovate and meet the transparency and interoperability requirements outlined by the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC). With that perspective in mind, we are pleased to share the following feedback on the potential updates.

[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone.

Updated X12 Transaction Standards

Costs

If organizations have conducted analyses of the cost impact to implement the updated X12 version 8020, NCVHS requests their input on the relative potential costs and if updated transaction implementation guides provide a net positive value.

Comments:

AHIP member health insurance providers report that they have not conducted analyses of the updated X12 version 8020 transactions as there are too many unknown variables at this stage, thereby impeding any efforts to conduct accurate cost impact estimates. Our members indicate that cost impacts are dependent on the actual changes proposed through a notice of proposed rulemaking (NPRM) and that they will conduct cost assessments once that is published. For example, the NPRM will recommend the most recently published version, which may be different from the version currently being analyzed; systems may change between now and the rulemaking stage; and costs will hinge on whether there is more than one allowable version.

We recommend that NCVHS provide additional time to learn from anticipated pilot testing and implementation plans before submitting cost and value estimates.

Operational Impacts

NCVHS seeks comment on whether organizations have conducted an operational assessment or workflow analysis of the impact of transitioning to the updated X12 8020 claims and remittance advice transactions. If so, it requests comment on what process improvements organizations have identified would result from implementation of the updated versions of any of the updated transactions.

Comments:

We have heard from a few AHIP member plans that they intend to conduct operational assessments once the NPRM is published. However, at this time, we do not have any operational assessment or workflow analysis to provide.

XML Schema

X12 has indicated that each of the X12 implementation guides included in their recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. In its letter to NCVHS, X12 noted that it mechanically produces these representations from the same metadata used to produce the implementation guide. X12 recommends that HHS permit both the 8020 EDI Standard representation (the implementation guide) and the XML representation, and that both be named in regulation as permissible syntaxes. It requests comment on the proposal to adopt the 8020 EDI and the XML representation as permitted syntaxes.

Comments:

Standards should not be limited to XML. X12 FHIR crosswalks assist with newer technology so that these tables may be included within HL7 FHIR implementation guidance (i.e., Prior Authorization Support, Clinical Data Exchange). Any alternate format should consider FHIR, which allows representation in multiple formats natively. HL7 FHIR includes other syntax that entities would like to include (i.e., JSON). If there are multiple syntax allowed, they should be semantically interoperable.

FHIR Crosswalks

X12 indicated that it intends to provide FHIR crosswalks for the proposed X12 version 8020 transactions (claims and remittance advice) submitted for consideration in time for inclusion in the rulemaking process. NCVHS solicits comment on how FHIR crosswalks would apply to the implementation of the HIPAA claims and remittance advice transaction standards.

Comments:

Dependable mapping would be helpful for implementing entities, may decrease the costs incurred by stakeholders, and ideally would enable more rapid, efficient development.

We note that everything must be fully built and tested. FHIR transactions are under rapid development and change, including many changes as entities transition from R4 to 5. Thus, it is imperative the X12 and HL7 work together to ensure accurate and robust mapping.

Unique Device Identifier (UDI)

NCVHS request input on the additional value, if any, that the device identifier (DI) and UDI provide as data elements in the updated version of the X12 claim transaction.

Comments:

Inclusion of specific device information on claims provides opportunities for additional data analysis. This allows stakeholders to uniquely identify a device and tie it to specific members to track patient outcomes, device defects, and recalls, ideally improving member experience. However, we note, primary responsibility for device recall activity should remain with manufacturers.

Alternative Payment Models (APMs)

NCVHS request input on whether the X12 version 8020 supports APM and value-based purchasing (VBP) claims.

Comments:

VBP claims use the same set of data as non-VBP claims, thus the 8020 version would inherently support VBP. APM support is provided by use of existing claim data elements, e.g., diagnosis codes, procedure code, provider identifiers, etc.

Implementation Timeframe

NCVHS request comment on the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e. g. does the window need to be longer than two years from the publication date of a final rule? Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?

Comments:

AHIP strongly encourages an implementation window of at least two years (three years for small plans) after publication of the final rule. We recommend inclusion of a safe harbor in case testing issues arise.

We appreciate that NCVHS is seeking feedback on operational details, such as what implementation start date should be used and whether January 1 or an alternative date is ideal. Our members report that an alternative date, rather than January 1, may be preferrable due to the number of program and other changes that go live at the first of the year. If an alternative date is selected (e.g., April 1), AHIP recommends that the two-year implementation window be maintained and not truncated due to any staggered start date.

AHIP recommend that Recommend entities have the option, as a voluntary practice to adopt concurrent standards. Mandating use of both version 8020 and version 5010 would require additional maintenance, resulting in unnecessary burden for health insurance providers.

Simultaneity

NCVHS requests input on what, if any, are the data impacts, limitations or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g., claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?

Comments:

Newer X12 versions tend to address unique claim scenarios and data needs. Plans may not be able to fully support the return of needed information on response transactions in a compliant manner. For example, the 837 8020 supports additional business scenarios that would benefit from use of the 8020 277CA that supports return of additional information beyond standard code set values. Plans would lose that opportunity early in the implementation of 8020 837 if forced to use an older version of a transaction.

Transactions that are closely aligned should use a similar implementation schedule to ensure data elements that can be “discussed” are consistent. For instance, following X12’s paired transactions at the same version would be required (e.g., Claims, Remittance and COB would need to be in the same version).

Specifically, if the provider and the first payer are operating at the elevated version level and the processed claim information needs to be sent to a third organization that is operating on the previous (non-backwards compatible) version, it is unknown the ramifications to the ecosystem.

CORE Operating Rules

CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Content Rule vEB.1.0

The CAQH CORE Eligibility and Benefits Single Patient Attribution Data Rule was approved in December 2020 to enable provider notification of an attributed patient under a value-based care contract within the eligibility workflow. Specifically, the rule requirements:

- Build upon the existing CAQH CORE Eligibility & Benefits (270/271) Operating Rule Set,
- Establish a foundation for exchange of explicit attribution status and effective dates of attribution for each of the CORE service type codes required when an X12 270 Request is submitted,
- Require the development of specific written instructions and guidance for providers regarding implementation of the operating rule,
- Specify the data extracted from an X12 271 Response must be displayed to the end user using human-readable text (i.e., Attribution Status: Yes; Attribution Status: No, etc.) to ensure clarity.

Comments:

Attribution rules may vary by model and some of this information may not be contained in current eligibility systems. The majority of value-based care arrangements currently use retrospective attribution methods to assign patients to providers based on claims data, thus the status is not known until after the year in which the services were provided closes. Other arrangements may prospectively identify the provider responsible for care (this could be based on purchase of a certain product, asking patients to choose, and other analytic methods), in which case a population level list of patients is furnished to the providers at the start of the period. Payers already have established methods to communicate to providers which patients are attributed to them, and a patient-by-patient check is not useful in either of these cases.

While some programs use tentatively attributed patient lists that are later reconciled, they are only refreshed semi-annually or quarterly. The resulting patient panels do not change with enough frequency to require re-running the analytics behind these files on a daily basis. Thus, implementation of individual enrollee status checks like envisioned in these operating rules would only refer back to the last run file that could be almost a quarter old. Moreover, implementation will likely require more cost and burden than benefit.

Additionally, under the new rule, payers will all be impacted by the requirement to return maximum and remaining benefit for 10 service types. These requirements would require changes to payer, provider, EMRs, clearinghouses systems that capture the information and create and receive the response. Furthermore, the support of procedure code inquiries and the evaluation of the procedure code to a service type would require significant changes to payer systems to respond at a procedure code level and map procedure codes to service types or vis versa. As such, AHIP asks NCVHS to recommend against adoption of this rule and permit payers to rely on existing systems customized to the specification of their contracts with providers.

Companion Guides

Comments:

Currently the CORE companion guides are burdensome to create and may be of limited value. AHIP recommends NCVHS work with CAQH CORE to simplify and streamline the companion guides.

CAQH CORE Connectivity Rule vC4.0.0

The CAQH CORE Connectivity Rule vC4.0.0 was updated in December 2020 to establish a method to facilitate exchange between administrative and clinical data systems, with the goal of fostering greater interoperability. Specifically, the updates to the rule:

- Add support for the exchange of Attachments transactions.
- Specify TLS 1.2 or higher for security and add OAuth 2.0 as an authorization standard to modernize the security requirements.
- Provide support for REST for X12 and non-X12 exchanges using JSON to exchange REST messages.
- Establish support for specific HTTP Methods, HTTP Error/Status Codes, and specifications for REST error handling.
- Set API Endpoint Naming Conventions.

Comments:

The updated connectivity rule references utilizing HL7 Fast Healthcare Interoperability Resources® (FHIR®) for exchange. However, the current FHIR Implementation Guides (IGs) also address these aspects. We recommend NCVHS work with HL7 to crosswalk the FHIR IGs and the updated Connectivity rule to ensure consistency. NCVHS should encourage CAQH CORE and HL7 to ensure alignment and harmonization in the connectivity rules and FHIR IGs. We also strongly encourage NCVHS to work with CMS on alignment of the updated attachments proposed rule, which we anticipate will be released soon.

Attachments Prior Authorization Infrastructure and Data Content Rules (vPA.1.0) and Attachments Health Care Claims Infrastructure and Data Content Rules (vHC.1.0)

CAQH CORE has proposed infrastructure and data content operating rules for Prior Authorization and health care claims.

The CAQH CORE Attachments Infrastructure Rules for prior authorization and health care claims were approved in February 2022 and apply to the conduct of attachments sent via the X12 v6020X316 275 and additional documentation sent without using the X12 275 transaction. Specifically, the rule requirements:

- Set a minimum amount of time that systems must be available to receive and send data (90 percent per calendar week) and the ability to track and report system downtimes.
- Allow optional use of an additional 24 hours of quarterly downtime to facilitate larger system migrations and updates.
- Require use of acknowledgements to ensure the transaction has been received and will be addressed.
- Lay out a common format that entities must use when providing information about their proprietary data exchange systems via “companion guides”.
- Establish minimums for document size and amount of data that must be supported.
- Provide support for the most recent version of CAQH CORE Connectivity.
- Establish electronic policy access requirements so services requiring additional documentation to adjudicate the claim are easily identifiable (Health Care Claims only).

The CAQH CORE Attachments Data Content Rules were approved in February 2022 and apply to the conduct of attachments sent via the X12 v6020X316 275 and those sent without using the X12 275 transaction. The rules address the reassociation or linking the attachment with the original prior authorization or claim transaction.

Specifically, the rule requirements:

- Require specific codes and reference data including Code EL to streamline the reassociation of a prior authorization or claim submission to an attachment, reducing the need for manual intervention.
- Establish the use of common CORE Connectivity Headers and data elements when sending additional documentation with the X12 275 transaction and when using nonX12 payloads.
- Require that the appropriate LOINC must be used to request the most specific additional information.

Comments:

AHIP has concerns about the potential burden associated with adopting these content rules at this time. AHIP supports of the adoption of attachment standards. However, it is premature to adopt operating rules prior to the adoption of standards. We recommend NCVHS not recommend adoption of the operating rules at this time and instead seek public comment after the relevant standards have been proposed.

We do note that as written the operating rules will be burdensome and costly to implement. For vHC.1.0 rule, the requirements for service level 271 responses will be challenging. We note the FHIR version of the 270/271 could allow for more flexibility. Similarly, for the vPA.1.0 rule, listing the exact service will require the provider to have sufficient detail. This will be expensive to build into workflows. Moreover, CMS has recently released the Advancing Interoperability and Improving Prior Authorization Processes proposed rule. CMS has proposed the development of a FHIR-based Prior Authorization Requirements, Documentation and Decision (PARDD) API that automates the process for providers to determine if prior authorization is necessary, what information is required, and facilitates the electronic exchange of both the request and the response. While we recognize these requirements would only apply to plans in federal program, we caution that we should proceed cautiously for different requirements for different insurance product lines. NCVHS should work with stakeholders to identify when it may be most appropriate to use FHIR standards, when X12 standards may be more appropriate, and when either could be used.

Conclusion

Thank you for the opportunity to provide input on the important issue. If you have any questions, please contact me at (202) 778-3246 or at dlloyd@ahip.org.

Sincerely,

Danielle A. Lloyd

Senior Vice President, Private Market Innovations & Quality Initiatives

From: Mike Nolan
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals, by December 15, 2022
Date: Wednesday, December 14, 2022 4:16:58 PM
Attachments:

From: Mike and Jeff Nolan
Sent: 12/14/2022
To: 'NCVHSmail@cdc.gov'
Subject: RFC on X12 and CAQH CORE Proposals, by December 15, 2022

We would like to respond to the question in the NCVHS Request for Comment on Updates on Proposals for X12 Transaction Updates that asked, "Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction." We are SME's in the field of barcode, RFID and generally AIDC (Automatic Identification and Data Collection). I have been in this industry since 1972 and involved in various industries digital transformations. My company, AIS has been involved in healthcare applications since 1993 and has met with and trained healthcare leaders in North and South America, Europe and Asia.

Healthcare is now in the midst of their digital transformation. This is a major global undertaking that has far reaching implications for all in healthcare, for all patients and their loved ones and for all taxpayers funding the public payment systems.

The new data we are expecting will provide the foundation for decisions guiding us to progress in all aspects of our healthcare systems. The analysts reviewing the data and providing insights look for several characteristics in their data; fullness ("Is that all catheters or just certain brands', depth ("Why are we missing the lot # on these data?", data quality ("Was this data key entered of scanned?") just to name a few. The more complete, the more granular and the higher quality data is the most valuable and requires the least manipulation by data scientists. That then should be our objective as we define the processes at the various data generating and collection points.

Each participant will use the data to achieve their particular objectives. If the claim has the full UDI then those responsible for payment will know if they are being asked to pay for a medical device that has been recalled, or out of date, or perhaps an item they have already paid for. Without the DI and PI they will not be able to answer these questions and we are certainly going to want to know those answers.

What we do not know will hurt us.

Payment of a claim is one link in the chain of transactions for a device. A break in the chain reduces the value of the data for all. Without the UDI in claims, the payment system is an information silo, disconnected from the enterprise and not a contributor to the common good of the enterprise.

Finally, this is one of the keys to increasing UDI participation. Money provides a strong incentive. We are certain that in a few short years we will not be asking 'Should we do it?' but 'Why did it take so long?'.

Thank you for considering our comments,

Mike and Jeff Nolan

AIDC100 members
LUC members

From: Amberly Hobbs
To: NCVHS Mail (CDC)
Subject: RE: Against X12 Proposal
Date: Tuesday, December 13, 2022 12:38:23 PM

We are against the X12 proposed addition of the "card payments" remittance information to 835 ERA. As a private practice, this would impact us greatly. We are already struggling to find ways to reduce expenses and increase revenue to keep our doors open.

Amberly Hobbs, MBA
Practice Manager

Alaska Neurology Center LLC
1100 E Dimond Blvd
Anchorage, AK 99515

James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT
james.madara@ama-assn.org

December 15, 2022

Jackie Monson, JD
Chair
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: Request for Public Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules

Dear Ms. Monson:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer a response to the National Committee on Vital and Health Statistics (NCVHS) Request for Comment (RFC) on updated X12 transactions and new and updated operating rules. The AMA has long advocated for the adoption of electronic transaction and code set standards and operating rules to reduce administrative burdens for physicians and their staff and promote uniform communication between practices and the many health plans with which they do business. Growing evidence linking practice burdens to professional burnout for physicians and other health care professionals underscores the importance of addressing these issues.[1,2] We appreciate the opportunity to provide the physician perspective on the updated transactions and new and updated operating rules addressed in the RFC. More broadly, the AMA prides itself in actively participating in cross-industry, multi-stakeholder efforts to advance health information technology (health IT) to meet unmet business needs and build consensus on the best path forward for adopting these innovations in real-world settings.

Global Approach to RFC Response

Many physicians—**particularly those working in small or rural practices or serving minoritized or marginalized communities**—face challenges in updating their health IT systems due to limited resources. Acknowledging this reality, the AMA formulated its response to the NCVHS RFC based on the following core principles:

- Successful transaction/code set standards and operating rules should be recognized, preserved, and enforced.
- The industry should prioritize identifying and addressing unmet industry business needs.
- Any new transaction standards or operating rules being considered for adoption should be rigorously evaluated and tested prior to a federal mandate to ensure their maturity, viability in real-world settings across organizations of all sizes, and overall value.

[1] Rao SK et al. The impact of administrative burden on academic physicians: results of a hospital-wide physician survey. *Acad Med*. 2017;92:237-243.
[2] Shanafelt TD et al. Relationship between clerical burden and characteristics of the electronic environment with physician burnout and professional satisfaction. *Mayo Clin Proc*. 2016;91:836-848.

- Only one transaction standard for a particular business function should be adopted at a time; new or revised standards should replace previously adopted standards.

We urge NCVHS to use this approach when evaluating and recommending new or updated transaction standards or operating rules for federal adoption.

Updated X12 Transaction Standards

1. Costs.

The AMA is not currently able to provide information on the costs, benefits, or value of the Version 8020 837 and 835. We have done a preliminary query of some state medical associations and national medical specialty societies. At this time, none of them have begun an analysis of the extent of the changes, cost impact, or value to physicians to implement the updated transactions.

Based on previous experiences with the adoption of other Health Insurance Portability and Accountability Act (HIPAA) mandates, we know that costs to physicians vary widely. Costs will be dependent on whether a practice develops and implements changes internally, uses a vendor, or uses a combination of the two. The implementation strategy utilized by practices will result in different cost impacts and value. Costs will also depend on the specific changes in the Version 8020 837 and 835 and the extent to which a practice currently uses those functions or is in need of the new functions. We also note that there will be indirect costs involved in adopting the updated transactions, such as training and reduced productivity as staff become proficient with the new technology.

We believe that physicians, and the industry as a whole, require more real-world data about the changes, the necessary work to implement them, and their impacts on business operations and systems. We are aware that X12 will be conducting pilots of the Version 8020 transactions. **We urge NCVHS to hold any recommendation about the adoption of the Version 8020 837 and 835 until after results of the pilot testing are made available to the industry.**

2. Operational Impacts.

The AMA is not aware that any physician practices have completed enough analyses to draw any conclusions about the operational impacts of the changes. **We believe physicians, and the industry as a whole, require additional time to fully analyze the changes before making any assessment of the impacts they will have on their current operations and workflows.**

3. XML Schema.

The AMA is aware that some organizations currently use the XML schema internally within their systems, but it is unclear what the benefit would be to adopting it under HIPAA. Any use of the XML schema could be managed through trading partner agreements, if is to be used external to an organization for sending or receiving transactions. The EDI format should remain mandated under HIPAA. **We do not believe that covered entities should be required to support both the EDI format and XML schema for X12 transactions unless through voluntary agreement.**

4. Fast Healthcare Interoperability Resources (FHIR) Crosswalks.

The AMA does not support a requirement to include FHIR crosswalks of the 837 and 835 with the HIPAA-mandated transactions. It is unclear to us at this time what the value of these crosswalks would bring to the claim and remittance advice/payment transactions.

The intent of FHIR is to allow application program interface (API) exchange of data, which is typically employed in real-time exchange scenarios. The current Version 5010 837 and 835 support real-time exchange of the transactions, but this function is not used. From the physician's perspective, the true value of conducting a real-time claim transaction is getting a real-time adjudication of that claim in order to provide the information to the patient at checkout. Until this ability becomes prevalent, there is no point in developing and implementing FHIR crosswalks for these transactions. In addition, translation between X12 and FHIR via these crosswalks could introduce errors that result in physician payment delays. Mapping projects between other X12 and FHIR transactions (e.g., X12 278 and FHIR for the Da Vinci Prior Authorization Support Implementation Guide) have shown the potential for errors in crosswalk development, which further underscores our concerns.

5. Unique Device Identifier (UDI).

The AMA has serious concerns about the inclusion of the ability to report the device identifier (DI) portion of a UDI for high-risk implanted medical devices in the claim transaction. Overall, we do not believe that health plans' collection of the UDI in the claim transaction will improve the current surveillance on implantable medical devices.

We, along with many other organizations, presented our concerns on numerous occasions to X12 during the time that this request was under consideration. The following are risks and challenges that we raised to X12 if UDI is reported in administrative transactions.

- There is no standard definition of a "high-risk" implantable device.
- The UDI in administrative transactions is insufficient to evaluate device performance, since the clinical information included in the claim is extremely limited.
- As stated in the question, the U.S. Core Data for Interoperability (USCDI) already includes the UDI and supports both the device and production identifiers. Certified health IT therefore supports the full UDI and the corresponding clinical information necessary to evaluate device performance. There is a clear value proposition in leveraging an electronic health record (EHR) and its inherent interoperability rather than administrative transaction claims.
- The reporting of UDI will add administrative burden on physicians and other providers since each health plan will request a different list of devices to be reported.
- Data collected and analyzed by a health plan are a small subset of that health plan's members and provider networks and may not represent the full patient population and experience of a device.
- Implementation of UDI in systems and business workflows will be costly.
- Patients change health plans, resulting in health plans not having current patient information to participate in contacting patients for device recalls and follow-up care.
- There are technological challenges for system integrations to link supply chain and inventory systems to revenue cycle systems as well as the ability to pull information from the clinical record/EHR to the billing system.
- The inclusion of the UDI adds risks to normal claims processing if there are errors with its entry in the claim.

- Not all implanted devices will be reported in claims, since trading partners will agree to a limited number of devices to report, and there will be variation among the willing trading partners doing the reporting.

At this time, the AMA submits the following comment for consideration as a change to the Version 8020 Professional and Institutional 837 implementation guides:

The sections (front matter and data segment) in the Version 8020 Professional Claim (837P) and Institutional Claim (837I) describing the reporting of the Unique Device Identifier (UDI) should include language stating this is "not a HIPAA-mandated usage." The reason for adding these notes is because the UDI data are not necessary for the adjudication of the claim or a reimbursement and are therefore not part of the HIPAA-mandated use of the 837, per §162.1101 of the Transactions and Code Sets Final Rule.[3]

This language should be included in 1.12.7 Unique Device Identifier Reporting, similar to the language in section 1.4.2.3 Coordination of Benefits – Subrogation, which states:

> "At the time of this publication, subrogation is not a HIPAA mandated business usage of the 837 Health Care Claim; however, willing trading partner may use this Implementation Guide for this purpose."

The language should also be included in the High Risk Implanted or Explanted Device segment notes, similar to the TR3 note for the Property & Casualty Claim Number segment, which states:

> "This segment is not a HIPAA requirement as of this writing."

This added language to the front matter and segment UDI notes does not change the current instructions and intent that the reporting of UDI is done through willing trading partner agreement. The purpose of adding this language is to prevent payers from circumventing the willing trading partner agreement requirement and telling physicians and other providers they must report all HIPAA-mandated data, which would include UDI unless it is identified as not being a HIPAA requirement.

6. Alternative Payment Models (APM) and Value Based Purchasing (VBP).

The AMA is not aware of any specific alternative payment model needs that are met by the changes in the Version 8020 837 and 835.

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[3] **§ 162.1101 Health care claims or equivalent encounter information transaction.**
The health care claims or equivalent encounter information transaction is the transmission of either of the following:
(a) A request to obtain payment, and the necessary accompanying information from a health care provider to a health plan, for health care.
(b) If there is no direct claim, because the reimbursement contract is based on a mechanism other than charges or reimbursement rates for specific services, the transaction is the transmission of encounter information for the purpose of reporting health care.

7. Implementation Time Frame.

The AMA supports a two-year implementation timeframe if it is decided to adopt the Version 8020 transaction.

At any given time, there are numerous regulations impacting health IT and data exchange with differing requirements in various stages of development and implementation. We do not foresee an open window in which to schedule the Version 8020 implementation. Physicians and other providers must balance limited resources among the many regulatory requirements. It is important that these requirements result in a decreased administrative burden, return on investment, or improved business processes. Moreover, health IT vendors require at least 18 to 24 months from the time of a final rule to implement regulatory requirements. Any timeframe should be aligned with the development cycles of health IT vendors, including those that service small medical practices or themselves are less resourced.

8. Implementation.

The AMA has consistently advocated for the adoption of electronic transaction standards to reduce administrative burdens for physicians and their staff, particularly given the growing recognition that these practice hassles play a major role in professional burnout for physicians and other health professionals. **However, we are alarmed that NCVHS has significantly deviated from the original goals of the HIPAA administrative simplification provisions by recommending the concurrent use of multiple versions of a standard over an extended period of time and/or multiple standards for the same business function. The allowance of multiple versions of the same standard and/or multiple standards for the same business function will lead to increased costs, major inefficiencies, and patient care disruptions.**

While the AMA appreciates the spirit of innovation and flexibility underlying the NCVHS recommendations, we strongly object to the apparent abandonment of the basic tenets underlying HIPAA administrative simplification—namely, that physicians and other providers should be able to interact with all health plans using the same transaction standard and same format and enjoy the cost savings and improved efficiency resulting from this standardization. Indeed, NCVHS seems to be suggesting a reversion to the pre-HIPAA world, in which every health plan used its own proprietary format for revenue cycle functions. Allowing the use of multiple versions and/or standards would return the industry to our previous "Wild West" environment, where the lack of uniformity necessitated costly translation between formats to conduct business.

NCVHS had suggested that while health plans would be required to support all adopted standards for a particular business function, providers could choose which one to use. This leniency is not included in the final recommendation letter and suggests that physicians—many of whom are small business owners—would also be required to support multiple standards for a single business purpose. For small- and medium-sized practices, this is simply an untenable financial proposition, as these organizations do not have the resources to invest in duplicative technology to support multiple formats. Even if the intent is to allow providers to choose which standard to support, this presumes a level playing field in contracting relationships between physicians and health plans. While in theory providers could "choose" which standard to use, health plans could force use of a particular standard via network contracting arrangements, particularly for smaller practices with less negotiating power. Physicians could be forced to support one adopted standard for Payer A and another for Payer B due to contracting requirements. For physicians, this situation would be unworkable, extremely burdensome and costly—**especially for physicians serving marginalized and minoritized communities.** Moreover, such a change would go

against the underlying efficiency goals of administration simplification and electronic transaction and code set standards, which support uniform communication between health care professionals and health plans. To be clear, medical practices often contract with a dozen or more payers.

The AMA also harbors strong concerns about the consequences of allowing the use of multiple versions of the same standard for an extended period of time. **Indeed, allowing multiple versions of multiple standards could exponentially compound the issues we have already identified and lead to a *standards explosion*.** We stress that health IT is not a traditional marketplace, and physicians, particularly those in small practices, do not have the bargaining power to negotiate for their "standard or version of choice" in payer contracts, meaning that they could end up being required to support multiple versions of multiple standards for a *single business function*. We again reiterate the basic tenets underlying HIPAA administrative simplification—cost savings and improved efficiency resulting from stakeholder uniformity.

Beyond the high costs and burdens involved in supporting multiple standards/versions, we are concerned about the testing and orchestration of several health IT systems that would be required by a medical practice to support such a complex scenario. In today's world, a snag in an upgrade to a single health IT system can bring the entire medical practice to a crawl—leading to care delays. Support for multiple versions would astronomically increase the potential for these sorts of harmful impacts on patient care delivery. These unnecessary disruptions would be compounded in less resourced medical practices such as small, solo, and rural clinics, which often serve marginalized and minoritized communities.

We also strongly caution against viewing clearinghouses or other intermediaries as an easy solution to versioning issues for physician practices. While vendors offering translation services may on the surface appear to solve the problem of practices needing to convert versions in-house, this outsourcing comes at substantial financial and administrative costs to physicians and, indeed, the entire health care system. Moreover, allowing multiple versions could stall the forward momentum of interoperability we are experiencing today. Without controlling for different versions, health IT systems would receive incompatible software updates, breaking information exchange and creating backward compatibility issues. In fact, in its July 2022 recommendation letter, NCVHS envisions a future in which a cardiology practice would upgrade to a new version of the electronic claim while another specialty might not.[4] This could lead to interoperability challenges between practices (e.g., preparation of good-faith estimates to meet requirements of the No Surprises Act [NSA]), to say nothing of problems between different trading partners.

The decision to allow multiple versions should not be taken lightly. Yet, if NCVHS were to recommend adoption of multiple versions of the same standard, only the two most recent versions should be allowed at any one time, and it is essential that these versions be backwards compatible. This would provide the minimal protection for market stability while also supporting innovation. In addition, there would need to be firm federal control and transition planning to support use of multiple versions. The Office of the National Coordinator for Health IT's Standards Version Advancement Process registry could perhaps serve as a model for version control and transitioning.

The AMA wholeheartedly supports adoption of newer technologies to address unmet business needs. However, we believe that allowing the concurrent use of multiple versions and/or standards would increase costs, confusion, and inefficiency in our health care system. Given the limited resources

[4] July 28, 2022, letter from NCVHS to HHS. Available at: https://ncvhs.hhs.gov/wp-content/uploads/2022/08/Recommendation-Letter-Modernize-Adoption-of-HIPAA-Transaction-Standards-508.pdf.

available to invest in health IT, we urge NCVHS to use the approach outlined at the beginning of this letter when evaluating Version 8020 of the X12 standards, namely:

- Recognize successful transactions and code set standards to preserve/enforce (i.e., "don't break what's working"). For example, the CAQH Index reports a 97 percent adoption of the Version 5010 837 for electronic claim submission,[5] suggesting that development dollars could be much better spent on other business functions and transactions.
- Rigorously evaluate and test any new transaction standards/versions considered for adoption. A robust piloting program is needed to evaluate standards' maturity, viability in real-world settings across organizations of all sizes, and overall value.
- Adopt a single transaction standard and version for a particular business function at a time; new or revised standards should replace previously adopted standards. This will avoid stepping backward to the pre-HIPAA world of many proprietary formats and costly translation.

Following this approach will ensure that limited health IT resources are invested wisely to address the most urgent unmet business needs and avoid diversion of development time and dollars to duplicative efforts.

9. Simultaneity.

Again, the AMA is alarmed by the NCVHS recommendation to allow multiple versions of the same transactions in production for an extended period of time, for the reasons stated above. We have serious concerns about how the multiple versions of multiple transactions would function. For example, it is not clear how adoption of Version 8020 for claims and electronic remittance advice would impact use of the 5010 version of the post-adjudicated claims data reporting guides, which are used to transmit claims data to all-payer claims databases. We believe this approach would return the industry to the pre-HIPAA era and certainly add unnecessary cost, burden, and inefficiency to a system that is already stretched for resources. In instances where Version 8020 and 5010 data need to be reconciled, we are concerned with data fidelity issues resulting in data distortion or imperfections. This could result in delays in care, impact physician revenue and, at worst, lead to patient harms.

10. Alternatives Considered.

The AMA has reviewed a list of changes to the Version 8020 837 and 835 transactions but has not conducted any in-depth analysis of the impact of these changes with regard to reducing burden on physicians and other providers. Nonetheless, the following are specific points we have about some of the changes that were identified by X12 as benefits for the 837 and 835.

- The change from the Claim Adjustment (CAS) segment to the Reason Adjustment (RAS) segment for coordination of benefits will have a significant technical and business impact for all covered entities, although physicians and other providers may bear more of the burden with analyzing the adjustments and amounts. Moreover, the utility of this information to practices will ultimately depend on how it is presented by their vendors.
- The new functionalities for predetermination, UDI, factoring agent, and tooth segment have limited uses, and it is unclear what the industry adoption will be of them. It is worth noting that the predetermination is currently available in Version 5010, although it is in a separate implementation guide.

[5] 2021 CAQH Index. Available at: https://www.caqh.org/sites/default/files/explorations/index/2021-caqh-index.pdf.

- The revisions for reporting property and casualty data, allowing subrogation by non-Medicaid payers, and reporting drug information will likely have limited use by most physicians or other providers.
- Increasing the number of diagnosis codes and diagnosis pointers that can be reported will benefit social determinants of health (SDOH) and risk adjustment needs for those specialties where these are factors. However, it is not clear if health plans will accept or use this additional information, or how these changes will impact data storage needs.
- Additional clarifications and updated language are good, but not necessary for those that already know how to use the Version 5010 837 and 835.
- There are many qualifier changes and changes in lengths of data fields, which will have significant technical and business impacts.

In addition, Version 8020 added the ability to report remittance information for virtual credit card (VCC) payments. Of note, some physicians have expressed concerns that through addition of the ability to include VCC information, the Version 5010 835 will essentially serve as an "enabler" of VCC payments. **The AMA has offered numerous testimonies and comments to NCVHS, the Centers for Medicare & Medicaid Services (CMS), and the Department of Health and Human Services (HHS) over the past nine years expressing strong concerns regarding the harmful impacts and coercive business tactics associated with VCCs.**[6] The AMA recognizes that the Version 8010 835 would not require physicians and other health care professionals to accept VCC payment; as clarified in guidance released by CMS in March 2022, physicians may request, and health plans must offer, standard ACH electronic funds transfer instead of VCC payments.[7] In the absence of real-world implementation data, the AMA cannot definitively assert that adoption of the Version 5010 835 will lead to increased use of VCC payments by health plans. However, given that this change could lead to significant financial hardships and administrative burdens for physicians, **the AMA believes it is premature to recommend adoption of Version 5010 835 without a full understanding how this could impact physicians and other health care providers.**

We do not have a definitive opinion at this time on the benefits achieved by Version 8020 or the cost of remaining on Version 5010. We believe that real-world testing of Version 8020 is necessary to quantify its benefits.

11. General.

The AMA believes it is premature to support the implementation of the Version 8020 837 and 835. More industry-wide data is needed about the costs, benefits, and value before a realistic decision can be made. We also harbor strong concerns regarding the opportunity costs of implementing these updated transactions. Given the fact that the Version 5010 837 electronic claim is the most widely adopted HIPAA-mandated transaction—97 percent industry adoption per the 2021 CAQH Index[8]—we question if implementing the Version 8020 X12 837 is the best use of physician practices' limited resources for health IT updates, particularly when other revenue cycle transactions desperately need a viable standard technological solution that will likely require significant investments across the industry.

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[6] See documents posted on "Administrative Simplification Advocacy." Available at: https://www.ama-assn.org/practice-management/sustainability/administrative-simplification-advocacy.

[7] Guidance on health plans' payment of health care claims using Virtual Credit Cards (VCCs) and adopted HIPAA standards for Health Care Electronic Funds Transfers (EFT) and Remittance Advice (ERA) transactions. Available at: https://www.cms.gov/files/document/guidance-letter-vcc-eft-era.pdf.

[8] 2021 CAQH Index. Available at: https://www.caqh.org/sites/default/files/explorations/index/2021-caqh-index.pdf.

Specifically, CMS just released the Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule,[9] and while we anticipate that, if finalized, this regulation will streamline the prior authorization (PA) process, improve efficiency, and prevent patient care delays, stakeholders will need to devote substantial resources and time to meeting its technological requirements. It is also unclear what if any societal cost or benefit will result in the implementation of the Version 8020 837 and 835.

Committee on Operating Rules for Information Exchange (CAQH CORE) Operating Rules

1. Efficiency Improvements: Infrastructure Updates to the Adopted Eligibility and Benefits and Claim Status Operating Rules.

The AMA actively participates in CAQH CORE operating rule development and tirelessly advocated for increasing the system availability requirement beyond the current 86 percent per calendar week. Health care is a 24/7 industry, and our member physicians regularly express frustration when health IT systems are unavailable outside of strict "9 to 5" business hours. Patients do not stop falling ill or seeking care because it is after 5 p.m. or it is the weekend. **It is therefore imperative that physicians and their staff have reliable access to eligibility and benefits and claim status information whenever they are providing patient care.** Ideally, CORE would set system availability at 95 percent or higher, as the 90 percent threshold still allows health plan systems to be down over 16 hours per week. That said, **the AMA strongly supports adoption of the updated infrastructure rules, as this represents a major improvement from the status quo in system availability.**

In addition to the positive impact on physician practice efficiency, the updated infrastructure rules also will improve the timeliness of patient care. Practices regularly check a patient's insurance coverage using the electronic eligibility transaction prior to scheduling care. If coverage cannot be confirmed due to a health plan's system being down, scheduling will be delayed until practice staff can manually check the patient's benefits or the plan's system becomes available. Increasing system availability will prevent care delays and ensure that practices can check insurance coverage whenever the patient seeks treatment. **This direct benefit to patient care further solidifies the AMA's support for the updated infrastructure rules.**

2. Data Content Updates for Eligibility and Benefits Operating Rule.

The AMA actively participated in the revision of the Eligibility and Benefits Data Content Operating Rule and strongly supported changes that would increase **both the volume of information included in eligibility responses but also the granularity and specificity of the data.** Nearly every patient encounter with a physician or other health care professional begins with a confirmation of the patient's insurance benefits and specific details of coverage. The 2021 CAQH Index reports that medical providers can save 21 minutes per transaction by performing eligibility checks electronically,[10] clearly demonstrating the value of the electronic eligibility transaction. However, practice staff often have to resort to manual (e.g., phone) or partially electronic (e.g., proprietary plan portals) means to confirm eligibility if the information provided in the X12 transaction is unclear, confusing, or too general to be useful. While these other communication channels are time-consuming and burdensome, practices routinely default to their use when the data provided in the electronic transaction standard proves

[9] Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule CMS-0057-P. Available at: https://www.federalregister.gov/public-inspection/2022-26479/medicare-and-medicaid-programs-advancing-interoperability-and-improving-prior-authorization.

[10] 2021 CAQH Index. Available at: https://www.caqh.org/sites/default/files/explorations/index/2021-caqh-index.pdf.

insufficient or unreliable. The data content enhancements in the updated operating rule significantly increase the quality and quantity of the eligibility transaction's data. **As such, the AMA strongly supports adoption of the updated operating rule, as it addresses unmet business needs. Moreover, we expect that physician practices will increase utilization of the transaction due to the inclusion of valuable new information.**

This updated operating rule addresses several important recent trends in the health care industry. First, the rule requires health plans to indicate when a service is eligible for telehealth coverage. **The provision of telehealth coverage information in the eligibility transaction is crucial given the significant shift toward provision of care virtually during the COVID-19 pandemic and beyond.** Next, the revised operating rule addresses the increasing complexity of benefit design and requires health plans to include new details about a patient's coverage. Specifically, health plans must now provide a patient's maximum benefit limitation and remaining benefits for specified service types. In addition, health plans must return the tiered network status and the associated benefit information for that tier to the inquiring provider. **These valuable enhancements will allow physician practices to quickly ascertain the complexities of a particular patient's coverage and align the eligibility transaction's capabilities with today's more intricate health plan benefit designs.**

Another major improvement in the rule is the requirement that health plans provide coverage and patient financial responsibility for an expanded list of service type codes, as well as specific procedure codes for physical therapy, occupational therapy, surgery, and imaging. The availability of more granular data regarding coverage and patient responsibility in the eligibility transaction will support informed conversations between physicians and their patients about the cost of care and aligns with ongoing efforts to improve health care price transparency. By expanding the list of service type codes for which health plans must provide eligibility data, we anticipate that the rule will also reduce provider burdens by increasing uniformity of data sent across health plans. Finally, the provision of more specific coverage data in the eligibility transaction will allow physicians and other providers to determine if a service is not covered and, as required under the NSA, issue a good faith estimate for self-pay care. **As such, the operating rule addresses a currently unmet business need related to NSA implementation.**

Finally, the updated data content rule addresses one of physicians' priority concerns: the transparency of health plans' PA requirements. In the AMA's 2021 PA survey, 62 percent of physicians reported that it is difficult to determine whether a medical service requires PA.[11] Importantly, under the revised operating rule, health plans must indicate whether a specified group of service types and procedures require PA in the eligibility response, significantly improving transparency for physician practices. **While ideally health plans would provide procedure-level PA requirements across all services, the data content rule represents a major step forward to increasing transparency in PA programs.**

3. New: Patient Attribution. Content Rule Within the New Eligibility and Benefits Operating Rule (vEB.1.0).

Physicians need accurate, timely patient attribution information in order to successfully participate in value-based contacts (VBCs). Physicians face significant challenges in obtaining actionable patient attribution data, and AMA policy calls on health plans to "provide attribution information to physicians in a timely manner" and offer "mechanisms to allow physicians to verify and correct attribution data as

[11] 2021 Update: Measuring progress in improving prior authorization. Available at: https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf.

necessary."[12] The new Single Patient Attribution Data Content Operating Rule offers exactly such a mechanism, as it requires health plans to provide information regarding a patient's attribution status in an electronic eligibility response. This allows practices to quickly and easily determine if the patient is included in the physician's panel for a particular VBC and take appropriate action, whether that be closing care gaps, engaging in quality reporting activities, or correcting any inaccurate attributions with the health plan. As our health care system increasingly transitions away from traditional fee-for-service payment towards VBCs and other innovative payment models, timely communication of accurate patient attribution will become even more important. **As such, the AMA strongly supports adoption of the patient attribution operating rule.**

4. Companion Guide Template.

Health plans publish companion guides to communicate the specifics of how they implement electronic transaction standards. Historically, companion guides have varied across health plans in format, structure, and content, which leads to confusion and wasted time for physician practice health IT staff who must review, interpret, and implement electronic transactions across the wide range of health plans with which a practice conducts business. CAQH CORE developed a companion guide template to increase document uniformity across health plans. The increased uniformity in companion guides' structure and format afforded by the CORE template has benefited practice health IT staff and other users by allowing them to quickly find information and more efficiently use the guides.

CAQH CORE updated its Master Companion Guide template to allow health plans to address newer (i.e., post-5010) versions of X12 transaction standards and non-X12 standards, such as HL7 FHIR. **Expanding the application of the Master Companion Guide to additional standards and versions should benefit physician practices by increasing documentation uniformity between plans and reducing administrative burdens.**

5. New Connectivity Rule.

The updates to the CAQH CORE Connectivity Rule reflect modern technology advances and IT best practices, and as such, should improve interoperability in the health care industry. Specifically, the rule requires Transport Layer Security (TLS) 1.2 or higher, thereby increasing the security of information exchange. The rule no longer permits use of outdated username and password authentication and instead requires digital certification based on X.509. In addition, the rule also supports stronger authorization standards based on OAuth 2.0. These updates save stakeholders the costs and other resources involved in maintaining outdated connectivity and security technologies that no longer represent best practices. More importantly, the new rule supports physician practices in ensuring the security, accuracy, and integrity of patient health information for which they are responsible for protecting. Physicians' business depends on the security and reliability of their health IT connections, without which they could lose revenue, experience increased costs, be exposed to significant liability, and suffer reputational harm. **The revised CAQH CORE Connectivity Rule modernizes security, authorization, and authentication requirements, and as such, protects physicians' vital business and professional interests.**

The rule also addresses new and emerging technologies, which further increases its value and utility. For example, the rule provides support for exchange of electronic attachments—a key unmet business need across stakeholder groups. In addition, this update incorporates REST standards and provides support for

[12] AMA Policy H-390.849 Physician Payment Reform. Available at: https://policysearch.ama-assn.org/policyfinder/detail/attribution?uri=%2FAMADoc%2FHOD.xml-0-3327.xml.

API integration, as well as instituting an API endpoint naming convention. Importantly, while the rule supports more modern technologies and standards, its safe harbor provisions ensure that existing connections do not need to be abandoned if continued usage is mutually agreed upon between trading partners. Moreover, it would likely be necessary for this rule to be adopted, implemented, and tested prior to moving trading partners off current claims systems and onto FHIR, APIs, and X12 mappings.

In a November 2020 letter to the HHS Secretary, NCVHS recommended against adoption of Connectivity Rule Version C3.1.0 and instead encouraged CAQH CORE to complete an updated connectivity rule with enhanced security requirements and inclusion of new and emerging technologies such as RESTful APIs and OAuth.[13] The updated Connectivity Rule achieves these goals and aligns with modern advancements in health IT. **The AMA anticipates that these changes will benefit physician practices, and as such, we recommend adoption of the rule.**

6. Implementation Costs.

The AMA does not have data regarding the projected costs to physician practices of implementing the updated eligibility and benefits and claims status operating rules. However, as detailed above, we strongly believe that the increased system availability and data content requirements offer significant value to our members. Increasing required system availability to at least 90 percent represents a meaningful improvement for our 24/7 industry and will prevent delays in scheduling patient care. Requiring inclusion of telehealth, tiered networks, and procedure-specific coverage information offers the potential for major efficiency improvements and costs savings for physician practices, as staff can obtain granular data needed to support today's complex benefits structure easily and within 20 seconds vs. relying on manual, costly, and burdensome telephone or portal benefit checks. Moreover, the updated eligibility data content rule brings much-needed transparency to health plans' PA requirements, a major pain point for physicians and their staff, as well as patients. These enhancements will drive further provider adoption of the electronic eligibility transaction and reduce administrative waste throughout our health care system. **The AMA strongly supports adoption of these operating rules due to the benefits they bring to both physician practices and patients.**

7. Alternatives Considered for Operating Rules.

The AMA strongly believes that federal adoption of the updated operating rules will benefit physicians and their staff through improved workflow efficiencies, reduced time spent on administrative tasks, increased time for patient care, and addressing unmet and emerging business needs. We further expect that the rules will positively impact patients. Please refer to our earlier responses for complete details on the anticipated value of these updated rules. Here we briefly identify the benefits of the rules for physician practices:

- Increased system availability better meets the 24/7 needs of the health care industry, avoids practice workflow disruptions, and prevents delays in scheduling and delivering care.
- Through the improved data content of the eligibility rule, practices will be able to ascertain more complex plan provisions, such as telehealth coverage, maximum benefit limitations and remaining benefits, and tiered network via the electronic transaction instead of time-consuming phone calls.

[13] November 23, 2020, letter from NCVHS to HHS. Available at: https://ncvhs.hhs.gov/wp-content/uploads/2020/11/NCVHS-recommendations-on-Operating-Rules-FINAL-11-24-2020-508.pdf.

- Health plans will be required to provide coverage information for additional service types and specific procedures, which will increase benefit transparency for both practices and patients, as well as support identification of self-pay services for NSA purposes.
- Provision of PA requirements for specific service types and procedures will significantly increase transparency and reduce administrative burdens.
- Inclusion of patient attribution data in the eligibility response will support physicians' success in VBCs, which will be increasingly important as our health system transitions away from a fee-for-service model.
- The update connectivity rule provisions enhance the security, integrity, and reliability of the electronic transactions that practices rely upon to run their business.

8. Attachments PA Infrastructure and Data Content Rules and Attachments Health Care Claims Infrastructure and Data Content Rules.

For years, the AMA, as well as many other health care stakeholders, has called for adoption of an electronic transaction standard for PA and claims attachments. In the absence of a standard, both providers and health plans waste considerable time and money on archaic faxes and snail mail to exchange medical documentation. In a 2021 AMA survey, 88 percent of physicians reported the burdens associated with PA as high or extremely high.[14] Beyond just the practice burdens associated with this process, clinicians overwhelming report that PA leads to care delays that can result in patient harm, with 91 percent of physicians saying that PA can lead to negative clinical outcomes. **Standardizing the electronic exchange of supporting documentation plays a key role in addressing both PA-related practice burdens and patient harms. The CAQH CORE attachments operating rules offer important and much-needed industry direction to support uniformity and efficiency in the implementation of electronic attachments.**

Of note, both attachments' infrastructure rules include the updated system availability and connectivity requirements previously discussed, bringing improved reliability, security, and data integrity to the exchange of electronic attachments. Importantly, the infrastructure rules require health plans and their agents to accept at least a 64-mb file size, creating important consistency between health plans and reducing initial rejections and costly resubmissions for physician practices. For X12 attachment transactions, the rule also sets requirements for maximum response times, acknowledgments, and handling of errors. **Taken in whole, these infrastructure requirements establish valuable uniformity and common expectations regarding the exchange of electronic attachments.**

The attachment data content requirements further enhance the benefit of this rule set. Specifically, the rules address a common workflow challenge related to clinical documentation exchange: the reassociation of attachments to the related claim or PA request. The rule includes requirements to support reassociation for both X12 and non-X12 attachment transactions and also recommends inclusion of reference data to further assist with association. In addition, the rule recommends that health plans use LOINCs when requesting supporting documentation to ensure that practices send the correct information. This provision addresses another common challenge for physicians and their staff, which is identifying the specific clinical data a particular health plan needs to complete claim adjudication or process a PA request.

[14] 2021 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

The AMA believes that the PA and claims attachments operating rules offer an important steppingstone to the health care industry's adoption of electronic attachments. By promoting uniform implementation, as well as addressing common workflow challenges such as reassociation, these rules will benefit physician practices and improve efficiency. **We urge NCVHS to recommend adoption of the attachment infrastructure and data content attachments operating rules.**

9. Attachments Operating Rules – General Question.

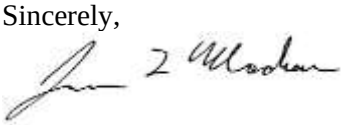
The AMA strongly recommends *concurrent adoption* of electronic transaction standards for attachments and associated operating rules. As previously stated, the health care industry has waited for many years for an attachments standard. In the absence of a standard, physician practices have been forced to use slow, expensive methods of transmitting clinical supporting documentation (e.g., faxes and mail) or faced with a myriad of proprietary, plan-specific solutions. Given the high costs associated with these inefficiencies, as well as the care delays associated with burdensome PA-related clinical data exchange, attachment standards and operating rules should be mandated together to avoid further implementation delays.

Beyond the long wait for an electronic attachment solution, there are other convincing reasons to simultaneously move forward with attachment transaction standards and operating rules. First, operating rules bring additional uniformity and conformance to transaction implementation by addressing business rules outside the strict purview of standards. For example, the CORE attachments operating rules establish a minimum attachment size limit, which sets common expectations across stakeholders and prevents failed transactions and costly resubmissions. Additionally, the operating rules provide critical support for attachment reassociation, which the industry has repeatedly identified as a workflow challenge. Having this additional structure and guidance in place during the initial implementation will increase conformance and consistency across the industry. **In turn, this uniformity will reduce confusion and improve efficiency, which we expect will increase physician practices' adoption of an electronic attachment transaction standard.** Finally, we expect that implementing attachment standards and operating rules simultaneously as one health IT project will be easier for most organizations and more efficient than addressing operating rule compliance at a later stage. **For these reasons, we believe that attachments transaction standards and operating rules should be simultaneously adopted and implemented.**

Summary

Thank you for the opportunity to provide comments on the proposed adoption of updated/new X12 electronic transaction standards and CAQH CORE operating rules. We look forward to continuing our dialog with NCVHS on how the health care industry can best leverage new technology to address unmet business needs without jeopardizing smoothly operating workflows or diverting limited health IT resources away from higher priority needs, such as PA automation. If you have any questions regarding our comments, please contact Margaret Garikes, AMA's Director of Federal Affairs, at 202-789-7409 or margaret.garikes@ama-assn.org.

Sincerely,



James L. Madara, MD

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December 7, 2022

CMS
Proposed Rule (X12/NCVHS)

To Whom it May Concern:

Payers use of virtual credit cards has increased the cost to our medical practice by an estimated $60K annually. The cost comes in the form of credit card processing fees of 3% and labor cost to process the transactions. Often times with the addition of the credit card fee the amount of net reimbursement for the service does not pay for the cost of the service. This is especially true when drug codes are paid via virtual credit card. This formula is unfair to the medical practice and forces the practice to take an additional "write off" on services.

Regarding labor cost, the clinic has a staff member dedicated to daily retrieval of these payments from multiple portals. The process is labor and time intensive. Our staff can post hundreds of thousands of dollars in EFT claims processed through our clearing house in milliseconds. For a virtual credit card it can take up to 10 minutes to process and post one transaction which may value at $24.42 the secondary payment on a Medigap plan.

CMS allowing payers to use virtual credit cards is not fulfillment of the administrative simplification rule promised medical groups. This practice needs to be banned or requirements changed. First, payments need to process through a clearing house so that transactions can be electronically posted. Second, payers should cover the processing fees. It is unfair for medical groups to have to incur additional cost in order to receive their contractual payment from the payer. Third, if the medical group does not want virtual credit card payments they should have the right to opt out and the payer should have to send payment via EFT to the clearing house of the medical practices choice.

Please take action on this rule to protect the rights and revenue of the medical practice. If medical practices do not exist and remain financially viable there will be no healthcare industry.

Sincerely,

Rebecca Hamilton, CMA, MHCL, FACMPE
Administrator

ADMI NCVHS Comment Letter – CAQH CORE Operating Rules for Mandate 2022

Re: Request For Comment (RFC) on CAQH CORE New and Updated Operating Rules

Aspen Dental Management, Inc. ("ADMI") appreciates the opportunity to provide comment on the following CAQH CORE Operating Rules proposed to the National Committee on Vital Health Statistics (NCVHS) for federal adoption:

- Updated CAQH CORE Connectivity Rule vC4.0.0
- Updated CAQH CORE Infrastructure Rules for Federally Mandated Operating Rules
- Updated CAQH CORE Eligibility & Benefits (270/271) Data Content Rule vEB.2.0
- New CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Content Rule
- New CAQH CORE Attachments Operating Rules

ADMI is a dental support organization that provides non-clinical business support and administrative services to over 1000+ Aspen Dental-branded practices, comprising the largest group of branded dental offices in the world. The company was founded with a simple goal in mind: to break down the barriers that doctors and patients face when it comes to dental care with the mission to bring better care to more people.

Federal adoption of the proposed CAQH CORE Operating Rules will drive greater automation across revenue cycle and clinical workflows, increase operational efficiencies, improve timely patient care, and enhance provider and dental plan information exchange both for Aspen Dental-branded practices and across the dentalcare industry. These operating rules represent necessary progress towards achieving national interoperability goals by enhancing common administrative transactions and building a supportive infrastructure for emerging opportunities including the use of APIs.

An overarching goal for ADMI is administrative simplification, which will enable the doctors we support to focus on care delivery. The proposed CAQH CORE Operating Rules support this goal by automating key revenue cycle transactions. The CAQH CORE Connectivity Rule vC4.0.0 supports secure and modern methods to exchange data enabling Aspen Dental-branded practices to leverage emerging API-based technologies for real-time access to information. Updates to the CAQH CORE Infrastructure Rules, such as improved system availability requirements, help broaden the availability of information as many of our supported practices are open after normal business hours and on weekends. Requiring dental plans to deliver comprehensive benefit information during eligibility determination via the CAQH CORE Eligibility & Benefits (270/271) Data Content Rule vEB.2.0 enables Aspen Dental-branded practices offices to have informed dialogue with their patients about treatment options and financial responsibility when scheduling appointments or follow-up visits. Further, the new CAQH CORE Attachments Operating Rules allow our supported providers to bypass burdensome phone or faxed based methods when trying to assess clinical documentation required for the purposes of purposes of claims adjudication or prior authorization, reducing the time for reimbursement and delivery of patient care.

ADMI fully supports the proposal by CAQH CORE and encourages NCVHS to promote industry progress by advancing these industry-driven operating rules for federal adoption. Detailed comments pertaining to the value and benefits of each proposed operating rule set are included below. Feedback pertaining to questions posed by NCVHS has been integrated and aligned to each CAQH CORE Operating Rule set being proposed for federal adoption.

Please do not hesitate to reach out with questions.

Sincerely,

Margaret Schuler
Senior Vice President, Practice Support Operations and Revenue Cycle Management
Aspen Dental Management, Inc.

1. Efficiency Improvements. Infrastructure updates to the adopted Eligibility and Benefits and Claim Status Operating Rules.

CAQH CORE infrastructure updates include increasing system availability from 86% to 90% for the Eligibility & Benefits and Claim Status Operating Rules, integrating the most recent published CAQH CORE Connectivity Rule (currently CAQH CORE Connectivity Rule vC4.0.0), and updating the CAQH CORE Master Companion Guide Template. As dental care evolves to meet industry demands through use of emergent technologies and standards, current federally mandated infrastructure rules should be updated to align with current best practices.

Aspen Dental-branded practices operate after normal business hours and on weekends, increased system availability promotes electronic exchange at these practices through the assurance that dental plan systems are readily available to receive and respond to information requests during off-hours. Globally, enhancements to system availability ensure that providers have the data they need when they need it the most by facilitating a reliable, consistent, and predictable schedule.

The updates to CAQH CORE Connectivity Rule and CAQH CORE Master Companion Guide Template requirements bring value by providing flexibility in an environment where technologies and standards are evolving at a fast pace. By referencing the updated Connectivity Rule, adoption of the proposed Infrastructure Rules allows implementers to advance communication and security protocols aligned with current industry priorities. Updates to the Master Companion Guide Template allows implementers to indicate the latest versions of the X12 standards, where previously they were limited to referencing the HIPAA-mandated v5010. The format can also be used as a starting point for companion guide development for non-X12 standards. Common connectivity mechanisms and uniform documentation to support implementations reduces cost and burden for ADMI.

The current versions of the federally mandated CAQH CORE Infrastructure Rules were adopted a decade ago and do not align with the security and flexibility our current environment demands. The proposed updates are imperative to support the business needs of dentalcare organizations today and into the future. ADMI strongly encourages NCVHS to recommend the updated CAQH CORE Eligibility & Benefits, Claim Status and Payment & Remittance Infrastructure Operating Rules to HHS for federal adoption.

2. Data Content updates for Eligibility and Benefits Operating Rule.

While adoption of electronic transactions in the dental industry is on the rise, there is still significant opportunity for greater automation. According to the 2021 CAQH Index, 71% of eligibility and benefit verifications were conducted electronically, while manual and portal-based transactions cost the dental industry an additional $839 million annually and take an additional 6 to 10 minutes of staff time per transaction. The updates to the CAQH CORE Eligibility and Benefits Data Content Rule fill critical information gaps related to benefit structure and patient financial responsibility that allow our practices to carry out more transactions fully electronically. Specifically, the operating rule updates expand the number of required service types, support eligibility verification at a procedure level, enable identification of remaining benefits, indicate if a prior authorization or certification is required, and provide more granular level data for members of tiered benefit plans all within an electronic eligibility transaction.

In the dental industry, many services are limited to a specific number of occurrences during a given period (e.g., two dental hygiene visits per year or one filling per tooth every two years). Therefore, the need to access detailed patient benefit and coverage information in real time is crucial at our practices. The updates to the CAQH CORE Eligibility & Benefits Data Content Rule reduce staff time and effort spent conducting manual eligibility verifications and assures confidence in the specificity of information being returned. Access to this information prior to a patient encounter enables dental practices to understand granular coverage detail, reduce surprise bills, and collaborate with patients to make informed care decisions.

ADMI strongly supports the inclusion of ten new dental service type codes as part of the data content rule update. The expansion of service types of codes bring immense value to the dental industry as providers are now able to receive accurate and comprehensive information related to a patient's coverage benefits and financial responsibility from dental plans. Further, the updated rule requires dental plans to return benefit and coverage information at the procedure level for certain categories of service including surgery and imaging. These

requirements provide critical support to the dental community as stakeholders including oral surgery providers navigate and understand benefit designs that are at the intersection of medical and dental coverages.

ADMI strongly supports federal adoption of the updated CAQH CORE Eligibility & Benefits (270/271) Data Content Rule vEB.2.0. According to the CAQH Index, for each eligibility verification completed electronically, the dental industry saves an average of $9.12 per transaction. Given that ADMI conducts over 1 million eligibility inquiries per year, the potential cost savings for our practices is significant.

3. New: Patient Attribution. Content rule within the new Eligibility and Benefits Operating Rule (vEB.1.0).
As the dental industry explores moving into the value-based care space, ADMI appreciates the potential future value this operating rule will have in supporting the exchange of attribution data within our existing eligibility workflows. The rule creates a consistent pathway for providers to receive the attribution status of a single patient and avoid the proliferation of proprietary approaches as adoption of value-based payment models continue to expand. ADMI supports NCVHS recommending this rule to HHS for federal adoption.

4. Companion Guide Template.
As previously noted, ADMI supports the use of the updated Master Companion Guide Template as a standard format that is easily understood and creates common points of reference across multiple plans to support transaction implementation. We also appreciate its applicability to the CAQH CORE Attachments Infrastructure and Data Content Rules that reference X12 v6020.

5. Updated Connectivity Rule.
The updated Connectivity Rule expands support for APIs and enhances security, digital certification, and authorization. Though these changes may require some upfront investments to support implementation from ADMI, the long-term benefits are significant. Additionally, under current mandates, industry must maintain support for the outdated Phase I and II CAQH CORE Connectivity Rules which is costly and hinders technological growth and interoperability across the industry.

The CAQH CORE Connectivity Rule v4.0.0 enables ADMI to use a single, modern connectivity approach across EDI transactions and trading partners. The connectivity infrastructure at ADMI is designed to support the CAQH CORE Connectivity Rules. We anticipate implementation and onboarding costs associated with updates will be modest because the updated rule does not abandon requirements specified in the mandated versions of the rule and enhances many of its original requirements.

Given that the connectivity safe harbor is a foundational component of the connectivity rule, ADMI can optimize its relationships with our key industry stakeholders and trading partners without the need to overhaul existing, mutually agreed upon connections. Additionally, the enhanced, secured, and modernized connectivity requirements offered by the CAQH CORE Connectivity Rule vC4.0.0 enables ADMI to exchange data across a wider array of stakeholders via uniform communication pathways; opening access and easing the sharing of information to support care delivery and outcomes.

ADMI strongly recommends that NCVHS support federal adoption of the CAQH CORE Connectivity Rule v4.0.0. A modern, safe harbor connectivity method enables provider organizations, both large and small, to efficiently and securely connect to myriad trading partners while minimizing costs. These rules support long-term industry interoperability by deploying the most modern security and data-exchange standards.

6. Costs.
The proposed operating rules updates provide necessary data and security that will enable ADMI to exchange a greater number of eligibility, claim status, and electronic remittance advice transactions electronically. According to the 2021 CAQH Index, the dental industry saves $9.12 and 10 minutes of provider time for each eligibility transaction conducted electronically versus manually. Similar cost and time savings opportunities exist for claim status at $10.76 and 14 minutes of provider time. These estimated savings are significant for ADMI since over 50%

of ADMI visits are insured. These time and cost savings will be realized based on several updates included in the updated operating rules:

- Increased system availability leads to a more predictable, reliable schedule of uptime enabling a higher volume of electronic transactions.
- Connectivity updates guarantee a safe and efficient mechanism for transactions to be delivered using multiple formats and standards enabling ADMI to securely accommodate existing X12 standards and emerging standards, without the need to maintain multiple connections.
- Eligibility data content updates will address gaps that emerged since the electronic X12 standard (270/271), and original CAQH CORE Operating Rule were adopted. These gaps are related to the growth of complex benefit structures, an increase in the use of prior authorization, and the addition of dental service type codes.

7. Alternatives considered for operating rules.
The consequences to ADMI if NCVHS recommends adoption of the updated versions of the updated CAQH CORE Eligibility & Benefits, Claim Status, and ERA Operating Rules will be extremely positive. Our responses to the prior comments outline in detail the benefits of the updated operating rules. A greater concern is the added cost of supporting outdated connectivity methods and the ongoing costs of manual and portal-based transactions that will occur if NCVHS does not recommend the rules to HHS.

8. Attachments Prior Authorization Infrastructure and Data Content Rules (vPA.1.0) and Attachments Health Care Claims Infrastructure and Data Content Rules (vHC.1.0).
The exchange of clinical information or supplemental documentation between providers and dental plans is a highly manual and burdensome process. The 2021 CAQH Index reported that 81% of dental attachments are exchanged manually and just 19% are sent electronically. ADMI expends a tremendous number of resources – both in time and money – processing dental attachments frequently required by dental plans for claims adjudication. This slow and costly adjudication of manual attachments can lead to delays in patient care and negatively impacts revenue. Of particular value are the file size requirements for attachments, as dental x-rays and impression scans are often very large. More uniform guidelines across dental plans will reduce attachment rejections and manual processing.

Industry adoption of electronic exchange methods for attachments is impeded by the lack of federal electronic standards. This has led to the adoption of proprietary and manual approaches to facilitate attachments workflows. As a result, ADMI cannot establish a single, predictable workflow and is forced to navigate varying requirements. The proposed CAQH CORE Attachment Rules support the industry's need to advance the uniform implementation of electronic attachments by establishing data content and infrastructure requirements that seamlessly support exchange and reassociation workflows across multiple standards. ADMI values that the operating rules provide guidance to an industry seeking both standards and a means by which to exchange them across trading partners – meeting industry need for flexibility to meet various use cases and formats.

It should be noted that - in addition to specifying common infrastructure, data content, and connectivity requirements - the proposed operating rules align with the standards previously proposed by NCVHS for attachments in addition to HL7 FHIR. As such, the proposed operating rules meet the predominant desires of the industry and the Subcommittee and provide the necessary guidance to align and scale industry implementation of attachments.

9. Attachments operating rules – general question.
The dentalcare industry has been waiting for federal guidance related to electronic attachment standards for over 20 years and has been waiting more than 10 years for operating rules in the wake of the Affordable Care Act requirements. Despite pilot activities demonstrating the value of electronic exchange of attachments, CAQH Index data shows widespread adoption has not yet occurred. Therefore, a solution is needed to stimulate

implementation of methods that facilitate the electronic exchange of attachments. ADMI strongly supports the adoption of the proposed operating rules.

We also encourage the Subcommittee to recommend the concurrent adoption of the proposed operating rules alongside the anticipated, imminent regulations expected to name attachments standards. The industry can no longer withstand a lack of uniformity and naming standards with the supporting framework of operating rules will stimulate prompt, scaled, and standardized implementation and optimize timelines for conformance. Furthermore, the operating rules will serve as a foundation across whichever standards are selected by HHS and enable uniform expectations regardless of the standard in use.

athenahealth

December 16, 2022

Jacki Monson, JD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: RFC CAQH CORE Proposal

Submitted electronically to NCVHSmail@cdc.gov

Dear Ms. Monson:

Thank you for the opportunity to provide feedback on the CAQH Committee on Operating Rules for Information Exchange (CORE) Proposal to the National Committee on Vital and Health Statistics (NCVHS). athenahealth fully supports the proposal and recommends the new and updated CAQH CORE Operating Rules for federal adoption under HIPAA.

Over the past twenty-two years, athenahealth has built a network of over 160,000 providers in both the ambulatory and acute settings. We provide electronic health record ("EHR"), practice management, care coordination, patient engagement, data analytics, revenue cycle management, and related services to physician practices and hospitals. More than 150,000 of our clinicians utilize our single instance, continuously updated, cloud-based platform. Since announcing a combination with Virence Health in early 2019, we also support on-premise software solutions. In both hosting paradigms, athenahealth seeks out and establishes connections with partners across the care continuum, enabling our clinicians to improve the quality of care they deliver. Interoperability is part of the athenahealth DNA and we integrate with more than 1,800 insurance payers, 122,000 lab and imaging centers, and 75,000 pharmacies in the U.S.

The mission of athenahealth is to create a thriving ecosystem that delivers accessible, high-quality, and sustainable healthcare for all. Through incorporation of modern technical best practices and contemplation of critical business scenarios – including increased support of standardized exchange of structured data and attachments – the proposed new and updated CAQH CORE Operating Rules advance our mission and allow us to drive automation and secure data exchange across our integrated platforms. Downstream, these updates benefit our provider partners and the patients they serve by streamlining operations, promoting exceptional care management, and bolstering a smooth and predictable revenue cycle.

We strongly urge NCVHS to recommend the proposed rule package for full federal adoption. Operating Rules are a proven and effective tool in promoting the electronic exchange of health information uniformly and securely. The new and updated Operating Rules represent commonly accepted best practices and address data content gaps that will promote wider adoption of automation. Without reiterating the full scope of the new and updated operating rule requirements, below we highlight the most significant benefits accrued to athenahealth, our partners, and ultimately patients should the proposed rules be federally mandated.

Eligibility & Benefits, Claim Status, and Payment & Remittance Infrastructure Rule Updates

- Increased system availability for eligibility and claim status balances the desire of our partners for 24/7 availability of our platforms with the need to accommodate reasonable timeframes for system maintenance and upgrades.
- The updated CAQH CORE Master Companion Guide Template is X12 version-agnostic, providing flexibility to meet the needs of partners at different stages of technical development and facilitating implementation of transactions that reference newer versions of the standard.
- Through references to the most recent CAQH CORE Connectivity Rule, the proposed infrastructure rules modernize connectivity and security requirements, eliminating the need for athenahealth and its partners to maintain support for the outdated CAQH CORE Phase I and II Rules.

Connectivity Rule v4.0.0

- The updated Connectivity Rule provides a runway for advancing interoperability while setting a reasonable standard for partners with fewer IT resources to maintain up-to-date systems.
- Increasing the minimum requirements for security standards decreases the likelihood of malicious activity for our partners and their patients.
- The flexibility to support SOAP, REST, and other API resources builds off existing communication frameworks and supports athenahealth partners at varying stages of technologic maturity. It is important for us that regulation support advancement in technologies and prevent situations in which outdated technologies may become the only approved way to communicate.
- The safe harbor provision assures that athenahealth and its partners can connect with multiple trading partners via a uniform, secure connectivity method, reducing costs and implementation timelines associated with myriad connections.

Eligibility and Benefits Data Content Rule Updates

- Based on athenahealth data, physicians and practice staff spend upwards of 15 hours securing 31 prior authorization per physicians each week only to learn that an authorization was not needed a large percentage of the time. Inclusion of prior authorization determination requirements in the updated operating rule reduces unnecessary prior authorization requests and increases the likelihood of approval.
- Increased details for benefit structure and patient financial responsibility supports price transparency and improve care coordination for patients. It is important for our industry that critical information is sent as structured and standardized data and is not ad hoc entered into free form fields (e.g., MSG) or attachments where it could get lost or circumvent reliable automation.
- Telehealth coding requirements enable athenahealth and its partners to automate and streamline eligibility processes for telehealth visits, reducing manual follow up. The use of the EB12 segment of eligibility benefits response rather than the E37 service type code will help eliminate significant confusion for our practices.
- Moving to CPT specific coverage responses is a necessary direction for our industry in order to help patients make the right choices and avoid unpleasant surprises. Athenahealth is therefore supportive of these updates, although we also recognize that this will require substantial investment and time to achieve full benefits.

New Single Patient Attribution Data Rule

- A federally mandated approach for sharing individual patient attribution information within existing eligibility workflows will increase athenahealth's ability to support provider partners in value-based contracts; uniform data from health plans will enable greater automation and transparency.

New Attachments Operating Rules for Health Care Claims and Prior Authorization

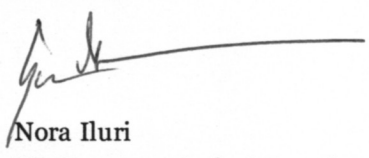
- Proposed operating rules support both X12 and non-X12 standards, including the X12 275, HL7 CCDA, and HL7 FHIR, and empower athenahealth to uniformly meet the needs of our partners across the spectrum of IT implementation.
- The attachments infrastructure rule requirements build on existing infrastructure investments made to conform with HIPAA mandated transactions, minimizing implementation costs while maximizing value.
- athenahealth supports 11+ million attachment exchanges per year via non-standardized methods. A federally mandated standard supported by the implementation uniformity engendered through operating rules will help our partners realize significant cost and time savings.
- If, as anticipated, HHS adopts more than one standard for attachments, the proposed operating rules will enable unification of infrastructure, connectivity, and reassociation requirements - resulting in lower implementation costs, improved patient experience, and faster payments.

Given the synergy between named standards and the proposed operating rules, athenahealth strongly urges NCVHS to recommend to HHS that both attachments standards and operating rules be proposed for federal adoption within the same regulation. Such an approach simplifies implementation efforts, streamline conformance timelines, and address gaps across the standards, lowering implementation costs.

Over 100 organizations across the healthcare industry, including athenahealth, participated in the development of the proposed CAQH CORE Operating Rules in an iterative, bottom up, approach. During deliberations, our team weighed the costs and benefits of the proposed requirements and determined these sets of operating rules result in increased efficiencies for athenahealth and our partners that far exceed the resources required to align our systems and leverage our existing investments. If federally mandated, the value of all HIPAA-covered entities conforming to the new and updated operating rule requirements will drive improvements in automation, reducing expenditures and staffing resources for both athenahealth and our partners.

Thank you for the opportunity to share feedback on this important proposal. athenahealth reiterates our support for NCVHS to recommend the full set of proposed new and updated CAQH CORE Operating Rules to HHS for federal adoption. Please do not hesitate to reach out with questions.

Sincerely,



Nora Iluri
VP, Revenue Cycle & Practice Management
athenahealth

From: Desiree Tyrpak
To: NCVHS Mail (CDC)
Subject: Protest VCCs
Date: Wednesday, December 14, 2022 9:08:01 AM
Attachments: High

Importance:

I'm against the X12 proposed addition of the "card payments" remittance information to 835 ERA, and wish to protest the use of virtual credit cards for the payment of medical services rendered for multiple reasons:

1. It further reduces the already substantially reduced negotiated payment rate that the insurance companies have agreed to pay providers for their services. And that is if they pay because before the insurance companies pay a pre -authorization has already been received and coding has to be correct to THEIR way of doing things. And that is not to say that if they decide to recoup the funds afterwards on a technicality the entire negotiated amount would be recouped by the insurance company.
2. The use of virtual credit cards places a 3rd party between the insurance company and the provider and the only party that this negatively impacted is the physician. Checks and EFT's should be the only acceptable types of payments to providers. (VCC are taking money away from the providers, and laughing all the way to the bank. I would not be surprised if the insurance companies are not somehow benefitting from using these VCC companies via kick-back or taking work off of the insurance companies)

Insurance companies make the money, not the physicians, so please stop taking what little payment they do get away from them.

Sincerely,

Desiree Tyrpak
Director of Provider Services
Austin Palliative Care
4107 Spicewood Springs Rd, Suite 100
Austin, TX 78759

Blue Cross Blue Shield Blue Care Network of Michigan

December 15, 2022

National Committee on Vital and Health Statistics
Subcommittee on Standards
3311 Toledo Road
Hyattsville, MD 20782-2002

RE: RFC on X12 and CAQH CORE Proposals

This document conveys responses from Blue Cross Blue Shield of Michigan to some of the stakeholder questions posed by the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards.

Blue Cross Blue Shield of Michigan (BCBSM) is a nonprofit mutual insurance company founded in 1939. We are the largest health insurer in Michigan, serving 4.5 million people in Michigan and 1.6 million more in other states. Our network of doctors and hospitals is also the largest in Michigan, with 152 hospitals and more than 33,000 doctors. We thank NCVHS and the Subcommittee on Standards for the opportunity to provide feedback regarding the submitted requests for adoption of the updated X12 version 8020 Health Care Claim (837) standards, the X12 version 8020 Health Care Payment/Advice (835) standard, as well as the updated and new CAQH CORE Operating Rules. The following provides our responses to stakeholder posed questions.

Updated X12 Transaction Standards

NCVHS posed stakeholder question:
Costs. If your organization has conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional, or dental claim) and remittance advice transactions, to what extent, relative to the potential cost of implementation, do the updated transaction implementation guides provide net positive value? Please explain.

BCBSM Response:

Blue Cross Blue Shield of Michigan's experience with implementation of version 5010 involved a three year effort with actual cost in excess of $25M. Timeline and cost associated accommodated implementation of all version 5010 standards. We recognize implementation of version 8020 standards will be broken out into separate timeframes; however, it is anticipated the cost for full 8020 implementation will be significantly higher due to increased complexity (differences between version 5010 and 8020 standards), labor costs and inflation. A full cost analysis has yet to be conducted.

Blue Cross Blue Shield Blue Care Network of Michigan

Re: BCBSM responses – RFC on X12 and CAQH CORE proposals

NCVHS posed stakeholder question:
Implementation time frame. HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, what would be the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e. g. does the window need to be longer than two years from the publication date of a final rule?

Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?

BCBSM Response:

BCBSM recognizes the need for a minimum of 24 months to accommodate implementation of the 3 version 8020 Health Care Claim 837 standards (dental, institutional, and professional) as well as the version 8020 Health Care Claim Payment/Advice 835. This is based on implementation impacts experienced with the previous version 5010 version. There was considerable effort during the previous dual version period implementation to ensure alignment with third party vendors and subsidiaries.

We also agree a January 1 implementation date is problematic. It requires implementation during a time of the year we experience resource constraints due to the holiday season and other overlapping end of the year project efforts. Our recommendation for a targeted industry implementation date of June 1. Our review to determine this date included consideration for the following:

- BCBSM efforts affiliated with core business projects (e.g. membership enrollment) and other projects to support enterprise directives (e.g. State mandates; CMS mandates; other core business enhancements/changes).
- A timeframe where overlapping project implementations are typically lower.
- The anticipated ongoing work effort to support implementation for each set of mandated version 8020 standards until the industry has implemented use of the full suite of version 8020 standards.

NCVHS posed stakeholder question:
Implementation. NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?

BCBSM Response:

Implementation of version 5010 did support a dual version period. Based on our experience, BCBSM does not recommend supporting a dual version period and supports a definitive cutover date for the industry. A dual version period creates additional cost and burden for health plans.

Blue Cross Blue Shield Blue Care Network of Michigan

Re: BCBSM responses – RFC on X12 and CAQH CORE proposals

- A health plan must be able to honor a health care provider's request to use a mandated standard, in turn, health plans will be required to support both versions at the start of a dual version period. This places burden on a health plan as their implementation timeframe is shortened.
- Additional cost is incurred to support and operate dual systems in order to process both versions of the standards as well as to retain data for audit, legislative and legal purposes.
- The ability to convert version 8020 to version 5010 (837 and 835 standards) or vice versa may not be a cost effective approach to support use of both standards during a dual version period due to structure and data content differences (i.e. backwards compatibility). For example:
    - There are increases in maximum lengths for several data elements within the version 8020 standards. This poses risk of data truncation when converting version 8020 data to version 5010 data.
    - Version 8020 standards support new functionality and, consequently, contain new data which is not available in the version 5010 standards. Examples of this are Pay-To-Factoring Agent information (i.e. an entity who purchases health care provider receivables and should be paid instead of the provider), reporting of the Unique Device Identifier, and the health plan's Allowed Amount for payment of a service (via the 837 for coordination of benefit claims or via the 835).
    - There is data supported in version 5010 standards which has been deleted from version 8020 standards. If a health plan is using this data to process a version 5010 standard today, there may not be a way to crosswalk that information within a version 8020 standard.
    - Enhanced functionality available in version 8020 may not accurately transition between version 5010 and version 8020 standards. An example is the enhanced ability to communicate an explanation of financial adjustment to payment or an explanation of denial for payment of a service. Version 8020 implements an enhanced structure via a new RAS segment. This adds the capability to report a complete explanation for the adjustment or denial by enabling the capability to report a Claim Adjustment Reason Code (CARC) along with its supporting Remittance Advice Remark Code(s) (RARC). The alignment of CARC with its supporting RARC(s) does not exist in the current version 5010 835 or in the version 5010 837 (for coordination of benefit claims). In version 5010, CARCs are reported via a CAS segment (along with the applicable financial amount) and all RARCs are reported in a separate segment of the transaction. Trying to align RARCs with their applicable CARC will be challenging in a version 5010 835 to version 8020 835 standard conversion.
- Accommodating a dual version period sets the industry expectation of a continuing dual version period until all version 8020 standards are mandated for use. Consequently, this creates additional cost and burden for health plans (e.g. needing to support and operate dual systems in order to process both versions of the standards; resource constraints based on other mandates as well as other enterprise directives/priorities).

- Industry alignment to start using the same version at the same time would better prepare the industry for mandated use/implementation of the future mandated version 8020 standards and would help to minimize industry cost and operational impacts.

NCVHS posed stakeholder question:

Simultaneity. What, if any, are the data impacts, limitations or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g. claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?

BCBSM Response:

BCBSM notes the following gaps:

- Data present in version 8020 which is not available in version 5010 limits the health plan's ability to identify specific data impacting the health plan's ability to accept and/or adjudicate a claim. For example:
    - Version 8020 Health Claim [837 – Professional and Institutional] standards as well as the Health Care Claim Payment/Advice (835) standard support reporting up to 8 modifiers per service line procedure, version 5010 Health Care Claim Acknowledgement (277CA) and the Health Care Claim Status Request and Response (276/277) standards only support up to 4 modifiers per service line procedure.
    - The version 8020 837 professional and institutional standards and 835 standard support real-time pre-determination adjudication request and response; the version 5010 277CA does not support identification of a claim being pre-determination only.
    - Version 8020 837 professional standard has the capability to report tooth information when warranted for certain medical/surgical procedures (i.e. TOO segment). The version 5010 277CA and 276/277 standards do not support reporting tooth information.
- The Health Care Eligibility Benefit Inquiry and Response (270/271) standard is typically the first standard used to validate a patient's eligibility and available benefits. It enables a health care provider to determine a patient's financial responsibility as well as services billable to their health plan. The version 5010 270/271 (including its addenda, version 5010A1) was published over 14 years ago; consequently, it is not always able to communicate, in a standardized way, the changes in benefits which have occurred in the industry over the past 14 years.
- Version 8020 is not fully backward compatible with version 5010. Data supported in version 8020 is not always supported in version 5010 and vice versa. This adds to the complexity of implementation for a health plan.
- There is no industry alignment of an acknowledgement standard for either version which creates inconsistency and additional cost for the industry. Blue Cross Blue Shield of Michigan recommends adoption the following version 8020 standards to support industry alignment: 1) X12C Implementation Acknowledgment for Health Care Insurance (999) standard; 2) X12N Health Care Claim Acknowledgment (277CA).

Blue Cross Blue Shield Blue Care Network of Michigan

Re: BCBSM responses – RFC on X12 and CAQH CORE proposals

NCVHS posed stakeholder question:
General. Does your organization support HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards? Please provide a brief rationale.

BCBSM Response:
BCBSM does support the adoption of the X12 version 8020 837s and 835 standards as these address long standing industry needs for the exchange of administrative data.

CORE Operating Rules

NCVHS posed stakeholder question:
Efficiency Improvements. Infrastructure updates to the adopted Eligibility and Benefits and Claim Status Operating Rules. CAQH CORE has proposed updates to the adopted versions of the eligibility and benefits and claim status operating rules currently required for use. Updates include an increase in system availability from 86% per calendar week to 90%, and for the response time for a claim status request from 20 seconds 86% of the time to 20 seconds or fewer 90% of the time. Please comment on the potential for improvements in efficiency for your organization these updates would contribute when using the adopted X12 HIPAA transaction standards.

BCBSM Response:
Blue Cross Blue Shield of Michigan routinely meets threshold; thereby, no efficiencies would be gained. However, BCBSM recognizes updating to the CAQH CORE Eligibility & Benefits (270/271) Infrastructure vEB 2.0 and the CAQH CORE Claim Status (276/277) Infrastructure vCS2.0 Operating Rules may contribute to overall industry efficiency and supports the industry adoption of these operating rules.

NCVHS posed stakeholder question:
Data Content updates for Eligibility and Benefits Operating Rule. The updated version of the Eligibility and Benefits operating rule includes the requirement to indicate coverage of telemedicine, remaining coverage, and tiered benefits, and to indicate if prior authorization or certification is required. The rule has been updated to include a list of CORE-required service type codes (section 5) and CORE-required categories of service for procedure codes. If your organization has conducted an analysis of these updates and the potential impact to increasing use of the adopted standard, please comment on your assessment of these enhancements for **your organization** and/or your trading partners.

BCBSM Response:
Blue Cross Blue Shield of Michigan has not completed a full operational analysis and is not able to comment at this time. However, we would like to note the level of granularity to support benefit information at a procedure code level introduces complexity, system impacts

and cost not encountered under the existing CAQH CORE Eligibility & Benefits (270/271) Infrastructure Operating Rule.

NCVHS posed stakeholder question:

New: Patient Attribution. Content rule within the new Eligibility and Benefits Operating Rule (vEB.1.0). CAQH CORE has proposed a new operating rule to apply to the selection of value-based payment models by providers. If your organization has conducted an analysis of this operating rule, please provide information on your organization's evaluation of the extent to which the proposed operating rule requirements support the adopted HIPAA transactions or improve administrative simplification.

BCBSM Response:

Blue Cross Blue Shield of Michigan has not conducted an operational analysis and is not able to comment from that perspective at this time. However, we note the next X12N 270/271 version includes Provider Network Status Inquiry and Response reporting functionality. This will provide codified (standardized) network status information of a health plan member/patient to the health care provider. As this information is not currently supported in version 5010 270/271, the CAQH CORE Patient Attribution Operating Rule must use an open text field (called the MSG segment) and require use of certain text in order to convey the member/patient attribution (or provider network status) information. This non-standardized solution will require additional programming time and cost in order to support translation of the information into the MSG segment as well as extracting it from the MSG segment. Supporting this Operating Rule may be a stepping stone/stop gap, but, with VBP being fairly new there is concern regarding building a solution the industry may not yet be ready to use as well as the solution not being fully standardized (i.e. not fully codified). We request NCVHS consider not recommending this Operating Rule for adoption as it will require the industry to build a non-standardized solution which will need to be modified when the next version of the X12 270/271 standard is adopted for use.

NCVHS posed stakeholder question:

Companion Guide Template. CAQH CORE has updated the requirements for the companion guides in the adopted operating rules to promote flexibility. Please comment on your organization's experience with the companion guide template in the first set of operating rules, how it has impacted workflows and whether your assessment of the proposed new template indicates value for implementations of the standard transactions.

BCBSM Response:

BCBSM has been using the CAQH/CORE Companion Guide for all X12 standards we support. This is to ensure consistency in communicating with our trading partners. Its use in the industry provides value to trading partners by enabling consistency. We have not received any negative feedback from our trading partners and have no concerns with its continued use.

Blue Cross Blue Shield Blue Care Network of Michigan

Re: BCBSM responses – RFC on X12 and CAQH CORE proposals

NCVHS posed stakeholder question:

New Connectivity Rule.

A) As part of the re-structuring of the CAQH CORE operating rules for each administrative transaction, CAQH CORE updated the connectivity requirements and published a stand-alone Connectivity Rule (vC4.0.0), for which it is seeking a recommendation for adoption. In addition to the requirements for the use of HTTPS over the public internet and minimum-security conditions, the Connectivity Rule addresses Safe Harbor, Transport, Message Envelope, Security, and Authentication. What changes would be necessary to your organizational infrastructure, policies, and contracts to implement the CAQH CORE c4.0.0 Connectivity rule?

B) The new Connectivity rule adds support for the exchange of attachments transactions, adds OAuth as an authorization standard, provides support for X12 (HIPAA) and non-X12 (non-HIPAA) exchanges, and sets API endpoint naming conventions. The CAQH CORE letter states that the impact of mandating these requirements for HIPAA covered entities includes: "setting a standards-agnostic approach to exchanging healthcare information in a uniform manner using SOAP, REST and other API technologies; facilitates the use of existing standards like X12 in harmony with new exchange methods like HL7 FHIR, and enhancing security requirements to align with industry best practices." Please comment on the scope of the CAQH CORE Connectivity operating rule vC4.0.0 under consideration for adoption under HIPAA.

BCBSM Response:

Blue Cross and Blue Shield of Michigan supports adoption of the CAQH CORE Connectivity Rule c4.0.0. The updates within this rule align with our enterprise objectives. The requirements within the rule are in alliance with current best practice security and authentication controls and protocols. Adoption of this rule will also place the health care industry in a better position to expand upon the use of APIs which further support the exchange of electronic health care administrative data.

NCVHS posed stakeholder question:

Attachments operating rules – general question. HHS has not proposed adoption of a standard for attachments under HIPAA. Please comment on the proposed operating rules for attachments. What should NCVHS consider prior to making any recommendations to HHS regarding operating rules for attachments?

BCBSM Response:

Operating rules are intended to enhance gaps found in the exchange of or within the existing requirements of a mandated electronic transaction standard. As HHS has not yet mandated a standard(s) for the exchange of electronic attachments (claims or prior authorization), adoption of these Operating Rules seems premature. Blue Cross Blue Shield of Michigan recommends CAQH CORE revisit these Operating Rules after HHS has specified the standard(s) for use to ensure these requirements still address gaps.

BlueCross BlueShield of North Carolina

December 15, 2022

Richard Landen and Denise Love, Co-Chairs
National Committee on Vital and Health Statistics (NCVHS)
Subcommittee on Standards
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

By electronic submission to NCVHSmail@cdc.gov

RE: RFC on X12 and CAQH CORE Proposals

Dear Mr. Landen and Ms. Love,

Blue Cross and Blue Shield of North Carolina (Blue Cross NC) writes to comment on the standards developed by the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Operating Rules. The National Committee on Vital and Health Statistics (NCVHS) is currently considering recommending the following for federal adoption: updates to the CAQH CORE Eligibility & Benefits (270/271) Data Content Rule vEB.2.0, CAQH CORE Connectivity Rule vC4.0.0 and Federally Mandated CAQH CORE Infrastructure Rules, as well as new CAQH CORE Attachments Operating Rules and CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Content Rule vEB.1.0.

Blue Cross NC is committed to affordability and access to health care for North Carolinians. Adoption of rules like these improve the care experience for many groups touched by the health care system, including patients, providers and payers, by reducing burden and speeding up administrative processes between payers and providers.

Electronic data exchange defined through CAQH CORE operating rules can reduce the administrative burden on payers, providers and patients. These rules allow payers and providers to electronically exchange transactions, attachments and attribution status, and will result in a significant reduction of manual efforts and lower operating expenses for payers and providers. The Eligibility and Benefit Data Content Rule will allow plans to reduce support calls and emails due to the capability to receive detailed coverage, financial and benefit information in real-time through the transaction. Additionally, Blue Cross NC could save roughly 12,000 hours per year by replacing phone and fax-based methods with electronic attachment capabilities for claims and prior authorization data.

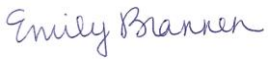
These rules support Blue Cross NC's goal of promoting value-based care through efforts of electronically providing attribution status, which is a key foundational data element of value-based care models. Electronic exchange of attribution status will standardize data across stakeholders and eliminate the burden of ad-hoc data requests and extracts that plans currently generate to support value-based care models. As mentioned above, the rules will also reduce burden on payers and providers for existing processes, which will enable more consistent, straightforward and timely population management and further our value-based care goals.

If the operating rules are adopted by NCVHS and considered by U.S. Department of Health and Human Services (HHS) for future rulemaking, consideration should be given to the appropriate implementation

runway to ensure success across payers, providers and patients. We look forward to engaging as the process continues.

We appreciate the opportunity to provide these comments and to continue serving the health care needs of individuals and families in the State of North Carolina. If you have any questions regarding our comments, please feel free to contact us.

Sincerely,



Emily Brannen
Vice President
Digital Strategy
Blue Cross Blue Shield of North Carolina

BEESLEYS POINT FAMILY PRACTICE

JERRY A. HOROWITZ, D.O.
JILL McINTYRE, APN-C

618 North Shore Road
Beesleys Point, NJ 08223
Telephone: (609) 390-0693
Fax: (609) 390-1147

December 15, 2022

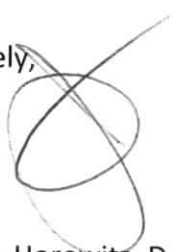
National Committee on Vital and Health Statistics

Dear NCVHS:

I am a "boots on the ground" primary care physician with 30 years experience. I'm independent, nobody owns me. I have a large, loyal, well cared for patient population. I'm going to keep this short and to the point as I'm sure you're tired of reading innumerable well intended but overstated letters/emails. Your consideration of mandatory adoption of VCC and credit cards is yet another bad idea in a seemingly endless series of bad ideas by "suits, bureaucrats, and non-practicing physicians" in the name of " value, cost, savings, and ease of use." This never works out well for the physicians or patients. The only winner of course are the greedy merchants who process payments. I provide the service, that 3% I earned. I'm sure you wouldn't approve of 3% cut in your revenue, for work that you do, given to a third party billionaire, that essentially does nothing.

The plan is a travesty at best, closer to unconscionable. Doctors don't need another reason for burnout and retirement. Medicine doesn't need another bad idea moved forward in the name of progress. Please listen to what I am sure is unanimous consensus amongst independent healthcare providers-reject the proposal, now and forever. Thank you.

Sincerely,



Jerry A. Horowitz, D.O.

December 14, 2022

National Committee on Vital and Health Statistics

CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002
By email: NCVHSmail@cdc.gov

RE: RFC on X12 and CAQH CORE Proposals

Dear NCVHS Members,

We are providers of EMS services to our community and are writing to comment on the X12 proposal that the current standard is updated from version 5010 to version 8020 for the adopted administrative standard for the health care claims (professional, institutional, and dental) and the remittance advice 835 transactions.

The June 7, 2022 letter from X12 to NCVHS, https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf states that X12 has "Added the ability to report remittance information related to **card payments (p-card, debit card, and credit card) to facilitate auto-posting**" to **008020X322** X835 transaction rules.

We are writing to inform NCVHS that we are **AGAINST** the adoption of this standard in its current form. We are **against** the X12 proposed addition of the "card payments" remittance information to 835 ERA.

As you are aware, card payments are universally **opt-out**; **independent healthcare providers do not willingly accept card payments**. There is no "demand" in the healthcare industry among healthcare providers for "card payments." In fact, as you are aware, through prior testimony from the AMA, WEDI, and other organizations to NCVHS, healthcare providers have complained about the **unfair business practices** of sending virtual credit cards by health plans and charging fees for healthcare ACH EFT transactions.

There is **unanimous opposition** to card payments by independent healthcare providers. Card payments **raise consumer costs** and offer **no meaningful 'value-added' to providers** or consumers. That is why the only way it can exist is through 'opt-out' forced imposition on healthcare providers. In other words, there are **no 'willing buyers' for "card payments" when it comes to standard electronic healthcare**

payments. If no provider wants 'card payments, there is **no basis or justification to add the ability to 'report remittance information related to card payments.'**

Healthcare providers do not want the ability to 'autopost' card payments, as most healthcare providers do not want to receive card payments to start with. **When they do get unsolicited card payments, they do not want to autopost them.** Instead, providers spend an inordinate amount of time and money to "opt-out" from card payments. At most, the inability to autopost is a minor negative characteristic of 'card payments'. **Adding the ability to auto-post does not change the nature of card payments – they are costly and unwanted.** What healthcare providers wanted from CMS was to ban credit card payments, not making them 'less evil.' CMS's **unfortunate** position is that it is not illegal to send the first payment as a credit card, even while they raise the cost of healthcare relative to paper checks and certainly relative to standard ACH EFT.

Healthcare providers are very satisfied with the current healthcare ACH EFT standard. The provider complaints related to ACH EFT originate from (1) the fees that some plans and their affiliates impose on ACH EFT; (2) barriers to enrollment; (3) failure by many banks to provide re-association data in electronic format at an affordable cost.

It is critical to remember the intended goal of the legislation, HIPAA Act of 1996, Section 1172 (b): REDUCTION OF COSTS:

> To amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to **simplify the administration of health insurance**, and for other purposes.
>
> 42 US Code § 1320d–1 **(b) REDUCTION OF COSTS.** —Any standard adopted under this part shall be consistent with the objective of **reducing the administrative costs** of providing and paying for health care. (Previously classified as Section 1172)

The proposed allowance to include card payments information on 835 ERA transactions is **not consistent with the plain text of the law**, as card payments universally raise transaction costs, increase administrative costs, and raise the cost of healthcare, even compared to the baseline historical option that the HIPAA standards sought to eliminate, which are paper checks. The mere addition of card payment information to 835 also raises costs without any quantifiable benefit to healthcare providers.

We request that X12/NCVHS/CMS **remove** the section allowing card payments on remittance advice from 008020X322 immediately, as this has a significant **detrimental effect** on healthcare providers.

We appreciate the opportunity to provide our comments to NCVHS. If you have any questions, please do not hesitate to contact us.

Shelley Streahle

CFO

From: Lauren Ott
To: NCVHS Mail(CDC)
Subject: RFC on X12 and CAQH CORE Proposal
Date: Friday, December 9, 2022 9:52:10 AM

Hi, my name is Lauren, I co-own a small private medical practice. We are already very bogged down with the documentation and billing requirements currently in place, and **We are against the X12 proposed addition of "card payments" remittance information to 835 ERA.**

Please take into consideration all parties that will be affected by this - especially small medical practices that exist to serve specific populations in need, and try to improve patient care outside of large hospital systems. This will, like all other implemented policies, have a disproportionately negative effect on small practices who inherently have less resources and smaller profit margins.

Thank you for your consideration,
Lauren
--
Lauren Ott, PA-C
Boston Hernia
bostonhernia.com

From: Michael Reinhorn
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals, by December 15, 2022.
Date: Tuesday, December 13, 2022 10:24:22 AM

We are against the X12 proposed addition of "card payments" remittance information to 835 ERA.
Running a high value medical practice is hard enough as it is without additional waste in the form of fees.
Thanks for your attention to this matter

Michael Reinhorn MD, MBA, FACS
Boston Hernia
Associate Clinical Professor in Surgery Tufts University
www.bostonhernia.com

CARDIOLOGY ASSOCIATES
MEDICAL GROUP, INC.

Jeffery C. Brackett, M.D., F.A.C.C. Jonathan W. Dukes, M.D. Brian Martinez, PA-C
Alon A. Steinberg, M.D., F.A.C.C. Craig S. Mansour, M.D., F.A.C.C. Julie Morantz, PA-C
Shaun T. Patel, M.D., F.A.C.C. Subeer Wadia, M.D.
Omid Fatemi, M.D., F.A.C.C. Ayhan Yoruk, M.D.

December 7, 2022

National Committee on Vital and Health Statistics

CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002
By email: NCVHSmail@cdc.gov

RE: RFC on X12 and CAQH CORE Proposals

Dear NCVHS Members,

We are writing to comment on the X12 proposal that the current standard is updated from version 5010 to version 8020 for the adopted administrative standard for the health care claims (professional, institutional, and dental) and the remittance advice 835 transactions.

June 7, 2022 letter from X12 to NCVHS, https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf states that X12 has "Added the ability to report remittance information related to **card payments (p-card, debit card, and credit card) to facilitate auto-posting**" to **008020X322** X835 transaction rules.

We are writing to inform NCVHS that we are **AGAINST** the adoption of this standard in its current form. In particular, we are **against** the X12 proposed addition of the "card payments" remittance information to 835 ERA.

Our primary objection to the addition of “card payments” is the cost shift to medical practices of the card discount rate – this is a cost of doing business for the seller of the insurance benefit it is not a cost of providing medical care at a contracted rate.

With card payments providers are not paid the contracted rate they have agreed to. It appears that these “card payment’ companies are colluding with insurance carriers and providing carriers with kickbacks from the discounts taken out of payments owed to providers. Attached is a link to a “card payments’ web site that is marketing the “rebates” as a benefit of virtual cards.

https://acom.com/wp-content/uploads/The-Benefits-of-Virtual-Cards.pdf

Potential to generate revenue by earning rebates for your AP spend.

CARDIOLOGY ASSOCIATES
MEDICAL GROUP, INC.

Jeffery C. Brackett, M.D., F.A.C.C.
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Ayhan Yoruk, M.D.
Brian Martinez, PA-C
Julie Morantz, PA-C

These rebates are based on revenue theft from practices since the card discount rate exceeds the cost of "service" the card payment companies are providing.

CMS has significant penalties for medical practices for kickbacks related to volume-based referrals, this is a similar model of volume-based payments, the difference is that the carriers are getting the kickbacks from card processors.

People familiar with accounts payable are now seeing invoicing that includes cost increases for use of credit cards – an additional 3 to 3.5% is what we typically see and it is our choice to pay the higher price for the "benefit" of using a credit card.

An "opt-in" to receive a "card payment" or a boost in the payment amount to cover the card discount so providers are receiving payment that meet the contracted rates they have agreed to might be a viable option.

Thank you for your consideration.

Phil Janke MBA
Chief Operating Officer
Cardiology Associates Medical Group Inc
168 N. Brent Street Suite 503
Ventura, CA 93003
805-653-0101
FX 805-641-0434

December 15, 2022
Richard Landen and Denise Love, Co-Chairs
National Committee on Vital and Health Statistics
Subcommittee on Standards
Centers for Disease Control and Prevention/ National Center for Health Statistics
3311 Toledo Road, Hyattsville, Maryland 20782

Submitted electronically to: NCVHSmail@cdc.gov

RE: NCVHS Request for Comment (RFC) on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules Version 3 – November 28, 2022

Dear Mr. Landen and Ms. Love:

Thank you for the opportunity to respond to the Request for Comment (RFC) to inform the National Committee on Vital and Health Statistics (NCVHS) as it develops recommendations to HHS regarding the proposed mandatory updates to four HIPAA-adopted transactions, mandatory updates to four adopted operating rules, and six new operating rules. Centene Corporation (Centene) is a leading multi-national healthcare enterprise that is committed to helping people live healthier lives. Centene takes a local approach – with local brands and local teams – to provide fully integrated, high-quality, and cost-effective services to government-sponsored and commercial healthcare programs, focusing on under-insured and uninsured individuals. Centene offers affordable and high-quality products to nearly 1 in 15 individuals across the nation; inclusive of Medicaid and Medicare members (including Medicare Prescription Drug Plans), as well as individuals and families served by the Health Insurance Marketplace, the TRICARE West Region program, and individuals in correctional facilities. Centene also contracts with other healthcare and commercial organizations to provide a variety of specialty services focused on treating the whole person. Moreover, we focus on long-term growth and value creation as well as the development of our people, systems, and capabilities so that we can better serve our members, providers, local communities, and government partners

Centene appreciates NCVHS' initiation of this important dialogue. Centene is committed to development of better electronic sharing of data across the healthcare system and has received Certification from the Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Core Rules (CORE). We are currently CORE Certified for X12 270/1, 276/7 and 835. As healthcare becomes increasingly technology-driven, operating rules and standards are important to ensure data can be shared quickly, accurately, and seamlessly. As a stakeholder in the management and use of these CORE Operating rules, we look forward to helping to drive greater efficiency for our healthcare partners, including the providers that serve our members.

Please see below our responses and recommendations regarding the request for comments on the proposed transactions and operating rules, intended to help on delivering the best value to the healthcare industry through these proposed updates.

Centene Comments on Proposed Rules and Updates

Attachments: Attachments, the specific documentation included to support a claim or the necessity for a procedure or service, are sent in a wide variety of different formats today. In addition, the Prior Authorization (PA) and Claims Transactions (X12 278 and 837) typically have a prolonged cycle for adjudication when they are not accompanied by the required documentation for review and dispositioning a request for authorization or payment. Attachments have had very low adoption so far, due to the lack of a mandated transaction to accompany the PA or Claim transaction. The CORE proposed operating rules provide a much-needed standard to send attachments with these transactions and thus help improve adoption either with the X12 275 Transaction or without. Simplifying how a PA or claim is reassociated to an attachment can reduce the need for manual processes, leading to quicker decisions and lower burden.

Eligibility & Benefits: The new CORE proposed rules to enhance the Eligibility and Benefits Transaction (X12 270/271) bring much needed enhancements to enable providers to serve our members more effectively. Support for Telemedicine and Procedure Code-level specificity will also help reduce call center volume by providing answers electronically, leading to time saved and an improved experience. Similarly, increasing the Service Type Codes support to 178 from 52, and requiring communication if a Prior Authorization is required at Procedure Level, provide much needed visibility for Providers and Members at the Point of Service and reduce the need to place calls to Customer Service. The additional Service Type Codes help aid providers to get more detailed and granular information.

Recommendations

Centene has seen great value in standards and improvements for these transactions and we have been active participants in workgroups to develop these operating rules; therefore, we highly recommend these standards be approved.

We do recognize that these CORE Operating Rules can be a challenge for the industry to implement and would thus recommend a generous timeline to implement as part of the CORE Certification process that would lead to greater adoption of the standards and improved collaboration with providers.

Concluding Comments

We again thank NCVHS for the opportunity to express feedback on the proposed new and updated CORE Operating Rules. We look forward to any potential partnership to continue providing feedback.

If you have questions or need more information, please contact me at anika.gardenhire@centene.com.

Sincerely,

Anika Gardenhire
Chief Digital Officer
Centene Corporation

CSRO
Coalition of State Rheumatology Organizations

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December 15, 2022

National Committee on Vital and Health Statistics
Subcommittee on Standards
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted electronically: NCVHSmail@cdc.gov

Re: RFC on X12 and CAQH CORE Proposals

Dear Sir or Madam:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist. Today, we write in response to your Request for Comment (RFC) on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules.

Updated X12 Transaction Standards

Rheumatology practices are deeply concerned that moving to the updated X12 transaction standards will prompt an increase in health plans use of virtual credit card (VCC) payments for health care claims. When plans make payment via VCC, practices incur additional costs in the form of processing fees. These processing fees can be considerable, particularly for rheumatology practices that may be submitting claims for high-cost medication therapies. Worse yet, some of these VCC fees are going back to the plans, as some of them have established their own banking institutions (e.g., Optum Bank, a subsidiary of Optum/United Health Group).

We understand that practices 1) are not required to accept VCC payments, 2) can "opt-out" of VCC payments, and 3) can request that plans make payments through EFT via the ACH network or paper check. However, plans are increasingly using VCC and making it administratively challenging for practices to opt-out and receive payments via EFT or paper check. Indeed, some practices tell us they must opt-out of VCC payments on a recurring basis, and in extreme situations, on a claim-by-claim basis. The process for opting-out is not simple; practice staff must call the plan, wait on an extended hold, and work with a plan representative to change the payment to EFT or paper check. This diverts practice staff away from patient care activities, not to mention significantly delays reimbursement to practices that are already facing financial shortfalls due to high inflation. Indeed, for those offices that opt-out of VCC, some practices report that an EFT or paper check is delayed – in some cases, for more than a month – causing significant cash flow issues.

While X12 has simply "[a]dded the ability to report remittance information related to card payments (p-card, debit card, and credit card) to facilitate auto-posting," we are concerned that plans will increase their use of VCC payments with the new standards, making it even more administratively challenging for already strained physician offices. This is particularly true for plans that have a financial incentive to use VCC because they receive the processing fees. The lack of guardrails to prevent

practices from having to repeatedly opt-out of VCC and request their payments through EFT or paper check goes against the letter and spirit of the HIPAA Administrative Simplication rules.

We urge NCVHS to consider these concerns during the upcoming deliberations, and as part of any recommendation to adopt the new X12, that NCVHS would include a recommendation that CMS/HHS provide clear instructions that plans 1) are prohibited from forcing physician practices to accept VCC payments, and 2) that plans can only make VCC payments to practices that have affirmatively "opted-in" (meaning that plans are disallowed from using opt-out mechanisms). Further, we recommend that NCVHS urge CMS/HHS to make changes to its March 22, 2022 guidance consistent with the recommendations provided by WEDI in its July 26, 2022 letter (registration required) on this matter.

Thank you for considering the feedback of practicing rheumatologists. Should you have any questions, please contact me at gfeldman@csro.info.

Sincerely,

Gary R. Feldman, MD, FACR
President

Madelaine A. Feldman, MD, FACR
Past President and Vice President, Advocacy & Government Affairs

From: Domingo D. Price
To: NCVHS Mail (CDC)
Subject: Virtual Credit Cards
Date: Tuesday, December 13, 2022 10:13:07 AM

To Whom It May Concern:

As physicians we are already short staffed and not able to pay our staff what they are worth due to all the cutbacks from CMS and other insurance companies . Please do not initiate Virtual Credit Cards, as the fees that are charged are not worth it. In a small medical practice, every penny counts for overhead. People tend to think private physicians are overpaid, when in reality we are not. Again, I cannot stress enough that we do not need the fees that go with virtual credit cards.

Kind Regards,

Domingo D. Price
Practice Administator
Colon-Rectal Surgery Associates, PC
410 University Pkwy, Suite 2100
Aiken, South Carolina 29801

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December 5, 2022

RE: RFC on X12 and CAQH CORE Proposals

To Whom it May Concern:

Cook Medical ("Cook") submits this letter to provide comments to the National Committee on Vital Health Statistics (NCVHS) Request for Comment (RFC) on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules. Specifically, in response to request #5 concerning Unique Device Identifier (UDI), Cook strongly supports the inclusion of the device identifier (DI) portion of the UDI in the updated Medicare claims form. By requiring the inclusion of the device identifier, an inherent linkage is created from the patient to the safety and performance data associated with the use of medical devices. This change is a necessary first step toward improving device-specific patient outcomes.

Cook is a family-owned group of domestic and international corporations engaged in the manufacture of diagnostic and therapeutic products for use in various medical specialties including interventional radiology, cardiology, vascular surgery, critical care, gastroenterology, urology, reproductive health, wound care and surgery. We invent, manufacture, and deliver a unique portfolio of medical devices to healthcare systems of the world that includes more than 14,000 different product variations. Our company employs about 12,000 people around the world. Eight thousand of those employees are based in the United States and while more than 56 percent of our products are used outside the United States, more than 70 percent are manufactured in this country.

Real world evidence (RWE) continues to provide tremendous value for stakeholders, the sustainability of the U.S. health care ecosystem, and for patients. Cook is actively working with FDA and other regulatory authorities to identify solutions to incorporate RWE into the medical device regulatory decision-making processes. One of the largest data sources of RWE, covering a substantial portion of the U.S. patient population, is the Medicare claims data. Incorporation of UDI into Medicare claims forms is a critical component necessary to maximize the potential of this data source. Medical device manufacturers are required by law to include the UDI on the labeling associated with each medical device. Unfortunately, there has been no mandate for the UDI to be scanned or collected by the hospitals in the patient's medical chart or billing. By requiring UDIs on the claims forms, the infrastructure is established for providing valuable data necessary to analyze the safety and performance of a medical device, rapid identification of potential product concerns, and prompt notification to affected patients, physician providers, and regulators - all of which support our top priority of patient safety.

While some have argued that the UDI is better suited for inclusion in the electronic health records, Cook believes this argument sets up a false choice between the two. Inclusion of the UDI in both electronic health records and claims forms, will lead to a more robust system of real

world data, with far greater granularity than what is currently available. This detailed information regarding device usage, safety, and performance - combined with patient treatment and outcomes - will better inform physicians, manufacturers, patients, payors, regulators, and others on aspects of medical device development that will lead to new and next generation technologies to enhance patient care.

The question of whether to include the DI in Medicare claims forms was exhaustively considered by the American National Standards Institute's Accredited Standards Committee (X12), and X12 ultimately recommended to NCVHS that the DI portion of the UDI be included in Medicare claims forms. We look forward to NCVHS making its recommendation on this critically important issue to the Department of Health and Human Services. If an automotive manufacturer can link a specific car to the owner through the VIN number, why can't the U.S. healthcare system make a similar link from a medical device to the patient treated with the device?

We thank you for the opportunity to share these comments and for your attention to this important issue and the significant and positive impact it will have on patient care.

Sincerely,

Stephen L. Ferguson
Chairman of the Board

December 15, 2022

To the National Committee on Vital and Health Statistics' (NCVHS), Subcommittee on Standards:

Re: NCVHS Standards Subcommittee January Hearing RFC Questions V3

On behalf of the Cooperative Exchange[1], I am writing to provide comments in response to the National Committee on Vital and Health Statistics Standards Subcommittee Request for Comment ahead of the January 18-19, 2023, public hearing on requests for new and updated transaction standards and operating rules.

Cooperative Exchange Comments:

Comments on behalf of Cooperative Exchange members are provided in the attached "Cooperative Exchange Comments - NCVHS RFC X12 & CORE – FINAL" document which contains the following sections:

- Page 1: Intro – simple indication that we are responding to the Version 3 – November 28, 2022, RFC
- Pages 2-5: NCVHS RFC – X12 – comments specific to the X12 RFC questions
- Page 7: Multiple Version 3 Year Cycle – a visual representation of a hypothetical federally established known and predictable version update schedule provided to support and illustrate our comments
- Pages 8-10: NCVHS RFC – CORE - comments specific to the CAQH CORE RFC questions

Cooperative Exchange appreciates the opportunity to comment, and we welcome the chance to discuss and elaborate on our comments if needed. We look forward to participating and providing oral testimony as an invited organization at the upcoming January NCVHS Subcommittee on Standards meeting.

Sincerely,

Pam Grosze, Board Chair, Cooperative Exchange,
Vice President, Senior Product Manager, PNC Healthcare

The Cooperative Exchange Background

The Cooperative Exchange is a nationally recognized association representing the healthcare clearinghouse industry in the United States. Our 23[1] clearinghouse member companies represent over 90% of the nation's clearinghouse organizations and process over 6 billion healthcare claims, reflecting over 2 trillion dollars in billed services annually. Our association members enable nationwide connectivity between over 1 million provider organizations, more than 7,000 payers, and 1,000 Health Information Technology (HIT) vendors. The

[1] The Cooperative Exchange (CE) is comprised of 23 of the leading clearinghouses in the US. The views expressed herein are a compilation of the views gathered from our member constituents and reflect the directional feedback of the majority of its collective members. CE has synthesized member feedback and the views, opinions, and positions should not be attributed to any single member and an individual member could disagree with all or certain views, opinions, and positions expressed by CE.

Cooperative Exchange truly represents ***the U.S. healthcare electronic data interstate highway system*** enabling connectivity across all lines of healthcare eCommerce in the United States.

Cooperative Exchange member clearinghouses support both administrative and clinical industry interoperability by:

- Managing tens of thousands of entities and connection points
- Exchanging complex administrative and clinical data content in a secure manner
- Supporting both real-time and batch transaction standards
- Enabling interoperability by normalizing disparate data to industry standards
- Delivering flexible solutions to accommodate varying levels of stakeholder readiness (low tech to high tech)
- Providing strong representation and participation across all national healthcare standard and advocacy organizations with many of our members holding leadership positions

Therefore, we strongly advocate for standardization and administrative simplification within the healthcare industry.

NCVHS Request for Comment (RFC) on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules Version 3 – November 28, 2022

The National Committee on Vital and Health Statistics' (NCVHS), Subcommittee on Standards will host a hearing on January 18-19, 2023. The purpose is to receive input to inform the Committee's deliberations as it develops recommendations to HHS on adopting proposed updated standards from X12 and proposed updated and new operating rules from the Committee on Operating Rules for Information Exchange (CAQH CORE) as described in the Federal Register Notice.2 The standards and operating rules are those adopted by HHS through policies established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and section 1104 of the Affordable Care Act (ACA). In addition to information obtained at the hearing, NCVHS is soliciting written comments through a Request for Comment (RFC) from any individual and organization that would like to provide input. NCVHS will review written submissions in advance of the hearing and consider them together with the hearing testimony. Please note, the set of questions below are offered as a guide, and other commentary is welcome. The questions provided here represent the type of information sought from stakeholders. Commenters should provide any other information about the proposed standards and operating rules under HIPAA they deem relevant to inform the Committee's recommendations to HHS.

Please submit comments to NCVHSmail@cdc.gov with the subject line: RFC on X12 and CAQH CORE Proposals, by December 15, 2022.

#	RFC Questions:	Cooperative Exchange Response:
1	**Costs**. If your organization has conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional or dental claim) and remittance advice transactions, to what extent, relative to the potential cost of implementation, do the updated transaction implementation guides provide net positive value? Please explain.	There are several unknown factors that influence the ability of stakeholders to conduct a true cost impact analysis. X12 is making a series of recommendations in a phased approach in sets of logically grouped transactions. NCVHS is soliciting public feedback based on this phased approach. This approach is different than the historical approach taken during the migration to v4010 and update to v5010 where the majority of HIPAA transactions were named in regulation and all stakeholders were aware of the regulated approach and effective date. Also, in a July 2022 letter to the HHS secretary, NCVHS made recommendations to allow the adoption and use of more than one standard per business function and support of one or more versions of adopted standards for business functions. Will regulations and effective dates also be mandated in a phased manner? Will regulations allow multiple standards and multiple versions of multiple standards? What additional workflow dependencies / consequences would be encountered with this approach? A true cost analysis cannot be conducted until affected stakeholders have a solid understanding of the implementation approach and adjudication of the July 2022 NCVHS recommendations. Given the fact that the version 5010 standards are 15+ years old (published between 2006 - 2008), and that many CE members are also members of X12 and participated in the development the v8020 IG enhancements, Cooperative Exchange is supportive of the v8020 standards and conclude there is a net positive value in both the substantive and non-substantive updates made to the guides from 2006 through 2021. Note that X12 is actively conducting a Proof of Concept (PoC) program with select X12 licensing partners to verify the benefits, opportunities, challenges, and potential costs to upgrade from the current to proposed future versions.
2	**Operational impacts.** If your organization has conducted an operational assessment or workflow analysis of the impact of transitioning to the updated X12 8020 claims and remittance advice transactions, what process improvements has your organization identified would result from implementation of the updated versions of any of the updated transactions? Please provide information for the Committee to reference in its considerations and feedback to HHS.	See above. A true operational impact assessment cannot be conducted until stakeholders have a solid understanding of the implementation approach and adjudication of the July 2022 NCVHS recommendations. Cooperative Exchange supports both the substantive changes to add/evolve business functionality as well as the non-substantive updates which decrease misinterpretation/ambiguity and promote precision in deployment across all stakeholders thus reducing the overall operational costs to support the updated implementation guides.
3	**XML Schema**. X12 has indicated that each of the X12 implementation guides included in their recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. In its letter to NCVHS, X12 noted that it mechanically produces these representations from the same metadata used to produce the implementation guide. X12 recommends that HHS permit both the 8020 EDI Standard representation (the implementation guide) and the XML representation, and that both be named in regulation as permissible syntaxes. Please comment on the proposal to adopt the 8020 EDI standard and the XML representation as permitted syntaxes.	Cooperative Exchange supports the X12 recommendation to allow both X12 and XML (and JSON if industry demand warrants) as adopted and permitted syntaxes as long as they are semantically equivalent and testing outcomes demonstrate as such. Clearinghouses could play a role to translate between syntax preferences and allow stakeholders to utilize the syntax of their choice.

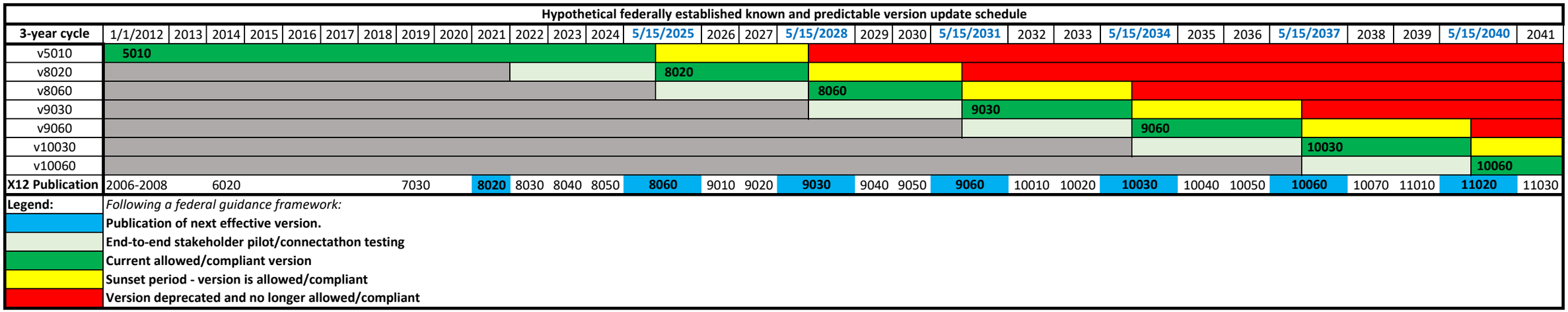
4	**FHIR Crosswalks**. X12 indicated that it intends to provide FHIR crosswalks for the proposed X12 version 8020 transactions (claims and electronic remittance advice) submitted for consideration in time for inclusion in the Federal rulemaking process. Please comment on how FHIR crosswalks would apply to the implementation of the HIPAA claims and remittance advice transaction standards.	Cooperative Exchange supports and applauds the efforts of X12 and HL7 towards alignment and use of harmonized data terminology with a goal of semantic interoperability between SDO implementation guides that support the same business use case. Effective FHIR or X12 crosswalks can only be realized if both SDOs work collaboratively toward a semantically equivalent data dictionary, data usage requirements, and metadata profiles. Currently, this level of semantic interoperability does not exist for all X12 and FHIR data elements and profiles, nor do functionally / semantically equivalent FHIR implementation guides exist to support all HIPAA named administrative healthcare transactions. Directionally, Cooperative Exchange supports this vision and we support regulatory oversight to ensure that semantically equivalent standards interoperability is realized and maintained.
5	**Unique Device Identifier (UDI)**. The device identifier (DI) portion of a medical device's unique device identifier (UDI) is now included as a data element on the updated claim transaction in the institutional and professional version of the 8020. The UDI is also an element in the US Core Data for Interoperability (USCDI) for Certified Health Technology required by the Office of the National Coordinator, and can be found in certified Electronic Health Records, and in standardized hospital discharge reports. Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction.	Cooperative Exchange members understand the significance of situationally incorporating UDI into the claim transaction standard and overarching goal of improving the quality of care provided to patients where medical devices are involved in treatment. We will fully support the exchange of situational UDI data in administrative transaction workflows but we feel that providers, payers, patients/patient advocate organizations, and other interested stakeholders are better positioned to address the question of additional value.
6	**Alternative Payment Models (APM) and Value Based purchasing (VBP)**. Does X12 version 8020 support VBP claims? In what ways does the version 8020 of the claims transactions accommodate APMs such as medical homes or accountable care organizations (ACOs)? Please discuss the implications of this topic to HIPAA administrative simplification policies and continued innovation of non-fee-for-service business models.	Cooperative Exchange is not aware of any industry communicated hardship due to X12 standards nor any maintenance requests to enhance X12 standards to support APMs and/or VBC/VBP models. We expect that X12 v5010 or v8020 would continue to support care and payment model innovation and the transition from fee-for-service to a non-fee-for-service business model.

7	**Implementation time frame**. HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, what would be the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e. g. does the window need to be longer than two years from the publication date of a final rule? Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?	Cooperative Exchange advocates for industry regulations that allow and accommodate new or updated HIPAA transaction standards in a federally established consistent and predictable schedule. We recommend that industry comments be solicited as to the standards update cycle frequency. We support an effective date that does not fall on the end or beginning of a month or year and avoids major holidays.

8	**Implementation**. NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?	Cooperative Exchange supports allowing early adoption of new functionality via updated standards, as well as permitting continued use of existing standards, to ease burden and allow additional time to implement updated standards. With that said, allowing up to *only* two versions of a standard to coexist is strongly recommended. More than two increases the complexity significantly from both a technical and operational perspective. This would allow industry flexibility as a new standard is introduced (per established consistent & predictable cycle). The former version would become legacy and use would be allowed through its legacy runout lifecycle after which the legacy standard would be considered non-compliant (retired), the former “new” would become legacy, and the next "new" version would restart the cycle. Transitioning from the current "federal effective date" cycle that requires a cumbersome and time consuming regulatory review and rulemaking process to a federally established known and predictable cycle of every X years would allow the industry to realize innovation and apply version updates in smaller incremental changes vs. huge steps / major changes due to long regulatory timeframes. Cooperative Exchange supports NCVHS recommendation #4 in its July 2022 letter to the HHS secretary which calls for the creation of a guidance framework for Standards Development Organizations and other industry stakeholders that outlines how to develop and report measures for new and revised standards readiness, costs, and overall adoption value to support HIPAA standards development, testing, evaluation and adoption. With a federal SDO guidance framework in place under a federally established known and predictable version update cycle, industry stakeholders would become acclimated to the framework process/requirements providing a more consistent means to participate and comment on proposed standards or operating rule updates. A known and predictable version update cycle would also allow affected stakeholders to plan, budget, and resource effectively and introduce changes in a flexible cadence as their business needs warrant, while also, by nature of the process, advance the industry forward to continuously improve and modernize applicable standards. For example: assuming a hypothetical 3-year cycle using v5010, v8020, and v9010 over time as a use case – v8020 would have an hypothetical effective date of 5/15/2025 at which time v5010 would run out its 3-year legacy cycle and become non-compliant after 05/14/2028. On 5/15/2028, v9010 would be the new compliant and allowed version and v8020 would then be allowed to run out its 3-year legacy cycle. The next regulated version would be published 3 years in advance of its effective date to allow industry pilot/connectathon testing ahead of the cycle effective date. So, in effect, each regulated version would have a 3 year pilot/connectathon testing period, a 3 year current, and 3 year legacy lifespan for a total lifespan of 9 years and total production compliant/allowed lifespan of 6 years. This approach would minimize the "big-bang" cutover impact experienced in the transition from v4010 to v5010. See section "Multiple Version 3 Year Cycle" for a visual representation of a hypothetical 3-year version update cycle. A federally established known and predictable version update cycle, under a federal guidance framework that allows two versions of a standard to co-exist, would present some challenges. If the version update is not backwards compatible, clearinghouses and payers would be required to support two distinct workflows over a period of time to allow the legacy version to run out its legacy lifecycle. Software vendors acting as a business associate of a provider would be required to accommodate updated versions in their software solutions and transition their provider customers to updated standards within the effective cycle window for a given version. These same challenges are applicable regardless of the underlying standard be it HL7, HL7 FHIR, NCPDP, X12, or other. The ONC Standards Version Advancement Process (SVAP) could be reviewed and considered as a potential national register of published and approved standards. Clearinghouses would continue to fulfill a pivotal role enabling both low and high tech stakeholders to transition to updated standards and versions between cycle updates.
9	**Simultaneity**. What, if any, are the data impacts, limitations or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g. claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?	Cooperative exchange does not support multiple regulatory effective dates for sets of logically grouped transactions for a given version of a standard (see: https://x12.org/news-and-events/x12-recommendations-to-ncvhs). Traversing and maintaining a "phased" regulatory approach for logically grouped transactions for a given version would be very costly, complex, and confusing across the entire industry. Interdependencies and compatibility between logical groupings across multiple effective dates would need to be continually analyzed for each newly introduced version. As outlined in our response to question 8, Cooperative Exchange supports regulations allowing new or updated HIPAA transaction standards on a federally established consistent and predictable schedule under a federally established SDO / implementation framework. If payers (health plans), clearinghouses, and vendors were required to support the suite of v8020 and v5010 during a given consistent and predictable compliance window, data impacts, limitations, or barriers would be minimal as providers could continue to conduct v5010 (and payers, clearinghouses, and vendors would be required to maintain/support v5010) and then migrate to the v8020 suite of transactions at anytime during the transition window until v5010 is expired as non-compliant.

10	**Alternatives Considered**. X12 indicated that there were over 2,000 changes identified in the change logs for the four updated transactions in version 8020, categorized by operational, technical and editorial. If your organization has conducted assessments of the technical changes, what is your determination of these with respect to reducing burden on payers or providers once the updates have been implemented? What is the opportunity cost of remaining on Version 5010 and not implementing the updated version 8020 of the claims and remittance advice transaction standard? What will the healthcare industry risk by not adopting version 8020?	The version 5010 standard is 15+ years old (published between 2006 - 2008). As accurately noted in the RFC question, thousands of updates have been made to the subset of the HIPAA transactions that X12 included in its initial recommendation - the claim and remittance standards. A significant number of changes will also be identified in future X12 recommendations. This is logically an expected outcome after a 15+ year existence of the v5010 standards. Regardless of the underlying SDO or syntax, the federal regulatory process has made it extremely difficult for healthcare industry stakeholders to embrace innovation and realize change, whether operational, technical, or editorial, in support of administrative simplification and efficiency. The alternative lies not with a potentially different standard, syntax, or data exchange method, but with fixing the cumbersome and time consuming regulatory review and rulemaking process which continues to stifle innovation and advancement of our industry. Again, we strongly advocate for a change to the current regulatory review and rulemaking process and its known challenges and support a federally established known and predictable version update cycle, under a federal guidance framework that allows two versions of a standard to co-exist. Many years of effort across every stakeholder constituent are reflected in the X12 v8020 standard updates. As outlined in the October 2021 Cooperative Exchange No Surprises Act GFE-AEOB Provisions white paper (https://s3.amazonaws.com/amo_hub_content/Association618/files/Cooperative%20Exchange%20White%20Paper%20-%20No%20Surprises%20Act%20GFE-AEOB%20Provisions.pdf), the v8020 updates also include support for the predetermination (estimation) of professional and institutional services and items for covered individuals as required by the No Surprises Act. As our industry is operating on standards that were initially published over 15 years ago, the opportunity cost and risk of not accommodating innovation and change required to advance our industry forward cannot be truly measured. The current process is unpredictable and we need to collectively identify root cause and embrace change.
11	**General**. Does your organization support HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards? Please provide a brief rationale.	As outlined in the our responses to the questions above, Cooperative Exchange supports regulations allowing new or updated HIPAA transaction standards on a federally established consistent and predictable schedule under a federally established SDO / implementation framework.

The Cooperative Exchange (CE) is comprised of 23 of the leading clearinghouses in the U.S.
The views expressed herein are a compilation of the views gathered from our member constituents and reflect the directional feedback of the majority of its collective members.
CE has synthesized member feedback and the views, opinions, and positions should not be attributed to any single member
and an individual member could disagree with all or certain views, opinions, and positions expressed by CE.



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#	RFC Questions:	Cooperative Exchange Response:
1	**Efficiency Improvements**. Infrastructure updates to the adopted Eligibility and Benefits and Claim Status Operating Rules. CAQH CORE has proposed updates to the adopted versions of the eligibility and benefits and claim status operating rules currently required for use. Updates include an overall increase in system availability from 86% per calendar week to 90%, and an optional 24 additional hours of system downtime per quarter to accommodate large system migrations, mitigation and more integrated system needs, when applicable. Please comment on the potential for improvements in efficiency for your organization these updates would contribute when using the adopted X12 HIPAA transaction standards.	Cooperative Exchange supports the operating rule updates for existing federally adopted eligibility and benefits and claim status infrastructure rules. Stakeholders have been operating under the current infrastructure rules for nearly a decade. Increasing system availability for real-time eligibility and claim status transactions is a logical step forward to improve overall availability. Note: Federally mandated operating rules should be published to include *only* the rule requirements under federal mandate. For example, rule publications/specifications that include requirements for acknowledgements that have been excluded in federal rulemaking is confusing to the industry at large. CAQH CORE should be required to publish operating rules that are fully aligned with federal rulemaking requirements and can alternatively publish non-mandated certification requirements that include other requirements (such as acknowledgements) for purposes of voluntary certification. Voluntary certification requirements should be clearly noted as such.
2	**Data Content updates for Eligibility and Benefits Operating Rule**. The updated version of the Eligibility and Benefits operating rule includes the requirement to indicate coverage of telemedicine, remaining coverage and tiered benefits, and to indicate if prior authorization or certification is required. The rule has been updated to include a list of CORE-required service type codes (section 5) and CORE-required categories of service for procedure codes. If your organization has conducted an analysis of these updates and the potential impact to increasing use of the adopted standard, please comment on your assessment of these enhancements for your organization and/or your trading partners.	Cooperative Exchange supports the operating rule updates for existing federally adopted eligibility and benefits data content rules. Recent legislative and regulatory actions support a higher level of information at the point of service to inform and protect patients. Updating the eligibility and benefits data content operating rule will support these actions by providing a more robust eligibility response that will alleviate the burden on patients, providers, and payers by providing needed information at the time of service as it relates to benefits, pricing, patient cost, and the requirements for prior authorization. Note: Federally mandated operating rules should be published to include *only* the rule requirements under federal mandate. For example, rule publications/specifications that include requirements for acknowledgements that have been excluded in federal rulemaking is confusing to the industry at large. CAQH CORE should be required to publish operating rules that are fully aligned with federal rulemaking requirements and can alternatively publish non-mandated certification requirements that include other requirements (such as acknowledgements) for purposes of voluntary certification. Voluntary certification requirements should be clearly noted as such.
3	**New: Patient Attribution**. Content rule within the new Eligibility and Benefits Operating Rule (vEB.1.0). CAQH CORE has proposed a new operating rule to apply to the selection of value-based payment models by providers. If your organization has conducted an analysis of this operating rule, please provide information on your organization's evaluation of the extent to which the proposed operating rule requirements support the adopted HIPAA transactions or improve administrative simplification.	In general, clearinghouses already support the requirements of the new CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Content Rule and the exchange of patient attribution data content when present in eligibility workflows. But, we feel that providers, payers, patients/patient advocate organizations, and other interested stakeholders are better positioned to address the question of administrative simplification improvement and potential adoption under federal regulation.
4	**Companion Guide Template**. CAQH CORE has updated the requirements for the companion guides in the adopted operating rules to promote flexibility. Please comment on your organization's experience with the companion guide template in the first set of operating rules, how it has impacted workflows and whether your assessment of the proposed new template indicates value for implementations of the standard.	The CAQH CORE Master Companion Guide Template enables a standardized information flow and format for payers and clearinghouses to convey operational and technical specific requirements for X12 implementation guides to their trading partners. This has been a very effective means to communicate trading partner specific information in an industry common manner to simplify implementation and onboarding. CAQH CORE has indicated that the June 2022 template has been updated to be X12 version agnostic to allow support and use for updated X12 versions. Cooperative Exchange supports the June 2022 CORE Master Companion Guide Template updates.

5	**Updated Connectivity Rule**. **A)** As part of the re-structuring of the CAQH CORE operating rules for each administrative transaction, CAQH CORE updated the connectivity requirements and published a stand-alone Connectivity Rule (vC4.0.0), for which it is seeking a recommendation for adoption. In addition to the requirements for the use of HTTPS over the public internet and minimum-security conditions, the Connectivity Rule addresses Safe Harbor, Transport, Message Envelope, Security, and Authentication. What changes would be necessary to your organizational infrastructure, policies and contracts to implement the CAQH CORE c4.0.0 Connectivity rule? **B)** The updated Connectivity rule adds support for the exchange of attachments transactions, adds OAuth as an authorization standard, provides support for X12 (HIPAA) and non-X12 (non-HIPAA) exchanges, and sets API endpoint naming conventions. The CAQH CORE letter states that the impact of mandating these requirements for HIPAA covered entities includes: "setting a standards-agnostic approach to exchanging healthcare information in a uniform manner using SOAP, REST and other API technologies; facilitates the use of existing standards like X12 in harmony with new exchange methods like HL7 FHIR, and enhancing security requirements to align with industry best practices." Please comment on the scope of the CAQH CORE Connectivity operating rule vC4.0.0 under consideration for adoption under HIPAA.	The vC4.0.0 connectivity rule is a hybrid as it contains both updated and new rule requirements. To address known security vulnerabilities in the current CORE connectivity rule C2.2.0, Cooperative Exchange supports the operating rule updates in the CORE C4.0.0 connectivity rule outlined in question 5 A). The CORE connectivity enhancements outlined in question 5 B) are directionally correct in accommodating secure internet based REST API + OAuth2 connectivity/access. Cooperative Exchange recommends that NCVHS solicit a wider perspective from health care industry stakeholders and the at-large technical community regarding the specification of normative naming conventions for API endpoints and the base set of metadata required to be used for the exchange of REST messages. As such, Cooperative Exchange does not support the inclusion of the naming conventions for API endpoints and base metadata as specified in the C4.0.0 rule at this time to allow further review and input from health care industry stakeholders and the at-large technical community. Note: Federally mandated operating rules should be published to include *only* the rule requirements under federal mandate. For example, rule publications/specifications that include requirements for acknowledgements that have been excluded in federal rulemaking is confusing to the industry at large. CAQH CORE should be required to publish operating rules that are fully aligned with federal rulemaking requirements and can alternatively publish non-mandated certification requirements that include other requirements (such as acknowledgements) for purposes of voluntary certification. Voluntary certification requirements should be clearly noted as such.
6	**Costs**. If your organization has conducted a cost analysis to determine the impact of implementing the updated eligibility and benefits and or claim status operating rule updates for your entity type, what are the estimated costs or types of costs for system and operational changes? In what programmatic ways do the updates to the operating rule for infrastructure (system availability and response time), data content, additional data elements for telemedicine, prior authorization coverage benefits, tiered benefits and procedure-level information add value for your organization? Please provide examples pertinent to your organization.	Similar to NCVHS RFC questions regarding cost analysis determinations for X12 transactions, there are several unknown factors that influence the ability for stakeholders to conduct a true cost impact analysis. CAQH CORE recommendations include a mix of both updated and new operating rules. If a specific transaction standard version required a specific operating rule version due to the associated business function and associated business rules for that version, would operating rules specific to each transaction standard version be required/allowed (i.e. multiple rules paired specific to a given transaction standard version)? In the example of CORE Safe Harbor operating rules, priority consideration should also be made when security vulnerabilities are discovered and it is in the industry's best interest to render specific rule requirements obsolete / non-compliant and support only connectivity methods / rules that do not have known vulnerabilities.
7	**Alternatives considered for operating rules**. What are the consequences to your organization if NCVHS recommends adoption of the updated versions of the eligibility or claim status operating rules? Please provide specific examples to describe the impacts (benefits, opportunities) of the changes included in the update for each operating rule.	The current federally mandated operating rules are over 10 years old (developed between 2006-2012). Aligned with the statutory requirements of Section 1104 of the Patient Protection and Affordable Care Act to create as much uniformity in the implementation of the electronic standards as possible, and consistent with NCVHS recommendation #4 in its July 2022 letter to the HHS secretary, Cooperative Exchange recommends that establishment of, or updates to, federally regulated operating rules be developed and deployed within a federally established SDO and ORAE guidance framework and known and predictable version update schedule. As our industry is regulated under operating rules that were initially published over 10 years ago, the opportunity cost and risk of not accommodating innovation and change required to advance our industry forward cannot be truly measured. The current process is unpredictable and we need to collectively identify root cause and embrace change.

8	**Attachments Prior Authorization Infrastructure and Data Content Rules (vPA.1.0) and Attachments Health Care Claims Infrastructure and Data Content Rules (vHC.1.0).** CAQH CORE has proposed infrastructure and data content operating rules for Prior Authorization and health care claims. The proposed infrastructure rules for attachments for prior authorization and health care claims include requirements for the use of the public internet for connectivity, Batch and Real Time exchange of the X12 v6020 275 transaction, minimum system availability uptime, consistent use of an acknowledgement transaction, use of uniform data error messages, minimum supported file size, a template for Companion Guides for entities that use them, a policy for submitting attachment specific data needed to support a claim adjudication request (standard electronic policy), and support for multiple electronic attachments to support a single claim submission. The operating rules include the requirement for a health plan or its agent to offer a "readily accessible electronic method to be determined…. For identifying the attachment-specific data needed to support a claim adjudication request by any trading partner, and electronic policy access requirements so services requiring additional documentation to adjudicate the claim are easily identifiable (health care claims only)." The CAQH CORE letter indicates that the proposed attachments data content rules for prior authorization and health care claims apply to attachments sent via an X12 (HIPAA) transaction and those sent without using the X12 transaction (non-HIPAA). Please provide your assessment of this proposed operating rule.	As codified in 42 U.S. Code § 1320d–2 - Standards for information transactions and data elements; subsection (g), Operating rules shall support standards under HIPAA regulation. As attachment transaction standards have not yet been named in federal regulation, it is premature to propose attachment operating rules for federal mandate consideration.
9	**Attachments operating rules – general question**. HHS has not proposed adoption of a standard for attachments under HIPAA. Please comment on the proposed operating rules for attachments. What should NCVHS consider prior to making any recommendations to HHS regarding operating rules for attachments?	By design under federal code, Operating Rules are required to directly associate with the regulated transaction standards they support. Therefore, new or updated Operating Rules should create additional uniformity in the implementation of the electronic standards and reflect the necessary business rules affecting health plans and health care providers. Cooperative Exchange recommends that SDOs and the Operating Rule Authoring Entity (ORAE) collaborate and coordinate to ensure regulated transaction standards and operating rules are aligned as appropriate to assure industry adoption in a pragmatic and synchronized manner.

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From: Deanna DiMascio
To: NCVHS Mail (CDC)
Cc: mapibd; Alex Keszeli; Adam Mariotti; Joseph Smith; Kerrie Jason
Subject: RFC on X12 and CAQH CORE
Date: Friday, December 16, 2022 9:00:29 AM
Attachments:

To the National Committee on Vital and Health Statistics:

I am writing on behalf of the board certified otolaryngologists at Ear, Nose and Throat Associates of Chester County located in Pennsylvania. It has come to our attention that various federal agencies are considering updating claims and payment transmission electronic standards in a way that could further enable health plans use of virtual credit cards, imposing on physician practices unnecessary costs. This, along with soaring inflation and declining reimbursements poses a direct threat to the stability of our practice. Hence, **we are against the X12 proposed addition of the card payments remittance information to 835 ERA.**

Thank you for your consideration,

Deanna DiMascio, MBA
Practice Administrator

www.entacc.com

From: Yarczower, Bret
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Friday, December 2, 2022 3:11:17 PM

Thank you to NCVHS for the opportunity to respond to the recent Request for Comment regarding the additional value of the DI and UDI in the updated version of the X12 claim transaction. I would like to express my strong support for adding these elements, as they will have tremendous benefits for integrated health delivery systems, health plans, manufacturers, health services researchers, and most importantly our patients and members. I am the Senior Medical Director, Health Services for Geisinger Health Plan, part of Geisinger, an integrated health delivery system in central and northeastern Pennsylvania covering 620,000 lives.

As a payor, we routinely rely on our insurance claims info to conduct analyses to examine how well we are providing quality care to our members, and transparency of information is key to everything that we do. National Drug Code numbers (NDC) give us full visibility to the pharmaceutical products used by our members, but in implant procedures we have always only been able to see the type of procedure (via the billed code) and not the specific manufacturer or model of implant used. That lack of visibility may have been somewhat justifiable when there was no national, standardized system for identifying medical devices, but now that the UDI rules have been implemented and are being adhered to by manufacturers, it would be difficult to understand why our healthcare providers and health plans should not be making full use of that information. I believe that health plans, should they want to consume the information, have every reason to want to know specifically what medical device products are being used and paid for, for quality and safety reasons as well as economic ones.

I was also a part of our team at Geisinger, working with Harvard/Partners Healthcare and Blue Cross-Blue Shield of Massachusetts, that published two peer-reviewed, PCORI-funded papers that demonstrated how we were able to record and transmit DIs on the existing insurance claim (using an empty field) without undue burden. (These papers have probably been mentioned by other commenters, and can be found here and here). Part of the analysis confirmed that patients with implanted devices seek care from multiple providers and health systems, so having DI in the claim was able to tie together these patients' experiences and capture their follow-up outcomes better than electronic health records can. So while having the UDI in the electronic health record is a good first step, there is indeed significant additional value to putting this information into the claim. As our publications describe, transmitting the DI to the claim was accomplished in two different ways by our two health systems, and the burden or effort required was no more than any other periodic update that we regularly make to our information systems. In conclusion, I strongly support the capture of DI and UDI information in electronic claims, as it will allow us to identify the devices our members are using, facilitate recalls or dissemination of other safety issues, identify devices involved in adverse events, improve visibility into the numbers of different devices used, and allow better long-term outcomes research. Thank you again to NCVHS and ASC X12 for proposing this important update.

Thank you,

Bret Yarczower MD, MBA
Senior Medical Director
Chair of Technology Assessment
Geisinger Health Plan

From: Graham, Jove H.
To: NCVHS Mail (CDC)
Cc: Weissman, Joel S.,Ph.D.; Stanley Nachimson; Terrie Reed; Natalia Wilson; Reich, Amanda J.; Platt, Richard (CDC harvard.edu); Ben Moscovitch (benmosc@amazon.com); Dan Krupka; Joseph Drozda
Subject: RFC on X12 and CAQH CORE Proposals
Date: Wednesday, November 9, 2022 9:15:45 AM

I would like to respond to the question in the NCVHS Request for Comment on Updates on Proposals for X12 Transaction Updates that asked, "Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction." I am a health services researcher embedded at Geisinger health system in Pennsylvania, and I participated in the initial meetings and discussions that brought this change request forth in the ASC X12 committee from 2014 onwards. I thank NCVHS and ASC X12 for proposing this addition of device identifiers (DIs) to the claim transaction.

Integrated health delivery systems, health plans, manufacturers, and health services researchers routinely use claims databases moreso than electronic health records to conduct analyses of the safety and performance of **drugs** and **vaccines**, and device identifiers (DI) in claims will allow much better **device** safety assessments as well. We have performed PCORI-funded, peer-reviewed and published research in this specific area (see papers here and here). Data in the second publication specifically demonstrated the added value of having DI in the claims for the purpose of tracking patient outcomes, since patients (even in mostly rural regions like ours) seek medical care from multiple providers, spanning multiple different electronic health records, and the claims add significant value in being able to see a more complete picture of patients' care and outcomes.

In these publications, together with collaborators at Partners Healthcare and Blue Cross-Blue Shield of Massachusetts, we demonstrated that providers, including hospitals, were able to record and transmit to insurers the DI portion of the UDI without undue burden. Our two systems accomplished this goal using two different information pathways, showing that hospitals and providers will still have flexibility and freedom to implement in ways that are best for them. Since 2010 at Geisinger, we have scanned UDI's of implanted devices at the point of care, and minimal effort was required to modify our systems to transmit these DI's to the claims. People who imply that adding the DI would be too expensive or difficult have not done it themselves like we did, and are being disingenuous if they suggest that addition of the DI would be more difficult than any of the other updates needed whenever there is an updated X12 claim transaction.

Including the device identifier (DI) on insurance claims is an important step forward in advancing patient safety by allowing better linking of devices to patients and their post-procedural outcomes. Including the device identifier (DI) in the claims transaction is also the right thing to do for patients, as it will increase transparency around the specific devices used in their care, increase the likelihood that problems with their device may be detected, and increase the likelihood that they can be contacted more quickly in case a safety issue is identified with the type of device they have.

In conclusion, capturing device identifiers (DI) in electronic claims interchange can help improve several gaps in existing approaches to postmarket surveillance, recalls, and transparency including enabling better identification of devices involved in adverse events, better reporting on the total number of devices in use, and better long-term outcomes data on patients who are seen by multiple

hospital systems and providers. Thank you for your consideration.

Sincerely,
Jove Graham, PhD
Associate Professor, Geisinger

From: Sharon Marcum
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals by December 15, 2022
Date: Thursday, December 15, 2022 8:57:15 AM

We are against the X12 proposed addition of the "card payments" remittance information to 835 ERA. This is just another added expense for the providers that causes another reduction in reimbursement on top of everything else that is being reduced with reimbursement. It is not fair that in the medical community that overhead continues to increase, and reimbursement continues to decrease, and more and more demands are put in place that have to be met that causes more work and more overhead like MIPS, Prior Auths, Denials etc. The system is going to crack if something is not fixed and in the end the patients are going to be who suffers!

Sharon Marcum, COPM
Practice Manager
Hampton Roads ENT-Allergy

Public Health Service

Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

DEPARTMENT OF HEALTH & HUMAN SERVICES

December 15, 2022

The National Committee on Vital and Health Statistics (NCVHS)
National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: RFC on X12 and CAQH CORE Proposals, by December 15, 2022

To our colleagues at NCVHS,

The U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) appreciates the opportunity to submit comments to the National Committee on Vital and Health Statistics' (NCVHS), Subcommittee on Standards' recommendations to the Department of Health and Human Services on adopting proposed updates to the X12 claims transaction standard, including the addition of the Unique Device Identifier (UDI)-Device Identifier (UDI-DI) in claim transactions.

The FDA established the unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use. The UDI system seeks to improve the identification of medical devices by making it possible to rapidly and definitively identify a device and certain key attributes related to a device's safe and effective use. Fully realizing the benefits of the UDI system depends on UDIs being integrated into data sources throughout our healthcare system, including the supply chain, electronic health records, registries, and claims transactions. In particular, integration of UDIs in claims transactions is important to understand real-world device performance generally, and in sub-populations, to optimize patient care, support expanded uses and label changes, facilitate post-market activities such as adverse event reporting and recalls, and inform the decision-making of healthcare providers, patients, payers and others in the healthcare ecosystem.

A UDI is a unique numeric or alphanumeric code that generally consists of the following:

- Device identifier (UDI-DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device.
- Production identifier (UDI-PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
    - Lot or batch number within which a device was manufactured;
    - Serial number of a specific device;

- Expiration date of a specific device;
- Date a specific device was manufactured;
- Distinct identification code required by 21 CFR 1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

Under 21 CFR 801.40(a), FDA requires that the UDI appear on device labels and packages in two forms:

- Easily readable plain-text; and
- a form that uses automatic identification and data capture (AIDC) technology. AIDC means any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process.

Inclusion of the UDI-DI in claims transactions is an important step in UDI adoption and use throughout healthcare systems. In the future, use of the UDI-DI and the UDI-PI (collectively referred to as the "full UDI") will provide additional, greater value in X12 claim transactions.

Current NCVHS Proposal – Benefits of including the UDI-DI in claims transactions

The UDI-DI provides a standardized way to identify the manufacturer and the model or version of a medical device. This enables consistent identification of a device from manufacturer to supplier to provider to patient use, enabling tracking of devices through their life cycle. Including the UDI-DI in the claim enables health plans to collect device information for their beneficiaries and use the information for helpful purposes, including:

- Enhancing analysis of devices on the market by providing a standard and clear way to document device use as part of real-world data set in electronic health records, clinical information systems, claims data sources and registries.
- Reducing medical errors by enabling healthcare professionals and others rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- Enabling more accurate reporting, reviewing and analyzing of adverse event reports at the device version or model level so that device problems can be identified and corrected or removed more quickly. A more robust post-market surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices
- Enable device performance evaluation and patient outcome and quality of care analysis at the device version or model level by enabling linkages across disparate data sources such as claims, electronic health records, adverse events, recalls and registries.

In addition, incorporation of the UDI-DI into claims data may help clinicians and researchers be better informed about the devices they choose for their patients and their

research and procedural outcomes, which has the potential to positively influence patient care.

CDRH fully supports the inclusion of the UDI-DI in the updated electronic claim transaction standard. We understand that the current proposal is to include UDI-DI for high-risk implantable devices. While this limits the range of devices for which information is required to be collected and limits our ability to fully realize the benefits of UDI, it is an important step in collecting this information in a broader context and enabling the industry to begin achieving the benefits of the UDI system.

Future Considerations – Benefits of the Full UDI (UDI-DI and UDI-PI) in claims transactions

In future iterations of the electronic claim transaction standard, to achieve the benefits of UDI more fully, CDRH would encourage and support inclusion of the full UDI for all device types. The full UDI provides more value, by enabling capture of additional, more specific Production Identifier (UDI-PI) information in addition to the UDI-DI. CDRH recommends capturing the full UDI in claim transactions for all device types, all transaction types and amongst all trading partners, without any limitations/restrictions. The full-UDI would provide richer real-world data to enable additional device performance and patient outcomes analysis.

Because of the specificity in the UDI-PI (including the lot number, serial number, and manufacture date), use of the full UDI should enable manufacturers, healthcare providers, and FDA to better identify and assess device performance and safety issues at a more granular level. Use of the full UDI also has the potential to improve the efficiency of device recalls, which is important to patient health and safety. The specificity of information in the full UDI can, for example, help identify specific patients with an implanted device because the full UDI would contain the device's serial number. This level of specificity can also help the healthcare system broadly, from hospitals to health insurance providers, provide targeted information to patients using affected devices. Being able to identify specific patients can help ensure manufacturers and providers reach affected patients more quickly and address patient needs appropriately.

Conclusion

In addition to the benefits outlined above, we believe the UDI will offer a range of benefits to industry, FDA, consumers, healthcare providers and healthcare payers and systems by:

- Providing a standardized identifier that allows manufacturers, distributors, and healthcare facilities to more effectively manage medical device recalls.
- Providing a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.
- Leading to the development of a medical device identification system that is recognized around the world.

CDRH fully supports the inclusion of the UDI-DI in the updated electronic claim transaction standard, and believes the current proposal is an important first step in

collecting this information in a broader context to begin achieving the benefits of the UDI system.

In future iterations of the electronic claim transaction standard, to achieve more fully the benefits of the UDI system, and to realize on the patient safety goals of the UDI system, the FDA would encourage and support inclusion of the full UDI (UDI-DI and UDI-PI) for all device types, all transaction types and amongst all trading partners, without any limitations/restrictions.

We are available to answer any questions you may have and look forward to future developments on this matter.

Sincerely,
The FDA UDI Team
On behalf of Center for Devices and Radiological Health

HL7® International

December 15, 2022

Denise E. Love, BSN, MBA
Co-Chair
Subcommittee on Standards
National Committee on Vital and Health Statistics (NCVHS)
Centers for Disease Control and Prevention (CDC)/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Richard W. Landen, MPH, MBA
Co-Chair
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National Committee on Vital and Health Statistics (NCVHS)
Centers for Disease Control and Prevention (CDC)/National Center for Health Statistics
3311 Toledo Road
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CC:
Jacki Monson, JD
Chair
National Committee on Vital and Health Statistics (NCVHS)
Centers for Disease Control and Prevention (CDC)/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted electronically to:
NCVHSmail@cdc.gov

RE: RFC on X12 and CAQH CORE Proposals

Dear NCVHS Subcommittee on Standards Co-Chairs Love and Landen:

Health Level Seven (HL7) International welcomes the opportunity to provide feedback on the November 28 Request for Comment (RFC) seeking input, as NCVHS develops recommendations to the U.S. Department of Health and Human Services (HHS) on adopting proposed updated standards from X12 and proposed updated and new operating rules from the Committee on Operating Rules (CAQH CORE). Our organization's views detailed here build on HL7 testimony and the written follow-up related to the June 9, 2022 NCVHS Subcommittee on Standards listening session. This testimony contained many important points, including that HL7 urges NCVHS to formally recognize HL7® FHIR® as an alternate standard to existing mandated HIPAA transaction standards, furthering the nation's journey of intersecting of clinical and administrative frameworks and related interoperability objectives. Our RFC feedback detailed here also provides a foundation for further sharing HL7 views at the planned January 18-19, 2023 NCVHS hearing.

As you know, HL7 is the global authority on health care interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing health care consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms. A critical part of the HL7 mission is to provide a comprehensive framework and related standards for electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 produces a family of standards, including FHIR, as well as Implementation Guides and Specifications, which enable both routine and cutting-edge health care functions. FHIR aids in removing barriers to many of the challenges to interoperable health care data exchange – as stand-alone specifications and as a bridging mechanism across standards. The HL7 product family is robust end-to-end and is well supported by the health care industry, as reflected by our Accelerator community, long-standing Work Group structure, and expanding technical capabilities to support the HL7 development and implementation divisions. HL7 also actively supports cross-community terminology and value set needs to further benefit data driven policy and operational needs.

Our HL7 FHIR Accelerators drive groundbreaking cross-sector innovation in interoperability and bridging historical investments through partnerships to provide capabilities needed in today's modern health care eco-system. Examples are the Da Vinci Project, addressing value-based care data exchange efficiencies, the HL7 FHIR at Scale Taskforce (*FAST)* for infrastructure and connectivity, the Gravity Project for social determinants of health, Helios for public health and CodeX for improving data interoperability related to oncology, cardiovascular medicine and genomics. As the nation works toward converging administrative, financial, and clinical data we must keep in focus the broader interoperability needs such as public health and patient engagement. We are confident HL7's standard and implementation specifications are comprehensive enough to rise to this challenge and provide the necessary business rules and guidelines for the exchange of electronic exchange of information using HL7 work products. And if there are gaps, then we are well positioned to fill those gaps. For example, development cycles are responsive to industry needs through our collaboration and partnering efforts across the industry including interoperability federal policies and programs.

On the overall issue recommendations contained in the RFC, HL7 supports our sister ANSI accredited Standards Development Organization (SDO) X12's efforts but we are also concerned with the industry compliance strain related to a range of requirements related to multiple federal and state departments and programs. Further, determining the appropriate balance in this scenario may be challenging without robust cost information, which is typically an analysis not performed by industry until a formal mandate is released. We urge if any update is to be recommended, NCVHS also consider HIPAA policy shifts that could be included in proposed rulemaking, not just technical standards proposals at this critical juncture. Lastly, to continue being efficient, clean lines of responsibility should be ensured to minimize risk of confusion and expense to the Health IT industry that has come far in embracing standards development, adoption and support because of our nation's HIPAA journey.

Comments detailed in this RFC response reflect the combined perspectives of HL7's leadership, the Policy Advisory Committee, the Payer/Provider Information Exchange (PIE) Work Group and the HL7 FHIR at Scale Taskforce (*FAST*). Should you have any questions about the attached document, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and as always, offer our assistance to NCVHS and its Subcommittee on Standards.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
HL7 International

Andrew Truscott
Board of Directors, Chair
HL7 International

NCVHS Request for Comment: X12 and CAQH CORE Proposals	
I. OVERARCHING COMMENTS	
Comments	
• HL7 emphasizes that HL7 FHIR-based implementation guides are developed in an open, public, consensus-based process and are systematically tested and reviewed by industry stakeholders in order to proceed with publication. This consensus-based process precludes the need for other organizations to define operating rules, where historically that role may have been needed. • HL7 and its FHIR Accelerators such as the Da Vinci Project, HELIOS and *FAST* will continue to work with the community of relevant stakeholders to identify FHIR infrastructure and scalability barriers that need to be addressed to support national interoperability. • Relevant to this RFC -- *FAST* --the HL7 FHIR Accelerator focused on FHIR infrastructure and scalability, is laying the groundwork for a national interoperability approach that enables consistent data exchange via application programming interface (API) using FHIR. *FAST* implementation guides do not include HIPAA transactions and will continue to follow the HL7 ANSI-accredited processes for developing, testing, and publishing standards.	
II. Updates: X12 Transaction Standards	
Question	**HL7 Comments**
Costs: If your organization has conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional or dental claim) and remittance advice transactions, to what extent, relative to the potential cost of implementation, do the updated transaction implementation guides provide net positive value? Please explain.	• Operational assessments will be conducted when the Notice of Proposed Rulemaking (NPRM), is published in the Federal Register. We are aware that there are significant changes (with these changes come costs) within the X12 837 8020 version of the Claims that will impact providers, vendors and payers.

Operational Impacts: If your organization has conducted an operational assessment or workflow analysis of the impact of transitioning to the updated X12 8020 claims and remittance advice transactions, what process improvements has your organization identified would result from implementation of the updated versions of any of the updated transactions? Please provide information for the Committee to reference in its considerations and feedback to HHS.	• Operational assessments will be conducted when the Notice of Proposed Rulemaking (NPRM) is published in the Federal Register.
XML Schema: X12 has indicated that each of the X12 implementation guides included in their recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. In its letter to NCVHS, X12 noted that it mechanically produces these representations from the same metadata used to produce the implementation guide. X12 recommends that HHS permit both the 8020 EDI Standard representation (the implementation guide) and the XML representation, and that both be named in regulation as permissible syntaxes. Please comment on the proposal to adopt the 8020 EDI standard and the XML representation as permitted syntaxes.	• Standards should not be limited to XML. X12 to FHIR crosswalks do assist with newer technology so that these tables may be included within HL7 FHIR IGs. (i.e. Prior Authorization Support, Clinical Data Exchange). Unless there is a substantial industry need of XML, any alternate format should consider FHIR. This allows representation in multiple formats natively. HL7 FHIR includes other syntax that entities would like to include (i.e., JSON). If there are multiple syntax allowed, they should be semantically interoperable. • While additional syntax representations can be viewed as a positive aim of the X12 organization, it should be noted that other syntactical considerations exist that would provide the healthcare industry with a more homogeneous solution. The use of JSON (JavaScript Object Notation) would better align with industry standards developed for healthcare solutions. • Adding additional standard formats to be supported does place more burden on the healthcare payer community as these organizations must support all standards formats and do not recover any of the development costs, especially related to formats their trading partners will not use. Whereas organizations that provide the services to convert to various formats can pass along the costs to providers that have contracted with their organization.

FHIR Crosswalks: X12 indicated that it intends to provide FHIR crosswalks for the proposed X12 version 8020 transactions (claims and electronic remittance advice) submitted for consideration in time for inclusion in the Federal rulemaking process. Please comment on how FHIR crosswalks would apply to the implementation of the HIPAA claims and remittance advice transaction standards.	• Overall, X12 to FHIR crosswalks assist with newer technology so that these tables may be included within HL7 FHIR IGs (e.g., Da Vinci Prior Authorization Support, Clinical Data Exchange). Mapping development and maintenance would need to be a joint effort with HL7, given HL7's FHIR responsibility and leadership and so that all FHIR elements are crosswalked in the best manner possible. • There is a need for crosswalks such as these. HL7 appreciates current crosswalk limited license access but optimally; they should be more broadly available. • Unless NCVHS were to allow FHIR claims to be submitted in a HIPAA context, there would be no impact. However, for non-HIPAA covered use cases, this could help. • It is unclear until fully built and tested, the utility of FHIR crosswalks to HL7 FHIR claims and remittances. • Advance Explanation of Benefits- dependable crosswalks between elements are useful. • The community developing FHIR-based specifications and solutions is progressing rapidly. HL7 recommends, and is willing to support, a mapping process that is open, transparent, and responsive to the evolving needs of the industry. • FHIR Crosswalks are helpful for implementers but only part of the entire solution. Industry writ large must be educated on the various components --e.g., cyber security and trading partners management -- along with server configuration and best practices. • Notable is that dependable mapping should decrease costs involved to providers with more rapid, efficient development.
Unique Device Identifier (UDI): The device identifier (DI) portion of a medical device's unique device identifier (UDI) is now included as a data element on the updated claim Posted online at:	• This allows health plans and industry players to uniquely identify a device and tie it to specific members to track patient outcomes, device defects and recalls, thus improving member experience. Inclusion

https://ncvhs.hhs.gov/January-2023-Standards-Subcommittee-Hearing-Public-CommentGuidelines Page 3 of 6 transaction in the institutional and professional version of the 8020. The UDI is also an element in the US Core Data for Interoperability (USCDI) for Certified Health Technology required by the Office of the National Coordinator, and can be found in certified Electronic Health Records, and in standardized hospital discharge reports. Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction	of specific device information on claims provides opportunities for additional data analysis. • We are concerned however that if UDI is implemented, this might make payers responsible for all recall information, scheduling and other elements that may occur around the devices. Responsibility should remain with the device company.
Alternative Payment Models (APM) and Value Based purchasing (VBP): Does X12 version 8020 support VBP claims? In what ways does the version 8020 of the claims transactions accommodate APMs such as medical homes or accountable care organizations (ACOs)? Please discuss the implications of this topic to HIPAA administrative simplification policies and continued innovation of non-fee-for-service business models.	• X12 version 8020 supports the use of individual diagnoses and procedure codes that are used in value-based purchasing. Additional information can be accommodated in a claim attachment as necessary.
Implementation Time Frame: HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, what would be the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e.g. does the window need to be longer than two years from the publication date of a final rule? Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?	• The utility and appropriateness of a two-year implementation timeframe depends on the scope and impact of the update. Industry will comment on implementation timeframe issues once the regulation is published. CMS should provide incentives and/or enforcement actions if timeframe is not met. • The months of June or July would be optimal implementation dates. • Any implementation timing should acknowledge and provide appropriate weight to other existing mandates for industry and relevant health care stakeholders. In addition, thoughtful consideration should be given to exactly what to upgrade in order to advance the interoperability journey. While upgrade requires concerted effort, the longer the waiting period to amend existing mandated standards, the harder the lift. • Implications of vendor readiness to support covered entities should also be thoughtfully considered, since vendors are not Covered Entities.

Implementation: NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?	• Yes, HL7 sees a benefit in supporting a dual use period for multiple versions of a standard related to a like business function that is semantically interoperable. We would recommend a definitive sunset date within 2-3 years. • Having concurrent versions aligns to thinking that underlies both the Standards Version Advancement Process (SVAP) and United States Core Data for Interoperability (USCDI). Having a floor in this process is good, while supporting newer versions being vetted to address to technical aspects.
Simultaneity: What, if any, are the data impacts, limitations or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g. claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?	• Following X12's paired transactions at the same version would be required. The impact with other transactions is unknown. As an example, Claims, Remittance and Coordination of Benefits (COB) would need to be in the same version. • Specifically, if the provider and the first payer are operating at the elevated version level and the processed claim information needs to be sent to a third organization that is operating on the previous (non-backwards compatible) version, the ramifications to the ecosystem are unknown.
Alternatives Considered: X12 indicated that there were over 2,000 changes identified in the change logs for the four updated transactions in version 8020, categorized by operational, technical and editorial. If your organization has conducted assessments of the technical changes, what is your determination of these with respect to reducing burden on payers or providers once the updates have been implemented? What is the opportunity cost of remaining on Version 5010 and not implementing the updated version 8020 of the claims and remittance advice transaction standard? What will the healthcare industry risk by not adopting version 8020?	• There have been significant revisions and changes in the X12 Technical Report Type 3 (TR3) to help promote clarity. The changes in the 837 will help support accuracy of payment as well. The 837 8020 version supports new claim data as well as supporting pre-determination transactions that will be leveraged to support Advance EOB and Good Faith Estimate efforts. • Version 5010 was published around 2008-2010. The 8020 has improvements that will support new business capabilities that have evolved within the industry since then, 8020 adoption of the four updated transactions would be necessary to implement new business capabilities that are not easily available in 5010. • The risk of not adopting is the inability to implement new capabilities.

General: Does your organization support HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards? Please provide a brief rationale.	• Yes, HL7 supports HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards. It makes sense to promote the update of a widely adopted, currently in use standard. • We do caution in this scenario about the limitations in adopting and implementing the 11th edition of the International Classification of Diseases (ICD-11) and lifecycle reliability as upgrades are being brought forward. In other words, ICD11 is not supported in the version being proposed. • HL7 also emphasizes its support above for concurrent use of multiple versions of a standard and multiple standards over an extended period of time for flexibility and to advance innovation. • The X12 835(Electronic Remittance Advice) was updated to support different payment models including virtual card. The 835 has had many front matter revisions to support COB and Recoupments. These two developments alone are a significant pain point for industry and the suggested updates will help with streamlining the use of the 835 in reporting. • Several other data elements have been added to support Diagnosis-Related Group (DRG) and taxonomy, as well as the new structure for Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC). This will help promote provider autoposting and reduce calls. • The X12 837 (Healthcare Claim/Encounter) supports new claim data and pre-determination transactions that will be leveraged to support Advance Explanation of Benefits (AEOB) and Good Faith Estimate efforts. Other 835 8020 comments: • Regarding new types of DRGs the guides need to support, HL7 observes that right now they cannot but with new versions, they will be able.

Other: Are there other topics NCVHS should consider when making recommendations to HHS regarding adoption of proposed updates of the X12 standard?	• New and more collaborative models for testing could also be considered. HL7 is available to provide more perspective and details if desirable.
II. CORE Operating Rules	
Efficiency Improvements - Infrastructure updates to the adopted Eligibility and Benefits and Claim Status Operating Rules: CAQH CORE has proposed updates to the adopted versions of the eligibility and benefits and claim status operating rules currently required for use. Updates include an increase in system availability from 86% per calendar week to 90%, and for the response time for a claim status request from 20 seconds 86% of the time to 20 seconds or fewer 90% of the time. Please comment on the potential for improvements in efficiency for your organization these updates would contribute when using the adopted X12 HIPAA transaction standards.	• The new response time proposals may require a notable effort and cost to participants and could impact system update and release schedules.
Data Content updates for Eligibility and Benefits Operating Rule: The updated version of the Eligibility and Benefits operating rule includes the requirement to indicate coverage of telemedicine, remaining coverage and tiered benefits, and to indicate if prior authorization or certification is required. The rule has been updated to include a list of CORE-required service type codes (section 5) and CORE-required categories of service for procedure codes. If your organization has conducted an analysis of these updates and the potential impact to increasing use of the adopted standard, please comment on your assessment of these enhancements for your organization and/or your trading partners.	• Significant updates to internal payer systems -- along with clearinghouses and provider systems -- will be required if this schema is approved for final rule. • A Service Type Codes addition of new discretionary and mandatory service types is a significant change to multiple systems.
New - Patient Attribution Content Rule within the New Eligibility and Benefits Operating Rule (vEB.1.0): CAQH CORE has proposed a new operating rule to apply to the selection of value-	• A key challenge is that some of the cited data may not be contained in existing eligibility systems. This could perhaps be contained in a future roadmap.

based payment models by providers. If your organization has conducted an analysis of this operating rule, please provide information on your organization's evaluation of the extent to which the proposed operating rule requirements support the adopted HIPAA transactions or improve administrative simplification.	
Companion Guide Template: CAQH CORE has updated the requirements for the companion guides in the adopted operating rules to promote flexibility. Please comment on your organization's experience with the companion guide template in the first set of operating rules, how it has impacted workflows and whether your assessment of the proposed new template indicates value for implementations of the standard transactions. What specific strategies, technical solutions, or policies could CMS implement to facilitate timely and accurate directory data updates?	• HL7 has no issue with the CAQH CORE requirement updates for the companion guides.
New Connectivity Rule: A) As part of the re-structuring of the CAQH CORE operating rules for each administrative transaction, CAQH CORE updated the connectivity requirements and published a stand-alone Connectivity Rule (vC4.0.0), for which it is seeking a recommendation for adoption. In addition to the requirements for the use of HTTPS over the public internet and minimum-security conditions, the Connectivity Rule addresses Safe Harbor, Transport, Message Envelope, Security, and Authentication. What changes would be necessary to your organizational infrastructure, policies and contracts to implement the CAQH CORE c4.0.0 Connectivity rule? B) The new Connectivity rule adds support for the exchange of attachments transactions, adds OAuth as an authorization standard, provides support for X12 (HIPAA) and non-X12 (non-HIPAA) exchanges, and	• Overall, HL7 does not believe that the CAQH CORE Connectivity operating rule vC4.0.0 under consideration for adoption under HIPAA aligns with industry best practice. • HL7 agrees with the Safe Harbor, as some healthcare entities may not be implementing HTTPS and APIs like FHIR for some time. A complete analysis would need to be conducted with HL7 technical resources, in regard to this modification with X12 standards. • HL7 notes that there is a combination of HL7 FHIR *FAST* Implementation Guides[1] that are comparable guidelines to the Connectivity Rules.

[1] HL7 FHIR at Scale Taskforce (*FAST*) , *FAST* Implementation Guide Dashboard, https://confluence.hl7.org/display/FAST/FAST+Implementation+Guide+Dashboard

sets API endpoint naming conventions. The CAQH CORE letter states that the impact of mandating these requirements for HIPAA covered entities includes: "setting a standards-agnostic approach to exchanging healthcare information in a uniform manner using SOAP, REST and other API technologies; facilitates the use of existing standards like X12 in harmony with new exchange methods like HL7 FHIR, and enhancing security requirements to align with industry best practices." Please comment on the scope of the CAQH CORE Connectivity operating rule vC4.0.0 under consideration for adoption under HIPAA.	
Costs: If your organization has conducted a cost analysis to determine the impact of implementing the updated eligibility and benefits and or claim status operating rule updates for your entity type, what are the estimated costs or types of costs for system and operational changes? In what programmatic ways do the updates to the operating rule for infrastructure (system availability and response time), data content, additional Posted online at: https://ncvhs.hhs.gov/January-2023-Standards-Subcommittee-Hearing-Public-CommentGuidelines Page 6 of 6 data elements for telemedicine, prior authorization coverage benefits, tiered benefits and procedure-level information add value for your organization? Please provide examples pertinent to your organization.	• Operational assessments will be conducted when the Notice of Proposed Rulemaking (NPRM) is released. We are aware that there are significant changes.
Alternatives Considered for Operating Rules: What are the consequences to your organization if NCVHS recommends adoption of the updated versions of the eligibility or claim status operating rules? Please provide specific examples to describe the impacts (benefits, opportunities) of the changes included in the update for each operating rule. What use cases would benefit from data being verified and what sort of assurances would be necessary for trust and reliance on those data?	• Operational assessments will be conducted when the Notice of Proposed Rulemaking (NPRM) is released. We are aware that there are significant changes.
Attachments Prior Authorization Infrastructure and Data Content Rules (vPA.1.0) and	• HL7 does not agree with this proposed rule, as an Attachment Rule has yet to be released. Until that time

Attachments Health Care Claims Infrastructure and Data Content Rules (vHC.1.0): CAQH CORE has proposed infrastructure and data content operating rules for Prior Authorization and health care claims. The proposed infrastructure rules for attachments for prior authorization and health care claims include requirements for the use of the public internet for connectivity, Batch and Real Time exchange of the X12 v6020 275 transaction, minimum system availability uptime, consistent use of an acknowledgement transaction, use of uniform data error messages, minimum supported file size, a template for Companion Guides for entities that use them, a policy for submitting attachment specific data needed to support a claim adjudication request (standard electronic policy), and support for multiple electronic attachments to support a single claim submission. The operating rules include the requirement for a health plan or its agent to offer a "readily accessible electronic method to be determined…. For identifying the attachment-specific data needed to support a claim adjudication request by any trading partner, and electronic policy access requirements so services requiring additional documentation to adjudicate the claim are easily identifiable (health care claims only)." The CAQH CORE letter indicates that the proposed attachments data content rules for prior authorization and health care claims apply to attachments sent via an X12 (HIPAA) transaction and those sent without using the X12 transaction (non-HIPAA). Please provide	there should not be a CAQH CORE proposed data content rule. Noted is that the following is currently at the OMB in review for an attachments rule: HHS/CMS RIN: 0938-AT38Publication ID: Spring 2022 Title: Administrative Simplification: Adoption of Standards for Health Care Attachment Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Standard (CMS-0053) • HL7 notes that the Da Vinci Project Accelerator has received a HIPAA exception to support projects validating the efficiency of a FHIR only solution for prior authorization support. This includes three implementation guides: Coverage Requirements Discovery (CRD)[2], Documentation Templates and Payer Rules (DTR)[3] and Prior Authorization Support (PAS)[4]. The three guides support end-to-end FHIR based exchanges between provider and payer systems to reduce burden in prior authorization workflows. Recognizing the most current versions of these initial three IGs, supports other federal policy[5] to reduce burden through technology and policy-related enhancements. • HL7 observes that Prior Authorization done right doesn't require a supplemental data request because transparency in coverage is created, as well as their specific requirements. HL7 is developing this in their FHIR pattern and methodology. This and other guides enable a level of specificity needed by payers.

[2] HL7 Da Vinci Project, Coverage Requirements Discovery Implementation Guide, December 2020, https://confluence.hl7.org/pages/viewpage.action?pageId=21857602

[3] HL7 Da Vinci Project, Documentation Templates and Payer Rules Implementation Guide, December 2020, https://confluence.hl7.org/pages/viewpage.action?pageId=21857604

[4] HL7 Da Vinci Project, Prior Authorization Support Implementation Guide, December 2021, http://hl7.org/fhir/us/davinci-pas/

[5] U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria, RIN 0955–AA04; FR 2022-01309, January 24, 2022, https://www.federalregister.gov/documents/2022/01/24/2022-01309/request-for-information-electronic-prior-authorization-standards-implementation-specifications-and

your assessment of this proposed operating rule.	
Attachments Operating Rules – General Question: HHS has not proposed adoption of a standard for attachments under HIPAA. Please comment on the proposed operating rules for attachments. What should NCVHS consider prior to making any recommendations to HHS regarding operating rules for attachments?	• HL7 does not agree with this proposed rule, as an Attachment Rule has yet to be released. Further, it is anticipated that the long-anticipated proposed rule will be based on the related 2016 NCVHS recommendations. When that recommendation was prepared it was best of breed thinking. We believe that in today's landscape any proposed regulation for Attachments should consider the Da Vinci Clinical Data Exchange FHIR Standard for Trial Use Version 2 Implementation Guide (CDex). This guide, balloted earlier this year and to be published soon, defines a more current approach to support Electronic Attachments. The CDex guide leverages EHR based FHIR capabilities to automate the exchange of both solicited and unsolicited Claims Attachments as well as supporting requests for additional information not identified and exchanged during the initial prior authorization and quality measure exchange processes defined by other Da Vinci FHIR Implementation Guides. Finally, the CDex guide aligns with NCVHS March 2022 letter recommending regulatory flexibility to allow the use of FHIR standards along with X12 HIPAA adopted standards.
Other: Are there other topics NCVHS should consider when making recommendations to HHS regarding the current proposals from CAQH CORE?	• Please see comments above supporting the release of an attachments rule, which includes new standards such as HL7 Clinical Data Exchange (CDex) and FHIR APIs. • An additional topic to be considered is how should the current proposals from CAQH CORE be ranked in terms of priority against other relevant mandate and requirements.

Department of Health and Human Services
National Committee on Vital and Health Statistics
Subcommittee on Standards
December 15, 2022

Jopari Solutions would like to thank the National Committee on Vital and Health Statistics Subcommittee on Standards (NCVHS) for holding these important hearings and allowing Jopari to comment on the value, benefits, and costs of the proposed updates to the X12 standard transactions from a Property and Casualty perspective.

Jopari Solutions Industry Background
Jopari is a national corporation that provides technology solutions and clearinghouse services between medical providers and their software solution vendors and payers in the Property and Casualty (P&C) industry, commercial and government lines of business.

Jopari is actively engaged in the following Standard Setting and Professional Organizations, which includes but not limited to, Cooperative Exchange (CE) a national clearinghouse association, Accredited Standards Committee (ASCX12N), Work Group for Electronic Data Interchange (WEDI), Healthcare Information and Management Systems Society (HIMSS) and the International Association of Industrial Accidents Boards and Commissions (IAIABC) the international workers' compensation standards organization. I am also the appointed X12N liaison to the IAIABC and Co-Chair of the WEDI Property and Casualty workgroup.

Jopari is recognized as a Property and Casualty industry leader and represents over 60% of the Property and Casualty marketplace through direct payer connectivity and channel partners.

Summary Background - Property and Casualty (P&C)
- P&C is a legal system verses a healthcare system
- State regulated and exempted from HIPAA regulations
- P&C Lines of Business include Auto and Workers Compensation Insurance
- Many of the health care providers, solution vendors, and some payers that are engaged in P&C electronic transaction processing also are the **same entities** submitting /processing X12 5010 transaction sets today for Government and Commercial Carriers**.**

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- P&C claim processing requires clinical documentation to support the level of services billed for all claim types on a high percentage of claims submitted, with the exception of pharmacy billing.
- Many states have adopted the IAIABC "National Workers' Compensation Electronic Medical Billing and Payment Companion Guide" based on the **X12 5010 transaction sets**.
- The IAIABC Companion Guide addresses stakeholder business use cases and data requirements that are **not in the X12 5010** transaction sets.
- There are **12 "eBill" states**[1] that have implemented electronic medical billing and payment mandates specified in statute and or administrative rules which may include the following X12 5010 transactions sets:
    - ASC X12N/005010X222 Health Care Claim: Professional (837)
    - ASC X12N/005010X223 Health Care Claim: Institutional (837)
    - ASC X12N/005010X224 Health Care Claim: Dental (837)
    - ASC X12N/005010X221 Health Care Claim Payment/Advice (835)
    - ASC X12/005010X214 Health Care Claim Acknowledgment (277)
    - ASC X12N/005010X213 Health Care Claim Request for Additional Information (277)
    - ASC X12N/005010X210 Additional Information to Support a Health Care Claim or Encounter (275)
    - ASC X12N/005010X212 Health Care Claim Status Request and Response (276/277)
    - ASCX12/005010 TA1 Acknowledgment
    - ASC X12C/005010X231 Implementation Acknowledgment (999)
- Since **2008**, the high cost of manual paper claims and attachment processing has been a **motivating factor** for states to move to adopt HIPAA X12 5010 EDI standards including the proposed 2005 X12 Attachment and Acknowledgements transactions
- States required to adopt a new X12 named version, and or CAQH CORE Operating Rule would require administrative rule making and or statute regulations
- The stakeholder impact of states who choose to not adopt X12 named versions will require them to support the X12 5010 transactions and existing work arounds to comply with state P&C regulations

Please refer to **Appendix A** below for Jopari Solutions Property and Causality response to NCVHS Request for Comment (RFC) on Proposals for Updates to X12 Transactions – November 28, 2022.

[1] "eBill" States are defined as states that have adopted X12 5010 TR3 Implementation Guides for medical billing, attachments, acknowledgements, and payments; Refer to Appendix B: List of eBill State EDI Regulatory Resource References

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Please refer to **Appendix B** below for a List of P&C eBill States and Regulatory Resource References.

Recommendations

In summary, we would recommend that the Department of Health and Human Services moves forward with the adoption of the updated X12 8020 versions for Claims and Remittance Advice to address stakeholders' business needs that are not addressed in the X12 5010 versions. The X12 8020 versions will facilitate a standard EDI workflow across **all lines of healthcare business and P&C** to ensure increased adoption by all parties, which will effectively remove unnecessary administrative costs and facilitate interoperability.

Jopari Solutions would like to thank the members of the Subcommittee for the opportunity to present our P&C industry experience, and recommendations regarding the "Proposal for Updates to X12 Transactions".

We hope this information will be useful to you. Should you have questions or need any further information, please do not hesitate to contact us.

Sincerely,
Sherry Wilson, Executive Vice President, and Chief Compliance Officer
Jopari Solutions
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Appendix A

NVHS Request for Comment (RFC) on Proposals for Updates to X12 Transactions and New and Updated CORE1 Operating Rules Version 3
November 28, 20222

NCVHS Request for Comment: Jopari Solutions: Property and Casualty Stakeholder Considerations	
II. Updated X12 Transaction Standards	
NCVHS Questions	**Jopari Solutions Comments**
Costs: If your organization has conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional, or dental claim) and remittance advice transactions, to what extent, relative to the potential cost of implementation, do the updated transaction implementation guides provide net positive value? Please explain.	There is a net positive value in transitioning the industry to the updated X12 8020 claims and remittance advice transactions as referenced, in the X12 June 7, 2022, letter to NCVHS regarding transaction enhancements.[2] Property and Casualty (P&C) eBill states[3] over the past 15 years in an effort to automate business processes and increase administrative efficiencies have adopted by administrative rule and or statute the X12 5010 transaction standards for claims, acknowledgements, attachments, and remittance advice. The X12 8020 versions addresses the P&C state mandated data requirements and business use cases (legal system) that are **not in the X12 5010 versions, however over the last 15 years have been included in the X12 8020 versions**. The adoption of the X12 8020 versions decrease stakeholder administrative burden by mitigating:

[2] X12 June 7, 2022 Letter to NCVHS defining X12 8020 Claims and Remittance Advice enhancements: https://ncvhs.hhs.gov/transcripts-minutes/letter-to-ncvhs-x12-standards-request-june-7-2022/
[3] "eBill" States are defined as states that have adopted X12 5010 TR3 Implementation Guides for medical billing, attachments, acknowledgements, and payments: Refer to Appendix B for a list of eBill States and regulatory references.

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	• States creating separate EDI companion guides and workaround solutions. • Stakeholder administrative burden to comply with multiple state EDI mandates A cost benefit analysis would need to be conducted when the Notice of Proposed Rulemaking (NPRM) is officially published in the Federal Register providing specificity to the implementation approach and published stakeholder guidance framework.
Operational Impacts: If your organization has conducted an operational assessment or workflow analysis of the impact of transitioning to the updated X12 8020 claims and remittance advice transactions, what process improvements has your organization identified would result from implementation of the updated versions of any of the updated transactions? Please provide information for the Committee to reference in its considerations and feedback to HHS.	We have been actively engaged in the X12 Standard organization for over 13 years, advocating for states and P&C industry business needs to increase workflow automation and administrative efficiencies that are **not in the X12 5010 transaction** sets. We have identified the following industry process improvements that can be gained by transitioning to the X12 8020 versions: • Standardizes stakeholder implementation across **all lines of healthcare including P&C** reducing cost and increasing administrative efficiencies • Eliminates state and payers separate EDI workaround companion guides • Automates stakeholder regulatory EDI data compliance requirements • Third Party Vendors, similar to the 4010 /5010 transition would provide X12 5010 and X12 8020 data normalization and format conversions to mitigate stakeholder operational transition impact. **Property and Casualty Stakeholder Considerations:** • Stakeholders would not conduct an operational assessment until **state** regulations are amended and or adopted.

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	• States may choose not to amend and or adopt HHS transaction requirements, resulting in stakeholders implementing and **maintaining multiple X12 versions** (X12 5010 and X12 8020 version)
XML Schema: X12 has indicated that each of the X12 implementation guides included in their recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. In its letter to NCVHS, X12 noted that it mechanically produces these representations from the same metadata used to produce the implementation guide. X12 recommends that HHS permit both the 8020 EDI Standard representation (the implementation guide) and the XML representation, and that both be named in regulation as permissible syntaxes. Please comment on the proposal to adopt the 8020 EDI standard and the XML representation as permitted syntaxes.	We support the X12 recommendation [4] that HHS permits both the X12 8020 EDI Standard and XML representation, and that both be named in regulations as permissible syntaxes. The use of the XML Schema allows stakeholders to manipulate data with APIs and other tools that accommodates different business use cases and facilitates workflow automation and interoperability. **Property and Casualty Stakeholder Considerations:** States may find it beneficial to permit both the 8020 EDI Standard and XML representation. States may choose to align with either format; however, it **would require state administrative rule and or statutory changes.**
FHIR Crosswalks: X12 indicated that it intends to provide FHIR crosswalks for the proposed X12 version 8020 transactions (claims and electronic remittance advice) submitted for consideration in time for inclusion in the Federal rulemaking process. Please comment on how FHIR crosswalks would apply to the implementation of the HIPAA claims and remittance advice transaction standards.	We support the X12 recommendation to implement a FHIR Crosswalk for the proposed X12 8020 versions. There will be business use cases in which stakeholders may choose to use FHIR for clinical data applications and X12 8020 for administrative/ financial applications. The FHIR Crosswalks to X12 8020 transactions would accommodate different stakeholder business needs and allows for interoperability between the two standards.

[4] X12 June 7, 2022 Letter to NCVHS defining X12 8020 Claims and Remittance Advice enhancements: https://ncvhs.hhs.gov/transcripts-minutes/letter-to-ncvhs-x12-standards-request-june-7-2022/

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Implementation Time Frame: HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, what would be the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e. g. does the window need to be longer than two years from the publication date of a final rule? Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?	We would recommend a three-year implementation time frame from the date of the final rule publication to accommodate for stakeholder EDI readiness (low to high tech). We support NCVHS March 30th, Letter of Recommendation[5] to HHS to streamline the industry regulatory process to accommodate new and or updated HIPAA transactions to support industry business needs. We recommend a June or July implementation timeline to accommodate other regulatory and or business priorities that usually occur at the start of a new year. **Property and Casualty Stakeholder Considerations:** If a state chooses to adopt the new HHS version of standards for electronic billing and payment, the implementation timelines would be according to **state mandates** as specified in statute and or administrative rule.
Implementation: NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?	We see an industry benefit in the concurrent use of multiple versions over a defined period of time (similar to X12 4010/5010 implementation). A implementation phased approach would accommodate for the varies levels of stakeholder EDI readiness (low to high tech) and reduce administrative burden. **Property and Casualty Stakeholder Considerations**: If a state chooses **not to adopt** the X12 8020 version stakeholders would be required to continue to support the X12 5010 versions to comply with state

[5] March 30, 2022 - Recommendation Letter-HIT Standards Modernization to Improve Patient Care-March 30 2022

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	regulations.
Simultaneity: What, if any, are the data impacts, limitations, or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g., claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?	We would recommend a gap analysis to identify data content and industry business use cases that could be impacted in using other X12 5010 mandatory transaction versions simultaneously, e.g., eligibility, authorization, enrollment and claim status. As a clearinghouse, we would support both X12 5010 and X12 8020 to mitigate stakeholder implementation impact.
Alternatives Considered: X12 indicated that there were over 2,000 changes identified in the change logs for the four updated transactions in version 8020, categorized by operational, technical, and editorial. If your organization has conducted assessments of the technical changes, what is your determination of these with respect to reducing burden on payers or providers once the updates have been implemented? What is the opportunity cost of remaining on Version 5010 and not implementing the updated version 8020 of the claims and remittance advice transaction standard? What will the healthcare industry risk by not adopting version 8020?	It is difficult to assess stakeholder technical cost benefits of the X12 identified changes for the four updated transactions in version X 8020 as compared to remaining on the 5010 version, since there have been no pilot implementations. The X12 8020 versions represent **over 15 plus years** of stakeholder efforts to address business use cases and increase administrative efficiencies across all lines of business. **8020 Version Opportunities**: • Provides data harmonization across transaction sets • Request for Information (RFI) based on emerging business needs, usage clarification and or emerging technology over the past 15 years has been addressed in the 8020 version • The 837 and 835 TR3 additional data content will facilitate automated end to end transaction processing and increase administrative efficiencies • The 835 TR3 data content supports new electronic alternative payment methodologies adopted by states, commercial and government lines of business • The 837 TR3 data content accommodates the business use case for pre-determination transactions that can be used to support Advance EOB and

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	Good Faith Estimate efforts **Property and Casualty Stakeholder (P&C) 8020 Version Opportunities:** • Property and Casualty EDI business needs are addressed across all four updated transactions, which mitigates states and payers implementing separate EDI companion guides • Practice management systems and third-party vendors will have P&C business requirements included in the HIPAA implementation guides and providers will not be forced to drop to costly manual paper processing • Additional TR3 information guidance has significant impact in standardizing implementation across all lines of businesses **Additional Property and Casualty Stakeholder Considerations:** If a state chooses to **not adopt** X12 8020 transactions, stakeholders will be required to support the following X12 5010 transaction sets and workaround solutions: • Claims (X12 837) • Remittance Advice (X12 835) • Acknowledgements (TA1, 999, 277CA) • Attachments (X12 275) • Request and Response (X12 276/277) • Request for Additional Information (X12 277) If a state chooses **to adopt** the X12 8020 versions, it will require amended regulations: administrative rule and or statutory changes/additions. The stakeholders' implementation time frame would be dependent on state regulations

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APPENDIX B:

List of P&C eBill States and Regulatory Resource References

1. **Texas** Workers' Compensation: Effective Date: January 1, 2008: Medical billing (texas.gov)
2. **Minnesota**
   Department of Health (includes Auto): Effective Date June 15, 2009
   AUC Minnesota Uniform Companion Guides - MN Dept. of Health (state.mn.us)
   Department of Labor Workers' Compensation: Effective Date: June 15, 2009:
   https://www.dli.mn.gov/business/workers-compensation/work-comp-hipaa-835-health-care-claim-paymentremittance-advice
3. **Georgia** Workers' Compensation: Voluntary Administrative Rule: Effective Date: September 10, 2012:
   https://sbwc.georgia.gov/document/publication/georgia-e-bill-rule-review/download
4. **California** Workers' Compensation: Effective Date: October 18, 2012: https://www.dir.ca.gov/dwc/ebilling/ebilling.html
5. **Louisiana** Workers' Compensation: Effective Date: June 1, 2013
   https://www.doa.la.gov/media/2wxg4qhw/40.pdf
6. **North Carolina** Workers' Compensation: Effective Date: June 1, 2014
   https://www.ic.nc.gov/ncic/pages/EBPCguide.pdf
7. **Oregon** Workers' Compensation: Effective Date: January 1, 2015
   Oregon Workers' Compensation Division: eBilling : Electronic Data Interchange (EDI) : State of Oregon
8. **Tennessee** Workers Compensation: Effective Date: June 1, 2018
   https://www.tn.gov/content/dam/tn/workforce/documents/injuries/TNCompanionGuideforeBilling1418.pdf
9. **New Jersey**
   Workers' Compensation: Effective Date: May 21, 2019: Workers' Compensation Law (nj.gov)
   Auto Regulations: Effective Date: September 1, 2019: NJDOBI | PIP Information for Health Care Providers (state.nj.us)
10. **Illinois** Workers' Compensation: Effective Date: August 19, 2019
    http://www.iwcc.illinois.gov/PA97-18summary032112.pdf
11. **Virginia** Workers' Compensation: Effective Date: June 1, 2019
    https://workcomp.virginia.gov/content/contact-commission
12. **North Dakota** Workers' Compensation: Monopolistic State: Effective Date: June 15, 2021
    https://www.workforcesafety.com/medical-providers/billing-payment

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From: Joseph Drozda
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals, by December 15, 2022
Date: Friday, November 4, 2022 12:24:15 PM

I would like to respond to the following question that appears in the NCVHS Request for Comment on Updates on Proposals for X12 Transaction Updates:

> **5. Unique Device Identifier (UDI)**. The device identifier (DI) portion of a medical device's unique device identifier (UDI) is now included as a data element on the updated claim transaction in the institutional and professional version of the 8020. The UDI is also an element in the US Core Data for Interoperability (USCDI) for Certified Health Technology required by the Office of the National Coordinator, and can be found in certified Electronic Health Records, and in standardized hospital discharge reports. Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction

I am a cardiologist and, until I retired earlier this year, was Director of Outcomes Research at Mercy, the 4-state regional health system headquartered in St. Louis. I spent much of the last 12 years leading multi-stakeholder teams in performing medical device research. The aim of our work was to develop systems for using real world data to assess the effectiveness (what works best for our patients) and safety of medical devices. UDI enabled us to link our supply chain device data directly with electronic health record data and with the FDA's AccessGUDID, which contained key device information (attributes) that enabled efficient research (minimal manual work) at a very granular level. Our most recent work supported FDA's focus on using real world data in a system of medical device active surveillance. It is clear from that experience that active surveillance with real world data is not feasible without UDI-DI which enables the required linkage among databases (various health systems' EHRs, supply chain databases, and AccessGUDID).

One of the biggest challenges we faced in our work, which was aimed not only at doing research but also at providing our clinicians and patients with actionable information regarding devices, was the incomplete outcome identification resulting from our reliance on our EHR for such information. Our patients and those of other health systems often obtain care at other health systems with the data captured in those systems' EHRs which are not available to us. If the insurance claim captured UDI-DI, it would be possible to identify significant patient outcomes like hospitalizations, repeat procedures, and device extraction no matter where they were performed. Such data will be critical, in particular, for a national active safety surveillance system. Having UDI-DI in the claim also enables efficient communication back to patients/insureds when problems are identified with their devices.

For the above reasons, I strongly support the addition of UDI-DI to the claim transaction.

Joseph P. Drozda, Jr., M.D.
Researcher Emeritus
Mercy
Chesterfield, MO

From: Sarah Coffmon
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Tuesday, December 13, 2022 10:33:53 AM

We are against the X12 proposed addition of the "card payments" remittance information to 835 ERA.

We do not accept virtual card payments.

Thank you,

Sarah Coffmon, CMPE, CPC-A
Practice Manager
Kidney Specialists, Inc.

From: Monica Hansen
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Thursday, December 15, 2022 11:10:19 AM

Allowing Insurance companies to process our payments through VCC is costing the physician offices 3% which decreases our funds. We are already carrying the cost of PayGo and even the cost of a required EMR system to run our businesses. These expenses are not added to the patient's billing because we are not allowed to pass the fee on.

Retail stores etc can increase the cost of products to compensate for the additional cost but we as physicians cannot. The insurance companies should be the ones paying the VCC fees since they are using the process for their convenience. We already are paying CC fees for the patients who are using Credit Card form of payments as we should not have to carry the Insurance Companies burden of the cost.

Please give us a break.
Thank you,

--

Monica Hansen, ***BBA, CMPE***

Administrator

Kidney Specialists of South Texas, PA

1521 S. Staples Ste 601

Corpus Christi, TX 78404

From:	Dan Krupka
To:	NCVHS Mail (CDC)
Cc:	Weissman, Joel S.,Ph.D.; Stanley Nachimson; Terrie Reed; Jove Graham (jhgraham1@geisinger.edu); Natalia Wilson; Reich, Amanda J.; Platt, Richard (CDC harvard.edu); Ben Moscovitch (benmosc@amazon.com)
Subject:	RFC on X12 and CAQH CORE Proposals
Date:	Sunday, November 6, 2022 5:34:21 PM

National Committee on Vital and Health Statistics:

The DI portion of the UDI in the updated X12 claim transaction represents the linchpin in a long-needed post-market surveillance system for implanted devices.

As we have demonstrated, providers, including hospitals, are able to record and transmit to insurers the DI portion of the UDI with modest incremental expense: The UDI of implanted devices would be one of the items scanned at the point of care, and only minor changes would be required to the providers' and insurers' information systems. Moreover, as we suggested in the publication, the modifications to accommodate DIs would represent only one of many in the implementation of the updated X12 claim transaction.

In a related publication, we drew attention to the importance of a post-market surveillance system for tracking problems with implanted devices, listed the barriers to the implementation of such a system, and showed how those barriers could be overcome. In particular, we described the steps that the CMS and FDA should be taking now to ensure that a post-market surveillance system for implanted devices is implemented as soon as providers and insurers have modified their information systems to accommodate the updated X12 claim transaction.

Dan C. Krupka, PhD, Managing Principal, Twin Peaks Group, LLC

Joel S. Weissman, PhD, Deputy Director and Chief Scientific Officer of the Center for Surgery and Public Health at Brigham and Women's Hospital in Boston, and Professor of Surgery in Health Policy at Harvard Medical School

November 20, 2022

Jacki Monson, JD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

RE: RFC on X12 and CAQH CORE Proposals

Thank you for the opportunity to comment on the National Committee on Health and Vital Statistics' (NCVHS) proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules, which were issued on October 26, 2022.[1]

We, the undersigned, write to express our support for the incorporation of the device identifier (DI) component of Unique Device Identifiers (UDI-DI) into X12 claims transactions. We believe that this modification to claims forms will enable significant improvements in medical device safety for patients, advance postmarket surveillance efforts for the U.S. Food and Drug Administration (FDA), ensure that public and private payers are reimbursing medical devices whose benefits outweigh risks, and inform patient-physician clinical decision-making. Below, we have included specific comments related to NCVHS's questions related to the Updated X12 Transaction Standards, with a specific focus on items 5, 8, and 9.

5. Unique Device Identifier – Proposed Modification: Work with X12 to include the production identifier component of the UDI, along with the device identifier component, in the updated claims form

Congress in both 2007 and 2012 passed legislation authorizing the FDA to work with medical device manufacturers to establish the UDI system to help "*adequately identify the device through distribution and use*". Just as National Drug Codes have done for pharmaceuticals, UDIs were intended to be a facile mechanism for addressing medical device safety, and for monitoring utilization, spending, and outcomes related to medical devices in the American health care system. Subsequent rulemaking from FDA established guidelines for UDIs, and as of September 2022, over 3.5 million devices have UDIs – including nearly all moderate- and high-risk medical devices.[2]

However, the benefits of UDIs have yet to be realized despite their growing uptake on medical devices and labels. This is because UDIs have not been included in claims forms, meaning that use of individual devices cannot be linked to specific patients, clinicians, hospitals, or payers. As we have previously written, this omission limits the utility of UDIs for improving postmarket surveillance and advancing medical device safety.[3] Without the UDI, real-world evaluations of the safety and effectiveness of medical devices using claims data are near impossible for most medical devices. Because current claims only identify general classes of devices and device-based procedures (e.g., all coronary stents or percutaneous coronary intervention), studies about the performance of specific devices (e.g., coronary stents of a given model) are precluded. As a consequence, there are major gaps in our understanding of the safety and effectiveness of most

medical devices – including those permanently implanted in patients. Integration of the UDI-DI in claims would be the largest possible advance in closing that gap.

To illustrate the consequences of this policy gap, consider a recent example of an ongoing medical device recall.[4] Philips Respironics has recalled over 22 million face masks and positive pressure ventilators; one of the largest device recalls in history, and one that has been received the FDA's most severe designation (Class I) due to the associated risk of adverse health consequences or death. However, despite the scope of the recall, Philips, the FDA, and clinicians have had no way of tracking which patients may be using a faulty device. As such, the company has had to rely on durable medical equipment vendors to try and identify affected patients; unfortunately, this is a spotty process and only 2 million devices have been replaced more than a year after the recall's initiation.[5,6] If Philips' devices had UDIs, and had such UDIs been tracked on claims forms, clinicians and payers could have identified affected patients in more comprehensive and timely fashion. This is especially salient for the updates to X12, as the majority of affected patients in the Philips recall are older adults, and could have benefited from coordination between Medicare (their payer), FDA, and the manufacturer.

Beyond safety, the adoption of UDIs would also help address waste in the health care system. Because medical device recalls are largely voluntary exercises initiated at the behest of manufacturers, and because many recalls do not require withdrawal of medical devices from the market, it is likely that Medicare and other insurers are still paying for the use of medical devices even after safety concerns are brought to light. For example, a previous investigation by the Office of the Inspector General indicates that Medicare unnecessarily spent billions of dollars on faulty medical devices because neither CMS nor the FDA were able to address faulty devices in a timely manner. Further, CMS did not receive refunds from manufacturers for failed medical devices (and, thus, ends up paying for both the faulty device as well as the replacement); this is an issue that UDIs would directly help to address.[7,8]

While the proposed updates to X12 are an important advance which we fully support, **we also urge NCVHS to work with X12 to update claims form to include the production identifier component of the UDI**, as the current updates are limited to the device identifier. This would offer several benefits. For one, it would ensure that claims forms include information such as serial numbers (which are helpful if a device recall applies only to a specific lot of devices, and is not due to a systemic design flaw in the device) and expiration dates (which are especially helpful for implantable devices, or drug-device combinations that might include a biological or pharmaceutical component). Furthermore, including the full UDI now, as opposed to staggering the change, would minimize the number of changes required for claims forms in the future, reducing regulatory friction for Medicare and easing the administrative burden for health systems and commercial payers. Medical devices are already labeled with both the device identifier and production identifier, and it would be ideal to utilize both of these UDI components in claims forms.

8. Implementation and 9. Simultaneity – Proposed Modification: Establish a definitive cutover date

In the RFC, NCVHS requests feedback on how the implementation of X12 updates should occur. In item 8 and 9, NCHVS asks about potential benefits or challenges associated with allowing for a transition period in which both versions are active versus having a definitive cutoff date.

We acknowledge that the implementation of any X12 updates has challenges and requires resources. Specifically, health systems will need to develop processes by which to collect and integrate the UDI into patient health records and transmit the UDI-DI as part of facility and/or physician claims. We are confident that such implementation is very feasible; prior research has demonstrated that transmission of the device identifier from health systems to insurers is achievable without any heavy burden – mostly an upgrade of systems (which are occurring regularly).[9,10] However, we are concerned that a period of concurrent use would only create further confusion and administrative challenges for patients, clinicians, hospitals, and payers. In the context of UDIs, concurrent claims form versions would introduce unnecessary noise into postmarket surveillance efforts, and potentially further delay the transition to a national surveillance system for medical device safety. **We instead suggest that NCVHS should recommend "*having a definitive cutover date*"**, such as occurred with the transition to ICD-10 in October 2015. We appreciate that a successful transition will require coordination across many stakeholders, and in the context of UDIs, would recommend convening experts from academia, public health, medical device manufacturers, payers, health systems, and government (FDA, CMS, and ONC). However, it is our perspective that having a clear point of transition, rather than an in-between regulatory gray area, would provide stakeholders with more clarity and minimize complications for payers, health systems and patients.

Sincerely,

Kushal T. Kadakia, MSc
Harvard Medical School

Sanket S. Dhruva, MD, MHS
University of California, San Francisco

Joseph S. Ross, MD, MHS
Yale School of Medicine

Harlan M. Krumholz, MD, SM
Yale School of Medicine

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STAT+

For safety's sake, it's time to get medical device identifiers over the finish line

By Kushal T. Kadakia, Sanket S. Dhruva *and* Harlan M. KrumholzJuly 18, 2022

Adding identifiers for medical devices like pacemakers to claims forms would help improve device safety.
SEBASTIEN BOZON/AFP via Getty Images

This week, an under-the-radar U.S. government advisory group called the National Committee on Vital and Health Statistics (NCVHS) can vastly improve medical device safety.

The NCVHS, which was founded in 1949, is responsible for developing recommendations and common standards for organizing information and data across the U.S. health care system. This charge includes oversight of the claims forms that facilitate all billing and insurance-related activities.

Policymakers and others use claims data to track the flow of medical products and services, spending, quality, and outcomes.

One notable absence from claims forms is specific information about medical devices — products ranging from pacemakers to hip implants and ventilators — which account for nearly $200 billion in annual health care spending. This omission is specific to medical devices; claims forms contain National Drug Codes that enable tracking of pharmaceuticals.

The inability to track medical devices after they are purchased by providers or used by patients can harm care in myriad ways: The safety and effectiveness of medical devices used in the real world cannot be studied. Unsafe medical devices that are recalled cannot be efficiently identified, nor can patients be reliably notified of defective equipment. In fact, most people lack specific information about the make, model, and features of the devices used in their care. Health care dollars are also wasted, with the Department of Health and Human Services Inspector General estimating that Medicare has spent billions of dollars just on defective cardiac devices because Medicare could not track and receive refunds for recalled devices.

To solve this issue, Congress authorized in 2007 and 2012 the creation of unique device identifiers (UDIs). These are standard labels that manufacturers must affix to each device to enable tracking. In 2013, the FDA finalized regulations for UDIs and, as of 2021, more than 3 million devices now have UDIs.

But these now-abundant identifiers are essentially useless. The reason? Policymakers never incorporated UDIs into claims forms, so they can't be used for monitoring. This is like supermarkets placing barcodes on groceries that cashiers can't scan at checkout.

Over the past decade, a bipartisan effort endorsed by legislators and by leaders at the Centers for Medicare and Medicaid Services and the Food and Drug Administration has sought to add device identifiers to Medicare's claims forms. This would enable safety surveillance of medical devices and the ability to track recalls, and would also give Medicare the ability to analyze device use and spending. Furthermore, Medicare policies — which serve as a bellwether for private insurers — would spur UDI adoption by commercial payers, who have already voiced support for including this information on claims forms.

After years of waiting, policymakers finally have their window for change. X12 — a national advisory body in charge of developing standards for electronic data exchange used business processes, such as medical claims — officially endorsed in June the incorporation of device identifiers on Medicare claims forms and sent the recommendation to the NCVHS for approval.

While the end is in sight, policymakers must clear several hurdles to get device identifiers over the finish line. The NCHVS — which meets on July 20 — must now endorse X12's proposal and officially recommend to Medicare that it include device identifiers on claims forms. Medicare must then propose rulemaking to require the device identifier on a form as a condition for reimbursing medical device-related procedures.

Claims are an essential first step to encourage providers to use UDIs in clinical practice, as many hospitals naturally configure electronic health records around claims forms designed for billing purposes. But to fully realize the potential for device identifiers, CMS must also work with other federal partners, such as the Office of the National Coordinator for Health Information Technology, which sets standards for electronic health records.

Unfortunately, X12's proposal represents only half of the solution. UDIs have two parts: a device identifier and a production identifier, which encompasses production-specific information such as serial numbers and expiration dates. X12 recommends including only the device identifier. While this is a meaningful step forward for medical device regulation, including the production identifier as well would ensure harmonization with the FDA and provide vital data for safety surveillance. CMS should consider including the changes to minimize regulatory friction and burden for providers and payers to update their systems.

Device identifiers are a core building block of the effort to build a national system for monitoring health products in the real world. Including device identifiers on claims forms is a long-overdue step that will improve patient safety and reduce wasteful spending.

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About the Authors

EDITORIAL

HEALTH CARE POLICY AND LAW

The Philips Respironics Recall of Ventilators and Positive Airway Pressure Machines—Breakdowns in Medical Device Surveillance

Kushal T. Kadakia, MSc; Joseph S. Ross, MD, MHS; Vinay K. Rathi, MD, MBA

In June 2021, Philips Respironics (Philips) initiated one of the largest medical device recalls in history, affecting more than 10 million devices in the United States and 15 million devices worldwide.[1] Philips recalled 14 models of ventilators and positive airway pressure machines (both bilevel positive airway pressure [BPAP] and continuous positive airway pressure [CPAP] machines) using polyester-based polyurethane (PE-PUR) sound abatement foam owing to concerns that foam degradation could harm patients through inhalation of toxic particles and emissions. The US Food and Drug Administration (FDA) categorized this recall as Class I (the most severe designation), indicating reasonable probability that device use could cause serious adverse health consequences or death.

In April 2022, Philips received a subpoena from the US Department of Justice for information on events leading to the recall, and as of July 2022, the company was in discussions "regarding the terms of a proposed consent decree to resolve the identified issues."[2] In August 2022, the FDA reported that it had received more than 69 000 reports of adverse events—including cancer, pneumonia, and chest pain—and 168 reports of death linked to the recalled devices.[1] This ongoing public health crisis highlights the need for reforms to medical device regulation in the US to better protect patients.

Clinical and Regulatory Context

The recalled devices are used for the treatment of obstructive sleep apnea (CPAP and BPAP devices) and respiratory insufficiency (ventilators) in a wide range of populations (pediatric and adult) and care settings (home and facility). The FDA classified the Philips devices as moderate risk (ie, Class II). The agency requires Class II devices to undergo review via the 510(k) pathway for marketing authorization. Premarket clinical studies are typically not required for 510(k) clearance.[3] Instead, manufacturers must demonstrate that a device is "substantially equivalent" to a previously cleared predicate device and conforms to device-specific controls. For example, manufacturers of CPAP and BPAP devices must demonstrate that patient-contacting portions of the device are biocompatible and that the device can withstand typical forces expected during use.[4]

Following clearance, FDA oversight of moderate-risk devices, like Philips', is largely passive.[5] The FDA rarely requires postmarket surveillance studies and instead relies on mandatory adverse event reporting by manufacturers and user facilities (eg, hospitals). However, adverse events are underreported because patients and clinicians are often unaware whether and how to submit actionable reports, and manufacturers exercise considerable discretion over what events must be reported.[6] When safety issues are identified, manufacturers are expected to voluntarily initiate recalls and communicate and implement plans to correct or remove affected devices.

Market History of Recalled Philips Devices

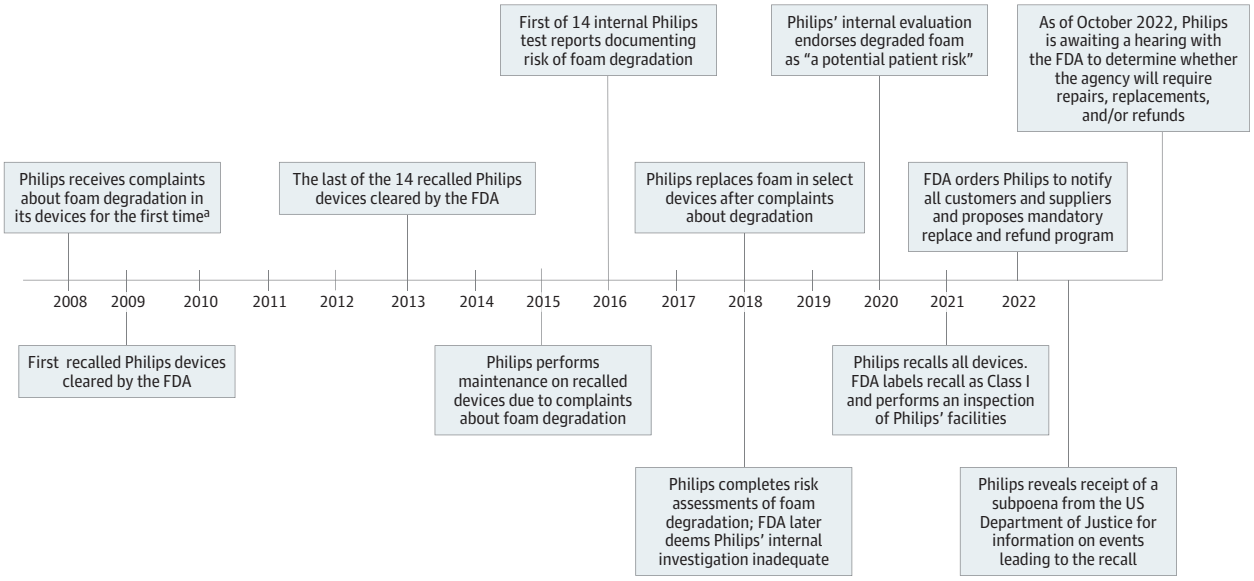
Philips' recalled devices (3 ventilators, 6 BPAP machines, and 5 CPAP machines) received FDA clearance[3,7,8] between March 4, 2009, and October 18, 2013 (**Figure**), without requirement for premarket or postmarket clinical studies. Publicly available documents for these devices and their 21 unique predicates do not reference PE-PUR foam. Therefore, it is unclear when Philips modified devices to include PE-PUR foam, whether Philips reported this design change to FDA, and what nonclinical testing Philips may have conducted to assess PE-PUR foam degradation.

On June 14, 2021, Philips recalled devices containing PE-PUR foam manufactured prior to April 26, 2021, stating that it had received several complaints of black particulates within air circuits and reports of mild adverse events.[9] Philips denied receiving reports of device-related deaths, but noted the foam's potential for toxicity and carcinogenicity. Given these substantial risks, the firm announced plans to replace PE-PUR foam with new materials.

On August 26, 2021, the FDA initiated a 10-week inspection of Philip's manufacturing facility that identified the firm's failure to adequately analyze, address, and report mounting safety concerns.[10] The FDA investigators discovered that Philips had received more than 1250 consumer complaints about foam degradation since 2014, many years before the company initiated the recall. Between April 2016 and January 2021, the firm conducted at least 14 assessments demonstrating the potential harms of foam degradation and emissions. In 2015, Philips began implementing preventive maintenance measures, and in 2018, the company began replacing components (including foam) for select devices already in use. However, the firm did not disclose safety concerns or attempts at corrective action to FDA.

Although Philips ultimately recalled the faulty devices, the firm's announcement was not the end of the story. In March 2022, the FDA ordered Philips to adequately notify all patients, clinicians, and supply chain intermediaries affected by the recall within 45 days.[8] The FDA issued this atypical mandate after determining that Philips had not appropriately alerted patients and other consumers to the recall, provided clinicians with necessary facts to counsel patients, or communicated the device replacement process clearly to

Figure. Timeline of Regulatory History for Recalled Philips Devices



[a] US Food and Drug Administration (FDA) analysis[8] of Philips Respironics' (Philips) internal data indicates that the firm received complaints related to foam degradation in 2008, when the firm began marketing the Trilogy ventilator.[7] These complaints predate FDA clearance of the Trilogy ventilator for US marketing.[3]

patients. These communication deficiencies in part stemmed from Philips' lack of comprehensive field tracking for the recalled devices, which compelled the firm to rely on durable medical equipment vendors to notify affected patients.[11] In May 2022, after concluding that notification efforts were insufficient to mitigate the public health risks, the FDA proposed to compel Philips to repair, replace, or issue refunds for all recalled devices.[12] As of October 2022, this proposal is pending an FDA hearing with Philips.

Separately, Philips' devices were also subject to recalls in August 2022 for plastic contamination (affecting 386 devices) and in September 2022 for magnet safety (affecting >17 million devices). These additional recalls also encompass some of the devices already recalled for PE-PUR sound abatement foam, broadening the scope of an already significant public health crisis.[13,14]

Implications for Patients

As of August 2022, Philips had only shipped 1.65 million of the 5.5 million devices requiring replacement in the US due to foam breakdown.[15,16] For patients with obstructive sleep apnea, recall-induced demand for new CPAP and BPAP machines has outpaced the capacity of competing manufacturers to produce them. Many patients with recalled devices have the choice of either continuing potentially deleterious exposure or discontinuing therapy. Shortages have additionally reduced the capacity of sleep centers to initiate treatment for newly diagnosed patients. For patients with chronic or acute respiratory failure, relying on putatively life-sustaining ventilators now carries potential hazards, which have been exacerbated by the ongoing COVID-19 pandemic. These delays and difficulties may be most likely to affect medically and socially vulnerable patient populations, especially poor, older adults.

Recommendations for Physicians and the FDA

In August 2021, a coalition of specialty societies, led by the American Thoracic Society, issued guidance to inform clinical decision-making.[17] These recommendations may help clinicians navigate uncertainties, such as when to discontinue therapy with recalled devices and how to formulate practice-level responses (eg, developing clinical assessment pathways). However, given the rapidly mounting scale and significance of the recall, additional FDA actions are needed to protect patients.

First, the FDA should implement its May 2022 proposal to require Philips to repair, replace, or issue refunds for all recalled devices.[12] Such a mandate could help ensure that Philips increases patient outreach efforts and expedites device replacements. Requiring refunds for recalled devices could also provide patients with the flexibility to purchase devices from competitors rather than waiting for replacements.

Second, the FDA should use its existing authority to order Philips to initiate a longitudinal postmarket surveillance study characterizing harms associated with the recalled devices. Requiring Philips to use existing clinical data registries and design the study in partnership with specialty societies could help promote rigorous, timely, and transparent results.

Third, the FDA should convene a meeting of the Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee. This meeting could help elicit patient concerns, gather expert opinions, and

inform subsequent regulation.[18] For example, the panel could help FDA answer important remaining questions, such as the safety of Philip's silicone-based foam, the potential contribution of ozone cleaners to PE-PUR foam breakdown, and the applicability of current device-specific premarket controls to degradation under typical conditions (eg, heat, humidity) of use.[1,12] The panel could also consider questions beyond foam breakdown, including the recently identified issues with plastic contamination and magnet safety for respirator face masks.[13,14] Leveraging independent expertise to clarify these issues could help the FDA address uncertainties for patients and clinicians and contribute to the safety of new models of the devices.

Recommendations for Systemic Reform

In addition to stemming the fallout from the Philips recall, the FDA's limited authority for oversight of medical devices should be addressed. The decade-long delay between Philips' initial receipt of safety complaints and the initiation of the recall reflects the inadequacy of a postmarket surveillance system largely reliant on voluntary action. To prevent such delays, Congress could amend regulations to include prespecified numerical (absolute or proportional) thresholds for consumer complaints that would trigger a FDA audit.

Furthermore, Philips did not adequately notify affected patients of the recall, even as the FDA depended on the firm to do so. This failure occurred because Philips, as has been the case for other manufacturers of moderate-risk devices, does not track individual devices using product registries or identifier systems.[19] Philips instead relied on durable medical equipment vendors to notify patients about the recall.[11] However, these contractors may not maintain long-term relationships or records of patients. Integrating unique device identifiers into claims data and electronic health records could permit the FDA to better identify patients using faulty devices. For Medicare to include unique device identifiers on claims forms, such a policy must first be endorsed by the National Committee on Vital and Health Statistics, which next meets in December 2022.[20]

As of October 2022, the Philips recall remains ongoing, and ventilators and CPAP and BPAP machines remain in shortage. To protect patients and the public health, the fundamental shortcomings in medical device regulation that the Philips recall has exposed should be corrected.

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The Post-Market Surveillance System For Implanted Devices Is Broken. Here's How CMS And The FDA Can Act Now To Fix It

Dan C. Krupka, Natalia A. Wilson, Amanda J. Reich, Joel S. Weissman

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Why don't we have an effective post-market surveillance system for medical implants? The need is clear and urgent.

Here is the problem: At present, the approval process for the majority of implants flows through the 510(k) pathway <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k> , which allows them to reach the market based on its similarity to a previously approved implant, without additional clinical trials. And, instead of a rigorous post-market surveillance system, we have a process with many

shortcomings <https://www.brookings.edu/wp-content/uploads/2016/07/Med-Device-ReportWEB.pdf> , including reliance on voluntary reporting of adverse events.

Meanwhile, the public has become increasingly aware of the harm associated with several implants. *The Bleeding Edge <https://www.netflix.com/title/80170862>* , a 2018 documentary film from Netflix, highlights complications suffered by women who received an implantable contraceptive device, now taken off the market by its manufacturer. In addition, the film illustrates patient harms ascribed to metal-on-metal hip implants, surgical mesh, and breast implants. Citing 80,000 deaths and two million injuries, a full-page editorial in the May 4, 2019, *New York Times* <https://www.nytimes.com/2019/05/04/opinion/sunday/medical-devices.html> called for a reckoning on implanted medical devices, including fixing post-market surveillance.

In contrast to the process for tracking the performance of implants, an effective solution has been developed for medications. Responding to the Food and Drug Administration (FDA) Amendment Act of 2007, the FDA created the Sentinel System <https://www.fda.gov/safety/fdas-sentinel-initiative> . It is operated by a contractor to the FDA and uses data from claims stored in insurers' information systems and providers' electronic health records (EHRs) to monitor the use of drugs and the outcomes of treatment. To do this, it relies on national drug codes <https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory> (NDC), which uniquely identify every prescription drug. Because claims are filed for the majority of prescription medications, such data permit the calculation of the rate, or prevalence, of potentially adverse events associated with a particular drug. While no dangerous drugs have been identified by Sentinel, Sentinel data are used to inform the FDA advisory meetings <https://www.sentinelinitiative.org/news-events/fda-advisory-committee-meetings> and FDA Safety Communications <https://www.sentinelinitiative.org/news-events/fda-safety-communications> . And these, in turn, have allowed physicians to make more informed decisions.

For devices, including implants, the FDA facilitated the establishment of unique device identifiers <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system> (UDI) analogous to NDCs. Since 2013, it has required manufacturers to label devices with UDIs. However, there is no requirement for providers, be they individuals, hospitals, or health systems, to use the UDIs to track the medical devices they implant. Earlier, in 2012, Congress extended the charter of Sentinel <https://www.govinfo.gov/content/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf> to include devices in addition to drugs.

Until UDIs are in broad use by providers, however, Sentinel will be unable to implement its updated charter. As we shall argue, an expanded Sentinel can be implemented by 2025. To achieve that goal, however, a number of barriers will have to be overcome. Furthermore—and this is essential—the Centers for Medicare and Medicaid Services (CMS) and the FDA will need to act now.

The barriers fall into two categories: technical barriers, including how to transmit data on implants from providers to insurers, and how to extend Sentinel's capabilities to include implants; and political barriers, including resistance of certain organizations to the introduction of a system that relies heavily on UDIs in insurance claims, and the absence of adequate leadership from responsible federal agencies.

The Technical Barriers Are The Less Daunting Barriers

We recently published a study <https://journals.lww.com/journalpatientsafety/Fulltext/2021/04000/Transmitting_Device_Identifiers_of_Implants_From.12.aspx.> in the *Journal of Patient Safety* describing how modest modifications to providers' and insurers' information systems permitted the transmission of data on implants from provider to insurer. In our demonstration project, conducted at two provider-insurer pairs, the UDI of each implanted device was scanned into an information system at the point of care. Then the device identifier (DI), the segment of the UDI that represents the manufacturer and device model, was transmitted to the insurer via the standard 837 digital claim form. As most providers and insurers rely on software vendors to make changes to their information systems, we concluded that a nationwide implementation of DIs in claims would not impose a heavy burden on the participating organizations. For most, the changes would represent just another upgrade of their systems.

Because the current claim form lacks a designated field for DIs, our project relied on a proxy field. Fortunately, an updated 837 claim form is expected to become effective in 2024: (X12. X12 Technical Report Type 3 [TR3], Health Care Claim: Institutional, TR3 ID "007030X324" [837], section 1.12.7, published in July 2020, available at: https://products.x12.org <https://products.x12.org>). This form will include a field for DIs of high-risk implanted devices and many other changes.

When the new form becomes effective, providers and insurers will be required to have modified their information systems to reflect the new features. Thus, at that time, providers will have the capability to transmit DIs of implants to insurers. According to the guidelines for the new claim form, however, DIs may only be transmitted when

provider and payer have mutually agreed to the transaction or when mandated to do so by state or federal regulations.

The major remaining technical challenge is the expansion of Sentinel to include implanted devices: upgrading its database structure, developing quality checks for the new data, and updating the tools to analyze the data.

The Political Barriers And How To Overcome Them

What then are the prospects for national adoption of DIs in claims? In an attempt to answer this question, we conducted, in 2019, semi-structured interviews with 20 stakeholders and experts on UDIs and on UDI policy. As this community remains small owing to the absence of any mandate for providers to include UDIs in their information systems, the interview participants represented a substantial fraction of all persons familiar with these topics. Our interviewees consisted of clinicians and others associated with provider institutions implementing UDIs, health plan leaders, employees of federal agencies and federally funded organizations, manufacturing executives, aides to Congress members with interests in UDIs, and members of advocacy organizations.

In addition to the barriers cited above, the interviewees identified: possible concern at CMS regarding the expense of modifying its claims-processing systems; providers' fear that insurers might use information on implants to impose device formularies; potential confusion regarding which devices should be included in the high-risk category for which reporting would be required; and the slow pace of the introduction of the updated claim form.

Our most significant finding, however, was that a majority of the interviewees believed that a nationwide implementation of DIs in claims would be triggered if CMS required providers to include DIs of implants in their claims. In other words, if CMS led, insurers would follow.

In light of the foregoing, here are three specific steps CMS and the FDA can take to create an effective post-market surveillance system by 2025:

First, CMS should alert providers that it expects their claims to include DIs of high-risk implants as soon as their systems are modified to comply with the specifications of the updated claim form.

Second, CMS should convene a standing advisory panel to help it identify "high-risk" implants. Its first task might be to establish criteria for inclusion in this category and then

identify the initial set of devices. As new devices are introduced, the panel would be consulted on classifying difficult cases.

Third, the FDA should alert the contractor that operates Sentinel—Harvard Pilgrim Health Care—to prepare its processes and systems to include devices as soon as the specifications for the updated claim form are available.

The need is urgent, the solution clear.

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Transmitting Device Identifiers of Implants From the Point of Care to Insurers: A Demonstration Project

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Background: For implanted devices, an effective postmarket surveillance system does not exist. For medications, the Food and Drug Administration's Sentinel Initiative plays that role, relying mainly on drug codes in insurance claims. Unique device identifiers (UDIs) could play an analogous role for implants, but there is no mandate for providers to include UDIs in claims or for payers to record them. Objections have been raised to incorporating UDIs into claims based on a potential burden on providers.

Methods: To assess this purported barrier, we modified information systems at 2 provider-payer dyads to allow for the transmission of UDI data from provider to payer. In addition, to illustrate the potential benefit of including device data in claims, we used our data to compare rates of 90-day adverse events after implantation using the electronic health record (EHR) alone with the EHR plus claims.

Results: The software system modifications were modest and performed as designed. Moreover, the level of difficulty of their development and implementation was comparable to that associated with a typical new release of an existing system. In addition, our data demonstrated the ability of claims-based data plus EHR data to reveal a larger percentage of postprocedure adverse events than data from EHRs alone.

Conclusions: Modifying information systems to allow for the transmission of UDI data from providers to payers should not impose a substantial burden on either. Implementation of a postmarket surveillance system based on such data in claims will require, however, the development of a system analogous to Sentinel.

Key Words: unique device identifier, UDI, implantable device, postmarket surveillance, 837 claim form, Sentinel, medical implant, NEST, patient safety, adverse events, real world evidence

(*J Patient Saf* 2021;17: 223–230)

At present, there is no reliable, national system for determining whether patients with a particular medical implant are experiencing suspiciously high rates of implant-related adverse events. Reporting of adverse events associated with implants[a] is currently performed through a variety of voluntary and mandatory reporting mechanisms, all having substantial limitations.[1] A serious shortcoming is that they report events, not rates. The calculation of the latter requires a denominator, that is, the total number of the devices that have been implanted. For drugs, the situation

[a]We use "implant" and "implanted device" interchangeably.

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is different. The Food and Drug Administration (FDA)'s Sentinel Initiative was established[2,3] to monitor the safety and comparative effectiveness of drugs by leveraging national drug codes[4] recorded at the point of care (POC) or the point of sale and transmitted to payers via insurance claims. Sentinel data are mainly derived from claims, which conform to a standardized format and allow patients to be tracked as they move among providers. Although Sentinel's purview includes devices, the FDA recently took steps to establish the National Evaluation System for Health Technology (NEST).[5] Among NEST's proposed objectives is to build an infrastructure and generate evidence on the postmarket performance of implanted devices. In addition to discovery of adverse events, the data stored in insurers' information systems could provide real-world evidence for studies such as comparative effectiveness research, and would complement data stored in registries.[6]

Until recently, one major barrier to device surveillance was the lack of a standard identification system. In 2013, the FDA published a final rule requiring manufacturers to label medical devices with the unique device identifier (UDI).[7] A UDI is a 2-part code consisting of a device identifier (DI), which indicates the manufacturer and model, and a production identifier, which can include production information such as lot number and expiration date. To encourage providers to use UDIs, the Office of the National Coordinator for Health Information Technology has ruled that electronic health records (EHRs) must have the capability to record UDIs to receive certification, but there is no mandate for providers to use this capability.[8]

A second major barrier to implant surveillance is the absence of a designated device field on the current standard electronic 837 claim form. This barrier may be eliminated, however, as over the past several years, the X12,[9] the body responsible for the 837 form, has been developing its next version. The latest draft, released in July 2020, includes a proposal to accommodate only the DIs—up to 9 per claim—for high-risk implantable devices and to be used in exchanges by willing provider-payer partners.[10] Implementation of this version, assuming the changes are approved, is not expected until 2023 or later.

A third barrier to nationwide postmarket device surveillance, and the focus of this work, is the design of processes to complete the "last mile" of data transmission: from POC to insurer. As part of such a system, providers would need to record DIs at the POC and transmit them to health insurers[b] via the claim form. Important stakeholders have held different positions on including DIs in claims. The American Hospital Association conditioned its support on the inclusion of certain features of the new claim form,[11] and these conditions have been met in the proposed version. The Centers for Medicare & Medicaid Services, after initially giving it support,[12] seems to have later changed its position, and the current perspective has not been made clear.[13] The device trade association AdvaMed and the American Medical Association are opposed. They base their opposition in part on the belief that including DIs in claims would impose an unnecessary burden on providers. They support postmarket surveillance based on UDIs in EHRs or local registries.[14,15]

To assess the barriers and facilitators to putting DIs in claims, we posed 3 questions:

1) What process changes and information system enhancements would providers and insurers need to make to add DIs of implants to insurers' claims-processing systems?
2) How difficult would it be to make these process changes compared with typical information system enhancements?
3) What benefits accrue from including DIs in claims compared with tracking devices through EHRs or EHR-based device registries?

To answer the first question, we conducted demonstrations at 2 hospital-payer dyads—Brigham and Women's Hospital (BWH), a member of Mass General Brigham, formerly known as Partners HealthCare, with Blue Cross and Blue Shield of Massachusetts (BCBSMA), and Geisinger Health (GH) with Geisinger Health Plan (GHP). To answer the second question, we interviewed those responsible for introducing the new processes, for modifying the software systems, and for the daily use of the new processes and systems. To answer the third question, we examined the rate of adverse events identified in EHRs plus claims compared with locally generated data from EHRs.

INFORMATION SYSTEM MODIFICATIONS

Method

The planning and design of process changes and modifications of software systems required to transmit DIs, recorded at the POC, to payers' systems took place from October 2016 to September 2017. We described the modifications in a previous publication.[16] Our project focused on 2 essential capabilities: (1) transmission of the DIs, recorded at the POC, to the billing systems that populate the claim form, and (2) enhancement of payers' information systems to accept the DIs and to make data available for subsequent analysis. At BWH, the project included the catheterization laboratory (cath lab), the electrophysiology laboratory (EP lab), and vascular operating rooms (OR), whereas at Geisinger, we restricted the project to the cath lab. Scanning was already in place in the cath lab and EP lab at BWH and the cath lab at GH. In addition, we arranged for the training of the nurses in the vascular ORs at BWH in scanning UDIs of implants.

For transmitting DIs from providers to payers, we selected—in the absence of a designated field for DIs in the current 837 institutional claim form[17]—the notes segment of the form.[c] Because that field was not used to support any claims-adjudication transactions between BWH and BCBSMA, the notes segment could accommodate up to 10 DIs. However, because GH and GHP were already using the notes segment for some transactions, only 2 DIs could be accommodated. In view of this constraint, we decided to transmit the 2 most expensive items scanned per case at GH, recognizing that some of these might not be implants.

Appendix A contains data-flow diagrams and descriptions of the information systems whose modifications were described in our previous publication.[16] The most obvious difference between the data flows in the 2 dyads is that different vendors are used for the main categories of information systems (e.g., inventory management, and billing and claims processing). The most significant process difference is that UDIs scanned at GH were stored in the inventory management system, whereas UDIs scanned at BWH were stored in the implant record of the EHR.

At BWH, the billing module was modified to retrieve the DIs from the EHR and include them on the claim. At GH, modifications to the inventory management system enabled it to select the DIs of the 2 most expensive items and transmit them to the billing system. In addition, minor modifications were made to the billing system to append this information to the notes segment of the claim. The level of effort required at BWH and GH was sufficiently low that formal requests for resources were deemed unnecessary.

To accommodate the DIs transmitted by BWH, BCBSMA made complementary modifications to one of its systems to identify patients whose claim forms contained DIs, and added a data table for these patients to its data warehouse. Because GH and GHP were

[b]We use "insurer," "health insurer," and "payer" interchangeably.

[c]Formally known as NTE segment, Loop 2300

already exchanging data in the notes segment, GHP did not have to modify its systems to accept DIs.

Results

Our primary performance objective was to successfully transmit the DIs of devices scanned at the POC to the payers. For the BWH/BCBSMA dyad, this meant that up to 10 DIs, scanned at the POC, would be recorded by BCBSMA. At GH/GHP, we wished to demonstrate that the DIs of the 2 most expensive items scanned at the POC—or the most expensive item, if there was only one—would be recorded by GHP.

Over the assessment interval for BWH/BCBSMA, which extended from November 1, 2017, to May 31, 2019, DIs for 347 patients covered by BCBSMA were correctly transmitted and received. We found that all DIs recorded in the cath lab were correctly received by BCBSMA, but because of an error in the programming logic, DIs for pacemakers and implantable cardioverter defibrillators from the EP lab were not. We also found that DIs of devices implanted in the vascular ORs were not being properly recorded; consequently, their DIs were not reaching BCBSMA. After careful assessment, we concluded these issues would be resolved in an institution-driven—as opposed to a research-driven—implementation of UDIs at BWH.

At GH/GHP, the assessment interval was January 1, 2018, to April 24, 2019. During this interval, 760 claims were generated, transmitting 1033 DIs. We found that 77% of these 1033 DIs corresponded to the 2 most expensive items per case, with catheter introducers (nonimplanted) being the most frequent, followed by drug-eluting stents. The remaining 23% of DIs were valid identifiers of products used that had incorrectly superseded more expensive ones. Investigation of these discrepancies led us to conclude that such errors would be eliminated if the claim form could have accommodated more than 2 items, if logic to select device were improved, and if UDI labeling were universal and more consistent. (Some products were drawn from stock that predated UDI introduction or used a different barcode standard).

ASSESSMENT OF DIFFICULTY OF PROCESS AND INFORMATION SYSTEM MODIFICATIONS

Method

We conducted 20 semistructured interviews with participants at the completion of our planning and development and a second set of 20 interviews 10 months after the start of implementation. Two members of the project team conducted the interviews, following an interview guide developed by the study team.

For the interviews conducted at the completion of the planning and development phase, the interviewees at BWH included staff members familiar with the affected information systems, application developers, and those responsible for generating reports on the activities of the cath lab. In addition, we interviewed a senior technician in the cath lab. At BCBSMA, our interviewees included a member of the strategy and planning organization, an expert in electronic data interchange, and a claims domain architect. At GH and GHP, we interviewed members of the inventory systems development organization, billing systems specialists, and a claims information systems specialist.

Ten months after the start of the implementation phase, we interviewed 2 categories of staff members at BWH and BCBSMA. The first category consisted of those responsible for troubleshooting the software modifications, including designers and developers of the information systems modifications, those who generated the regular reports on the patients and the implants they had received, and some of their managers. The second category consisted of technicians in the cath lab and nurses in the vascular ORs.

Our interviews addressed the following topics:

- the degree of difficulty of the task assigned to the interviewee for our project relative to similar projects recently completed, measured on a scale of 1 to 5;
- facilitators and barriers—people or processes that helped or hindered the interviewee in performing the task; and
- the interviewee's perception of the degree of difficulty of implementing similar processes nationally.

The interviews lasted approximately 1 hour and were recorded after securing the interviewee's consent. The interviews and the recording of interviews were approved by institutional review boards at BWH and GH. The research team conducting interviews also took detailed notes and referred back to the audio recordings to ensure accuracy. After independently reviewing their interview notes, 2 members of the research team compared their findings and, through an iterative process, arrived at the results.

Results

Interviews Conducted at the Conclusion of the Planning and Development Phase

At BWH and BCBSMA, interviewees involved in the design and development of the modifications to the information systems told us that the selection of the notes segment in the 837 claim form and the development of the software modifications were technically straightforward but that the tasks were complicated by the need to coordinate with members of multiple departments and organizations to ensure the integrity of claims processing. They acknowledged that the advice from EHR vendor staff was very useful and that weekly project conference calls helped to keep everyone informed regarding progress and problems. The technician in the cath lab, who had been scanning implants and supplies for more than 6 months before our project was launched, told us that she and her fellow technicians much preferred scanning to manual entry.

At GH, the responsibility for developing the necessary software modifications to the inventory management system was assumed by the vendor as part of an ongoing program of enhancing the system. The GH billing team assumed responsibility for developing the software modifications to its systems and coordinated its modifications with the inventory management team. The billing team reported that the level of difficulty encountered in the design and testing of the modifications was comparable to regular system updates.

Interviews Conducted 10 Months After the Start of Implementation

The first category of interviewees, described in the previous Method section, told us that the technical level of difficulty of the implementation phase was relatively low, but that the need to involve members from multiple organizations in troubleshooting raised the overall difficulty to a level comparable to typical implementations of new information system releases. Those who had designed and developed the information system modifications believe that, during a nationwide implementation of DIs in claims, most institutions would need to work with their system vendors to make the modifications necessary to transmit DIs from the POC to payers.

Among the second category of interviewees, the cath lab staff confirmed that scanning implants and supplies continued to be straightforward. They also told us that technicians are dedicated to the cath lab and are only occasionally assigned to the EP lab, where the same processes and software are used as in the cath lab.

The nurses in the vascular ORs, the other group in the second category of interviewees, offered a contrasting perspective. They acknowledged that scanning barcodes is much easier than manual entry of the data; however, because implants were used in only 5 to 10% of cases and were the only items available for scanning during our study, the nurses had to modify their standard process and remember when to scan. To compound the challenge, in contrast to the situation in the cath lab and EP lab, nurses working in the vascular ORs rotated through other ORs where scanning UDIs was not routine practice.

ANALYSIS OF CLAIMS-BASED OUTCOMES

To explore the benefits of using claims-based data that are device-specific, we analyzed data received at BCBSMA and GHP during our demonstration. We first identified the devices from their DIs using the FDA's Global Unique Device Identifier Database,[18] then analyzed all claims for patients during the 90 days after their discharge. We calculated percentages of patients with emergency department visits or rehospitalizations for all-cause, acute myocardial infarction (AMI), or stroke. We estimated these percentages twice: once using only claims from the originating facility and again using claims from *all* facilities where the patient might have been treated 90 days after discharge.

Our results confirmed that many patients receive care in the 90 days after discharge from providers outside the originating system, meaning that these outcomes would only be captured in a claims-based analysis and not in an analysis of EHR data recorded at the originating facility. Appendix B presents results for the 3 most frequent implants. For example, of 213 patients receiving drug-eluting stents, 9% had a rehospitalization at the originating facility, but an additional 12% were rehospitalized at other facilities. For emergency department visits, these percentages were 15% and an additional 10%, respectively.

DISCUSSION

Our study demonstrates that the technical challenges for moving DIs from the POC through the billing system and on to payers should not be a major barrier to establishing a postmarket surveillance system based on DIs in claims. We believe this conclusion is robust because it is based on results at 2 different provider-payer dyads with different systems architectures, requiring different software modifications.

Payers might estimate that the resources required just for adding DIs are sufficiently high to deter them from making the required changes. However, in the next several years, the modified 837 claim form will be introduced. In addition to a field for up to 9 DIs of implanted devices, the modified form will include many other changes, forcing both providers and payers to modify their systems. Therefore, in several years, all providers' information systems should have the capability of transmitting DIs to payers, and payers should have the capability of handling DIs in their claims-management systems.

The challenges encountered in the vascular ORs at BWH were associated, in part, with the need for the vascular OR nurses to make exceptions to their standard process during procedures requiring implants, which represented less than 10% of their cases. Moreover, no other procedure areas through which the nurses rotated had instituted scanning. It is not surprising, therefore, that they might not have remembered to scan implants. Consequently, we believe that the problem encountered in the vascular ORs is not fundamental to these procedure rooms: in a hospital-driven program—in contrast to our research study—in which all items, implants as well as supplies, are scanned, such problems would be resolved. Based on these observations, we speculate that orthopedic ORs, where the procedures may require multiple implant components, including perhaps many screws, processes for scanning the parts will be developed. For institutions that currently wish to institute the use of UDIs in procedure areas, a roadmap was developed by one of the authors (N.A.W.).[19]

One reason for enhancing payers' information systems with claims data for devices is that such data allow for the longitudinal tracking of a patient beyond the institution where the implant procedure was performed. Our comparison of claims generated by the initial provider with claims generated by all providers 90 days after the initial procedure confirms this important benefit.

LIMITATIONS

At both dyads, constraints were placed on resources to make all the modifications desired for an ideal study. At BWH, we did not pursue an additional modification to the billing system to ensure that DIs of pacemakers and ICDs would be transmitted to BCBSMA. At GH, the inventory management system was modified to transmit DIs for the most expensive items scanned, some of which were not implants.

Our study did not include an assessment of the cost to develop and test modifications to the payers' claims processing systems to accommodate DIs. At BCBSMA, no changes were made to the claims-processing system. Only the data warehouse was modified, and programming logic was added to extract the DIs from the notes segment. At GHP, no modifications of the claims-processing system were required because GHP already had the capability of transmitting data in the notes segment, and it would have been difficult to assess the incremental cost of developing that capability.

Finally, in our analysis of claims, we were unable to attribute adverse outcomes to the implanted devices. Our objective was solely to demonstrate the value of claims in this patient population to capture the treatment of adverse events beyond the originating institution.

CONCLUSIONS

Including device-specific information in insurance claims has the potential to greatly enhance postmarket surveillance and to provide essential data for performing research using real-world evidence. Our project, conducted at 2 different provider-payer dyads with different information systems architectures, has demonstrated that the modifications necessary to transmit DIs from the POC to the claim form were modest and relatively easy to implement. Although different modifications may be introduced in a national UDI implementation, we anticipate that they would likewise be achievable. Our study was unable to fully assess the difficulty of modifying payers' claims-processing systems to accept DIs because only one of the payers in our study, GHP, had modified its claims-processing system to accept DIs transmitted in the notes segment of the current 837 claim form. However, in the future, payers will have to modify their systems in response to anticipated changes in the next version of the claim form, which includes, among many other non–UDI-related changes, a field for storing up to 9 DIs per claim.

Even if all providers modify their information systems to permit the transmission of claims with DIs and if payers modify their claims-processing systems to accept DIs, a postmarket surveillance system will not automatically emerge. To fully realize the benefits of including device, DIs in claims will require not only an adequate percentage of payers' claims databases populated with these DIs but also enhancements to either Sentinel or NEST, if it becomes a functioning medical device evaluation system, or some combination of the 2 systems.

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APPENDIX A

Design of data flows incorporating DIs

Here we describe methods to:

1. transmit the DIs captured at the POC to the selected location on the claim form and
2. process claim forms received by the payer to select patients who received implants and to record their DIs.

The DI flows, highlighting the systems that were modified, are shown in Figures A1 and A2 for BWH/BCBSMA and GH/GHP, respectively.

DI flows at BWH/BCBSMA

As shown in Figure A1, at the POC the barcode of the UDI is scanned. If the scanned DI matches a DI that has been previously entered in the supply record (a reference database) of Epic (Epic Systems, Madison, Wisconsin), the scan is valid and the DI, lot number, and expiration date (if appropriate) are entered into the implant record of Epic. (Cupid for the cath lab and EP lab; OpTime for ORs.) Before our project started, UDIs of implanted devices and barcodes of supplies were already been scanned in the cath lab and EP lab but not in the vascular ORs. Because there was no direct link between the materials management system and Epic at BWH at the time of our study, the data required for scanning implants and supplies were manually entered into the Epic supply record.

To read DIs stored in the Epic implant record and to transmit them to BCBSMA, a software development team authorized to make custom modifications to local Epic modules, developed software dubbed the Extension Rule. Although the Extension Rule is depicted as a separate module in Figure A1, it consists of modifications to Resolute, the Epic billing module. The Extension Rule is invoked if:

- The charges in the patient's EHR are recorded by clinicians belonging either to the Cardiovascular Service or to the Vascular Service.
- The Revenue Code 278, designating "other implants," is present.

When these criteria are met, a field added to Resolute as part of the custom solution is populated with the DIs in the patient's implant record. If DIs are missing in the patient's implant record, the field is populated with 14 zeros for each missing DI. We added this feature to help us identify cases in which the UDI was not available for scanning, possibly because the DI was not entered into the Epic supply record.

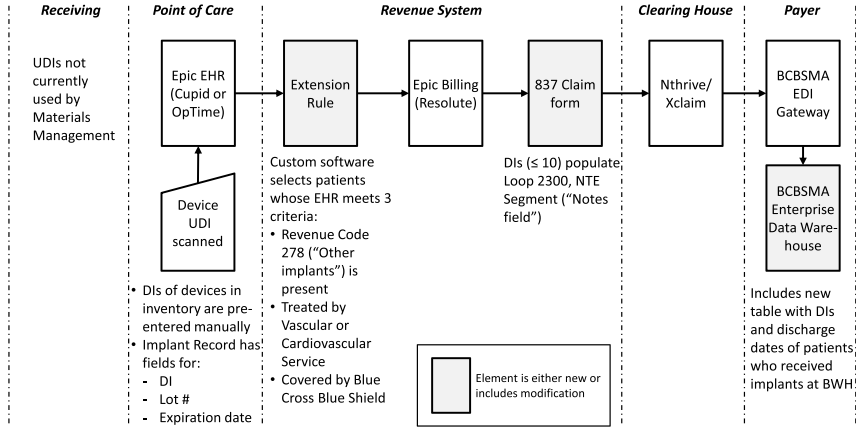
We initially planned to restrict the scope of our project to the cath lab and the vascular ORs. However, it was not possible to restrict it to the cath lab because the Epic EHR distinguishes by category of service, not by procedure room. Because the Cardiovascular Service encompasses both the Cath Lab and the EP Lab, we extended our pilot to include the latter. Moreover, because UDIs were already been scanned in the EP Lab, no incremental effort was required on our part.

The Extension Rule custom software also introduces a modification to Resolute's claim generation logic. The modification stipulates that if the payer is Blue Cross Blue Shield, the DIs of the patient's implants populate the note field of the 837 claim form. After passing through a third-party clearinghouse, claim forms with DIs are copied and their data entered in the BCBSMA Enterprise Data Warehouse (EDW) via a data table developed for our study.

DI flows at GH and GHP

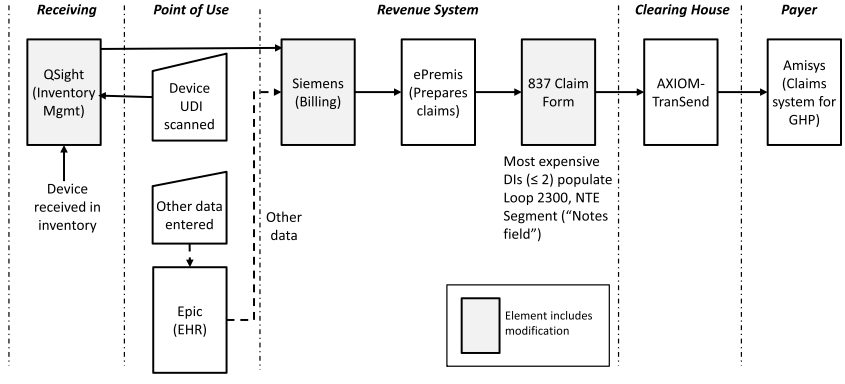
The DI flows at GH/GHP, shown in Figure A2, differ from those at BWH/BCBSMA. The most significant difference is that the UDIs, scanned at the POC, are entered into QSight (QSight, Owens & Minor, Mechanicsville, Virginia), the inventory management system—along with the patient's identification number—not into the EHR. In this architecture, the inventory management system becomes the "source of truth."At GH, a software patch was developed for QSight to enable it to select the DIs of the 2 devices with the highest price and to transmit the data to the revenue system. GH's revenue analysts created automated processes for downloading the files and then transmitting the data to the system that prepares claims, ePremis (RelayHealth, Atlanta, Georgia). Finally, after passing through a third-party clearinghouse, the patient's data, including DIs, are written into Amisys, GHP's claims system. Because GH and GHP already exchange data in the notes segment, Amisys required no modification.

FIGURE A1. DI flows designed for BWH/BCBSMA.



UDI: Unique Device Identifier; DI: Device Identifier; EHR: Electronic Health Record; EDI: Electronic Data Interchange
BCBSMA: Blue Cross Blue Shield of Massachusetts; BWH: Brigham and Women's Hospital

FIGURE A2. DI flows designed for GH/GHP.



UDI: Unique Device Identifier; DI: Device Identifier; EHR: Electronic Health Record;
GHP: Geisinger Health Plan

APPENDIX B

Side-by-side comparison of 90-day event rates for patients receiving different implant types, as estimated from claims from within the originating facility versus claims from any internal or external facility.

90-dEvents	Claims From Originating Facility	Claims From Any Facility	Absolute % Difference	Relative % Difference
Coronary drug-eluting stent (n = 213 patients)				
Readmission, all-cause	19 (9%)	45 (21%)	+12%	+137%
ED visit, all-cause	31 (15%)	53 (25%)	+10%	+71%
AMI	5 (2%)	10 (5%)	+2%	+100%
Stroke	1 (<1%)	7 (3%)	+3%	+600%
Permanent pacemaker electrodes (n = 46 patients)				
Readmission, all-cause	6 (13%)	10 (22%)	+9%	+67%
ED visit, all-cause	0 (0%)	3 (7%)	+7%	∞
AMI	0 (0%)	0 (0%)	+0%	+0%
Stroke	0 (0%)	32 (70%)	+70%	∞
Drug-eluting permanent RV/RA pacemaker electrodes (n = 43 patients)				
Readmission, all-cause	7 (16%)	12 (28%)	+12%	+71%
ED visit, all-cause	1 (2%)	8 (19%)	+16%	+700%
AMI	0 (0%)	2 (5%)	+5%	∞
Stroke	0 (0%)	3 (7%)	+7%	∞

December 15, 2022

Jacki Monson, JD
Chair
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted electronically via NCVHSmail@cdc.gov

RE: Laboratory Corporation of America Comments in Regards to NCVHS Subcommittee on Standards Request for Comments on X12 and CAQH CORE Proposals

Dear Ms. Monson:

On behalf of Laboratory Corporation of America (Labcorp), a leading global life sciences company with headquarters in Burlington, North Carolina, we would like to express our comments in regards to the National Committee on Vital and Health Statistics' (NCVHS) Subcommittee on Standards Request for Comments on X12 and CAQH CORE Proposals. Labcorp provides vital information to help doctors, hospitals, pharmaceutical companies, researchers, and patients make clear and confident decisions. Through our unparalleled diagnostics and drug development capabilities we provide insights and accelerate innovations to improve health and improve lives. With more than 70,000 employees, we serve clients in more than 100 countries.

Labcorp offers a comprehensive menu of frequently requested and specialty tests through an integrated network of primary and specialty laboratories across the United States. The company provides a range of specialty testing services in the areas of women's health, allergy, diagnostic genetics, cardiovascular disease, infectious disease, endocrinology, oncology, coagulation, pharmacogenetics, toxicology, and medical monitoring.

As a provider laboratory that provides a range of specialty testing services, Labcorp is a member of X12 and CAQH CORE. At Labcorp, we recognize the importance of adopting new technologies to facilitate the transmission of electronic health records.

Discussion:

NCVHS Subcommittee on Standards seeks comments to inform the Committee's deliberations as it develops recommendations to HHS on adopting proposed updated standards from X12 and proposed updated and new operating rules from the Committee on Operating Rules for Information Exchange (CAQH CORE).[1]

I. X12 Standard

[1] 87 Fed. Reg. 65782 (Nov. 1, 2022).

On June 7, 2022, X12 submitted a letter to NCVHS to recommend an update of mandated transactions and to propose the use of both the EDI (electronic data interchange) standard representation and the XML schema representation as permitted syntaxes. X12 proposed that the current standard be updated from version 5010 to version 8020 for the adopted administrative standard for the health care claims (professional, institutional, and dental) and the remittance advice transactions.[2]

1. *Costs*

Labcorp understands that the proposed changes to the X12 837 8020 version of the claims are significant, and as such will likely cause added costs. Labcorp has not conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional or dental claim) and remittance advice transactions; however, if Notice of Proposed Rulemaking (NPRM) is officially published in the Federal Register, an operational assessment will be considered.

2. *Operational Impact*

Because Labcorp has not conducted an operational assessment or workflow analysis on the impact of transitioning to the updated X12 820 claims and remittance advice transactions, the operational impact of is unknown at this time. Labcorp will consider an operational assessment of NPRM is officially published in the Federal Register.

3. *XML Schema*

Labcorp agrees with X12 in the recommendation that HHS permit both the 8020 EDI Standard and the XML representation. We support the use of both syntaxes and ask that NCVHS ensures that they are semantically interoperable.

4. *FHIR Crosswalks*

Labcorp is unsure how FHIR crosswalks would apply to the implementation of the HIPAA claims until those are fully built and tested.

5. *Unique Device Identifier*

No comments at this time on this issue.

6. *Alternative Payment Models (APM) and Value Based Purchasing (VBP)*

X12 version 8020 supports the use of individual diagnoses and procedure codes. These are used in value-based purchasing. Additional information can be accommodated in a claim attachment as necessary. It is unclear what the implications of this topic are at this time to HIPAA administrative simplification policies.

[2] Letter from X12 to NCVHS, June 7, 2022: https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf.

7. Implementation Time Frame

HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, it is difficult to determine an ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, as this would depend on the scope and impact of the update. Additionally, the ideal time frame would depend on what other new regulations are being implemented at the time (for instance, balanced with the No Surprises Act requirements) and what the priorities for the agency are. Labcorp agrees with the usual January 1 implementation timeline and would encourage NCVHS to issue a firm all in date.

8. Implementation

NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Labcorp supports the use of version 5010 and 8020 for an extended period of time with a specific date mandated for full integration into version 8020.

9. Simultaneity

Using version 5010 and 8020 simultaneously may be challenging but not a significant impact for Labcorp. In fact, it would allow us to poll the payers we work with to determine which payer is using which version. This would allow for a phased implementation, give us time to learn and test integration of version 8020. Therefore, we support the simultaneous use of both versions.

10. Alternatives Considered

Labcorp supports the change into version 8020. If the new version is not adopted now, the risk is the inability to implement new capabilities.

11. General

Labcorp supports HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards.

12. Other

NCVHS should consider recommending full adoption of the 277 CA Claim Response.

II. CORE Operating Rules

In May 2022, CAQH CORE submitted a letter to NCVHS requesting review of updates to the adopted eligibility and claim status operating rules for the adopted HIPAA transactions (version 5010), as well as a proposal for consideration of operating rules for connectivity and operating rules to support the adopted standard transaction for prior authorization. The letter

included a request to review an operating rule for attachments related to prior authorization, for which a standard has not yet been adopted under HIPAA.[3]

Section 1104 of the Patient Protection and Affordable Care of 2010 (ACA) amended HIPAA and introduced the requirement to adopt operating rules to support the business function of each adopted standard transaction.

1. *Efficiency Improvements*

CAQH CORE has proposed updates to the adopted versions of the eligibility and benefits and claim status operating rules currently required for use. Updates include an increase in system availability from 86% per calendar week to 90%, and for the response time for a claim status request from 20 seconds 86% of the time to 20 seconds or fewer 90% of the time. Labcorp supports this update and understand that the new response time proposals may require a lift and costs, and may impact system updates and release schedules.

2. *Data Content Updates for Eligibility and Benefits Operating Rule*

No comments at this time on this issue.

3. *New: Patient Attribution*

No comments at this time on this issue.

4. *Companion Guide Template*

CAQH CORE has updated the requirements for the companion guides in the adopted operating rules to promote flexibility. Labcorp is experienced in using the companion guide template in the first set of operating rules. If new standards are approved and move to a final rule, it should not be an issue for Labcorp to implement. Therefore, Labcorp supports the updated requirements to the companion guides.

5. *Updated Connectivity Rule*

In addition to the requirements for the use of HTTPS over the public internet and minimum-security conditions, the Connectivity Rule addresses Safe Harbor, Transport, Message Envelope, Security, and Authentication. It is difficult to determine what changes would be necessary to Labcorps' infrastructure, without a complete analysis of technical resources in regard to this modification with X12 Standards.

6. *Costs*

Labcorp has not conducted a cost analysis to determine the impact of implementing the updated eligibility and benefits and or claim status operating rule updates. Operational assessments may be conducted ones the NPRM is officially published in the Federal Register.

[3] Letter from CAQH CORE to NCVHS dated May 23, 2022: https://ncvhs.hhs.gov/wp-content/uploads/2022/09/CAQH-CORE-Board-Letter-to-NCVHS-re-New-Updated-OR-052322-508.pdf.

7. *Alternatives Considered for Operating Rules*

Labcorp is aware of the significant changes being proposed. These typically come with increased business costs; however, operational assessments may only be conducted when the NPRM is officially published in the Federal Register.

8. *Attachments Prior Authorization Infrastructure and Data Content Rules (vPA.1.0) and Attachments Health Care Claims Infrastructure and Data Content Rules (vHC.1.0)*

CAQH CORE has proposed infrastructure and data content operating rules for Prior Authorization and health care claims. The proposed infrastructure rules for attachments for prior authorization and health care claims include requirements for the use of the public internet for connectivity, Batch and Real Time exchange of the X12 v6020 275 transaction, minimum system availability uptime, consistent use of an acknowledgement transaction, use of uniform data error messages, minimum supported file size, a template for Companion Guides for entities that use them, a policy for submitting attachment specific data needed to support a claim adjudication request (standard electronic policy), and support for multiple electronic attachments to support a single claim submission. At this time, Labcorp does not support this proposed CAQH CORE rule because it may be in conflict of the Interoperability and Prior Authorization Proposed Rule by CMS that was published in the Federal Register on Dec. 13, 2022.

9. *Attachments Operating Rules – General Questions*

At this time, Labcorp does not support this proposed CAQH CORE rule because it may be in conflict of the Interoperability and Prior Authorization Proposed Rule by CMS that was published in the Federal Register on Dec. 13, 2022.

Conclusion:

We encourage NCVHS to consider these comments when drafting a new proposed rule.

Sincerely,
/s/
Gheisha-Ly Rosario Díaz, Esq.
RCM HealthCare Standards Compliance
Program Administrator
Labcorp

From: Greene, Loren Wissner
To: NCVHS Mail (CDC); Morris Auster
Subject: I don't accept virtual credit cards
Date: Wednesday, December 14, 2022 5:36:12 PM

Insurers have been sending me virtual credit cards for payments and I have been refusing them and asking for checks instead for payments. I never enrolled with them. I am in solo practice and I cannot afford any loss of payment from credit card fees
Loren Wissner Greene MD

From: Terence Gray
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals by December 15, 2022.
Date: Monday, December 19, 2022 5:48:47 AM

To whom it may concern,
I am a concerned physician. We are against the X12 proposed addition of the "card payments" remittance information to 835 ERA.

Dr. Terence K. Gray
President and Founder
Maine Comprehensive Pain Management, PC
www.painmanagementmaine.com

Medical Society of the County of Kings

The Academy of Medicine of Brooklyn

December 10, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Brooks-LaSure:

The undersigned physicians representing the 1200 physician members of the Medical Society of the County of Kings, Inc., write to express our strong concerns over unfair business practices with respect to electronic payments in health care. For over seven years, many of our organizations, as well as our individual members, have urged the Centers for Medicare & Medicaid Services (CMS) National Standards Group to clarify and enforce the right of physicians to receive electronic payments via the Automated Clearing House electronic funds transfer (EFT) standard without being forced to pay percentage-based fees for "value-added" services. In the absence of clear guidance and related enforcement on this issue, physicians have been plagued by financial losses and administrative burdens—an alarming result, given the efficiencies expected with the adoption of an electronic transaction standard. **We request that the Biden Administration swiftly address this problem by (a) issuing guidance that affirms physicians' right to choose and receive basic EFT payments without paying for additional services and (b) undertaking the associated enforcement activities.**

<u>EFT Transaction Standard: Promise vs. Practice</u>

The EFT transaction standard facilitates streamlined payer-to-provider claim payments and eliminates the manual burdens associated with processing paper checks for both health plans and physician practices. The 2020 CAQH Index estimates the per-transaction savings of replacing paper checks with the EFT standard for health plans at $0.49 ($0.57 vs. $0.08), with providers saving $1.99 per claim payment ($3.18 vs. $1.19).[1] This finding aligns with CMS' expectation in its final rule implementing the EFT standard, which anticipated that the creation of an efficient, uniform method of electronic payment " . . .will make health care claim payments via EFT more cost effective and will therefore incentivize increased usage of EFT by physician practices."[2]

1 2020 CAQH Index, p. 6. Available at: https://www.caqh.org/sites/default/files/explorations/index/2020-caqh-index.pdf. Note that these costs include the labor time required to process the payment.
2 77 Fed. Reg. 1556 (Jan. 10, 2012) at 1575.

Unfortunately, an increasing number of our physician members report that they are forced to incur mandatory, percentage-based fees for the receipt of electronic payments from health plans for payments made via the EFT transaction standard. A recent poll by the Medical Group Management Association (MGMA) confirms this trend: 57 percent of medical practices surveyed by MGMA reported that health plans charge fees that *the practice has not agreed to* when sending payments via the EFT standard, with 86 percent reporting average fees of two percent–three percent of the claim payment.[3] These fees are most often assessed by third-party vendors with which health plans require physicians to contract for EFT payment processing and represent charges for additional "value-added" services, such as customer service hotlines. While we recognize that some physicians may elect to receive supplementary services to the EFT standard for additional fees, these Vander Sloot offer physician practices the choice of electing basic EFT payments without charge. Consequently, physicians are left with no option but to "pay to get paid". **"This outrageous situation is analogous to an employee being required to enroll in a program that would deduct a percentage of each paycheck to receive direct deposit payments from an employer.**

Beyond just representing an unfair business practice, these coercive EFT fee-based program scan result in downstream negative consequences for patient care. Physician practices that lose up to five percent of claims payments due to EFT fees are less able to invest in the additional staff, medical equipment, data analytics, and information technology that could improve care access and quality. In addition, physicians and their staff report significant administrative burdens when they attempt to disenroll infect fee-based programs. This represents valuable practice time and resources that would be much better spent on direct patient care.

Existing Statutory and Regulatory Enforcement Authority

The National Standards Group has been reluctant to address this issue, citing doubts regarding its authority to publish clarifying guidance and enforce this administrative simplification issue. **We respectfully argue that CMS currently possesses sufficient statutory and regulatory authority to act and protect physicians' right to receive EFT payments without percentage-based fees, as outlined below:**

- 42 U.S.C.A. §1320d -§1320d-9 delegates to CMS the authority to adopt and enforce use of standards for "financial and administrative transactions," including "[e]electronic funds transfers." The statute states that adopted transaction standards "shall be consistent with the objective of reducing the administrative costs of providing and paying for health care."

[3] MGMA Stat. More than half of medical practices report being forced to pay to receive electronic payments from insurers. August 11, 2021. Available at: https://www.mgma.com/data/data-stories/more-than-half-of-medical-practices-report-being-f.

[4] § U.S.C.A 1320d-4.

[5] 45CFR 162.925(a)(2).

•The statute stipulates that "an insurance plan may not delay [a] transaction, or otherwise adversely affect, or attempt to adversely affect, the person or the transaction on the ground that the transaction is a standard transaction."[4] Federal regulation reiterates this prohibition: "A health plan may not delay or reject a transaction, or attempt to adversely affect the other entity or the transaction, because the transaction is a standard transaction."[5] **When health plans or their contracted payment vendors force practices to enroll in EFT programs that impose percentage-based fees, they are clearly adversely affecting the physician adoption of the EFT transaction standard—an obvious statutory and regulatory violation.**

•Regulation also states that "A health plan that […] requires an entity to use a health care clearinghouse to receive, process, or transmit a standard transaction may not charge fees or costs in excess of the fees or costs for normal telecommunications that the entity incurs when it directly transmits, or receives, a standard transaction to, or from, a health plan."[6] Health plan contracting with vendors for EFT transactions is comparable toa plan's use of a clearinghouse (the situation described in regulatory language). **As such, this provision establishes that physicians should not be forced to absorb the costs associated with a health plans decision to employ third parties for processing electronic transactions on behalf of the plan.**

•CMS clearly did not anticipate the assessment of percentage-based fees for EFT payments, stated in the final EFT rule's Regulatory Impact Analysis: "[We]estimate there will be no direct costs to physician practices and hospitals to implement the health care EFT standards."[7]

In sum, statutory and regulatory language grants CMS the authority to immediately act to protect the right of physicians and other health care professionals to choose EFT payments without being forced to pay for additional services.

Recommendations

At the time of the final rule implementing the EFT standard, CMS could not have foreseen that some industry players would view electronic health care payments as an opportunity for financial gain beyond the savings associated with the transition away from paper checks. As such, appropriate safeguards for this specific situation were not directly addressed in rulemaking. To be clear, our organizations are not advocating that "value-added" EFT payments should be prohibited; rather, we believe that physicians should have the opportunity to make an informed business decision regarding their electronic payment choices. The alarming rise in complaints from physicians being forced to enroll in fee-based EFT services warrants immediate guidance and enforcement from CMS to ensure fair business practices in health care, per the following recommendations:

[6] 45 C.F.R. § 162.925 (a)(5).

[7] 77 Fed. Reg. 1556 (Jan. 10, 2012) at 1582.

Medical Society of the County of Kings

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- **CMS should swiftly issue guidance stating that all health plans and their contracted vendors must offer at least one EFT standard transaction that does not require purchase of extra services for an additional fee.**

- **This guidance should also require full transparency from health plans and their contracted vendors in all EFT enrollment communications, to include(a) the clear option to select basic EFT without additional fees and (b) for any enhanced options with additional costs, a complete description of the "Value-added" services and associated fees.** Please review the attached example from the AMA Insurance Agency for an example of how various EFT options can be properly communicated to physician practices.

- **The CMS Division of National Standards should appropriately enforce compliance with this guidance, to ensure that health plans and their vendors are offering physicians the option of receiving EFT without additional services/fees and that this choice is clearly communicated in all EFT enrollment materials.**

By taking these actions, CMS will be supporting the underlying administrative simplification goals intended by the EFT regulation and creating the much-needed transparency that physicians and other providers need to make informed, independent choices regarding the appropriate payment method for their businesses.

Conclusion:

CMS and organized medicine share a mutual goal of improving the quality and efficiency of health care in our country. We are hopeful that the Biden administration offers the opportunity for a fresh look at this concerning issue that has financially and administratively burdened our nation's physicians for far too long. Should you have any questions or wish to discuss this matter, please contact Jagdish K. Gupta, MD, President, Medical Society County of Kings, jagdishkgupta@gmail.com

Sincerely,

Jagdish K. Gupta, MD

Jagdish K. Gupta, MD
President

Sherman Dunn, DO

Sherman Dunn, DO
Chairman, Board of Trustees

Medtronic

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December 15, 2022

National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Via email: NCVHSmail@cdc.gov

Re: Request for Comment on Proposals for Updates to X12 Transactions

Dear Committee Members:

Medtronic is the world's leading medical technology company, specializing in implantable and interventional devices that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high-quality products and innovative devices that improve health outcomes for patients. We appreciate the opportunity to comment on the recommendation from X12 to add the Device Identifier (DI) portion of a medical device's Unique Device Identification (UDI) to the proposed new version 8020 claim transaction.

Medtronic has been a strong supporter of the establishment of UDIs and the benefits of the UDI system as outlined by the FDA. We have committed substantial resources toward helping to shape the policies of UDI and adopting the new UDI rules to assure the most effective implementation of the system and realization of the benefits of its regulatory intent.

Medtronic continues to support the efficient use of UDI, and we are supportive of the formal adoption of UDI into the EHR in order to enhance post market surveillance and improve safety and quality in the healthcare system. However, for the reasons outlined further in this letter,

Medtronic does not support the inclusion of the DI on the proposed new version 8020 claim transaction.

Adoption of Claims-Based DI is Not Consistent with Original FDA Regulatory Intent

X12 has proposed to NCVHS that the DI portion of the device's UDI be added to the institutional and professional claims submissions with the stated goal of improving post-market surveillance for certain medical devices. In the final rule establishing the UDI systems (78 FR 58786), the FDA indicated that, "…while not required, FDA anticipates that providers will include the UDIs of a wide variety of devices in patients' Electronic Health Records (EHRs) and Personal Health Records (PHRs). This information will strengthen the health care community's ability to identify the specific devices implanted into patients and will improve response to post market surveillance activities, including adverse event reporting and recalls." Understanding the value of this information in the EHR, HL7 standards for clinical data exchange have accommodated UDI in the EHR.

Given that the original regulatory intent was to voluntarily include UDIs in the EHR, the inclusion of DI on the proposed new version 8020 claim transaction goes against the original intended use for the development of UDIs. The FDA regulation makes no mention of any need for DI to also be replicated on payer claims to support surveillance activities, so the inclusion of DI on claims transactions seems unnecessarily redundant and levies an added burden for providers being tasked to supply this information on claims.

Challenges Associated with Use of Claims-Based DI for Post-Market Surveillance

Several technical challenges exist to using claims-based DI for post-market surveillance. First, there is no standard for the DI portion of UDI - one product model or implanted device system could have several DIs, making it difficult to extract accurate data for tracking, research, and surveillance purposes. This leaves the resulting surveillance and research open to inaccuracies and inconsistencies.

In addition, the use of multiple DIs, which may be needed to accurately describe a full implantable device system, may not be consumable by current claim processing systems. Therefore, the full list of DI information may need to be submitted as an attachment to the claim, making submission process administratively burdensome for providers, taxing on payer claim processing systems, and ultimately creating the potential for delays in provider payment cycles. Finally, and most importantly, since it is unlikely that comprehensive attachment information from

claims could be queried through retrospective claims analyses, any resulting post-market surveillance or analyses would be unreliable and inaccurate.

Extensive Study is Needed to Validate the Use of Claims-Based DI for Surveillance

Given the factors outlined above, EHRs appear to be much better suited for post-market surveillance using DI information than claims. If, however, policymakers continue to explore the notion of including DI on claim transactions, Medtronic recommends that extensive further study be undertaken on the cost and reliability of DI information. Validation of the accuracy and reliability of data should occur before any requirements surrounding the inclusion of DI on claim transactions is implemented.

While Medtronic recognizes the many benefits of DI tracking in EHRs, we also recognize the significant burden and technical challenges of adding DI to provider and payer claim systems. Due to the practical burdens and the lack of validation of the accurate capture and effective, efficient extraction of DI data from claim transactions, extensive further study should be undertaken before there are any sweeping efforts requiring the inclusion of DI on claims. Such a study should evaluate the broader system costs of inclusion, the administrative burden on providers and payers, the reliability and accuracy of the DI information extracted from claims, and the appropriateness of the conclusions drawn from the inclusion of this information on claim forms.

For instance, collecting DI information on electronic claims presumes that health plans are equipped and willing to collect, store, analyze, and ultimately transmit critical device safety data, if needed, to affected stakeholders in a timely manner. There is risk to patient health if DI data on claim forms is poorly managed or incorrectly interpreted for clinical determinations about implantable devices. In addition, patients that change payers could not be tracked longitudinally through claims-based DI like could be the case with UDI in EHRs and registries. Therefore, the accuracy and reliability of the DI data on claim forms should be extensively studied prior to payers assuming this level of liability and accountability.

Including DI on payer claims assumes that payers would then be accountable and liable for sharing data for post-marketing safety surveillance. If the aforementioned studies are completed and found to fully validate the accuracy and reliability of DI on claims, a process would have to be implemented requiring payers to share adverse event findings with affected stakeholders, including the FDA, manufacturers, and patients. Given the need for extensive study related to the

use of claims-based DI for post-market surveillance, we believe the two-year implementation timeframe provided under HIPAA is too brief and implementation should be extended until full study and validation can be completed, and appropriate payer processes implemented.

Additionally, there have been many examples where claims data have been successfully linked to other data sources (e.g., device registration, clinical registries, clinical trials) that contain device-specific data elements such as manufacturer and serial number, to conduct post-market research without the need and associated administrative burden to include the DI on the claim forms.

Conclusion

Although Medtronic is a strong supporter of the establishment of UDIs and the benefits of the UDI system as outlined by the FDA, we believe post-market surveillance involving UDI is best conducted through the patient's EHR, consistent with the original intended use for the development of UDIs as established in regulation, and not through a claims-based DI requirement.

We appreciate the opportunity to comment on the X12's proposal and look forward to continuing to engage on this critical issue. If you have questions or need further information related to the comments provided in this letter, please feel free to contact me at (763) 505-2748 or christine.jackson@medtronic.com.

Regards,

Christine M. Jackson, J.D.
Vice President, Global Health Policy
Medtronic

December 7, 2022

National Committee on Vital and Health Statistics

CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002
By email: NCVHSmail@cdc.gov

RE: RFC on X12 and CAQH CORE Proposals

Dear NCVHS Members,

We are writing to comment on the X12 proposal that the current standard is updated from version 5010 to version 8020 for the adopted administrative standard for the health care claims (professional, institutional, and dental) and the remittance advice 835 transactions.

June 7, 2022 letter from X12 to NCVHS, https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf states that X12 has "Added the ability to report remittance information related to **card payments (p-card, debit card, and credit card) to facilitate auto-posting**"
to **008020X322** X835 transaction rules.

We are writing to inform NCVHS that we are **AGAINST** the adoption of this standard in its current form. In particular, we are **against** the X12 proposed addition of the "card payments" remittance information to 835 ERA. In summary, there are a number of reasons that the ability to report remittance information related to “card payments" should **NOT** be added to the 835 ERA transaction, which we will explain in great detail below:

1. There is near **universal provider rejection of card payments** as an option for standard healthcare payment. If no provider wants 'card payments, there is **no basis or justification to add the ability to 'report remittance information related to card payments.'**
2. There is no industry consensus that "card payment" information on ERA serves a 'useful' purpose.
3. There are no studies and no industry consensus that adding "card payments" to the 835 ERA transaction fills a "missing" need.
4. Since there is no need or provider demand for 'card payments' to start with, there is no need or demand to autopost 'card payment' remittance advice, a product of unwanted transaction.
5. Card payments are not an adopted healthcare payment EFT standard. Remittance information related to card payments is a product of a non-adopted payment method, illegal to be used as a standard healthcare EFT transaction. A product of ‘illegal’ transaction cannot be “legal” and cannot be incorporated into a legal standard.
6. The X12 standards for 835 transactions are adopted under the HIPAA Act of 1996, Section 1172 (b) REDUCTION OF COSTS. Legally, this act does **not** give CMS authority to add "card payments" to ERA as this proposal **does not satisfy the basic requirement** that it serves to "lower costs."

7. Adding card payment information to 835 ERA cannot occur without an act of Congress. An illegal or 'extra-legal' payment option cannot be adopted into and be reported in a legal, standard transaction.

We **disagree** with the September 23, 2014 statement from NCVHS and wish to **provide clarity** that we "**question and dispute the benefits of using VCC and credit cards** for payment of health care services."

- Card payments, including VCC and credit cards, do **not** offer any benefits to medical practices
- Card payments incur **higher costs** than checks or legally compliant standard healthcare ACH EFT payments that must be delivered to the physician practice bank at no cost to the physician, just as paper checks arrive to a USPS mailbox at no cost to the physician practice.
- Card payments involve additional administrative work
- Card payments are sent as **'opt-out**' payments precisely because they offer **no value** to physician practices, and no practice would ever choose it as a payment method without duress.

As you are well aware, card payments are universally **opt-out**; **independent healthcare providers do not willingly accept card payments**. There is absolutely no "demand" in the healthcare industry among healthcare providers for "card payments." In fact, as you are aware through prior testimony from the AMA, WEDI, and other organizations to NCVHS, healthcare providers have complained about the **unfair business practices** of sending virtual credit cards by health plans and charging fees for healthcare ACH EFT transactions. It is unclear what the reason is that X12 recommended the addition of 'card payment' information to 835 transactions, given near universal opposition to card payments by healthcare providers to start with.
There is **unanimous opposition** to card payments by independent healthcare providers. Card payments **raise consumer costs** and offer **no meaningful 'value-added' to providers** or consumers. That is why the only way it can exist is through 'opt-out' forced imposition on healthcare providers. In other words, there are **no 'willing buyers' for "card payments" when it comes to standard electronic healthcare payments**.

Healthcare providers do not want the ability to 'autopost' card payments, as most healthcare providers do not want to receive card payments to start with. **When they do get unsolicited card payments, they do not want to autopost them.** Instead physician practices spend an inordinate amount of time and money to "opt-out" from card payments. At most, the inability to autopost is a minor negative characteristic of 'card payments'. **Adding the ability to auto-post does not change the nature of card payments – they are costly and unwanted.** What healthcare providers wanted from CMS was to ban credit card payments, not making them 'less evil.' CMS's **unfortunate** position is that it is not illegal to send the first payment as a credit card, even while they raise the cost of healthcare relative to paper checks and certainly relative to standard ACH EFT.
X12 has not explained what is the nature of 'consensus' and detailed the vote that led to the recommendation to add 'card payment' remittance information to a standard 835 transaction. X12 has not detailed any studies it performed among independent providers to gauge a need for adding 'card payment' reporting to 835 transaction.
Healthcare providers are very satisfied with the current healthcare ACH EFT standard. The provider complaints related to ACH EFT originate from (1) the fees that some plans and their affiliates impose on ACH EFT; (2) barriers to enrollment; (3) failure by many banks to provide re-association data in electronic format at an affordable cost; in fact many banks use re-association data as a bargaining or extorsion item and require additional payment beyond what

the account holder pays for ACH EFT delivery, to 'see re-association numbers' even as banks hide it in their database.

If there are no willing provider users of card payments, there is **no legitimate need to add card payment remittance information to the 835 transaction**. You do not need information about something that you do not want to have. It's as simple as that.

Card payments involve more administrative work, including the implementation of additional processes and policies, than check payments or healthcare ACH EFT payments. The processing costs are many times more than either check payments or ACH EFT. Card payments do **not** offer greater efficiency, nor do they offer lower costs. In other words, they **cannot be adopted under 'delegated" authority under HIPAA**. There is no legitimate need to report in a standard 835 ERA an unwanted payment method that is costly, inefficient, and unwanted.

While paper checks are not an adopted standard, they were clearly mentioned in all legislative history as the **default predicated healthcare payment method** from which a move to electronic ACH EFT was legislatively encouraged. Thus, it is reasonable to report check payment information on a standard 835 ERA transaction as the **predicated** payment method. There is **no legal basis for equating the legal status of paper checks to card payments**, which were never considered as a legitimate payment option for standard transactions; card payments were never in wide use for healthcare payments by health plans to providers prior to the adoption of the HIPAA Administrative Simplification requirements. The option of using card payments was never considered to be legitimate enough to seek public comments on the issue during the adoption of HIPAA Administrative Simplification standards. There is no legitimate historical justification for adding card payment reporting to 835 ERA transaction.

Insofar as X12 rules are incorporated into federal law, the net result of remittance card reporting is to 'legitimize' card payments, which are currently not adopted as a 'standard EFT" transaction.
CMS does **not** have the **authority** under HIPAA to adopt standards that do not lower healthcare costs (42 US Code § 1320d–1 (b)). Neither card payments themselves nor reporting of card payment information on 835 transaction lower healthcare costs. Certainly, to report a card transaction information on 835 ERA, there has to be an associated card transaction; CMS has to look at them as a 'package' that raises the cost of healthcare and is not eligible to be added to any standard adopted under HIPAA.
It is critical to remember the intended goal of the legislation, HIPAA Act of 1996, Section 1172 (b) REDUCTION OF COSTS:

> To amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to **simplify the administration of health insurance**, and for other purposes.
> 42 US Code § 1320d–1 **(b) REDUCTION OF COSTS.**—Any standard adopted under this part shall be consistent with the objective of **reducing the administrative costs** of providing and paying for health care. (previously classified as Section 1172)

· Congressional intent was made clear again in section (2)(i)the different standard will **substantially reduce administrative costs** to health care providers and health plans compared to the alternatives;

The proposed allowance to include card payments information on 835 ERA transactions is **not consistent with the plain text of the law** , as card payments universally raise transaction costs, increase administrative costs and raise the cost of healthcare, even compared to the baseline historical option that the HIPAA standards sought to eliminate, which are paper checks. The mere addition of card payment information to 835 also raises costs without any quantifiable benefit to healthcare providers.
There is no mention of card payments in the HIPAA Act of 1996, Section 1172 (b) REDUCTION OF COSTS. HHS/CMS has **no authority to adopt regulations** that raise the cost of healthcare and make the administration of healthcare more complex. As you are aware, the X12 rule adoption by CMS/HHS relies on the delegation of congressional authority under 42 US Code § 1320d.

In the final interim rules adopting the ACH EFT as a standard transaction, section 5. EFT Conducted Outside the ACH Network states:

> The **health care EFT standards adopted in this interim final rule** with comment period do **not** apply to health care claim payments made via EFT outside of the ACH Network. Health plans are not required to send health care EFT through the ACH Network. They may decide, for instance, to transmit a health care EFT via Fedwire or via a payment card network . This interim final rule with comment period neither prohibits nor adopts any standards for health care EFT (as defined in § 162.1601(a)) transmitted outside of the ACH Network. When health plans do, however, send health care EFT through the ACH Network, they must do so using the health care EFT standards adopted herein.

Clearly, card payments are not 'legally' adopted as a healthcare EFT standard; thus, including them in a legally adopted standard transaction designed to report information about adopted standards "ACH EFT" and 835 ERA contents is not appropriate, **arbitrary, without precedent, a major change in policy**, and not legal.
There is a tremendous disagreement with this section of X12 rulemaking.
We request that X12/NCVHS/CMS **remove** the section allowing card payments on remittance advice from 008020X322 immediately, as this has a significant **detrimental effect** on healthcare providers.
There is **no legitimate industry demand or need** for this, and it is **universally opposed by independent healthcare providers that are not owned by or own health plans**. Legally, it cannot be adopted as this addition is **not authorized** under the governing law, and HHS/CMS has no delegated authority to add it to a federal standard.
As the NCVHS is well aware, **no standard can be adopted under HIPAA unless it has the effect to lower the costs of healthcare**. There are NO situations where a card payment is less expensive than the standard ACH EFT transaction, the current standard. Thus, card payments cannot legally be adopted as ‘a legal” EFT payment method under HIPAA as they cannot be demonstrated to lower costs, the fundamental **litmus test** to qualify a transaction for adoption under HIPAA.
The proposal to add card payment information to 835 ERA does **not** meet the **requirements** that they are based on '**consensus-based review and evaluation process**." The correct standard to use is that the transaction has 2 users: senders and receivers. Healthcare

providers is 50% of each transaction as a user – thus **any "consensus" must allow at least 50% representation of healthcare providers**. When >95% of healthcare providers are angrily **opposed to card payments** and have no need or desire for having card payments added to 835 ERA transactions, it is **mathematically impossible to claim that there is a "consensus"** or even a legitimate "majority" vote on this issue. See below for BBB complaints against providers of card payments (Zelis and ECHO Health).

> "Standards-setting organizations or the Designated Standards Maintenance Organization (DSMO) bring forward new versions of the adopted standards to NCVHS after completion of a consensus-based review and evaluation process. Under Section 1173(3)(B), the organizations with whom a DSMO should consult for input include the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (ADA)." CMS.

1. **Costs**. Medical practices do ***NOT*** foresee a situation where card payments offer any benefits, and there is no situation where any medical practice would voluntarily "opt-in" to receive card payments. Thus there are **no foreseeable benefits** from adding 'card payments' to 835 transactions. **Implementation costs** are estimated to be significant.

2. **Operational impacts. After a thorough analysis, we could not identify a positive operational impact on medical practices from the addition of 'card payment' information to 835 ERA transactions. The impact is strongly negative.**
    1. Adoption of the proposal to add card payments as a payment option to 835 ERA would require a significant expenditure of resources to retrain billing staff to recognize this situation. It would require vendors to update programming to add this option, and the costs are passed directly to physicians through subscription fees; in addition, given limited resources, implementation of this standard distracts vendor focus from more productive uses of programming resources to make medical practices more efficient and more profitable. There is a **significant material 'opportunity' cost to implementing an un-wanted and un-needed 'standard' update**.
    2. Practices would need to implement additional reconciliation steps between ERA and typical management of unwanted card payments – from which medical practices opt out whenever possible.

We cannot support the X12 835 8020, in its current form, with the inclusion of the ability to report remittance information related to "Card transaction."

1. We request that X12 / NCVHS / CMS provide published, peer-reviewed, real-world, non-simulated **studies** that sample a sufficiently broad spectrum of healthcare providers, including independent healthcare providers, small healthcare providers, healthcare providers offering services in rural areas, and healthcare providers not owned by or that own a health plan and that **demonstrate how the addition of remittance information related to "card payments" reduce healthcare costs, and make healthcare administration more efficient when no provider wants to accept 'card payments.**

0. We request that X12 / NCVHS / CMS provide published, peer-reviewed, real-world, non-simulated **studies** that sample a sufficiently broad spectrum of healthcare providers, including

independent healthcare providers, small healthcare providers, healthcare providers offering services in rural areas, and healthcare providers not owned by or that own a health plan, and that **demonstrate an 'unmet' demand or need for reporting remittance information related to "card payment" information on 835 ERA transaction.**

0. We request that X12 / NCVHS / CMS provide published, peer-reviewed, real-world, non-simulated **studies** that sample a sufficiently broad spectrum of healthcare providers, including independent healthcare providers, small healthcare providers, healthcare providers offering services in rural areas, and healthcare providers not owned by or that own a health plan, and that **demonstrate an 'unmet' demand or need for autoposting "card payment" information from 835 ERA transaction when nearly universally in our industry survey providers reject card payments, sometimes unsuccessfully; in no situations are providers' willing' and uncoerced recipients of card payments.**

Problem with the proposal to include "Card Payment" in Remittance Advice to Facilitate Autoposting Card Payments:

The rule as proposed is arbitrary and capricious, and is without legal support.

Card payments are not received 'whole'. Card processors deduct merchant fees from deposits. The actual reconciliation can only occur once the merchant processing fees are deducted from the card payment, as merchant fee varies by the type of the transaction (card present, card not present, regulated debit, exempt debit, credit, corporate credit card, gift card, ec).

Even if physicians were to choose to accept a card payment as a result of being exhausted of trying to opt-out and being re-enrolled in card payments against our will, card information that is proposed to be included by X12 in 835 standards **would not be helpful or useful** as it will NOT help physician practices with autoposting payments. In fact, it will create additional problems and would require additional expenditures to either manually review every 835 ERA to mark those that contain 'card payments' for separate manual processing or would require us to add additional programming to put 835 ERA with 'card payments' into a separate process that disallows autoposting.

Most physician practices would **not** choose to autopost card payments

Most physician practices would rather decline card payments and request a paper check. Autoposting would create a wrong entry. It would require extra effort for us to track the card payment itself; decline and request a paper check. At the same time would need to track what potentially could be an **inadvertent** autoposting of card payment that was **rejected** by the practice.

1. Many providers choose to treat merchant fees associated with unwanted card payments and EFT fees separately and bill them to the patient. The proposed X12 standard does not allow autoposting the card processing costs separately as it does not separate the gross amount into (1) net receipt by the practice after card processing fee and (2) the card processing fee / merchant processing fee itself. Typically, practices would only post the

'net' amount they receive from health plan via card payment and the balance attributable to the 'card processing' fees would remain as a patient liability. Alternatively, some practices charge fixed fees to account for card processing. It is not possible to autopost such fees as the X12 proposal does not account for them.

There are additional barriers to autoposting 'card payments' based on the current X12 prooposal:

- Would 'card payment" information in remittance advice 835 transaction include the actual merchant processing fee accounting to allow practices that choose to pass the fee to the patient to properly assign patient responsibility?

- In order to reconcile payments and to correctly attribute the merchant processing fee in accounting systems, additional information is necessary to auto-post payments, which the X12 proposal does not include.

- Does the card payment information on 835 provides information on the type of card payment that was sent: was it a regulated covered debit card transaction or an exempt debit card transaction? Corporate credit card, rewards credit card transaction? These carry vastly different interchange and merchant processing fees. This information would be necessary to reconcile payments and to comply with generally accepted accounting principles (GAAP). GAAP is the basis of 835 ERA, as X12 acknowledges. In fact, X12 rules require that each service line is 'balanced'. It would be arbitrary and capricious for X12 to propose an addition to the 835 ERA transaction that cannot be reconciled during auto-posting because adequate information is not included.

- Does the card payment information on 835 provide information on the type of card transaction triggered by the use of 'card payment': in-person card transaction or 'card-not-present' transaction? These carry vastly different interchange and merchant processing fees.

- Without this information, a healthcare provider would not be able to appropriately calculate the merchant fee and attribute it properly in the patient account to 'card fees' as opposed to 'patient care revenue' during auto-posting. Thus the transaction would have to be marked as 'exception' and would not be auto-posted, which eliminates the major purported benefit of including card payment remittance information in the 835 transaction.

- For a practice that generates $1 million in revenue per provider, a difference of 1% is $10,000 extra in merchant processing fees. If a covered debit card transaction costs $0.23 (0.23% for $100) vs 2% for in-person card vs 2.8% for 'card not present", these are meaningful differences. Even a 0.5% difference would result in a $5,000 difference in merchant processing fees – substantial amounts for any medical practice.

The proposed rule has missing calculations on cost-benefit analysis.

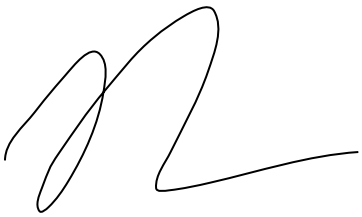
To accurately determine the costs and the benefits of the proposal, CMS must clarify:

1. What percent of independent medical practices **willingly** accept card payments?
2. What benefits do medical practices derive from card payments? If there are no net benefits from card payments to medical practices, it is questionable how can the inclusion of information about such payments be "net" beneficial to providers.
3. If only a small percentage of providers willingly accept card payments, the financial burden of implementing the proposal to include card payment information on 835 transactions may not be justified.
4. What percent of card payments are issued as 'opt-in" payments vs "opt-out" payments?
5. What percent of independent medical practices decline "opt-out" card payments when they receive them against their will? Providers that decline opt-out card payments would not benefit from having card payment information included in 835 transactions.
6. How many provider contacts occur yearly to health plans and their business associates to opt-out from card payments and request that a paper check replaces an unwanted card payment? What is the net cost of these contacts to providers? Health plans?
7. What percent of all "providers" decline out-out card payments?
8. What is the cost of each opt-out, including the cost of contacting the health plan on multiple occasions, waiting for 45 min on hold; not receiving the check, and needing to contact the payer again (as demonstrated in the attached BBB complaints against ECHO Health and Zelis).
9. What is the cost of processing a check payment vs processing a card payment?
10. What is the cost of autoposting a check payment or EFT payment on an 835 ERA vs **manual processing associated** with 835 ERA information of card payment that the practice does not want to autopost as the provider declined to accept card payment and requested that a check is sent instead?
11. What are the net financial benefit of including information in an 835 ERA transaction about unwanted card payments to an average small medical practice? This calculation would require the facts mentioned above: percent of providers willingly accept card payments from health plans vs the cost to those that decline and request paper checks. What percent of providers would autopost card payments vs the percent that would choose to manually process 835 transactions as an 'exception' in order to post the payment according to GAAP, as the full payment was not received and the merchant fees need to stay on the patient's account as a patient liability.

Without providing this information, **CMS cannot accurately compute the costs as required in its regulatory impact analysis**, making its determination that the benefits outweigh the costs "arbitrary" and "capricious".

We appreciate the opportunity to provide our comments to NCVHS. If you have any questions, please do not hesitate to contact us.

Sincerely,



Michael Reinhorn MD 12/13/2022

From: Steve Olive
To: NCVHS Mail (CDC)
Subject: NCVHS/ CMS to protest against virtual credit cards.
Date: Tuesday, December 13, 2022 9:34:34 AM
Attachments:

Premier Family Care 1, Inc. and Midland Inpatient Medical Associates are against the X12 proposed addition of the "card payments" remittance information to 835 ERA." The cost of this is too expensive.
Respectfully
Steve Olive

Steve Olive
Executive Director
Midland Health Group Management
Premier Family Care 1, Inc
Midland Inpatient Medical Associates
4214 Andrews Hwy, Suite 240
Midland, Texas 79703

December 20, 2022

National Committee on Vital and Health Statistics
Standards Subcommittee
NCVHSmail@cdc.gov

Re: RFC on X12 and CAQH CORE Proposals by December 15, 2022.
Hearing on Requests for New and Updated Transaction Standards and Operating Rules

To Whom it May Concern:

We are against the X12 proposed addition of the "card payments" remittance information to 835 ERA.

Our practice has already seen an increase in fees of 54% for the same time frame this year when compared to last year. Payors continually decrease the amount of money we are paid, and we should not have to bear the burden of paying a fee to be paid for the services we provided. The amount of time, effort, and expense to collect our rightful l payments continues to increase with increasing demands by insurance companies via prior authorization requirements, medical record requests, and payment delays. We do not have the luxury of arbitrarily increasing our prices, and the amounts we are paid to cover the cost of these banking fees.

Respectfully,

Rhonda Wild
Medical Office Administrator

From: Ming Lei
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Tuesday, December 13, 2022 7:58:52 AM

Dear NCVHS Subcommittee Members,

You know how much time I waste calling up insurance companies to opt out of their scam "quick pay" cards?

This is such obvious corruption racket by those "Quik-Pay" card companies to siphon off money from doctors and nurses. They provide ZERO advantages and benefits but want their 3% cut.

Michael Franzese would be proud of this racket. Imagine offering zero benefits to someone, forcing them to waste time to tell you to stop stealing from them, and then keep doing that for every single insurance in the hopes that at least some sucker falls for it.

No one likes this garbage, no one uses this garbage, but if we don't call in to say "no, please don't steal our hard-earned money", they just keep doing it.

This ignores the MASSIVE potential for FRAUD and THEFT. You know they just fax you these virtual cards? With the card number, CSV code, and expiration date right on there, exposed and easy to read. Anyone in office, employee or not, even a malicious patient, could take a photo of the card, go online, and cash out.

Regards,
Ming Lei
132-45 41st Rd
Queens, NY 11355

CMO
MONTEFIORE CARE MANAGEMENT

December 14, 2022

Thank you for the opportunity to provide comment on the CAQH Committee on Operating Rules for Information Exchange (CORE) Operating Rules proposed to the National Committee on Vital and Health Statistics (NCVHS) for federal adoption. The new and updated operating rules put forth by the CAQH CORE Board are integral to the advancement of automated and uniform transactions that streamline operations and promote efficiency, safety, and equity across the U.S. healthcare system.

Montefiore Health System is one of New York's premier academic health systems and is a recognized leader in providing exceptional quality and personalized, accountable care to approximately three million people in communities across the Bronx, Westchester, and the Hudson Valley. It is comprised of 10 hospitals, including the Children's Hospital at Montefiore, Burke Rehabilitation Hospital, and close to 200 outpatient care sites. The advanced clinical and translational research at its medical school, Albert Einstein College of Medicine, directly informs patient care and improves outcomes. From the Montefiore-Einstein Centers of Excellence in cancer, cardiology and vascular care, pediatrics, and transplantation, to its preeminent school-based health program, Montefiore is a fully integrated healthcare delivery system providing coordinated, comprehensive care to patients and their families.

Integrated into the communities we serve, Montefiore specializes in providing care for underserved populations, and as such we must be judicious with the resources available to us. The CAQH CORE Operating Rules empower us to automate common healthcare transactions, which helps us realize operational efficiencies leading to time and cost savings. The currently mandated rule sets have assisted us in establishing consistent and reproducible workflows. The proposed rule sets, through infrastructure modernization and the incorporation of new care settings and services will help us further automate key revenue cycle activities at Montefiore. Given the clear benefit the proposed new and updated CAQH CORE Operating Rules will provide Montefiore, we strongly urge NCVHS to recommend them to the Secretary of the U.S. Department of Health and Human Services (HHS) for federal adoption.

Thank you for the opportunity to speak in favor of this important proposal. We are pleased to outline the positive impact that the proposed set of operating rules will have on the healthcare industry and Montefiore in the specific questions posed by NCVHS below. Please do not hesitate to reach out with questions.

Sincerely,

John Williford
Vice President Population Health
Vice President and Chief Operating Officer
CMO, Montefiore Care Management

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1. Efficiency Improvements. Infrastructure updates to the adopted Eligibility & Benefits and Claim Status Operating Rules
Montefiore recognizes the importance of sharing sensitive health information between providers, health plans, and patients securely and efficiently. The mandated CAQH CORE Eligibility & Benefits and Claim Status Infrastructure Operating Rules establish a framework for doing so by setting minimum requirements for secure connectivity, response times, system availability, and by creating a standard format for accompanying companion guides. We would also like to note that the CAQH CORE has proposed updates to the Payment and Remittance (ERA) Infrastructure Operating Rule that would adopt updated connectivity requirements and the Master Companion Guide Template, driving efficiency for this transaction.

System availability: The updates made to the mandated CAQH CORE Eligibility & Benefits and Claim Status Infrastructure Operating Rules add necessary modernity to security and exchange standards, while better reflecting the 24/7 nature of healthcare. The updated rules require health plans to increase weekly system availability from 86% to 90%, with an off-setting, **optional** allowance of an additional 24 hours of downtime per quarter to accommodate larger system updates. Together, these changes enable an additional 364 hours of annual up time for health plans and their agents, depending on baseline conformance.

At Montefiore, these updates have clear benefits for our providers and patients. Increased health plan system availability ensures that more transactions can be fully automated in real time, which avoids potentially dangerous care delays that may occur if a provider or their staff must manually navigate complex phone trees or web portals to complete an eligibility verification. The increased system up time benefit extends to claim status transactions where automation allows us to quickly resolve errors, decrease duplicate claims, and secure prompt cash flow. Lastly, accommodation of additional downtime for larger updates ensure that our health plan partners are using the most up-to-date technology, guaranteeing that automation is smooth and durable.

CAQH CORE Connectivity: The proposed updates to the CAQH CORE Eligibility & Benefits, Claim Status, and ERA Infrastructure Rules reference the latest version of the CAQH CORE Connectivity Rule. The most current version is vC4.0.0, which has also been proposed for federal mandate to NCVHS. The updated Connectivity Rule provides necessary modernization to the federally mandated Phase I and II CAQH CORE Connectivity Rules which were adopted in 2013 and developed more than ten years ago. Key changes include support for digital certification, strengthened authorization requirements, and optimization of a standard agnostic approach that includes support for APIs through REST communication protocols.

Montefiore strongly supports the incorporation of updated connectivity requirements into the mandated CAQH CORE Infrastructure Rules. Adoption of updated Connectivity requirements provides us assurance that the exchange of sensitive health information is protected using the most up-to-date security requirements. Additionally, arising from Safe Harbor requirements, the rule empowers us to do business with any HIPAA-covered health plan or entity without the need to support multiple, disparate connections. We will further address the benefits of the updated Connectivity Rule later in this letter.

CAQH CORE Master Companion Guide Template: As part of the infrastructure updates, CAQH CORE Participants modified the Master Companion Guide Template that health plans and their agents use to specify data content requirements for common healthcare transactions. The updates allow stakeholders to reference newer versions of the X12 standards beyond the currently mandated v5010, enabling greater flexibility. Additionally, the template can be used to inform a format for transactions carried out using non-X12 standards, such as HL7 FHIR. We benefit from the updated Master Companion Guide Template because it provides a common format across health plans that can be incorporated in operations when establishing workflows to manage transactions.

Recommendation: Montefiore Medical Center strongly recommends that NCVHS recommend the updated CAQH CORE Eligibility & Benefits, Claim Status, and ERA Infrastructure Rules to HHS for federal adoption. As detailed above, the included updates to the Infrastructure Rules enable Montefiore to reliably automate common transactions securely across multiple

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trading partners. These changes avoid costly delays of care and simplify provider workflows. The necessary modernization of these rules will also add to operational efficiency.

2. Data Content Updates for Eligibility & Benefits Operating Rule
Montefiore strongly supports federal adoption of the updated CAQH CORE Eligibility and Benefit Operating Data Content Rule. The current mandated version was originally published in 2010 and does not address critical business needs and use cases that have emerged since this time.

Data from the 2021 CAQH Index shows high adoption of electronic eligibility and benefits transactions – about 89% of all transactions were performed fully electronically. However, the additional 11% of manual and partially manual transactions represent a continued savings opportunity of nearly $9.8 billion. This disparity confirms that the current operating rule requirements do not meet all use cases, which we have experienced first-hand at Montefiore. The updated rule addresses more business scenarios and allows us to automate a greater proportion of our eligibility and benefit transactions, saving time and money.

Telehealth eligibility: During the COVID-19 pandemic, more services shifted remotely to telehealth platforms to ensure safety and continuity of care. At Montefiore, we observed a significant increase in telehealth visits and although more care is returning to in-person settings, the use of remote modalities will persist. Confirmation of whether a service is eligible for telehealth is a largely manual process at Montefiore, driven by the fact that "covered services" lists differ between health plans and are subject to periodic updates precipitated by the waxing and waning of the pandemic. The updated Eligibility Data Content Rule provides a solution to automate this process by requiring health plans to return telehealth eligibility for a requested service using standardized CMS Place of Service (POS) codes. We estimate that through implementation of these requirements, we will automate a significant number of eligibility verifications that would otherwise be performed manually.

Updated CORE-required service type codes and newly added support for procedure codes: The CAQH CORE Eligibility Data Content Rule currently requires health plans and their agents to return patient financial information for CORE-required service type codes. The updated rule expands the CORE-required service type code list by 71 discretionary codes and 55 mandatory codes, increasing the total number to 178. Additionally, the updated rule requires health plans and their agents to return patient financial responsibility for procedure codes that fall into one of four categories: physical therapy, occupational therapy, surgery, and imaging.

These updates allow us to automate eligibility verification across a greater spectrum of services and procedures, alleviating the burden of manually determining coverage and patient financial responsibility using web portals or phone calls. As such, we strongly support updates to the service-type code and procedure code lists and recognize their role in demystifying patient financial responsibility.

Requirement to return prior authorization and certification information: For the expanded code list, health plans and their agents must automatically return whether the requested service or procedure requires prior authorization or certification. While this change does not fully automate the workflows required to complete a prior authorization request, it does reduce the necessity to manually confirm if it is required, which has significant implications for our organization. Tasks related to prior authorization involve about 175 FTEs at Montefiore and cost nearly $11 million. Automating the confirmation of whether a service or procedure requires prior authorization within existing eligibility workflows will reduce the resources we devote to this task. Automation of this process will also have downstream benefits by reducing claim denials and appeals.

Benefit structure: The updated rule improves support for complex benefit designs by requiring health plans and their agents to return patient financial responsibility for tiered benefit structures, as well as indications of maximum and remaining benefits. Montefiore strongly supports these additions as they promote transparency, minimizing patient and provider confusion that, in turn, promotes timelier care and increased satisfaction. Additionally, this update will reduce back-end

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claim denials by providing more granular information about benefit structure at the time of eligibility verification, allowing us to submit more accurate claims.

Application to No Surprises Act requirements: By way of returning patient financial responsibility for a broader set of service type codes and more detailed procedure codes – and through clarification of complex benefit designs – the proposed Eligibility Data Content Rule will aid health plans and providers in conforming with No Surprises Act requirements to provide an Advanced Explanation of Benefits (AEOB) or Good Faith Estimate (GFE). Montefiore benefits from the synergistic advantages of this updated rule as we seek to establish policies and workflows that meet the complex requirements of the No Surprises Act.

Recommendation: Montefiore strongly encourages NCVHS recommend the updated CAQH CORE Eligibility & Benefits Data Content Rule to HHS for federal adoption. According to the CAQH Index, each manual eligibility transaction cost industry upwards of $15.09 and 21 minutes of provider. As detailed above, federal adoption of this rule will close eligibility data content gaps, allowing us to automate transactions across a greater number of use cases. We also anticipate the updated rule will help us realize downstream efficiencies arising from synergy with forthcoming regulatory requirements for electronic prior authorization and the AEOB and GFE requirements of the No Surprises Act.

3. New: Eligibility & Benefits Single Patient Attribution Data Content Rule (vEB.1.0)
Montefiore is committed to the advancement of value-based care (VBC) and is an active participant in alternative payment models (APM) stewarded by Medicare, Medicaid, and other commercial plans. Participation in VBC models is complicated by methodologies that vary between health plans and contracts. At Montefiore, this variability is exemplified by patient attribution, which is shared in different formats and abides by different methodologies depending on the model being supported. The CAQH CORE Single Patient Attribution Data Content Rule provides a solution by requiring health plans to electronically report a patient's attribution status using standard formats and data content within the eligibility transaction. This approach streamlines communication of attribution status and simplifies workflows required to manage complex APMs by leveraging existing transactions.

Recommendation: Montefiore supports federal adoption of the proposed CAQH CORE Single Patient Attribution Rule for its promise in simplifying and supporting VBC operations within existing workflows. This rule also enables providers to identify and address care gaps relevant to the VBP contract. Additionally, it facilitates greater conformance with quality and utilization reporting requirements by identifying attributed patients at the point-of-care.

4. Companion Guide Template
Montefiore is pleased that the proposed updates to the CAQH CORE Eligibility & Benefits, Claim Status, and ERA Infrastructure Rules – as well as those newly proposed for the electronic exchange of attachments – reference an updated CAQH CORE Master Companion Guide Template. Updates to the Master Companion Guide Template allow implementers to indicate newer versions of the X12 standards and the template can also be used as a framework to create a companion guide for non-X12 standards, such as HL7 FHIR.

We support the use of the Master Companion Guide Template because it simplifies business processes by providing a standard format that is easily understood and can be incorporated into workflows that govern common transactions. We also appreciate its applicability to the CAQH CORE Attachments Infrastructure and Data Content Rules that reference X12 v6020. We are hopeful that this format will be adopted for use with non-X12 transactions, such as HL7 FHIR, promoting companion guide uniformity in a standard-agnostic environment.

5a. Updated Connectivity Rule: Impact and changes to organizational infrastructure
As highlighted previously in this letter, the updated CAQH CORE Connectivity Rule is essential to align security and exchange standards across the industry and is a central component of the updated CAQH CORE Infrastructure Rules proposed for adoption. As a HIPAA-covered entity and a CORE-certified organization, Montefiore and our vendor partners have

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maintained conformance with the HIPAA-mandated Phase I and II CAQH CORE Connectivity Rules that were federally mandated in 2013. Conforming to the updated requirements will require the devotion of additional resources; however, we believe the positive impact of updating outweighs the negative effects of maintaining outdated requirements. Further, there are several features of the updated Connectivity Rule that will help streamline workflows and minimize the resource burdens of implementation.

Carrying forward of existing requirements: vC4.0.0 maintains many requirements contained in the federally mandated Phase I and II CAQH CORE Connectivity Rules. Therefore, all HIPAA-covered entities, and CORE-certified organizations, of which Montefiore is both, already conformed with key requirements of the most current version. This limits the resources that must be devoted to implementation and minimizes the changes that must be made to existing workflows. Of the changes that have been carried forward, vC4.0.0 continues to provide a Safe Harbor for public internet and HTTPS transport standards, which means that Montefiore and its trading partners do not need to abandon existing connections that have already been mutually agreed upon and established.

Updates to digital certification: vC4.0.0 of the CAQH CORE Connectivity Rule references digital certification technology using an X.509 standard. This update modernizes the rule and aligns requirements with modern web-based traffic, removing reliance on outdated usernames and password authentication requirements and thus significantly reducing security risks. These new requirements allow Montefiore to reduce the administrative costs associated with maintaining outmoded technologies, offsetting any potential resources associated with updating these requirements. Further, digital certification platforms are provided freely by most major authorities and will not accumulate additional costs.

Alignment with CAQH CORE Infrastructure Rules: As a CORE-certified organization, Montefiore passed a rigorous, evidence-based evaluation of its technologic controls and conformance with the provisions set in the CAQH CORE Eligibility & Benefits and Claim Operating Rule Sets. Montefiore intends to maintain its CORE Certification and, as such, is committed to implementing the updated requirements of vC4.0.0 and will not hesitate to devote modest resources to do so.

Benefit of modernization: Generally, the updates to the CAQH CORE Connectivity Rule in vC4.0.0 create a secure, standard pathway to safely exchange health information. The positive impact of modernization outweighs any potential resources that must be devoted to implementation, which Montefiore anticipates will be modest given the requirements that have been carried over from past mandated versions of the Connectivity Rule. We expect other organizations are evaluating these requirements using a similar calculus to estimate the burden of implementation.

Updating the connectivity requirements will ensure consistent, best practice security and connectivity methods across administrative transactions that are durable over time. The CAQH CORE Connectivity Rule vC4.0.0 will enable Montefiore to use a common connectivity method across EDI transactions and trading partners. Security will be strengthened, and onboarding costs reduced. In the next section, we address the sufficient scope of updated rule.

5b. Updated Connectivity Rule: Scope

The benefits of modernizing the CAQH CORE Connectivity Rule have been clearly stated throughout this comment letter. Montefiore asserts that the updates contained in vC4.0.0 are of sufficient scope and support the creation of a durable and flexible infrastructure that facilitates the use of the most advanced security and exchange technologies into the foreseeable future.

Wide applicability: The updated rule continues Safe Harbor connectivity, allowing us and our trading partners to send electronic health information using a variety of formats and standards. Additionally, though we acknowledge this discussion is most applicable to the updated requirements in the CAQH CORE Infrastructure Rules, the updates contained in vC4.0.0 can support connections beyond these three transactions. As Montefiore and our vendor partners adapt to a changing technological and regulatory landscape, these updates help provide an efficiency of scale that facilitates alignment between existing and emerging standards, simplifying connections and de-burdening implementation efforts.

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Long-term utility: Montefiore participated in the deliberation to update the CAQH CORE Connectivity Rule. The express desire of this process was to support long-term industry interoperability by adopting the most modern security and data-exchange standards. This was achieved through the inclusion of the mechanisms that reflect a standard agnostic environment and support emerging technologies, such as REST APIs. To reiterate earlier points, at Montefiore these improvements may require upfront implementation resources, but they will reduce downstream maintenance, administrative costs, and security risks associated with maintaining outdated exchange and security requirements, lending to greater efficiency that can be reflected in the care we deliver.

Industry impacts: The comprehensiveness and flexibility of the CAQH CORE Connectivity Rule benefits the implementation of fully electronic administrative transactions by offering a common connectivity method that reduces the time and cost of carrying out transactions. It additionally enhances our business practices by allowing for connections to a greater number of trading partners. The updates to the rule expand the applicability and scope of connectivity by adding technical requirements that further support APIs through incorporation of the REST protocol.

Recommendation: Montefiore strongly supports federal adoption of the updated CAQH CORE Connectivity Rule vC4.0.0. While the safe harbor provisions of CORE Connectivity have enabled us to connect with multiple trading partners quickly and efficiently, Montefiore can no longer abide using the mandated Phase I and II CAQH CORE Connectivity Rules given security shortcomings and failure to represent current industry best practices. We welcome an updated, common connectivity method reflecting the most up-to-date technologies that can be used to accommodate the safe transfer of data between our organization and the health plans we work with.

6. Costs

Updates to the CAQH CORE Eligibility & Benefits Data Content and Infrastructure Rules, and the Claim Status and ERA Infrastructure Rules provide necessary modernity and close operational gaps that allow Montefiore to carry out a greater number of healthcare transactions fully electronically. Based on 2020 data, the 2021 CAQH Index **outlines time and cost savings** that can be achieved by automating healthcare transactions. These are shown in the table below. These estimated savings are both applicable to and significant for our organization, particularly when compared against annualized utilization that shows 79 thousand hospital admissions, 2.6 million ambulatory visits, and over 250 thousand emergency department visits.

Transaction	Cost Saving per Transaction (Comparison: Manual)	Provider Time Saving per Transaction (Comparison: Manual)
Eligibility & Benefits	$15.09	21 minutes
Claim Status	$16.65	22 minutes
ERA	$4.06	7 minutes

Below, we describe key features of the rule sets and how they will help Montefiore achieve time and cost efficiencies.

Infrastructure updates: The comprehensive benefits of the updated Infrastructure Rules are highlighted earlier in this response. Of note, we would highlight that increased system availability leads to a more predictable, reliable schedule of uptime. Programmatically, this allows more transactions to be performed fully electronically at Montefiore reducing costly, manual work.

Additionally, the security and connectivity updates in the CAQH CORE Connectivity Rule vC4.0.0 guarantee a safe and efficient mechanism for transactions to be delivered using multiple formats and standards. Operationally, this update allows Montefiore to securely accommodate existing X12 standards, as well as emerging HL7 FHIR standards, without the need to maintain multiple connectivity standards – a boon of efficiency that allows more savings opportunity to be captured.

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Data content updates: As previously stated, updates to the CAQH CORE Eligibility & Benefits Data Content Operating Rule close administrative gaps that emerged since the electronic X12 standard (270/271) and original CAQH CORE Operating Rule were adopted. The potential impact of these changes is well-represented by the previously shared data around the increase in telehealth visits, precipitated by the Public Health Emergency (PHE), as well as the FTE cost of supporting prior authorization activities. The updated rule will streamline these workflows, allowing greater operational efficiency.

We would also highlight the efficiencies of scale that the rule provides. Additional granularity surrounding prior authorization requirements, tiered benefit designs, and patient financial information allows us to unify implementation of the updated Eligibility Data Content Rule with those supporting emerging regulations related to electronic prior authorization and the No Surprises Act.

Recommendation: We reiterate our earlier recommendations outlining strong support for NCVHS to recommend the updated CAQH CORE Infrastructure and Data Content Operating Rules to HHS for federal adoption. The efficiencies these updated rules provide by streamlining electronic transactions and fulfilling existing and emerging use cases have great benefit for operations at Montefiore. The efficiencies won also have implications for reinvestment into the communities we serve.

7. Alternatives considered for operating rules
The impacts and advantages that the proposed new and updated CAQH CORE Operating Rules have at Montefiore have been highlighted throughout this letter. Alternatives to the proposed operating rules should not be considered at this time. The rules provide a critical basis for uniform implementation of common healthcare transactions and have been expanded to meet a growing number of business cases.

8. CAQH CORE Attachments Infrastructure and Data Content Operating Rules
The exchange of health information through attachments is widely recognized across the industry as a time-consuming, expensive, and burdensome process; our experience at Montefiore is no different. There is support throughout the industry to minimize the burden of this workflow by facilitating the electronic exchange of this information but, to-date, this method is underutilized. According to the CAQH Index, in 2020, only 21% of attachments transactions were carried out fully electronically. The remaining 79% relied on outmoded methods including proprietary portals, fax, email, and even snail mail.

This represents missed savings opportunities of almost $4.02 and 6 minutes of provider time per transaction.
A driving factor of why attachments are rarely exchanged fully electronically is that no standards have been named by HHS to support this workflow. Though regulations setting standards are anticipated, they have not yet been delivered, leading the industry to create proprietary requirements. Montefiore welcomes the standard agnostic CAQH CORE Attachments Infrastructure and Data Content Rules and recognizes their ability to support a uniform method for the exchange of electronic attachments that can be used without established standards and drive uniformity across any future mandated standards.

Variability of attachments exchange: Attachments are integral to healthcare operations and support the adjudication of prior authorization requests and health care claim transactions. Montefiore sends files using a variety formats, including C-CDA, Excel and PDF, depending on the requirements of the requesting health plan and the nature of the documentation being sent. We note that this variability can delay adjudication, as the non-standard formats are, at times, difficult to reassociate with the request. It is for this broad reason that we support the CAQH CORE Attachments Operating Rules that establish minimum data content and infrastructure requirements that aid in the submission and reassociation of attachments, streamlining exchanges and providing necessary guidance to an industry eager for implementation uniformity. Given the proliferation of attachment formats being used, the operating rules were created to be standard agnostic, align with previous NCVHS recommendations to HHS on attachments standards, and provide necessary flexibility to fulfill multiple use cases and exchange methods.

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Given their agnosticism, we view the attachments rules as a complement to any future regulations establishing attachments standards that will help speed implementation timelines and conformance across the industry given the additional level of uniformity provided. For these reasons, we strongly recommend that NCVHS recommend the CAQH CORE Attachment Operating Rules to HHS for federal adoption *simultaneously* with any proposed rulemaking setting attachment standards. This approach ensures that resources for implementation can be scaled appropriately across industry, promoting efficiency without sacrificing positive outcomes. Additionally, aligning adoption of the operating rules and a standard, will place each on the same or similar conformance timeline that is already extending into 2026. The industry cannot afford to delay the data content and infrastructure uniformity the operating rules provide beyond that date.

We would like to highlight several key structural components of the proposed CAQH CORE Data Content and Infrastructure Operating Rules that will advance industry uniformity and promote conformance with a range of standards including X12 275, CCDA, FHIR, etc.

Key components of infrastructure rules: The Attachments Infrastructure Rules require health plans to accept a maximum file size of at least 64mb. This change eliminates unnecessary rejection of supporting information and the costly follow-ups that result. The rules also carry forward the security, connectivity, and Master Companion Guide requirements outlined in the other CAQH CORE Infrastructure Rules proposed for federal mandate. This provides assurance that this transaction is supported by the same robust requirements as the other HIPAA-mandated transactions.

Key components of data content rules: The Attachments Data Content Rules support reassociation activities for both X12 and non-X12 standards, requiring providers and health plans to indicate when a request has been initiated or sent electronically. The rule additionally recommends that this process be strengthened using mutually agreed upon clinical code sets that help ensure consistency and completeness of the information being sent. These relatively small changes – through the establishment of predictable formats and notifiers – help Montefiore automate workflows and operations in support of the exchange of attachments.

Recommendation: Montefiore strongly recommends that the CAQH CORE Attachment Infrastructure and Data Content Operating Rules for prior authorization and health care claims be federally mandated. The lack of consistency that permeates the exchange of attachments between our organization and health plans adds time and financial costs to, what should be, relatively straight forward transactions that support claims submissions and prior authorization requests. We recommend that the rules be proposed for federal mandate in the same regulation that sets Attachments standards. This approach will align implementation timelines and provide common expectations across standards. Not doing so will lead to continued fragmentation, perpetuating proprietary approaches and adding to stakeholder burden.

9. Attachments operating rules – general question

CAQH CORE was designated as the operating rule authoring entity by HHS for attachments in 2012. Given the current state of implementation variability, the industry cannot wait for standards to be implemented prior to the adoption of operating rules. The proposed CAQH CORE Attachments Operating Rules provide necessary uniformity and have proven to be an effective tool in driving adoption of electronic standards. Additionally, the proposed rules unify data content and infrastructure requirements, but are standard agnostic and support varying formats and standards used to facilitate the exchange of attachments, including those that were previously recommended by NCVHS for federal adoption by HHS. There are several other points that should be considered.

Operating rules support implementation uniformity: Future regulations are anticipated to support more than one mandated standard for the electronic exchange of attachments. The CAQH CORE Operating Rules provide uniformity across standards and facilitate implementation alignment. This will lead to greater immediate adoption of impending standards and will optimize timelines for conformance.

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Operating rules support judicious resource use: Montefiore functions in an environment where efficiency and projects must be evaluated by their overall cost, benefit, and synergy with other initiatives. Aligning implementation of attachments standards with the requirements laid out in the CAQH CORE Attachments Operating Rules allows us to efficiently devote resources to a single project versus two, time-separated initiatives.

Operating rules promote transparency and reduce confusion: Adopting CAQH CORE Attachments Operating Rules simultaneously with an attachment standard establishes a predictable implementation timeline and will reduce ambiguity and implementation burden across the industry. For example, even if a standard were to be released through regulation in Q1 2023, typical implementation and conformance timelines extend to 2026. Adopting Operating Rules provides uniform implementation guidelines for data content and infrastructure development that will speed conformance and create a more durable framework.

Conclusion: We must also recognize that only naming a standard will not solve all the challenges associated with the exchange of attachments, as has been the case with other mandated standards. Our experience shows most plans have slight differences in what they require for the electronic exchange of attachments, making it near impossible to address attachments in a uniform manner, contributing to costly back and forth between our providers and health plans. Setting standards will help align expectations around format but it will do little to address varying requirements.

Operating rules engender implementation uniformity by defining key requirements such as connectivity, file size, and methods for electronic reassociation. In turn, these requirements spur implementation uniformity across the industry, whether standards are enacted or not, and will ultimately empower Montefiore to conduct a higher volume of these transactions fully electronically.

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To: NCVHS

From: Stanley Nachimson, Principal, Nachimson Advisors LLC

Subject: Support for including UDI-DI in the X12N 837 Claim Standards

I strongly support the inclusion of the Unique Device Identifier (UDI) – Device Identifier (DI) in the latest version of the X12N 837 electronic claim standard. The UDI-DI, and its situational rule for inclusion, was added to the 837 institutional and professional claim standards after considerable discussion. In fact, the topic required the formation of a Special Advisory Committee to develop the rationale and instructions for use. The final decisions were a compromise which allowed the addition of the DI portion of the UDI while minimizing the burden on providers and health plans. The situational rule allows for the exchange of the UDI-DI for high risk implantable devices only when both the provider and payer agree to the exchange. I was heavily involved in all of these discussions.

There are several benefits to collecting the DI on claims forms for implantable devices. Collecting the DI between willing trading partners would:

- Facilitate linkages across data sources that collect the DI (e.g. claims, electronic health records, implantable device lists and medical device registries) to address specific research and patient safety questions;
- Allow for evaluation of product performance and identification of safety concerns for devices at the model level;
- Facilitate the analysis of patient data for devices at the model level to help in surveillance efforts and device innovations;
- Help clinicians and researchers to obtain better information about the quality of care related to device selection, procedural outcomes and follow-up;
- Support program integrity by providing better information to link the patient and implanted device.

Some of these benefits were actually shown in pilot tests transmitting the UDI-DI information on claims. (for example, see https://pubmed.ncbi.nlm.nih.gov/30480650/). The feasibility of including the information on claims was also demonstrated, showing that benefits could be realized at minimal costs.

There are admitted weaknesses caused by the situational rule, namely the limitations on the number of providers and plans which may decide to exchange the information, as well as the lack of definition of a “high-risk implantable device”. However, these can be overcome with further industry discussions once the exchange of DI becomes more routine and well-known.

The UDI-DI inclusion, as well as the rest of the revised claim and remittance advice standards, should be approved by NCVHS and forwarded to the HHS Secretary as a recommended HIPAA standard.

NATIONAL ASSOCIATION OF HEALTH DATA ORGANIZATIONS
Improving Health Care Data Collection and Use Since 1986

December 14, 2022

Jacki Monson, JD
Vice President, Chief Technology Risk Officer, Chief Information Security Officer, and Chief Privacy Officer
Sutter Health
2200 River Plaza Drive
Sacramento, CA 95833

Submitted via email to NCVHSmail@cdc.gov.

RE: RFC on X12 and CAQH CORE Proposals

The National Association of Health Data Organizations (NAHDO) appreciates the opportunity to comment on proposed changes to the proposed updated standards from X12 and proposed updated and new operating rules from the Committee on Operating Rules for Information Exchange (CAQH CORE). We offer the following comments.

State agencies and legislatively appointed nonprofits administering statewide health data programs can benefit from some of the proposed changes in 8020 transactions and operating rules. Specifically, these proposed changes give organizations with a mandate to collect administrative health care data a lever for compliance to collect more complete data:

- 837 changes to accommodate zero-dollar claims to support value-based payments help clarify expectations for healthcare payment databases (e.g., all-payer claims databases).
- Expanding the number of diagnosis fields from twelve (12) to twenty-four (24) allows providers, particularly hospitals, more opportunities to share valuable diagnosis information, specifically social determinants of health commonly referred to as "Z-codes."

NAHDO appreciates your consideration of our comments and the opportunity to provide them. Please contact me at chawley@nahdo.org with questions or to discuss these issues further.

Sincerely,

Norman K Thurston, Ph.D.
Executive Director

December 15, 2022

Submitted electronically via email - NCVHSmail@cdc.gov

Jackie Monson, JD
Chair
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

RE: Request for Public Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules

Dear Ms. Monson,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP submits the following comments on the National Committee on Vital and Health Statistics (NCVHS) "*Request for Public Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules*."

Updated X12 Transaction Standards

1. Costs. If your organization has conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional or dental claim) and remittance advice transactions, to what extent, relative to the potential cost of implementation, do the updated transaction implementation guides provide net positive value? Please explain.

NCPDP Response: NCPDP recognizes the significant cost involved in upgrading any industry standard; however, no cost analysis has been completed.

2. Operational impacts. If your organization has conducted an operational assessment or workflow analysis of the impact of transitioning to the updated X12 8020 claims and remittance advice transactions, what process improvements has your organization identified would result from implementation of the updated versions of any of the updated transactions? Please provide information for the Committee to reference in its considerations and feedback to HHS.

NCPDP Response: NCPDP recognizes there is an organizational impact (e.g., utilization of a new version of an 835 and an 837 transaction will require additional technical and human resources for conversion and implementation efforts) when upgrading an industry standard; however, no operational impact analysis has been completed.

3. XML Schema. X12 has indicated that each of the X12 implementation guides included in their recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. In its letter to NCVHS, X12 noted that it mechanically produces these representations from the same metadata used to produce the implementation guide. X12 recommends that HHS permit both the 8020 EDI Standard representation (the implementation guide) and the XML representation, and that both be named in regulation as permissible syntaxes. Please comment on the proposal to adopt the 8020 EDI standard and the XML representation as permitted syntaxes.

NCPDP Response: NCPDP supports the naming of EDI Standard and XML representation for the 8020 version of the 835 and 837s in regulation.
Also refer to the September 23, 2014 letter from NCVHS to HHS at https://ncvhs.hhs.gov/wp-content/uploads/2018/03/140923lt1.pdf

4. FHIR Crosswalks. X12 indicated that it intends to provide FHIR crosswalks for the proposed X12 version 8020 transactions (claims and electronic remittance advice) submitted for consideration in time for inclusion in the Federal rulemaking process. Please comment on how FHIR crosswalks would apply to the implementation of the HIPAA claims and remittance advice transaction standards.

NCPDP Response: No Comment

5. Unique Device Identifier (UDI). The device identifier (DI) portion of a medical device's unique device identifier (UDI) is now included as a data element on the updated claim transaction in the institutional and professional version of the 8020. The UDI is also an element in the US Core Data for Interoperability (USCDI) for Certified Health Technology required by the Office of the National Coordinator, and can be found in certified Electronic Health Records, and in standardized hospital discharge reports. Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction.

NCPDP Response: NCPDP supports the inclusion of the device identifier (DI) portion of a medical device's unique device identifier (UDI). The FDA is identifying devices using the UDI and has accredited

multiple agencies to issue UDIs. The UDI is the standard for identifying devices. Other device identifiers, such as the National Drug Code (NDC) and the National Health Related Items Code (NHRIC), are being sunset.

6. Alternative Payment Models (APM) and Value Based purchasing (VBP). Does X12 version 8020 support VBP claims? In what ways does the version 8020 of the claims transactions accommodate APMs such as medical homes or accountable care organizations (ACOs)? Please discuss the implications of this topic to HIPAA administrative simplification policies and continued innovation of non-fee-for-service business models.

NCPDP Response: No Comment

7. Implementation time frame. HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, what would be the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e. g. does the window need to be longer than two years from the publication date of a final rule? Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?

NCPDP Response: NCPDP does not recommend a January 1 implementation date as many beneficiaries' plan benefit year begins at that time. Plans may be changing processors and/or changing plan benefit designs, so they will be focused on coding for those updates and delay programming required for a new version of the 835 and 837 transactions. The industry also experiences heavy new member enrollment/eligibility and formulary updates. Also, many employees like to enjoy time off the last quarter of the year affecting the number of resources available.

NCPDP recommends a thirty-six month implementation period to avoid disruption of patient care with multiple simultaneous standards' implementations (e.g., NCPDP Telecommunication Standard VF6). Having multiple standards being implemented at the same time may cause delayed adoption or increased requests for extensions. Additional costs may also be incurred by organizations to implement.

8. Implementation. NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?

NCPDP Response: NCPDP supports a transition period of at least twelve months with a definitive cutover date.

9. Simultaneity. What, if any, are the data impacts, limitations or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g. claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?

NCPDP Response: NCPDP membership understands resources and workflows would be impacted, and additional costs would be incurred to support a translator for multiple versions.

10. Alternatives Considered. X12 indicated that there were over 2,000 changes identified in the change logs for the four updated transactions in version 8020, categorized by operational, technical and editorial. If your organization has conducted assessments of the technical changes, what is your determination of these with respect to reducing burden on payers or providers once the updates have been implemented? What is the opportunity cost of remaining on Version 5010 and not implementing the updated version 8020 of the claims and remittance advice transaction standard? What will the healthcare industry risk by not adopting version 8020?

NCPDP Response: NCPDP reviewed previously reported concerns regarding the 7030 version of the 835 transaction, and the 8020 version has corrected several concerns previously identified including correcting references to available NCPDP resources; however, no burden or cost analysis has been conducted.

NCPDP also reviewed the 7030 version of the 837 Professional Claim (837P) and submitted fifteen comments. The comments could be categorized as nomenclature and value set changes needed in the 837P. Not all the resolutions to the comments were incorporated in the 8020 version. NCPDP has worked with X12 to submit a maintenance request (MR274) to align the SV4 Drug Service segment and element requirements with NCPDP. No burden or cost analysis has been conducted on the use of the 8020 Version of the 837P.

11. General. Does your organization support HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards? Please provide a brief rationale.

NCPDP Response: NCPDP supports HHS adoption of the updated version of the X12 transactions for claim and remittance advice as HIPAA administrative simplification standards to advance reporting within the industry. It is necessary the industry use a more current version of the standard to expedite workflows to ensure pharmacies and payers utilize transparency in financial transactions.

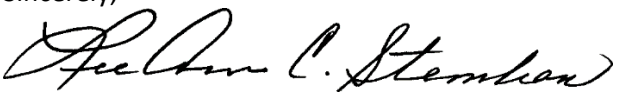
CORE Operating Rules

NCPDP Response: NCPDP will not be submitting comments on the CORE Operating Rules.

For direct inquiries or questions related to this letter, please contact:

Margaret Weiker
Vice-President, NCPDP Standards Development
standards@ncpdp.org

Sincerely,



Lee Ann C. Stember
President & CEO

National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260

NUBC
National Uniform Billing Committee

December 15, 2022

Jackie Monson, JD
Chair
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Dear Ms. Monson,

On behalf of the members of the National Uniform Billing Committee (NUBC), we are writing to provide comments in response to the National Council for Vital and Health Statistics Standards Subcommittee request for comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules. The NUBC appreciates NCVHS's efforts to solicit industry feedback and for the opportunity to provide comments.

The NUBC is a Data Content Committee named in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and is composed of a diverse group of health care stakeholders representing providers, health plans, designated standards maintenance organizations, public health organizations, and vendors. The NUBC develops and maintains a national uniform billing instrument for use by the institutional health care community. The Committee currently maintains the Uniform Billing (UB) 04 data set and form. The claim form is designed to convey a core set of data containing pertinent information about patient services, the clinical basis for treatment, related events surrounding the care, and other relevant information. Our goal is to promote the development of the data needs reported within the UB-04 claim for use by institutional health care communities and transmitted to all third-party payers.

As the HIPAA-named body responsible for producing the data content standard for claims, the NUBC commentary will focus on the proposals that most directly impact this transaction. As a result, the forthcoming responses are focused on the claim transaction, with commentary primarily on the impact of these regulations on the transmission of institutional claims.

Version 8020 837I Transaction

1. and 2. Costs and Operational Impact

To date, neither the NUBC nor any of its participating organizations have conducted a complete and thorough cost/benefit analysis on implementation of the updated X12 version 8020 claims transaction, as conducting such a test at this time would be resource intense, difficult, and potentially inaccurate/misinformed.

Based on experience with the transition from the 4010 to 5010 standard, we recognize that there will be significant costs to all industry stakeholders when implementing an updated version of standards.

However, gathering the more granular, specific information of a cost/benefit analysis requires a significant amount of resources. Stakeholders would need to project the specific ways in which a new standard would require systematic changes and corresponding workflow adjustments. The effort requires significant time to identify all the changes necessary in each entity's systems, determine how to capture and handle the new data, and change business rules. The effort also will require conducting thorough internal testing followed by robust testing among various business partners. Additionally, stakeholders would need to estimate the anticipated efficiencies and reduced burden that would be realized due to improved transactional capabilities. Stakeholders are unlikely to conduct such a thorough analysis at this stage, as the transaction has yet to be recommended to the Secretary and may be subject to change prior to its listing in a notice for proposed rulemaking (NPRM), particularly since X12 does not recommend implementation of the 8020 standard, but rather the version of the standard that has been most recently completed prior to the NPRM release date.

Prior to adoption of a new X12 version, we urge robust pilot testing both internally and across business partners. Such testing will aid in accurate cost analysis and reveal the benefits of adopting the revised version. This undertaking of thorough testing should not be underestimated and must be balanced against the anticipated benefits of the new version.

Importantly, we believe a significant unanswered factor in the cost analysis is whether more than one version of the standards will be allowable and/or required. Should stakeholders be required to support multiple versions simultaneously, tools and framework for supporting the versions will increase substantially even if the overlap is for an industry-defined short time period. Additionally, we note that requiring support for multiple versions simultaneously may reduce any potential benefit rendered by the new version implementation as not all transactions received would be utilizing the functionality of the most recent version. Moreover, should the industry adopt an approach wherein updates occur every year or every other year, entities may need to hire full-time teams to review and implement new versions of guides, which would necessitate a sustained capital investment.

3. XML Schema

The NUBC recognizes the benefits of offering the ability to report information using XML schema, as this offers a new flexibility to the exchange of claims information. Additionally, we recognize that XML schemas can more easily validate and convert data.

We stress, however, that because the infrastructure and operations currently in place utilize the EDI standard, and because XML schema carries higher storage and transportation costs, we believe that the EDI must remain the required syntax, with the XML being an optional additional function.

4. FHIR Crosswalks

The NUBC is unclear on the utility of FHIR crosswalks for the claims and remittance advice transaction standards. The X12 materials fail to specifically delineate the manner in which the crosswalks would be used to supplement or support the transaction, so it remains unclear as to how they will specifically benefit the transaction. Additionally, until the crosswalks are successfully built and tested, it is difficult to project usefulness.

We envision that, should multiple claim standards be allowable simultaneously, FHIR crosswalks may aid in efficient and accurate electronic communication between the standards. However, if multiple standards and versions are neither allowed nor required, the utility of FHIR crosswalks may be negligible.

5. Unique Device Identifier (UDI)

The NUBC strongly supports the improvement of medical device safety, and to the extent that adding the UDI to the claim furthers appropriate device surveillance and monitoring, the NUBC supports the proposal. However, in light of parallel efforts to efficiently track this information, such as UDI's inclusion in the USCDI, we are unclear on the specific benefits of its addition to the claim and would recommend additional specificity as to how this will be used to advance device safety using the new functionality.

Additionally, the NUBC recommends additional clarity on the identification of the high-risk implantable devices that the FDA recommends undergo surveillance using claims data. To date, the industry has not created a list or method of classifying a device as "high-risk" in order to direct necessary reporting and surveillance. There are millions of different medical devices, and hundreds of thousands of implantable devices. Having a list of the specific DIs that the FDA considers to be "high-risk implantable devices" would maintain efficiency and ensure that data on devices of interest are captured.

6. Alternative Payment Models (APM) and Value Based purchasing (VBP)

Without additional detail about the specific VBP program and methodology, the NUBC is unable to project the ways in which version 8020 may support VBP claims. However, we note that, to date, most alternative payment models (APMs) have been built on a fee-for-service architecture.

7. Implementation time frame

The NUBC recommends maintaining a two-year implementation window for health plans and providers after publication of a final rule. Additionally, we recommend considering alternative effective dates, such as April 1st or another date in spring, to avoid simultaneous go-lives with other health IT initiatives.

8 and 9. Implementation and Simultaneity

As previously stated, we are uncertain of the benefits of allowing for the concurrent use of multiple versions of a standard. Overall, the value of standards to the healthcare environment is that stakeholders can implement a single approach to communicating information across all parties with whom they interact. Standards increase efficiency and drive down costs. Therefore, we question whether the allowance of more than one version furthers the goal of ensuring uniformity and predictability across the industry.

If the industry moves toward allowing multiple standards or versions of transactions, this amplifies the need for substantial testing to be performed. Robust cross-standard testing is critical to determine the impact of multiple standards and versions.

Additionally, the NCVHS consideration of each HIPAA transaction individually, rather than as part of a comprehensive transaction suite, furthers the need for additional testing. Were regulations to follow a

similar process, the industry would be faced with implementing new versions of some standards while maintaining old versions of others. The use of such piecemeal approach should not be pursued without substantial testing that gives confidence that the versions are cross-compatible with one another.

Conclusion:

For reasons detailed above, the NUBC does not believe sufficient testing and clarity of implementation specifics has been released and, as a result, cannot currently recommend adoption and implementation of the proposed 837I transaction. At this time, the NUBC recommends additional piloting, testing, and cost analysis be conducted, along with the release of additional industry guidance regarding multiple standards and versions of standards, to be completed prior to consideration of recommending the transaction to the Secretary for implementation.

Version 8020 835 Transaction

As mentioned above, the NUBC's review of the 835 transaction was limited in scope to how the transaction specifics would impact claims processes. As such, the NUBC does not believe it useful to provide detailed analysis of the entire 835 transaction. In addition to our concerns regarding testing, clarification, and detailed cost/benefit analysis, which remain applicable to the 835 transaction, the NUBC wishes to highlight one issue for NCVHS consideration.

The proposed 835 transaction calls for replacing the Claims Adjustment Segment (CAS) with the Reason Adjustment Segment (RAS). Since this information is essential to secondary claims under Coordination of Benefits processes, we stress the need to carefully plan and test the methods in which the transition will be operationalized. For example, a claim processed prior to the transition from CAS to RAS must be permitted to submit secondary claims after the transition while presumably not having the RAS information.

CORE Operating Rules

The NUBC appreciates the ability to comment on the CAQH CORE proposed operating rules. As detailed above, the NUBC elects to focus its commentary on those aspects of the rule that are applicable to the institutional claim. Accordingly, the NUBC offers the following commentary:

Updated Connectivity Rule.

The NUBC is generally supportive of the updated Connectivity rule, which is applicable to all standards. The Committee appreciates that the rule enables enhanced security measures to be agreed upon by covered entities without adding additional burden to those participating parties.

Attachment Operating Rules

Although the NUBC recognizes the potential efficiencies that could be realized by passing an attachment standard and operating rule, we are unprepared to formally support either of the attachments rules at this time. Though we are supportive of the industry coalescing around common business practices in the absence of regulation, we believe it is likely premature to adopt controlling operating rules prior to naming a corresponding standard. While the industry has been long awaiting an attachments standard, CMS has recently indicated plans to release an attachment standard in the coming months. In order to ensure that any attachment operating rules adequately applies to the corresponding standard named under HIPAA, we encourage the industry to wait until the proposed rule is released, at which time a concurrent review of both the operating rule and the standard transaction could occur.

The NUBC appreciates the ability to provide commentary on the proposed standards and operating rules. If you have any questions, please do not hesitate to contact me at tcunningham@aha.org.

Thank you,

Terrence Cunningham
Chair
National Uniform Billing Committee

December 12, 2022

Jackie Monson, JD
Chair
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Via: NCVHSmail@cdc.gov

RE: Request for Public Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules

Dear Ms. Monson,

The National Uniform Claim Committee (NUCC) is pleased to submit the following comments on the National Committee on Vital and Health Statistics (NCVHS) "Request for Public Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules."

The NUCC is a Data Content Committee, Designated Standards Maintenance Organization (DSMO), and advisor to the Secretary of Health and Human Services (HHS) for the adoption of new and modified standards under the Health Insurance Portability and Accountability Act (HIPAA). We have a diverse membership of health care providers, health plans, designated standards maintenance organizations, public health organizations, and vendors. Our goal is to promote the development of a uniform claim "form" for use by the professional health care community to transmit related claim and encounter information to and from all third-party payers. As such, we provide a broad perspective on professional data reporting and claims processing needs impacting the industry.

The NUCC is committed to the work of maintaining a professional health care claim electronic transaction that meets the industry's data reporting needs and provides administrative simplification. Our member organizations see first-hand the burdens that come from manual, outdated processes. We appreciate the work to continue to standardize and automate administrative transactions, per the intent of HIPAA.

The NUCC submits the following comments. The comments on the claim transaction are limited to the professional implementation guide ("837P").

Updated X12 Transaction Standards

1. Costs. If your organization has conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional or dental claim) and remittance advice transactions,

to what extent, relative to the potential cost of implementation, do the updated transaction implementation guides provide net positive value? Please explain.

NUCC Response:
At this time, none of the NUCC's organization members have conducted an analysis of the cost impact to implement the updated X12 Version 008020 837P transaction. We are not currently in a position to offer an opinion on the costs, benefits, or net positive value.

There are expectations that costs will vary across stakeholders and be dependent on whether all the changes are implemented. Organizations that complete their own system changes, typically larger providers, payers, and clearinghouses, will have different cost impacts vs. smaller organizations, typically providers, that rely on vendors for system updates and support. Clearinghouses and payers will need to implement all changes to support data reporting, whereas providers may not need to implemented changes that are not relevant to their operations, such as factoring agents, drug reporting, tooth information, or predetermination of benefits.

We recommend that NCVHS provide additional time to the industry to complete full analyses of the changes, learn from anticipated pilot testing, and understand the implementation plans before submitting cost and value estimates.

2. Operational impacts. If your organization has conducted an operational assessment or workflow analysis of the impact of transitioning to the updated X12 8020 claims and remittance advice transactions, what process improvements has your organization identified would result from implementation of the updated versions of any of the updated transactions? Please provide information for the Committee to reference in its considerations and feedback to HHS.

NUCC Response:
The NUCC is aware that a few organizations have started preliminary reviews of the changes in the Version 008020 837P. These organizations have not completed enough work to provide any conclusions about the operational impacts of the changes.

We recommend that NCVHS provide additional time to the industry to complete full analyses of the changes before reporting on impacts to their current operations and workflows.

3. XML Schema. X12 has indicated that each of the X12 implementation guides included in their recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. In its letter to NCVHS, X12 noted that it mechanically produces these representations from the same metadata used to produce the implementation guide. X12 recommends that HHS permit both the 8020 EDI Standard representation (the implementation guide) and the XML representation, and that both be named in regulation as permissible syntaxes. Please comment on the proposal to adopt the 8020 EDI standard and the XML representation as permitted syntaxes.

NUCC Response:
The NUCC's understanding is that the XML schema is a different messaging format for the transactions from the EDI schema. Some organizations currently use the XML schema internally

within their systems and others have an interest in using this different format. Our concern is whether an end-user would be forced to change their systems to accommodate the XML format if an upstream sender uses it. We do not believe the XML schema should be required to be supported by all HIPAA covered entities. We believe the use and support of the XML schema should be on a voluntary basis. The EDI format should be required if an end-user requests that transactions be sent to them in that format.

4. FHIR Crosswalks. X12 indicated that it intends to provide FHIR crosswalks for the proposed X12 version 8020 transactions (claims and electronic remittance advice) submitted for consideration in time for inclusion in the Federal rulemaking process. Please comment on how FHIR crosswalks would apply to the implementation of the HIPAA claims and remittance advice transaction standards.

NUCC Response:
The NUCC is not aware that X12 had begun development of a FHIR crosswalk for the 837P. It is also our understanding that additional work is being done on the existing FHIR crosswalks to other X12 transactions. Considerable time will be needed by the industry to develop, review, and test an 837P FHIR crosswalk. Until the crosswalk is developed, it is unclear how it will apply to the implementation of the Version 008020 837P. We believe it is premature to consider including an 837P FHIR crosswalk in a proposed regulation for the Version 00820 837P.

5. Unique Device Identifier (UDI). The device identifier (DI) portion of a medical device's unique device identifier (UDI) is now included as a data element on the updated claim transaction in the institutional and professional version of the 8020. The UDI is also an element in the US Core Data for Interoperability (USCDI) for Certified Health Technology required by the Office of the National Coordinator, and can be found in certified Electronic Health Records, and in standardized hospital discharge reports. Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction.

NUCC Response:
The NUCC has questions about the value of including the ability to report the device identifier (DI) portion of a unique device identifier (UDI) for high-risk implanted medical devices. One concern is that there is no standard definition of a "high-risk" device. The situational rule for reporting the UDI requires trading partners to agree on which devices will be included in reporting. There will likely be wide variations in which devices are captured in claims reporting by payers, which will lessen the value of device surveillance. Another concern is the lack of clinical information provided in the claim, which is necessary to understand why a device was removed. Payers collecting the UDI data will have incomplete clinical information on which to base analyses of device removals.

The NUCC is not aware of any organizations that are planning to implement the UDI reporting in the claim. Overall, we do not believe this is a significant enough benefit in and of itself to warrant the implementation of the Version 008020 837P.

6. Alternative Payment Models (APM) and Value Based purchasing (VBP). Does X12 version 8020 support VBP claims? In what ways does the version 8020 of the claims transactions accommodate APMs such as medical homes or accountable care organizations (ACOs)? Please discuss the implications of this topic to

HIPAA administrative simplification policies and continued innovation of non-fee-for-service business models.

NUCC Response:
The NUCC's understanding of the current alternative payment models is that they are still, at their core, based on fee-for-service claims processing with reconciliation on the back end. We are not aware of any specific alternative payment model needs that are met by the Version 008020 837P.

7. Implementation time frame. HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, what would be the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e. g. does the window need to be longer than two years from the publication date of a final rule? Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?

NUCC Response:
The NUCC agrees that a two-year implementation timeframe is reasonable for the industry and is consistent with previous HIPAA regulatory requirements.

In relation to other changes in health care, it is uncertain at this time when a final regulation adopting the Version 008020 transactions will be published and what the two-year implementation timeframe will be. It is also unknown what other regulatory requirements will be under development or being implemented during this same time. One comment that has been consistent from organizations is that budgets and projects are not approved until there is a final regulation, meaning that early development and deployment will not occur.

The NUCC discussed several options for a compliance date for the Version 008020 transactions and operating rules. There was no consensus on a date, but there was agreement that January 1 is problematic for many organizations for various reasons.

8. Implementation. NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?

NUCC Response:
The NUCC has serious concerns about allowing multiple versions of the same standard in production for an extended period of time. Extensive, real-world testing will need to be done between different versions of the same transaction and different versions of related transactions to determine if multiple versions can function together.

Technical changes in the Version 008020 837P may make it not feasible for it to function with the Version 005010 837P or Health Care Claim Payment/Advice and Payment (835) transaction. The

following are a few examples where the functionality of multiple versions will need to be tested and confirmed:

1. 837P to 837P: If the sender transmits a Version 008020 837P and the receiver is using the Version 005010 837P, data elements that have changed in Version 008020 will not be recognized in the receiver's system, such as new qualifiers, increased data fields, new data elements, and new segments. The receiver will lack the data necessary to adjudicate the claim correctly, which will cause delays in payment to the sender.

2. 837P to 835: If the sender remains on Version 005010 837P and the receiver is on Version 008020 835, the sender of the 837P (and receiver of the 835) will not have the changes in their system to handle the updated claim adjustment data in the 835 resulting in an inability to post the remittance and handle any follow up actions required.

3. 837P for Coordination of Benefits (COB): If the sender of a COB claim is using the Version 008020 837P and the receiver is using the Version 005010 837P, the receiver will not be able to process the changes in the COB data causing issues with the adjudication by the secondary payer.

Supporting two different versions during a transition period from one version to the next often requires organizations to manage two different platforms and use workarounds to address incompatible data translations and exchanges. While this is expected for the short transition period, it is not sustainable for an extended period of time and will add burden and cost to the system. The complexities within systems to manage more than one version will grow exponentially as additional transactions beyond the 837P and 835 are added.

Additionally, if multiple versions of the same standard were allowed, there would be an overall reduction of any potential benefits of the newer version. The benefits of moving to an updated standard will only be fully realized if the entire industry moves to that updated standard.

9. Simultaneity. What, if any, are the data impacts, limitations or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g. claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?

NUCC Response:
Again, the NUCC has serious concerns about allowing multiple versions of the same transactions in production for an extended period of time. The NUCC has not evaluated the Version 008030 Eligibility and Benefit transaction or 008020 of the other mandatory transactions, since X12 has not yet requested their adoption under HIPAA. Significant, real-world testing will need to be done to ensure that the multiple versions of the multiple transactions will function together without adding additional burden or cost to the system. While flexibility to choose which version of a transaction to use may seem beneficial, it is not a benefit if it adds burden or cost, which goes against the purpose of HIPAA.

10. Alternatives Considered. X12 indicated that there were over 2,000 changes identified in the change logs for the four updated transactions in version 8020, categorized by operational, technical and editorial. If your organization has conducted assessments of the technical changes, what is your determination of these with respect to reducing burden on payers or providers once the updates have been implemented? What is the opportunity cost of remaining on Version 5010 and not implementing the updated version 8020 of the claims and remittance advice transaction standard? What will the healthcare industry risk by not adopting version 8020?

NUCC Response:
The NUCC completed a comparison of the Version 005010 and Version 008020 837Ps. The following table is an overview of the changes in Version 008020 and our comments about them.

Change Overview	Comments
Coordination of Benefits (COB): CAS Change to RAS The Claims Adjustment (CAS) segment has been replaced with the Reason Adjustment (RAS) segment to support the pairing of Claim Adjustment Reason Codes (CARC) and remark codes. These changes align the 835 payment and remittance advice with the 837P claim for COB. In 8020: • The RAS supports one adjustment per segment, which means more RAS segments are needed compared to the previous number of CAS. There is direct alignment between the CAS amount, CARC, and quantity and a single RAS. • Remark codes must be directly paired with the CARC, when one is reported. The RAS supports up to five remarks codes for one CARC. • The Health Care Remark Codes (LQ) segment was added to the claim and service line loops to support remark codes that are not associated with a claim or service line level CARC. • Information was revised in the front matter to explain the change from CAS to RAS. Allowed Amount The ability to report an allowed amount was added back in 8020 at the claim and service line levels. It had been in 4010 and was removed in 5010 because the amount was determined to be derivable from other reported data. With 5010 in place, a need was identified to be able to report an allowed amount different from the amount that was derivable, if the provider believed the amount was different.	CAS Change to RAS • In 8020, remark codes will be associated with the reason, group code, and dollar amount instead of being general at the claim level in 5010. • This will be a "big" technical and business change for all covered entities. • There will be additional work for providers to analyze the reasons and dollar amounts. • The impact of this change will depend on how payers and vendors automate and return the information in the 835. • Work on this change was started shortly after 5010 was finished. Allowed Amount Allows flexibility for reporting the amount.

Change Overview	Comments
Predetermination: • The ability was added to use the 837P format to obtain a predetermination of coverage and payment for a service prior to rendering it. • A new section in the front matter was added on how to interpret the date of service report in the transaction. • Notes on relevant segments and data elements were updated to explain the use for predetermination transactions.	Unclear what the adoption will be of this function if it is not used for No Surprises Act requirements.
Unique Device Identifier: <u>Implants and Explants</u> • The ability to report the Device Identifier portion of the Unique Device Identifier (UDI) was added to the transaction. • Information was added to the front matter explaining the UDI and situations in which it can be reported. • A new segment was added at the service line level for reporting the data. <u>Pharmacy Supplies</u> • Information was added to the front matter explaining that UDI has replaced National Drug Codes for reporting pharmacy supplies. • Segment and data element notes were updated to explain the use of UDI.	<u>Implants and Explants</u> Unclear what the adoption will be of this function. <u>Pharmacy Supplies</u> This change is necessary since UDIs have replaced NDCs for certain supplies.
Property & Casualty and Workers' Compensation: • More information was added to the front matter about property and casualty (P&C) claims and data requirements. • Notes were updated on information needed for P&C claims. • A new segment was added for state care tax at the service line level. This was in the K3 segment in 5010 and now has its own segment in 8020. • A new segment was added for reporting the state of jurisdiction for the claim. This was in the K3 segment in 5010 and now has its own segment in 8020. • Notes were added on information needed for workers' compensation claims.	These changes provide better alignment between the P&C and workers' compensation billing and health care claim requirements, which allows for the use of the 837P. Since P&C and workers' compensation are not covered under HIPAA, accommodating these claims allows for more efficiency and less manual billing for providers who render these services. A few states (at least Minnesota and possibly Texas) require P&C to use the 837P.

Change Overview	Comments
Factoring Agent: The ability was added to report a factoring agent. A factoring agent is a financial organization that purchases receivable accounts from providers and then collects the debt. The use of factoring agents has been more common in the P&C industry but is being increasingly used in health care.	Unclear what the adoption will be of this function
Prior Authorization and Referral: The ability was added to report prior authorization and referral numbers at the applicable service line levels.	More than one prior authorization or referral number can now be reported per claim, since they are reported with each service line and not at the claim level.
Diagnosis Codes and Pointers: Fields to report and point to diagnosis codes were expanded. • The number of diagnosis codes that can be reported increased from 12 to 24. • The number of diagnosis codes that can be pointed to per service line increased from 4 to 12.	• Benefit for reporting more diagnosis codes and pointers for SDOH and risk adjustment needs. • Will require system changes and increase data storage needs. • Will likely result in the 837P being out of sync with the paper 1500 Health Care Claim form.
Procedure Modifiers: The number of procedure modifiers that can be reported increased from 4 to 8.	• Benefit to accommodate more procedure modifiers. • Will require system changes and increase data storage needs. • Will likely result in the 837P being out of sync with the 1500 Health Care Claim paper form.
Claim Creation Date: A new segment was added for the date and time the transaction was created in the provider's system to avoid confusion of the meaning of the date and time reported in the header, which was at times overwritten by the clearinghouse or revenue cycle vendor.	Maintains the date and time that the transaction was created throughout the life cycle of the claim.
Regulatory and Legislative Data Reporting: Information was added to the front matter explaining the use of the K3 segment for reporting data required by regulation or legislation and how to obtain approval for the use of the segment.	This change provides control of the use of this segment for unapproved data needs.
Drug Reporting: New segments were added to report the following at the service line level: • Drug cost amounts at the service line level • Drug services (This work was done to align the 837 and NCPDP claim.) • Drug utilization	Limited use of 837P for reporting drugs.
Tooth Information: A new segment was added at the service line level to report tooth number and area of oral cavity.	Limited use for oral surgery services.

Change Overview	Comments
Subrogation: "Medicaid" has been removed from language about subrogation opening the potential for non-Medicaid payers to use the 837P for subrogation.	Unclear what the adoption will be of this function.
Additional Clarity and Updated Information: Information throughout the TR3 was updated to provide additional clarity of requirements and usage, including, but not limited to: • Transaction compliance • Header data elements • Middle name data elements • Name suffix data elements • Billing provider address reporting • Use of the patient vs. subscriber loops • Use of insurance type codes for the primary payer • Harmonization of other insurance information with claim information, including the Provider Accept Assignment Code field • Dates for assuming and relinquishing care separated into different segments	These changes are helpful, but not necessary for current usage of the transaction since those using the transaction have figured out the requirements.
Qualifier Changes: Many changes were made to add and delete qualifiers to align with relevant data elements. Descriptions were also added for qualifiers where they previously did not exist. Significant changes include, but are not limited to: • "G2 – Provider Commercial Number" for reporting a proprietary provider number was changed to "A6 – Provider Identifier," which is the same meaning. • "ABK" for principal diagnosis (used for the first diagnosis code reported) was changed to "ABF" because the concept of "principal diagnosis" is not used in the professional claim. • "OF" for Other Federal Programs was removed and "MD" for Medicare Part D was added (Current instruction for OF was to use it for Medicare Part D.) "ME" was also added for Medicare Advantage Plan.	The qualifier changes listed are potentially significant for technical and business work. Programming changes will be necessary to change the codes across stakeholders.

Change Overview	Comments
Response Codes: Several changes were made to response codes to clarify the meaning, including, but not limited to: • "N" for "No," instead of leaving the field blank, was added for pregnancy, homebound, emergency, EPSDT, and family planning. • Gender Code – The description for "U" was changed to use it when the patient's gender is not explicitly male or female. • Provider Agreement Code – Use of "P – Participation Agreement" has been added.	• Will require technical and business changes. • These changes are helpful, but not necessary for current usage of the transaction since those using the transaction have figured out the requirements.
Outdated and Unnecessary Information: Information that is outdated and unnecessary was removed, including, but not limited to: • Compliance data and implementation strategies for National Provider Identifier (NPI) • Compliance notes for Health Plan Identifier (HPID) • Compliance notes for ICD-10 • Inpatient and outpatient designation • Contract information • Hospice employee information • Service facility contact information • Sales tax amount	• Will require technical and business changes. • These changes are helpful, but not necessary for current usage of the transaction since those using the transaction have figured out the requirements.
Changes to Size of Data Fields: Many changes were made to the length of data element fields, including, but not limited to: • The transaction identifier in the header was decreased. • The communication number was increased. • The last name or organization name was increased. • The Reference Identification field was decreased for some data elements and increased for others. • The claim submitter identifier was increased. • The monetary amount was decreased.	• The changes to the data field lengths are technical changes to manage the sizes, but there may also be business impacts on data storage needs (for longer data elements). • The changes to data field lengths may cause issues with compatibility between 5010 and 8020 across transactions.

Change Overview	Comments
External Information: Various information was moved out of the TR3 to external links, including, but not limited to: • Diagrams • Certain code lists • Examples • Definitions of professional providers on the National Uniform Claim Committee (NUCC) website • Condition Codes on the NUCC website • Terms and definitions • External code sources	Allows the flexibility to update the information as needed without waiting for a new version of the TR3.

11. General. Does your organization support HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards? Please provide a brief rationale.

NUCC Response:
The NUCC believes it is too soon to make a decision in support of the Version 008020 837P. Testing of the new version must be done to provide the industry with estimated costs, benefits, and value.

CORE Operating Rules

1. Attachments Prior Authorization Infrastructure and Data Content Rules (vPA.1.0) and Attachments Health Care Claims Infrastructure and Data Content Rules (vHC.1.0). CAQH CORE has proposed infrastructure and data content operating rules for Prior Authorization and health care claims. The proposed infrastructure rules for attachments for prior authorization and health care claims include requirements for the use of the public internet for connectivity, Batch and Real Time exchange of the X12 v6020 275 transaction, minimum system availability uptime, consistent use of an acknowledgement transaction, use of uniform data error messages, minimum supported file size, a template for Companion Guides for entities that use them, a policy for submitting attachment specific data needed to support a claim adjudication request (standard electronic policy), and support for multiple electronic attachments to support a single claim submission. The operating rules include the requirement for a health plan or its agent to offer a "readily accessible electronic method to be determined…. For identifying the attachment-specific data needed to support a claim adjudication request by any trading partner, and electronic policy access requirements so services requiring additional documentation to adjudicate the claim are easily identifiable (health care claims only)." The CAQH CORE letter indicates that the proposed attachments data content rules for prior authorization and health care claims apply to attachments sent via an X12 (HIPAA) transaction and those sent without using the X12 transaction (non-HIPAA). Please provide your assessment of this proposed operating rule.

NUCC Response:
At this time, none of the NUCC's organization members have completed an impact analysis of the proposed Attachments Health Care Claims Infrastructure and Data Content Rules (vHC.1.0) to provide an assessment of the benefits and costs.

2. Attachments operating rules – general question. HHS has not proposed adoption of a standard for attachments under HIPAA. Please comment on the proposed operating rules for attachments. What should NCVHS consider prior to making any recommendations to HHS regarding operating rules for attachments?

NUCC Response:
The NUCC is very supportive of the adoption of a claim attachment standard and business practices to support a uniform process for electronically submitting additional information needed to support claim adjudication. We believe, however, that it is premature to adopt operating rules prior to the adoption of a standard.

The NUCC appreciates the opportunity to comment on this request for public comment. If you have any questions, please contact me at (202) 789-7489 or nancy.spector@ama-assn.org.

Sincerely,

/s/

Nancy Spector
Chair, National Uniform Claim Committee

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November 28, 2022

National Committee on Vital and Health Statistics

CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002
By email: NCVHSmail@cdc.gov

RE: RFC on X12 and CAQH CORE Proposals

Dear NCVHS Members,

As a background, New York Urology Specialists is a small, independent medical practice providing medical and surgical urological care to patients. We operate in a highly **competitive market**. We differentiate ourselves by offering cost-effective, affordable care enabled by technology and automation whenever possible. Our ability to stay competitive and offer affordable care is contingent on being productive and efficient and on having **low overhead**.

New York Urology Specialists have been active in advocating for the enforcement of HIPAA Administrative Simplification national standards, which play an essential role in our low-operating cost business model and allow us to provide care more efficiently and at a lower cost. National standards that lower the administrative costs of healthcare are an important factor in our ability to stay price competitive, especially when many patients have high deductibles and co-insurance costs. High prices have a significantly detrimental effect on the demand for our services; the demand for our services is fairly elastic. We have a very limited ability to raise prices as a result. Due to high fixed costs and decreasing reimbursement, we need to have at least 80-85% of our appointment calendar filled to break even.

New York Urology Specialists in the past had been a member of WEDI, where we contributed to the development of the **WEDI** REMITTANCE ADVICE & PAYMENT SUBWORKGROUP White Paper, "Best Practices for Health Plans that Sub-Contract Creation of the Remittance Advice" dated September 13, 2022. We also submitted numerous **Briefing Papers to the CMS Office of Burden Reduction** on issues related to HIPAA Administrative Simplification requirements such as "Telecommunication Fees", "Direct vs Indirect Standard Transactions". New York Urology Specialists have filed over 100 valid complaints with the CMS ASETT program related to health plan non-compliance with HIPAA Administrative Simplification requirements

Our comments consist of 2 parts: Part 1 – Comments on the X12 proposal and Part 2: Comments on the CAQH proposal.

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Part 1: Comments on the X12 Proposal

We are writing to comment on the X12 proposal that the current standard is updated from version 5010 to version 8020 for the adopted administrative standard for the health care claims (professional, institutional, and dental) and the remittance advice 835 transactions.

June 7, 2022 letter from X12 to NCVHS, https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf states that X12 has "Added the ability to report remittance information related to **card payments (p-card, debit card, and credit card) to facilitate auto-posting**" to **008020X322** X835 transaction rules.

We are writing to inform NCVHS that New York Urology Specialists is **AGAINST** the adoption of this standard in its current form unless the provision for the addition of the "card payments" to 835 ERA is removed. In summary, there are a number of reasons that the ability to report remittance information related to “card payments" should **NOT** be added to the 835 ERA transaction, which we will explain in great detail below:

1. The X12 standards for 835 transactions are adopted under the HIPAA Act of 1996, Section 1172 (b) REDUCTION OF COSTS. Legally, this act does **not** give CMS authority to add "card payments" to ERA as this proposal **does not satisfy the basic requirement** that it serves to "lower costs."
2. There is no industry consensus that "card payment" information on ERA serves a 'useful' purpose.
3. There are no studies and no industry consensus that adding "card payments" to the 835 ERA transaction fills a "missing" need.
4. Since there is no need or provider demand for 'card payments' to start with, there is no need or demand to autopost 'card payments.'
5. There is near **universal provider rejection of card payments** as an option for standard healthcare payment. If no provider wants 'card payments, there is **no basis or justification to add the ability to 'report remittance information related to card payments.'**
6. Adding card payment information to 835 ERA cannot occur without an act of Congress. The health plan industry cannot use X12 standards to achieve what it could not get Congress to do: allow card payments as a HIPAA standard provider payment option. An illegal or 'extra-legal' payment option cannot be adopted into and be reported in a legal, standard transaction.
7. Should NCVHS recommend the adoption of the X12 835 standard with the inclusion of "card payments" reporting and CMS adopt, New York Urology Specialists has the standing to sue and will protect itself from this costly, illegal, and unwanted standard. We do not have an objection to other aspects of the proposed updates to the X12 835 standard.
8. Currently, adopted standards are not being enforced by CMS Office of Burden Reduction, Division of National Standards – the ASETT Complaint system is based on the novel concept of 'voluntary compliance'. It is fairly pointless to implement standards if they are not enforced and if many counterparties violate the standards.

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9. Our comments on CAQH proposals are below.

We request that X12 / NCVHS / CMS provide published, peer-reviewed, real-world, non-simulated **studies** that sample a sufficiently broad spectrum of healthcare providers, including independent healthcare providers, small healthcare providers, healthcare providers offering services in rural areas, and healthcare providers not owned by or that own a health plan and that **demonstrate how the addition of remittance information related to "card payments" reduce healthcare costs, and make healthcare administration more efficient when no provider wants to accept 'card payments.**

We request that X12 / NCVHS / CMS provide published, peer-reviewed, real-world, non-simulated **studies** that sample a sufficiently broad spectrum of healthcare providers, including independent healthcare providers, small healthcare providers, healthcare providers offering services in rural areas, and healthcare providers not owned by or that own a health plan, and that **demonstrate an 'unmet' demand or need for reporting remittance information related to "card payment" information on 835 ERA transaction.**

We request that X12 / NCVHS / CMS provide published, peer-reviewed, real-world, non-simulated **studies** that sample a sufficiently broad spectrum of healthcare providers, including independent healthcare providers, small healthcare providers, healthcare providers offering services in rural areas, and healthcare providers not owned by or that own a health plan, and that **demonstrate an 'unmet' demand or need for autoposting "card payment" information from 835 ERA transaction when nearly universally in our industry survey providers reject card payments, sometimes unsuccessfully; in no situations are providers' willing' and uncoerced recipients of card payments.**

We want to note that the X12 proposal passed by a very one-sided "health plan" aligned industry participants that are either health plans themselves or highly **dependent** on their business survival on serving health plans. Nearly the entire leadership of the X12 Insurance Subcommittee represents organizations that are listed as either members or affiliates of the "American Health Insurance Plans" – a trade group for health plans.

X12 recommendations cannot be taken without a grain of salt. They require strict scrutiny by NCVHS and CMS for **bias and illegal imposition of costs** on other industry participants, such as healthcare providers who represent 50% of any electronic healthcare transaction but whose voice and votes are severely under-represented on the X12 Insurance Subcommittee and the X12 Board of Directors.

As you are well aware, card payments are universally **opt-out** , and there is **not a single independent healthcare provider that willingly accepts these**. There is absolutely no "demand" in the healthcare industry among healthcare providers for "card payments." In fact, as you are well aware, through prior testimony from the AMA, WEDI, and other organizations to NCVHS, healthcare providers have complained about the **unfair business practices** of sending virtual credit cards by health plans and charging fees for healthcare ACH EFT transactions. It is unclear what the reason is that X12 recommended the addition of 'card payment' information to 835 transactions, given near universal opposition to card payments by healthcare providers to start with.

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X12 has not explained what is the nature of 'consensus' and detailed the vote that led to the recommendation to add 'card payment' remittance information to a standard 835 transaction. X12 has not detailed any studies it performed among independent providers to gauge a need for adding 'card pyment' reporting to 835 transaction.

Healthcare providers are very satisfied with the current healthcare ACH EFT standard. The provider complaints related to ACH EFT originate from (1) the fees that some plans and their affiliates impose on ACH EFT; (2) barriers to enrollment; (3) failure by many banks to provide re-association data in electronic format at an affordable cost; in fact many banks use re-association data as a bargaining or extorsion item and require additional payment beyond what the account holder pays for ACH EFT delivery, to 'see re-association numbers' even as banks hide it in their database.

There are absolutely **no healthcare providers** that do not own a health plan that support the proposal that remittance reporting for "card payments" be added to 835 ERA transactions.

The only provider-side "supporters" of "card" payments are conglomerates that own both health plans and health providers, and profit from card payments. For example, United Healthcare **owns health plans** (UHC, Oxford, etc), owns a **major industry player in issuing and profiting from Card Payments** (Optum Financial and Optum Bank, formerly Vpay), **and owns healthcare providers** (Optum Medical care – CareMount, ProHealth, Riverside Medical Care, WellMed, American Health Network Unity Health Network). Essentially, in this situation, the net effect of "card" payment will be internal-corporate transfer of money while **imposing a real financial cost on competing medical practices** that it does not own. This is **anti-competitive**.

While prior comments to NCVHS included complaints that on top of the injury with costly "opt out" card payments, there is also an insult by not having the ability to autopost, the **solution that healthcare** providers sought was **not** an ability to 'autopost' card payments; the inability to autopost because it is not a standard payment was mentioned in contrast to standard ACH EFT payments, which could be autoposted. Healthcare providers do not want the ability to ‘autopost’ card payments, as most healthcare providers do not want to receive card payments to start with. **When they do get unsolicited card payments, we do not want to autopost them.** Instead we spend an inordinate amount of time and money to “opt-out” from card payments. At most, the inability to autopost is a minor negative characteristic of 'card payments'. **Adding the ability to auto-post does not change the nature of card payments – they are costly and unwanted.** What healthcare providers wanted from CMS was to ban credit card payments, not making them 'less evil.' CMS's unfortunate position is that it is not illegal to send the first payment as a credit card, even while they raise the cost of healthcare relative to paper checks and certainly relative to ACH EFT.

The health plan lobby along with financially dependent contractors that control the X12 Board of Directors is abusing the X12 privilege as a standard-setting body under federal law to achieve **'regulatory capture" of the healthcare payment market** and impose illegal costs on healthcare providers via X12 edict. Extraction of '**economic rent**' is not a legitimate use of standard-setting organization powers.

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Essentially, X12 is assisting some of its members to legitimize **"unfair and deceptive business practices"** through **regulatory capture of standard-setting organizations**. This raises a number of antitrust concerns that have been of interest to the US DOJ. To quote the DOJ: https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-antitrust-division-bernard-barry-nigro-jr-delivers

> What a competitive standard-development process looks like in this context will vary from organization to organization, but there are some commonalities: As set forth in Office of Management and Budget Circular Number A-119, each SDO should value openness, due process, and a desire to reach genuine consensus.[8] In an ideal world, a competitive standard-development **process requires meaningful involvement from a broad range of parties in the industry, with no single interest group dominating in the decision making**. Under these circumstances, the standard reflects a true consensus among the members, and hence the interests of the market as a whole. In contrast, **if a single group of interested persons suppresses minority interests, it may extract rents from the standard-development process — preventing the market and consumers from realizing the full benefits of interoperability, innovation, and safety**.
>
> Accordingly, **the Division may intervene when an industry standard itself limits competition or consumer welfare,** which is more likely when certain groups have undue influence on the standard-development process.

As you are well aware, there is **unanimous opposition** to card payments by independent healthcare providers. Card payments **raise consumer costs** and offer **no meaningful 'value-added' to providers** or consumers. That is why the only way it can exist is through 'opt-out' forced imposition on healthcare providers. In other words, there are **no 'willing buyers' for "card payments" when it comes to standard electronic healthcare payments**.

If there are no willing provider users of card payments, there is no legitimate need to add card payment remittance information to the 835 transaction. You do not need information about something that you do not want to have. It's as simple as that.

Card payments involve more administrative work, including the implementation of additional processes and policies, than check payments or ACH EFT payments. The processing costs are many times more than either check payments or ACH EFT. Card payments do **not** offer greater efficiency, nor do they offer lower costs. In other words, they **cannot be adopted under 'delegated" authority under HIPAA**. There is no legitimate need to report in an 835 ERA an unwanted payment method that is costly, inefficient, and unwanted.

While paper checks are not an adopted standard, they were clearly mentioned in all legislative history as the default payment method from which a move to electronic ACH EFT was legislatively encouraged. Thus it is reasonable to report check payment information. There is **no legal basis for equating the legal status of paper checks to card payments**, which were never considered as a legitimate payment option for standard transactions; card payments were never in wide use for healthcare payments by health plans to providers prior to the adoption of the HIPAA Administrative Simplification requirements. The option of using card payments was never considered to be legitimate

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enough to seek public comments on the issue during the adoption of HIPAA Administrative Simplification standards. There is no legitimate historical justification for adding card payment reporting to 835 ERA transaction.

On 11/10/2022, Ms. Cindy Leonard, the COO of Arizona Advanced Surgery LLC in Phoenix, Arizona, an independent 46-surgeon practice providing cost-effective surgery services, wrote the following to Mr. Daniel Kalwa, the Acting Director of the Division of National Standards at the Office of Burden Reduction referencing virtual credit card fees and EFT fees:

> "It is just insult to injury to see these fees especially as more payers are moving to these clearing houses – would love to know who is the benefactor of these fees. We are attempting to negotiate our contracts for additional 3% just to offset these fees, the payers claim no clue about them. We are happy to teach them."

Clearly, the costs of credit card payments cannot be absorbed by physician practices and are primarily passed to patients via higher prices.

Insofar as X12 rules are incorporated into federal law, the net result of remittance card reporting is to 'legitimize' card payments, which are currently not adopted as a 'standard EFT" transaction.

The health-plan aligned majority at X12, which represents only 50% of each 835 transaction is attempting 'force' card payments via **improper rulemaking** without an Act of Congress and to 'federalize' a transaction that has **universal opposition by the healthcare provider industry**. The nature of card transactions is to increase administrative burden, administrative costs, and transaction costs to healthcare providers. This **violates** the HIPAA administrative Simplification Requirements by **raising the cost of healthcare rather than lowering it**; a violation of federal law.

CMS does **not** have the **authority** under HIPAA to adopt standards that do not lower healthcare costs (42 US Code § 1320d–1 (b)). Neither card payments themselves nor reporting of card payment information on 835 transaction lower healthcare costs. Certainly, to report a card transaction information on 835 ERA, there has to be an associated card transaction; CMS has to look at them as a 'package' that raises the cost of healthcare and is not eligible to be added to any standard adopted under HIPAA.

It is critical to remember the intended goal of the legislation, HIPAA Act of 1996, Section 1172 (b) REDUCTION OF COSTS:

> To amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to **simplify the administration of health insurance**, and for other purposes.

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> 42 US Code § 1320d–1 **(b) REDUCTION OF COSTS.**—Any standard adopted under this part shall be consistent with the objective of **reducing the administrative costs** of providing and paying for health care. (previously classified as Section 1172)
>
> · Congressional intent was made clear again in section (2)(i)the different standard will **substantially reduce administrative costs** to health care providers and health plans compared to the alternatives;

The proposed allowance to include card payments information on 835 ERA transactions is **not consistent with the plain text of the law** , as card payments universally raise transaction costs, increase administrative costs and raise the cost of healthcare, even compared to the baseline historical option that the HIPAA standards sought to eliminate, which are paper checks. The mere addition of card payment information to 835 also raises costs without any quantifiable benefit to healthcare providers.

There is no mention of card payments in the HIPAA Act of 1996, Section 1172 (b) REDUCTION OF COSTS. HHS/CMS has **no authority to adopt regulations** that raise the cost of healthcare and make the administration of healthcare more complex. As you are aware, the X12 rule adoption by CMS/HHS relies on the delegation of congressional authority under 42 US Code § 1320d.

In the final interim rules adopting the ACH EFT as a standard transaction, section 5. EFT Conducted Outside the ACH Network states:

> The **health care EFT standards adopted in this interim final rule** with comment period do **not** apply to health care claim payments made via EFT outside of the ACH Network. Health plans are not required to send health care EFT through the ACH Network. They may decide, for instance, to transmit a health care EFT via Fedwire or via a payment card network . This interim final rule with comment period neither prohibits nor adopts any standards for health care EFT (as defined in § 162.1601(a)) transmitted outside of the ACH Network. When health plans do, however, send health care EFT through the ACH Network, they must do so using the health care EFT standards adopted herein.

Clearly, card payments are not 'legally' adopted as a healthcare EFT standard; thus, including them in a legally adopted standard transaction designed to report information about adopted standards "ACH EFT" and 835 ERA contents is not appropriate, **arbitrary, without precedent, a major change in policy**, and not legal. In times of poor reimbursement and rampant inflation, many physicians would rather get paid in 'chickens' or cryptocurrency than by virtual credit cards. It is not clear why X12 decided to add 'card payments' but not 'dogecoin' and 'chickens' to 835 ERA. We are certain that if X12 is to perform a broad-based, scientifically valid study, more medical practices will choose dogecoin or chickens than virtual credit card payments. New York Urology Specialists routinely offers free lunches to its staff. We would be more than willing to accept Costco Rotisserie Chicken or frozen Tyson chickens as payment for our services. But we will not accept card payments from health plans.

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The addition of this **highly contentious standard** to X12 835 ERA rules raises **antitrust** concerns about X12 actions.

There is a tremendous disagreement with this section of X12 rulemaking.

New York Urology Specialists request that X12/NCVHS/CMS **remove** the section allowing card payments on remittance advice from 008020X322 immediately, as this has a significant **detrimental effect** on New York Urology Specialists and other healthcare providers.

There is **no legitimate industry demand or need** for this, and it is **universally opposed by independent healthcare providers that are not owned by or own health plans**. Legally, it cannot be adopted as this addition is **not authorized** under the governing law, and HHS/CMS has no delegated authority to add it to a federal standard.

On 9/29/2022, the US Government itself, as represented by the **Department of Veterans Affairs** (Ms. Stacy Ekis – VHA FOIA Officer), wrote to Dr. Alex Shteynshlyuger:

> "The VA, through the Department of Treasury, does not receive, and **will not accept**, credit cards, virtual credit and debit cards for health care third party payer payments."

Clearly, there is **no "demand" or "need" for "card payments" information on 835** ERA as far as the **US Government is concerned**. The US government simply will not accept card payments and thus addition of card information to the ERA would serve no purpose. In other words, no matter how small the cost is, the cost-benefit ratio for the addition of 'card payment' information to the 835 ERA is infinitely 'unfavorable' from the perspective of the US government, as the denominator "benefit" is always zero.

See attached 9/23/2014 **letter from NCVHS to CMS**: "Re: Findings from the June 2014 NCVHS Hearing on Virtual Credit Cards and Credit Card Use" which lists the following problems with card payments, among others:

> "Added costs to providers, in the form of high transaction fees, with the consequent impact of reduced reimbursement.
> • Lack of informed choices and use of coercive practices by some to force VCC acceptance with no or difficult opt-in and opt-out options.
> • Inefficiency with the use of VCCs related to:
> o Staff time required to manually key in credit card information.
> o Additional time required to resolve entry errors.
> o Current electronic remittance advice standard being used by the industry not able to carry credit card information necessitating manual reconciling processes. "

See AMA 6/10/2014 Testimony to NCVHS: "Update: Virtual Credit Cards" – attached:

- 96% received virtual credit card payments without prior consent/notification (opt-out model)
- Interchange fees (up to 5%)

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NACHA 12/7/2018 comments to NCVHS:

> In many instances, NACHA has heard that some providers have experienced difficulties in enrolling in EFT; that payers or their vendors are charging fees to use the standard transaction; or **that they are paid involuntarily by virtual credit cards.**

MGMA 4/2/2018 letter to CMS is attached. In addition, excerpts testifying to unfair business practices related to card payments are below:

https://www.mgma.com/getattachment/b5fbc389-0f0c-4778-a8b6-1292956c80f7/MGMA-ePayments-Letter-to-Administrator-Verma-Final.pdf.aspx?lang=en-US&ext=.pdf

> "In a VCC payment, a health plan or its payment vendor sends a single-use credit card number to a provider by mail, fax, or email which the provider must then manually enter. This is known as a "virtual" card because a physical credit card is never created or presented to the provider. For these authorizations, providers are required to pay credit card interchange fees, typically ranging from 3 to 5% of the value of the payment.
>
> Not only are these fees unwarranted and unfair, but in the vast majority of cases, the practice did not choose this payment method. Opting out of VCCs and receiving payments via EFT from a reluctant payer or vendor is a manual, burdensome process that further delays payment. Even more disconcerting, the use of VCCs is contrary to the agency's stated priority of putting "patients over paperwork" and reducing physician administrative burden and cost. Importantly, VCCs do not meet the national EFT standard established by the Department of Health and Human Services (HHS) in the 2012 interim final regulation, nor do they support the Health Information Portability and Accountability Act (HIPAA) standard transaction for Electronic Remittance Advice (ERA), resulting in additional manual processing for practices along with significant associated costs
>
> Other unfair practices employed by health plans and payment vendors to discourage the adoption of EFT by providers include:
>
> Automatic opt-in for virtual card payments, forcing the provider to opt-out to receive payment by another method, including EFT;
> • Informing providers wanting to opt out of VCC payments that it takes 60 days or more to reissue the claims payment as either a check or ACH EFT payment, thus negatively impacting business cash flow;
> • Creating unnecessarily burdensome processes for opting out of VCC payments, such as not including payer contact information when issuing the VCC number;
> **Creating unnecessarily burdensome EFT enrollment processes**, such as refusing to permit enrolling all physicians in a group at the same time, to deter use of the EFT standard transaction;
> • Communicating inaccuracies about the lack of safety of banking information used in EFT transactions;
> • **Misrepresenting card system rules** such as informing providers that they must accept VCCs for claims payment if they accept patient credit cards; and

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• **Requiring VCC payments as part of provider contracts** by telling providers they are exempt from the requirement or that a VCC payment meets the definition of "electronic payment.".

Boost Payment Solutions also submitted comments to NCVHS on 6/6/2014. The only thing it did not mention in its comments is what it mentions on its website as a selling point to its clients: "Grow Interchange Revenue: Increase interchange revenue through incremental commercial card spend."

Boost Payment solution writes: "Getting input from all stakeholders will yield the most sound policy recommendations."

We request that CMS, X12 and NCVHS explain the role of "Boost Payments" in the healthcare industry as a stakeholder. The only role it may play, as we understand it, is to impose unnecessary costs on the healthcare industry and to extract profits **without** providing any value to patients or medical practices.

Free markets require a 'meeting of minds" for a buyer to purchase a product. Unfortunately, there is **no 'meeting of minds' when card payments are opt-out. To add insult to injury,** after opting out, healthcare providers are "automatically re-enrolled" – see attached call transcript with Echo Health, a clearing house for Meritain Health plan, that sends unwanted 'opt-out' virtual credit cards. Echo Health is a business partner of United Healthcare/Optum, Change Healthcare, and PNC bank, big industry players in sending Card payments as payment for healthcare services to healthcare providers. Incidentally, all 3 are well-represented on the X12N- insurance subcommittee. (Notarized **Transcript of Phone Conversation on 8/12/2019 between Echo Health and Dr. Alex Shteynshlyuger: ERA Delivery and ERA Fees; EFT Fees. (Part 2) - attached)**

Dr. Alex Shteynshlyuger: And if I don't choose MedPay, then what's the next payment method?

Angie – ECHO Health Supervisor: After that would just be a regular paper [0:10:00] check.

Dr. Alex Shteynshlyuger: Paper check. Now, did I previously opt out of a virtual credit card?

Angie – ECHO Health Supervisor: I'm not saying that you opted out for Meritain. That's what I have pulled up here. I'm showing that you're currently receiving Meritain virtual cards. 6 of 9: Echo Health Call Transcript – Dr. Alex Shteynshlyuger - 8/12/2019

Dr. Alex Shteynshlyuger: Yeah, we did it – this is how it works, when I enroll in EFT, **I also opted out of virtual credit cards and I'm still getting virtual credit cards. So the question is why**?

Angie – ECHO Health Supervisor: Let me take a look at your opt-out history [0:10:30] for all payers to see if I can see what happened.

Dr. Alex Shteynshlyuger: That would be good.

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Angie – ECHO Health Supervisor: Okay. I think I see what's happening here. **We have more than one virtual card offering. And you received card ID two which is our second card offering [0:11:00] that's offered 300 days after the initial opt-out of our first card offering.**

Dr. Alex Shteynshlyuger: I'm sorry, how does it work? Card ID two, what does it do?

Angie – ECHO Health Supervisor: **So we have more than one card offering, the card offering that you received is our secondary card offering and it's offered to you 300 days after your initial opt-out.**
Dr. Alex Shteynshlyuger: **So after I opt out of card ID one, 300 days after; I'm automatically enrolled in card ID two, right?**

Angie – ECHO Health Supervisor: [0:11:30] **Correct.**

Dr. Alex Shteynshlyuger: How many different cards IDs do you have?

Angie – ECHO Health Supervisor: We have three.

As the NCVHS committee is well aware, from May 6, 2015 testimony by Visa Inc to NCVHS, Visa did **not** list a **"lower cost"** as one of the "purported" benefits of card payments, because **card payments incur higher costs than a standard healthcare ACH EFT transaction or a paper check**. The high costs of card payment is what makes them so attractive to VISA Inc. Certainly, there is no Congressional authorization for CMS to fuel the profits of VISA INC or Mastercard (attached). As VISA testimony acknowledges, "card" payments are not 'legal' standard healthcare electronic payment method under HIPPAA. Something that is not "legal" is "illegal." In this context, "Exempt" is a synonym for "illegal". It is audacious for X12 to propose adding information about an 'illegal' transaction to a 'standard' legal 835 ERA transaction. Visa Inc also did not provide a list of independent healthcare providers that willingly accept card payments or 'happy customer' provider testimony in their comments. That is perhaps because there are no providers willing to accept card payments.

As the NCVHS is well aware, **no standard can be adopted under HIPAA unless it has the effect to lower the costs of healthcare**. There are NO situations where a card payment is less expensive than the standard ACH EFT transaction, the current standard. Thus, card payments cannot legally be adopted as ‘a legal” EFT payment method under HIPAA as they cannot be demonstrated to lower costs, the fundamental **litmus test** to qualify a transaction for adoption under HIPAA.

When Visa Inc mentions that ‘card payments’ are exempt under HIPAA; exempt in this situation is a synonym to ‘illegal’, as card payments **cannot** be a legal standard for EFT payment under HIPAA, as noted above.

The proposal to add card payment information to 835 ERA does **not** meet the **requirements** that they are based on '**consensus-based review and evaluation process**." The correct standard to use is that the transaction has 2 users: senders and receivers. Healthcare providers is 50% of each transaction as a user – thus **any "consensus" must allow at least 50% representation of healthcare providers**.

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When >95% of healthcare providers are angrily **opposed to card payments** and have no need or desire for having card payments added to 835 ERA transactions, it is **mathematically impossible to claim that there is a "consensus"** or even a legitimate "majority" vote on this issue. See below for BBB complaints against providers of card payments (Zelis and ECHO Health).

> "Standards-setting organizations or the Designated Standards Maintenance Organization (DSMO) bring forward new versions of the adopted standards to NCVHS after completion of a consensus-based review and evaluation process. Under Section 1173(3)(B), the organizations with whom a DSMO should consult for input include the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (ADA)." CMS.

1. **Costs**. We analyzed the cost of updating our processes to support a new standard, to incorporate an un-wanted and un-needed new standard, and incorporation of information about 'card payments' to 835 ERA transaction, that we do not foresee ever wanting to support or use voluntarily. We have consulted with a group of national medical practices which have been forcibly slammed with card payments (virtual credit cards, etc) by health plans in violation of federal standards. Not a single medical practice could foresee a situation where card payments offer any benefits, and there is no situation where any medical practice would voluntarily "opt-in" to receive card payments. Thus there are **no foreseeable benefits** from adding 'card payments' to 835 transactions. **Implementation costs** are estimated to be significant.

2. **Operational impacts. After a thorough analysis, we could not identify a positive operational impact on our practice from the addition of 'card payment' information to 835 ERA transactions. The impact is strongly negative.**
    - **a.** Adoption of the proposal to add card payments as a payment option to 835 ERA would require a significant expenditure of resources by our practice to retrain our billing staff to recognize this situation; due to the high turnover of payment poster employees, we expect it to be a significant recurrent annual cost. It would require our vendors to update programming to add this option, and the costs are passed directly to us through subscription fees; in addition, given limited resources, implementation of this standard distracts our vendor focus from more productive uses of programming resources to make our practice more efficient and more profitable. There is a **significant material 'opportunity' cost to implementing an un-wanted and un-needed 'standard' update**.
    - b. We estimate an **annual cost to our practice** to be in the range of $8,500-12,500 per year in direct and indirect costs.
    - c. We would need to implement additional reconciliation steps between ERA and our typical management of unwanted card payments – from which we opt out.
    - d. We propose that instead, CMS forbid opt-out card payments, which is within CMS power under HIPAA as the goal is to 'lower costs' and 'decrease administrative burdens" and what it should have done long time ago. Rent extraction from the healthcare industry is not a constitutionally protected right of Visa, Mastercard, Zelis Payments, Echo Health, Optum Vpay, or other parasitic organizations.

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General: New York Urology Specialists supports HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards **without the inclusion of support for "card transactions" as a payment method**.

We cannot support the X12 835 8020, in its current form, with the inclusion of the ability to report remittance information related to "Card transaction."

Problem with the Proposal to include "Card Payment" in Remittance Advice to Facilitate Autoposting Card Payments:

The rule as proposed is arbitrary and capricious, and is without legal support.

Card payments are not received 'whole'. Our card processors deduct merchant fees from deposits. The actual reconciliation can only occur once the merchant processing fees are deducted from the card payment, as merchant fee varies by the type of the transaction (card present, card not present, regulated debit, exempt debit, credit, corporate credit card, gift card, ec).

Even if we were to choose to accept a card payment as a result of being exhausted of trying to opt-out and being re-enrolled in card payments against our will, card information that is proposed to be included by X12 in 835 standards **would not be helpful or useful** to us as it will NOT help us with autoposting payments. In fact, it will create additional problems and would require additional expenditures to either manually review every 835 ERA to mark those that contain 'card payments' for separate manual processing or would require us to add additional programming to put 835 ERA with 'card payments' into a separate process that disallows autoposting.

We would **not** choose to autopost card payments, and neither would most other providers:

1. We would rather decline card payment and request a paper check. Autoposting would create a wrong entry. It would require extra effort for us to track the card payment itself; decline and request a paper check. At the same time would need to track what potentially could be an **inadvertent** autoposting of card payment that was **rejected** by us.
2. Many providers choose to treat merchant fees associated with unwanted card payments and EFT fees separately and bill them to the patient. The proposed X12 standard does not allow autoposting the card processing costs separately as it does not separate the gross amount into (1) net receipt by the practice after card processing fee and (2) the card processing fee / merchant processing fee itself. Typically, we would only post the 'net' amount we receive from health plan via card payment and the balance attributable to the 'card processing' fees would remain as a patient liability. Alternatively, some practices charge fixed fees to account for card processing. It is not possible to autopost such fees as the X12 proposal does not account for them.

There are additional barriers to autoposting 'card payments' based on the current X12 prooposal:

- Would 'card payment" information in remittance advice 835 transaction include the actual merchant processing fee accounting to allow practices that choose to pass the fee to the patient to properly assign patient responsibility?

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- In order to reconcile payments and to correctly attribute the merchant processing fee in accounting systems, additional information is necessary to auto-post payments, which the X12 proposal does not include.

- Does the card payment information on 835 provides information on the type of card payment that was sent: was it a regulated covered debit card transaction or an exempt debit card transaction? Corporate credit card, rewards credit card transaction? These carry vastly different interchange and merchant processing fees. This information would be necessary to reconcile payments and to comply with generally accepted accounting principles (GAAP). GAAP is the basis of 835 ERA, as X12 acknowledges. In fact, X12 rules require that each service line is 'balanced'. It would be arbitrary and capricious for X12 to propose an addition to the 835 ERA transaction that cannot be reconciled during auto-posting because adequate information is not included.

- Does the card payment information on 835 provide information on the type of card transaction triggered by the use of 'card payment': in-person card transaction or 'card-not-present' transaction? These carry vastly different interchange and merchant processing fees.

- Without this information, a healthcare provider would not be able to appropriately calculate the merchant fee and attribute it properly in the patient account to 'card fees' as opposed to 'patient care revenue' during auto-posting. Thus the transaction would have to be marked as 'exception' and would not be auto-posted, which eliminates the major purported benefit of including card payment remittance information in the 835 transaction.

- For a practice that generates $1 million in revenue per provider, a difference of 1% is $10,000 extra in merchant processing fees. If a covered debit card transaction costs $0.23 (0.23% for $100) vs 2% for in-person card vs 2.8% for 'card not present", these are meaningful differences. Even a 0.5% difference would result in a $5,000 difference in merchant processing fees – substantial amounts for any medical practice.

The proposed rule has missing calculations on cost-benefit analysis.

To accurately determine the costs and the benefits of the proposal, CMS must clarify:

1. What percent of independent medical practices **willingly** accept card payments?
2. What benefits do medical practices derive from card payments? If there are no net benefits from card payments to medical practices, it is questionable how can the inclusion of information about such payments be "net" beneficial to providers?
3. If only a small percent of providers willingly accept card payments, the financial burden of implementing the proposal to include card payment information on 835 transactions may not be justified.
4. What percent of card payments are issued as 'opt-in" payments vs "opt-out" payments?
5. What percent of independent medical practices decline "opt-out" card payments when they receive them against their will? Providers that decline opt-out card payments would not benefit from having card payment information included in 835 transactions.

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6. How many provider contacts occur yearly to health plans and their business associates to opt-out from card payments and request that a paper check replaces an unwanted card payment? What is the net cost of these contacts to providers? Health plans?
7. What percent of all "providers" decline opt-out card payments?
8. What is the cost of each opt-out, including the cost of contacting the health plan on multiple occasions, waiting for 45 min on hold; not receiving the check, and needing to contact the payer again (as demonstrated in the attached BBB complaints against ECHO Health and Zelis).
9. What is the cost of processing a check payment vs processing a card payment?
10. What is the cost of autoposting a check payment or EFT payment on an 835 ERA vs **manual processing associated** with 835 ERA information of card payment that the practice does not want to autopost as the provider declined to accept card payment and requested that a check is sent instead?
11. What are the net financial benefit of including information in an 835 ERA transaction about unwanted card payments to an average small medical practice? This calculation would require the facts mentioned above: percent of providers willingly accept card payments from health plans vs the cost to those that decline and request paper checks. What percent of providers would autopost card payments vs the percent that would choose to manually process 835 transactions as an 'exception' in order to post the payment according to GAAP, as the full payment was not received and the merchant fees need to stay on the patient's account as a patient liability.

Without providing this information, **CMS cannot accurately compute the costs as required in its regulatory impact analysis**, making its determination that the benefits outweigh the costs "arbitrary" and "capricious".

CMS previously wrote that it could not obtain information about card payments and EFT fees. See attached. It is not clear **how CMS can decide that including "card payment" information on 835 ERA does not increase costs** if it acknowledged that it has no information on card payments. See "Division of National Standards Concept Paper Fees in Excess of Costs for Normal Telecommunications 07/1/19" attached:

> "DNS has been unable to obtain any clarity with respect to what is actually being charged by whom and for what services. We do not have access to the data necessary to analyze exactly where these fees originate and whether or not they are in keeping with the costs of conducting business. We have attempted to obtain this data via our existing contracts with Gartner and MITRE, but neither can obtain the necessary data available to assist us in the analysis. At one point the WEDI offered to take up this task with its membership, however, upon further investigation, advised us that they would not be able to proceed. The NACHA data is limited and does not address payments made outside the ACHor via VCC, nor does it address other types of standard transactions. Lastly, even data supplied to us by provider organizations, such as the AMA and the MGMA, are not complete or conclusive and do not clearly identify charges andtheir sources."

12 CFR part 235 (which implements section 920 of the Electronic Fund Transfer Act) and the Dodd-Frank Act regulate debit card fees, which are significantly less costly than credit cards, in particular, covered debit card transactions are less costly than credit card transactions, but even these are more expensive than paper checks and ACH EFT.
https://www.federalreserve.gov/paymentsystems/regii-interchange-fee-standards.htm

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The **FTC** is concerned about unfair business practices by card issues in routing transactions. This is another issue in addition to unfair business practices of sending "opt-out" card payments instead of "opt-in".
https://www.ftc.gov/news-events/news/press-releases/2021/08/ftc-urges-federal-reserve-board-require-debit-card-gatekeepers-compete-fairly

We request that CMS / X12 explain what justifies including card payments tainted by unfair business practices into national standards. The governing law, HIPAA is designed to: to combat waste, fraud, and abuse in health insurance and health care delivery. CMS cannot include into a national standard a transaction that is tainted by waste, abuse, and unfair business practices.

> To amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery

To better inform NCVHS and CMS, we include a sampling of publicly accessible provider feedback on card payments, which should inform HNVHS that **no independent healthcare provider wants card payments,** and as a result, no independent provider has a need for card payment information on 835 ERA.

BBB complaints against providers of card payments (Zelis and Echo Health) are "gruesome." Sample examples are below (full printouts are attached); they can be publicly viewed at bbb.org.

We request that X12 / NCVHS / CMS provides at least an equivalent number of positive experiences from independent healthcare providers who are 'in love' with getting virtual credit cards, and the only thing they want more than a card payment is the inclusion of card remittance advice on 835 ERA.

BBB Complaints against Zelis Payments 570 Carillon Pkwy STE 500 Saint Petersburg, FL 33716-1343:

> Initial Complaint
>
> 10/11/2022
>
> **Complaint Type:**
>
> Problems with Product/Service
>
> **Status:**
>
> Resolved
>
> More info
>
> Unfortunately, it appears filing a complaint with the BBB is the only way to opt out of these virtual cards. You will wait on hold for over an hour - our staff has done this more times than our

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payroll can allow - sadly it is usually for an $18.00 check. No option to opt out online - you have to actually sit on hold in their que. Then their representative rudely gives you push back for wanting out of the cards. IF you want to get EFT, there are fees with this as well (almost equivalent to CC Merchant fees) - which is not disclosed until you have completed a crapload of data entry for their enrollment documents. We want a paper check mailed to us. Period. Why do they make this so miserable? Hopefully the receive enough complaints to make a more streamlined option. They should take a ****** from ECHO QuicRemit - easy opt out online and takes 30 seconds. These insurance carriers have no clue how poorly Zelis reflects upon the insurance carrier.

Initial Complaint

09/21/2022

Complaint Type:

Billing/Collection Issues

Status:

Answered

More info

My office begin receiving virtual credit card payments from insurance companies that we have never signed up for. I first thought that's how the insurance companies were paying claims until I looked at our CC fees. I called the insurance companies to receive paper checks and at that point was told I needed to call Zelis and opt out of the virtual CC payments. I have called for the past 2 months trying to opt out and every time a rep says a customer care rep will call us and assist with opting out but we never receive a call. We pay fees for each transaction and how is this legal!!!!! How did they receive our information to just intercept OUR payments and take some for themselves without OUR permission!!!!! Asked for a copy of the signed agreement between our office and Zelis and was hung up on. They are PURE THEIVES!!!!!!

Initial Complaint

08/30/2022

Complaint Type:

Problems with Product/Service

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Status:

Answered

More info

I,ve been trying to contact Zelis CS for more then a week. like everybody in here are in disbelieve about about the lack of disclosure and the way Zelis is doing business with providers. I just talked to ******** from their call center, she gave me the name of her supervisor ******. I'm hoping this time I can get solutions to this problem with Zelis. No supervisor we can talk to, I was told that it can take a months to get them on the phone!! We are requesting the following through this outlet since looks like Zelis is more diligent to responding here!1- We are opting-out from V-payments 2- We are opting out from ACH with fees.3- If we can't have EFT without a fees then and Only then#4 (I will need to get an explanation of why this option is not available since all payers are doing that at no cost.4- Paper check will be our prefer payment method. Our company is loosing money and can't allowed under my watch to witness this everyday, this is simply so wrong!

Initial Complaint

08/30/2022

Complaint Type:

Problems with Product/Service

Status:

Resolved

More info

Our dental office has been receiving multiple virtual credit card payments that we have never opted into or authorized. I have tried contacting Zelis multiple times and I am unable to get through to anyone. I would like for all of the virtual credit cards to be re-issued as checks, and to be opted out of all future virtual card payments.

Google Reviews (Echo Health Inc. 810 Sharon Dr, Westlake, OH):

Linda Kelsey

1 review

6 months ago

As another reviewer noted, one can call their customer service multiple times and still not get anywhere. I do not accept credit cards and at least 5 calls, including insisting on talking to a supervisor, has not gotten me any success at opting out. Once after 20+ minutes they routed me right back to where I originally started. Horrid company!

Eli L

4 reviews·1 photo

a year ago

If I could give this company negative stars I would. I have been on hold for 4 hours and 21 minutes. Sleazy company practice.

Eileen Starr

13 reviews·5 photos

5 months ago

Initially good, then became increasingly frustrating. My practice was erroneously placed in an "all payor" enrollment versus a single payor and I was being charged a fee. When I sent an email about this, they were prompt, but promptly took away all of my electronic payments and unenrolled me. So, now I'm not getting paid. Thanks a lot. 'preciate it.

BBB Complaints against ECHO Health 810 Sharon Dr Westlake, OH 44145-1521:

Initial Complaint

10/10/2022

Complaint Type:

Billing/Collection Issues

Status:

Resolved

More info

I have opted out from virtual credit card payments from Echo Health numerous times! and now I am receiving VCC once again! When I have called in the past the customer service reps at Echo pressure me as to why I do not want VCC payments. I get charged a fee for processing credit card transactions therefore not getting the full insurance reimbursement for the services

rendered. It is a headache to be going online everytime to cancel the VCC payment and request a live check! When I OPT OUT it means OPT OUT! I never authorized any virtual credit card payments for my business!

Initial Complaint

09/21/2022

Complaint Type:

Billing/Collection Issues

Status:

Answered

More info

I have been a counselor in private practice and complete my own billing. Now, against my will and without my request I am receiving virtual credit cards for payment in place of paper checks. Echo Health is not giving providers the option to opt out, and instead we have to go to their website and cancel every virtual credit card and then request a paper check which adds several more weeks to payment time. The inability to opt out entirely and just receive paper checks is unacceptable. I have spent multiple hours with different customer service agents and as a practitioner I do not have the time to sit on the phone for hours on end dealing with errors not caused by me. To add salt to the wound, they provided the wrong address and now I have to independently contact each insurance agency with a new W9 with an updated address. This is beyond frustrating. I have been in my field for many years and this is singlehandedly the worst, mindless thing I have encountered from a business.

Initial Complaint

08/17/2022

Complaint Type:

Billing/Collection Issues

Status:

Resolved

More info

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Our office has never opted-in for virtual credit card payments from Echo Health. They simply appear on our fax machine. I have attempted to opt-out of virtual credit card payments from Echo Health on multiple occasions. The wait time on hold is completely unacceptable, and I am told I have to call back on each occurrence. As a busy dental office, there is not enough time in a day to devote to their required opt-out procedures. They require our TIN for each call. Our TIN, and our desire to opt-out, should suffice for opting out of ALL virtual credit card payments.

Initial Complaint

06/20/2022

Complaint Type:

Problems with Product/Service

Status:

Answered

More info

We have repeatedly called Echo Health from the dental office to opt out of Virtual Card payment on our patients. We have been told they will indicate we are not wanting to receive virtual payments but rather hard copy checks but we continue to get these virtual card payments. What we have been doing is having to wait on payment when we have to call on each individual patient to cancel the virtual payment.

Initial Complaint

05/17/2022

Complaint Type:

Billing/Collection Issues

Status:

Answered

More info

We were never given an option to "opt in" for electronic credit card payments rather than paper checks but we continue to receive payments for insurance claims in this manner. Every time I get one I have to go online to their site and enter all of the information to get it canceled and then our office has to wait up to an additional 4 weeks to receive our payment in the form of a

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paper check. In order to "opt out" I am expected to download a spreadsheet and fill it our with each payment. This is all very time consuming and frustrating.

Initial Complaint

04/11/2022

Complaint Type:

Problems with Product/Service

Status:

Resolved

More info

This company profits by having providers select virtual payments or EFT payments. I believe this company is intentionally making their paper remittances (checks) difficult to read for electronic deposit banking apps in order to encourage more people to sign up for their paid services. I have consistently had difficulty depositing their checks electronically and they are the only company that uses such small font sizes and unnecessary asterixis before the payment amount. I suggest that this amount to bad business practices and requires correction.

Enforcement of Adopted Standards, including 835 ERA transaction and ACH EFT

Currently, adopted standards are not being enforced by the CMS Office of Burden Reduction, Division of National Standards – the ASETT Complaint system is based on the novel concept of '**voluntary compliance**'. Just like in a 'fairy tale', a health plan can close the complaint against it by simply stating that it is compliant – **CMS does not require any meaningful verification or an audit**. It is fairly pointless to implement standards if they are not enforced and if many counterparties violate the standards without repercussions. CMS data shows that millions of violations occur every day. The benefits of 'standards' are thus over-estimated given how much non-compliance and violations of standards occur – each of which imposes costs on counterparties and diminishes the utility derived from 'standard transactions."

We have submitted numerous ASETT complaints to the CMS Division of National Standards (>100 to date); few of them have been resolved, with many being open for >5 years. As X12 is aware, we have requested "formal" requests for interpretation from X12 for a number of questions and submitted them to CMS Office of Burden Reduction, Division of National Standards (DNS). Nonetheless, CMS DNS

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chose not to enforce violations by health plans even when X12 formal RFI (Request of Interpretation) showing non-compliance was submitted to CMS. The American Medical Association sent a letter to CMS complaining about the lack of meaningful enforcement of HIPAA Administrative Requirements against health plans.

CMS own data from the "Compliance Review Program" shows that for the 8 plans that completed the audit, 8 plans were found to have made 43 violations of 835 ERA transactions alone, >100% per transaction error rate (43/8 = more than 5 errors per 835 transaction per health plan)! CMS compliance review methodology is known to miss 90% of violations. (see attached):

https://www.cms.gov/files/document/admin-simp-cr-findings-report-2021-07-14.pdf

Part 2: Comments on the CAQH Proposal:

CAQH CORE:

CAQH CORE Infrastructure Rules

We believe that 90% availability per calendar week is a **very low threshold** in 2022. No other industry would accept such a threshold for the availability of critical IT infrastructure. We are not aware of any transaction in the Banking sector that has less than **95% or 99% availability** requirement. Certainly, it is hard to argue that the Banking industry is more critical than the Healthcare industry.

Similarly, the response time threshold of **20 seconds is too low**. Such a low threshold has **not** been used in any commercial processes outside healthcare since the 1980's. It is time to expect more in healthcare. Time is money. Twenty seconds per transaction adds up across hundreds of millions of transactions that occur daily, leading to **decreased productivity, increased healthcare costs, and a drag on the GDP**. The response time should be brought up to less than 2-5 seconds. In addition, the unacceptably low threshold of 90% does not serve the healthcare industry in 2022. It may have been an acceptable standard in 1980's-early 1990s. Not in 2022.

CAQH CORE rules for filing complaints for non-compliance with adopted standards.

CAQH CORE **complaint resolution system** is so stacked against small companies such as New York Urology Specialists as to be unavailable as an option. The CAQH CORE rules require a certain minimal number of non-compliance occurrences within a short period of time to 'qualify' to file a complaint.

It is virtually **impossible for a small provider to fulfill the violation frequency requirements of CAQH complaint rules** unless the complaint (1) involves a pervasive

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problem that occurs with nearly every claim, **AND** (2) involves one of the 4 major insurers: CIGNA, AETNA, UHC, or BCBS. For example, if a certain health plan violates a transaction requirement for one transaction/one CPT code and that health plan has a 10% market share, hundreds of same-type surgeries need to be performed in a short period of 1-3 months to qualify. Because a surgeon does many different surgeries, even if that particular surgery is 10% of the surgeon's surgeries, the surgeon has to do 300 surgeries just to get 3 transactions of the same type from the same plan. A typical busy surgeon may do less than that in a year, especially if it's a major surgery. Many health plans have less than 10% market share, and many surgeries are less common than 10% of the surgeon's volume. Thus to satisfy CAQH requirements, the physician group has to have at least 50 physicians billing the same CPT code, which excludes any smaller group from filing complaints.

Updates to Federally Mandated Eligibility & Benefits Data Content Rule

In the current form, an Eligibility transaction has minimal value if a practice is out-of-network with the health plan. The copay/coinsurance and deductible information do not provide sufficient information to inform a prospective patient about the cost of the visit.

We request that CAQH/CMS/NCVHS adds the requirement that health plans include information about the **contractual fee schedule rate** that is applicable to the out-of-network visit based on the patient's plan Summary Plan Description (SPD). In this situation, the contractual fee schedule refers to the amount that the plan is legally or contractually obligated to pay for the patient's care based on the patient's coverage contract. In the absence of this information, we are forced to call health plans in order to be able to quote patients their responsibility vs what the health plan would pay. Alternatively, we are forced to collect the entire amount from the patient, which is detrimental to **health equity** as patients who cannot afford to pay full cost would not have access to care even if they have contractual coverage that may cover the majority of the cost. Transparency is critical at the point of care. This information also facilitates health equity as it provides information to patients and protects them from surprise charges (often happens if a health plan's allowable amount is much less than expected, such as a plan that pays based on 70% of Medicare instead of the Usual and Customary charges.

CAQH Phase III CORE 380 EFT Enrollment Data Rule Maximum elements

1. **The maximum data elements requirement is meaningless if a health plan can just require random information such as check # as a condition of enrollment 'outside' the 'maximum enrollment data requirement' and still be compliant.**

2. As per CAQH: "The EFT/ERA enrollment data rules specify that a health plan may determine the actual electronic method to be used for enrollment."

Health plans 'determine' that PDF files are 'electronic' methods of enrollment. CAQH Core and CMS Office of Burden Reduction, Division of National Standards concurred that PDF files are considered an 'electronic method' of ERA / EFT enrollment, compliant with CAQH core operating rules.

NEW YORK UROLOGY SPECIALISTS
BETTER SCIENCE. BETTER HEALTH.
Alex Shteynshlyuger M.D.
Board Certified Urologist
Urology Care for Men and Women

This is a **major embarrassment for CAQH and CMS** to stand behind "PDF" files, faxes, and provider portals as "electronic" methods of enrollment in 2022. CAQH and CMS should immediately issue a clear rule that PDF files and other methods that do not allow database-to-database transmission of data or direct input into a database cannot be considered 'electronic' methods and are non-compliant. Failure by CAQH and CMS to update the rules **costs the healthcare industry billions of dollars in manual processing. It costs tens of thousands of dollars to our practice alone to fill out numerous PDF files again and again with the same information for 835 EFT/ERA enrollment. As NCVHS is well aware, there are more than 65,000 health plans in the US**, including 3,900 Medicare and Medicaid plans and more than 60,500 commercial plans.

> https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2021.pdf (Number of Health Plans in the US: (Report to Congress Annual Report on Self-Insured Group Health Plans Al Stewart Acting Secretary of Labor March 2021) Table 2. Form 5500 Group Health Plans Summary Information, 2018 Reflecting Statistical Year Filing)
>
> KFF: **Total Number of Plans.** In total, **3,550 Medicare Advantage plans** are available nationwide for individual enrollment in 2021) https://www.kff.org/medicare/issue-brief/medicare-advantage-2021-spotlight-first-look/

3. **Enrollment in EFT and ERA should be mandated to be supported via API database-to-database enrollment.** Similarly, physician health plan in-network credentialing/enrollment should be a database-to-database transaction via an API. Cooperative Exchange (https://www.cooperativeexchange.org/) has reported that >90% of ERA, EFT, and provider credentialing transactions are currently **handled by hand, "filling out PDF" forms** or typing in information in health plan provider portals. That is a tremendous burden in terms of financial costs and administrative waste on healthcare practices.

We appreciate the opportunity to provide our comments to NCVHS. If you have any questions, please do not hesitate to contact Dr. Alex Shteynshlyuger (dralex@newyorkurologyspecialists.com).

Sincerely,

Recoverable Signature

X Alex Shteynshlyuger

Signed by: d4aa26c7-f0c1-4b84-8cb9-1bcedd7cfccb

Alex Shteynshlyuger MD
Director of Urology

NEW YORK UROLOGY SPECIALISTS
BETTER SCIENCE. BETTER HEALTH.

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New York, N.Y. 10036

NCVHS
National Committee on Vital and Health Statistics

September 23, 2014

The Honorable Sylvia M. Burwell
Secretary, Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Findings from the June 2014 NCVHS Hearing on Virtual Credit Cards and Credit Card Use

Dear Madam Secretary,

The National Committee on Vital and Health statistics (NCVHS) is the statutory advisory committee with responsibility for providing recommendations on health information policy and standards to the Secretary of the Department of Health and Human Services (DHHS). Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), NCVHS advises the Secretary on the adoption of standards and code sets for the HIPAA transactions. The Patient Protection and Affordable Care Act (ACA) {Sec. 1104(g)(3)} enacted on March 23, 2010, calls for NCVHS to assist in the achievement of administrative simplification to "reduce the clerical burden on patients, health care providers, and health plans."

Each year, NCVHS holds industry hearings to evaluate and review the standards, code sets, identifiers and operating rules adopted under the HIPAA and the ACA, and determine whether there is a need for updating and improving any of these standards and operating rules. NCVHS is pleased to present in this letter, findings from our June, 2014 Subcommittee on Standards hearing on the use of virtual credit cards (VCCs) and credit cards by health plans for payment of health care services to providers.

VCCs are generally 16-digit credit card numbers (without the plastic card) sent by a payer to a provider to pay for services rendered. Providers then enter the virtual card number in their regular payment system, and receive the payment. The use of VCCs is growing in the health care industry, and is seen as a method to minimize the use of printed and mailed paper checks.

At the June 2014 hearing, testifiers did not question or dispute the benefits of using VCCs and credit cards for payment of health care services. Rather,

several groups continued to express strong concerns with current business practices related to the VCCs and credit cards used to pay and transfer funds to providers for health services rendered. Specifically, concerns expressed by providers were consistent with, and expanded on similar findings and testimony from the February, 2014 hearing, and centered on the following themes:

- Added costs to providers, in the form of high transaction fees, with the consequent impact of reduced reimbursement.
- Lack of transparency in the process of enrolling or becoming a user of VCCs, and on the costs and fees associated with them.
- Lack of informed choices and use of coercive practices by some to force VCC acceptance with no or difficult opt-in and opt-out options.
- Financial incentives between banking and health plans to move providers to virtual card payment options.
- Degree to which virtual cards may not comply with HIPAA-defined EFT standards.
- Disincentives or barriers to the use of the named national HIPAA compliant electronic fund transfer (EFT) standard, in favor of using VCCs.
- Inefficiency with the use of VCCs related to:
    - Staff time required to manually key in credit card information.
    - Additional time required to resolve entry errors.
    - Current electronic remittance advice standard being used by the industry not able to carry credit card information necessitating manual reconciling processes.
- Current electronic remittance advice (ERA) standard does not include a code to identify credit cards or virtual cards as a valid payment option on health care claims.
- No code in VCCs to allow a provider to make a reassociation between a payments and claims and know which payment applies to which claim.

In addressing the concerns raised by the health care industry regarding the use of VCCs and credit cards, NCVHS acknowledges the importance of fostering innovation in payment methods in formulating its recommendations. NCVHS also recognizes that the theme of this hearing focused on the difficulties expressed by the industry on the use of virtual cards. Therefore, NCVHS believes that at this time there is a more pressing need to foster full transparency and disclosure, informed optionality, and to eliminate business practices that are restrictive or that force entities to adopt specific options without choice. NCVHS recognizes that there are health plans and providers who see the virtual credit card as a better value than other forms of payment. Consequently, NCVHS will stand ready to participate in future discussions regarding the use of virtual credit cards.

NCVHS believes that now is the time to advance the industry adoption of good business practices in the use of VCCs and CCs, and conformance with national standards, as electronic methods of payment further develop and mature. Accordingly, NCVHS recommends:

Recommendation 1 – HHS should issue guidance that:

- Defines whether, when, and how VCCs and CCs comply with national HIPAA-adopted standards for Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA), and are valid options for health care claim payments.
- Clarifies and emphasizes the current provisions that prohibit practices that discourage or prevent the use of a national HIPAA-adopted standard, in lieu of other transaction methods.

Recommendation 2 – HHS should work with the health care industry and other appropriate agencies to:

- Encourage the increased adoption of EFT and ERA by identifying and disseminating best practices.
- Ensure there is full transparency, disclosure, and informed optionality between trading partners regarding the use of VCCs and CCs.
- Identify and encourage the use of nationally accepted good business practices in the financial sector with respect to the use of VCCs and CCs.
- Ensure that health care providers understand their rights with respect to acceptance or declining to accept VCCs and CCs as payment methods for their services.

Recommendation 3: HHS should work with the health care industry and other appropriate agencies to identify market-driven solutions that support the industry as it:

- Continues to innovate and improve administrative efficiency.
- Educates itself on the use of health care administrative transaction standards as it relates to VCCs and CCs.
- Identifies and emphasizes generally accepted best practices of electronic payment and VCC and CC use.
- Seeks to eliminate coercive business practices in the use of VCCs and CCs.
- Develops mechanisms to monitor and resolve inappropriate and unfair payment practices.

Closing Comments

NCVHS recognizes the challenges that the health care industry faces today and will continue to experience over the coming years as they adjust to these transformative changes in the use of credit cards/virtual cards as well as other innovative methods in payment transactions. NCVHS will continue to support your efforts to increase the adoption of standards and operating rules that help move the industry forward with technology to achieve greater efficiency.

Sincerely,

/s/

Larry A. Green, M.D. Chairperson,

National Committee on Vital and Health Statistics

Cc: HHS Data Council Co-Chairs

Compliance Review Program Findings

The CMS National Standards Group, on behalf of HHS, administers the Compliance Review Program. The program aims to promote compliance with HIPAA Administrative Simplification rules for electronic health care transactions. Our nation's health care system could save an estimated $16 billion[1] a year if all covered entities complied with required standards and operating rules for electronic transactions.

Since the program launched in April 2019, NSG has conducted 20 compliance reviews with a mix of clearinghouses and health plans. As of March 2021, 8 of the 20 participants have completed their reviews.

To help covered entities prepare for compliance reviews, CMS is releasing the following lists of the most common issues and violations found during reviews.

1 https://www.caqh.org/sites/default/files/explorations/index/2020-caqh-index.pdf

Common Violations of Standards

1. Health Care Claim Payment/Advice — 43 total violations requiring corrective action

- **Most common violation involved** the NM1 Corrected Patient/Insured segment in Loop 2100. Covered entities unnecessarily included either a first, middle, or last name, or organization name or ID number in the segment.
- **More information** is available in 005010X221A1 X12 implementation guides (TR3 Report) for the 835 transaction. See guidance related to Loop 2100, NM1 Corrected Patient/Insured, NM103/04/05, and the NM109 Situational Rule.
- **Why it matters:** 28% of all 835 violations were due to covered entities including unnecessary information in their transactions. Removing unnecessary data reduces the chance for errors and can help transactions be completed more quickly.

Common Violations of Standards (continued)

2. Health Care Eligibility Verification Response — 17 total violations requiring corrective action

- **Most common violation involved** the EB segment of Loops 2110C/D. Covered entities used an improper structure for Subscriber/Dependent Eligibility or Benefit Information.
- **More information** is available in 005010X279A1 guides (TR3 Report) for the 271 transaction. See guidance related to Loops 2110C/D in the EB segment, along with TR3 Note #3 and X12 RFI #2267.
- **Why it matters:** 35% of all 271 violations were due to covered entities inefficiently reporting benefit information. Streamlining data reporting can speed transactions and reduce the chance for errors.

3. Health Care Claim Status Response — 7 total violations requiring corrective action

- **Most common violation involved** the incorrect use of external Revenue and Facility Type codes.
- **More information** is available in 005010X212 guides (TR3 Report) for the 277 transaction regarding external code source rules.
- **Why it matters:** 28% of all 277 violations were due to covered entities incorrectly using standardized industry code sets. When responding to a claim status inquiry with the 277, invalid codes can lead to inaccurate claim status information.

Common Violations of Operating Rules

Out of a total of 30 operating rules violations requiring corrective action, 9 were related to the Payment Remittance Reassociation CCD+/835 Rule. This rule requires that health plans and clearinghouses:

- Inform providers of the minimum CCD+/835 data elements for reassociation
- Track the elapsed time between when the 835 and EFT are issued
- Have a written procedure for late or missing EFT/ERA transactions

Preparing for a Compliance Review

Find out how to prepare for a compliance review. Visit the Administrative Simplification Enforcement website and check out the What to Expect Q&A and Prep Steps resources.

Division of National Standards

Concept Paper

Fees in Excess of Costs for Normal Telecommunications

07/1/19

Legal Background

45 CFR 162.92S(a)(S):

"A health plan that operates as a health care clearinghouse, or requires an entity to use a health care clearinghouse to receive, process, or transmit a standard transaction may not charge fees or costs in excess of the fees or costs for normal telecommunications that the entity incurs when it directly transmits, or receives, a standard transaction to, or from, a health plan."

The August 2000 Transactions rule in which 45 CFR 162.925(a)(5) appears as a Final Rule is found at the following link: https://www.federalregister.gov/documents/2000/08/17/00-20820/health-insurance- reform-standards-for-electronic-transactions.

We believe that the statutory authority HHS relied on for the excessive fees provision at 45 CFR 162.925(a)(5) is 1175(a)(1)(B) of the Social Security Act:

SEC. 1175. [42 U.S.(. 1320d-4] (a) CONDUCT OF TRANSACTIONS BY PLANS.-

(1) IN GENERAL-If a person desires to conduct a transaction referred to in section 1173(a) (1) with a health plan as a standard transaction-

(A) the health plan may not refuse to conduct such transaction as a standard transaction;

(B) the insurance plan may not delay such transaction, or otherwise adversely affect, or attempt to adversely affect, the person or the transaction on the ground that the transaction is a standard transaction;

The only preamble discussion we are aware of that corresponds to 162.925(a) (5) is from page 50316 of the August 17, 2000 Transactions final rule:

> If a *covered* entity (for example, a health care provider) uses a health care clearinghouse to submit and receive no_nstandard/standard transactions, the health care clearinghouse is the *covered* entity's business associate. If a health plan operates as a health care clearinghouse, or requires the use of a health care clearinghouse, a health care provider may submit standard transactions to that health plan through the health care clearinghouse. However, the health care provider must not be adversely affected, financially or otherwise, by doing so. (For example, the costs of submitting a standard transaction to a health plan's health care clearinghouse must not be i.n excess of the costs of submitting a standard transaction directly to the health plan.

Issue

For several years health care providers have complained that they are being charged fees which they consider unreasonable and excessive for the use of certain standard transactions. Providers believe that these fees are not in compliance with the regulation at 45 CFR 162.925(a)(5). They maintain that these fees impede implementation and adoption of the standards and operating rules, diminish the benefits of administrative simplification, and increase costs and burden to providers.

Providers have filed a number of formal complaints with DNS alleging non-compliance with HIPAA Administrative Simplification rules. Provider groups have also expressed dissatisfaction with the fees being charged, and have requested that DNS clarify what constitutes an excessive fee. Of particular concern are fees charged to providers for Electronic Fund Transfers (EFT) and Electronic Remittance Advices (ERA), including charges for the use of virtual credit cards (VCC) through which some payers are providing remittances.

Background

Standard transactions are exchanged between covered entities through a variety of business arrangements involving trading partner agreements that are not governed under the authority of the HIPAA Administrative Simplification provisions. HIPAA covered entities may send and receive the standard transactions directly to or from any of the following types of organizations and systems for processing:

1. Providers' and plans' own contracted clearinghouses;
2. Other clearinghouses with whom trading partners are contracted;
3. Vendors;
4. Third party value added networks and Third Party Administrators (TPAs);
5. Web portals that connect directly between entities (direct data entry or DDE); and
6. Other arrangements which we are unable to specify, as we don't know all of the existing business arrangements.

When covered entities exchange standard transactions, the charges for the services may include telecommunications, the rental of equipment, payment processing, translation services, repackaging of the transactions, etc. The fees charged for various transactions may be dependent on the number and type of standard transactions involved, and the scope of work required to process the transactions, e.g. edits, translation, coding, attachments, storage, etc. Fees may be charged based on a percent of total payments, merchant fees, value added services, fees in addition to standard bank fees and various other charges. Fees may be charged by the health plan, by the health plan's clearinghouse, by a business associate of the health plan, by the provider's clearinghouse, by a business associate of the provider's clearinghouse, by a vendor contracted to the provider for value added services and by merchant card issuers. All arrangements will be unique to the contracts negotiated among the entities.

Discussion

According to the National Automated Clearing House Association (NACHA), the processing and delivery system for many electronic fund transfers, the fee for an EFT made via the Automated Clearing House (ACH) Network is typically around $.034 per transaction (based on 2017 data). In 2017 DNS issued an FAQ that cited the NACHA data as a source of information regarding fees. This FAQ generated substantial discussion within the industry, and was widely misinterpreted as being a rule prohibiting

costs in excess of that amount. It also generated press in some professional journals and newsletters. We withdrew the FAQ due to the widespread misinterpretation, and have not reposted it as it is only references partial data, now understood as more confusing than useful to the industry. Our policy direction after the withdrawal of the FAQ has been to attempt to obtain a robust set of data and a clear map of the business relationships involved, in order to present the data the industry, providing them with the information they need to make informed business choices when dealing with their partners.

DNS has been unable to obtain any clarity with respect to what is actually being charged by whom and for what services. We do not have access to the data necessary to analyze exactly where these fees originate and whether or not they are in keeping with the costs of conducting business. We have attempted to obtain this data via our existing contracts with Gartner and MITRE, but neither can obtain the necessary data available to assist us in the analysis. At one point the WEDI offered to take up this task with its membership, however, upon further investigation, advised us that they would not be able to proceed. The NACHA data is limited and does not address payments made outside the ACH or via VCC, nor does it address other types of standard transactions. Lastly, even data supplied to us by provider organizations, such as the AMA and the MGMA, are not complete or conclusive and do not clearly identify charges and their sources.

Options:

1. Repeal the regulation at 45 CFR 162.925(a)(5) as HHS has no authority to regulate the financial arrangements of any covered entity or their business partners. Because the amount charged for transmission of transactions is not an Administrative Simplification standard HHS has no enforcement authority, nor authority to demand pertinent information that might assist covered entities in determining appropriate amounts.

   Pros: This would clearly message the industry that charges for the processing of HIPAA covered transactions are beyond the purview of HHS. There is the potential that professional organizations would respond to the needs of their membership by developing aides for their members to use when negotiating costs. The repeal of the regulation would finalize the Department's decision.

   Cons: The provider community will likely feel let down by the decision to repeal the regulation rather than to solve their problem. With the affirmation that HHS has no regulatory authority over such costs, there is the potential that costs could increase further, discouraging utilization of adopted standards. This is a labor intensive approach that will use significant DNS resources, and will not be final for at least 18 months.

2. Maintain the regulation as is, and issue a guidance letter clarifying that providers may not be charged more than the telecommunications cost for transmission and processing of HIPAA standard transactions, and that the amounts charged and paid for value added services are not HIPAA standards regulated under 45 CFR 162.925(a)(5), but are business decisions negotiated among business partners.

   Pros: This would message the industry that there may be no charges for the processing and transmission of HIPAA standard transactions outside of the charges the provider would typically pay for transmission of the transaction. There is the potential that professional organizations would respond to the needs of their membership by developing aides for their members to use when negotiating costs for services beyond the standard transactions.

Cons: This guidance likely would be challenged by plans and clearinghouses, as well as other third parties, whose costs could increase and profits decrease if they can no longer pass them on to providers. This would likely result in a prolongation of the discussion and continued investment of resources. It could result in legal challenges.

3. DNS could suggest that business associations develop their own guidelines to help their membership determine when charges are inappropriate, and how to negotiate those charges.

   Pros: This would signal to the industry that they have a responsibility for their own business decisions, and with that understanding may spur action in the provider community.

   Cons: The recommendation for industry action might not be taken up, and providers would continue to look to HHS for a solution to this business problem. This solution may be ineffectual and may do nothing to relieve the complaints that are continually submitted to DNS.

Recommendation:

Options 2 and 3: Maintain the regulation as is, and issue a guidance letter clarifying that there may be no charges to the provider in excess of usual telecommunications costs for HIPAA standard transactions, and that the regulation is not applicable to value added services. Amounts charged and paid for additional services which are not HIPAA standards are business decisions. Suggest that business associations develop their own guidelines to help their membership determine when charges are excessive, and how to negotiate those charges.

DECISION TO MOVE FORWARD

_proved

_Disapproved

___Additional Information/Discussion Required

Signature: _____ Date: 07/03/19

Centers for Medicare & Medicaid Services
Karen.jackson1@cms.hhs.gov
410-786-0079

From: DiBlasio, Carla (CMS/OA)
Sent: Wednesday, November 8, 2017 4:06 PM
To: Jackson, Karen E. (CMS/OA) <karen.jackson1@cms.hhs.gov>
Subject: Fwd: CMS

Karen,

Can I put you in touch with Brad?

Thanks!

Page Adobe 294

Begin forwarded message:

From: "Lucas, Jane (HHS/IOS)" <Jane.Lucas@hhs.gov>
Date: November 8, 2017 at 3:47:16 PM EST
To: "DiBlasio, Carla (CMS/OA)" <Carla.DiBlasio@cms.hhs.gov>
Cc: b6 b6 @capitolcounsel.com" b6 b6 @capitolcounsel.com>
Subject: Fwd: CMS

Carla, could you please help point Brad in the right direction?
Thank you!
Jane

From: "Brad Mollet" b6 b6 @capitolcounsel.com>
Subject: CMS
Date: 08 November 2017 15:45
To: "Lucas, Jane (HHS/IOS)" <Jane.Lucas@hhs.gov>

Hey Jane, it's been great running into you at Little Scholars. I was hoping to run into you this week to ask you a question regarding a CMS issue a client of ours is having. It's regarding CMS issuing an unclear rule requiring health plans to deliver electronic payments at no cost to the providers. CMS won't directly answer the interpretation. I have attached the white paper above. Any help on this would be awesome. If it's not your purview, i understand but just wanted to find out where CMS is on the issue.

Thanks,
Brad

Brad Mollet
Capitol Counsel, LLC
700 13th Street, NW, 2nd Floor
Washington, DC 20005
(202) 540-1942 Direct Dial
b6 b6 Cell
b6 b6 @capitolcounsel.com

These FAQs are regarding entities charging fees for receipt of an EFT payment via the ACH network, and for entities requiring use of virtual cards for payments. These FAQs were removed from the site for revision, and have not been replaced. There is a significant need for this guidance in the industry, as there continue to be entities that charge providers a fee which is a percentage of the payment (not an interchange fee or transmission fee) for receiving a payment via EFT rather than a virtual card (which incurs fees as well). There also are entities that require the providers to receive virtual card payments, or default to virtual card payments (opt-out) and make it difficult for providers to receive payments by other methods. This guidance gives the providers information to go back to these entities and show that these practices are outside of CMS's guidance. It would be very beneficial to have this information available for the providers.

Thank you!

Pamela A. Grosze
Vice President , Senior Product Manager

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Update: Virtual Credit Cards

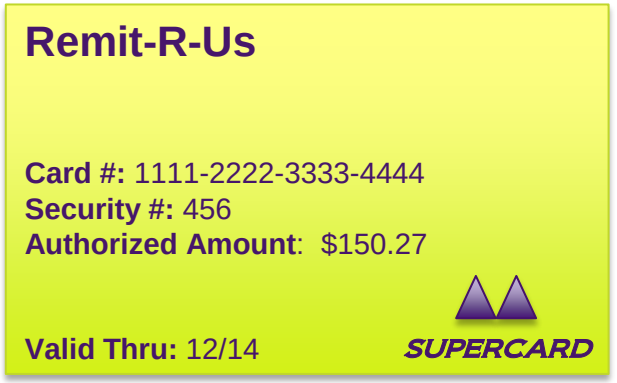
NCVHS SUBCOMMITTEE ON STANDARDS

JUNE 10, 2014

AMA
AMERICAN MEDICAL ASSOCIATION

Virtual Credit Cards 101

- Health plans mail, fax, or email single-use credit card payment information and instructions to physicians to pay claims (as opposed to sending paper check or electronic funds transfer [EFT] via the ACH Network)
- Physician office staff process as they would a patient credit card payment







Virtual Credit Cards: Provider Concerns

- Erosion of provider income/contracted fee
  - Interchange fees **(up to 5%)**
- Administrative burden
  - Manual entry of card information
  - Manual payment posting/reconciliation
- Lack of provider choice
  - Opt out vs. opt in
- Health plans heavily incentivized to use virtual cards
  - Up to 1.75% cash-back offers

Scope of Issue: Outlier vs. Mainstream?

- AMA is frequently (and increasingly) contacted by medical society staff with questions and complaints on virtual cards
- Informal survey of medical society staff (March/April 2014)
  - 44% of state medical society staff reported receiving >5 physician complaints related to virtual cards
  - 24% reported receiving >10 complaints






Scope of Issue: Outlier vs. Mainstream? (cont'd)

- Informal survey of physician practices (May/June 2014)
- 68% of respondents had received payment via virtual credit cards
  - Geographically spread across country (not localized issue)
- 96% received virtual credit card payments without prior consent/notification (opt-out model)
- 40% reported being unaware of interchange percentage fee associated with virtual credit cards

Virtual Credit Card Case Study: Large North Carolina Radiology Practice, 2014 YTD

Month	# VCC Transactions	Total VCC Claim Payments	Total VCC Fees
January 2014*	176	$62,878.64	$1,257.57
February 2014	397	$108,709.16	$2,174.18
March 2014	372	$74,975.54	$1,499.51
April 2014	570	$114,327.39	$2,286.55
May 2014	564	$116,910.63	$2,338.21
Total	**2079**	**$477,801.36**	**$9,556.02**

*January record-keeping began 1/16/14.
VCC = virtual credit card. Interchange fee = 2%.





Case Study Comments

- Fees add up quickly
- This reflects only 4.5 months of data for a single practice
- Interchange fees may be higher than 2% depending upon merchant agreements
- Need to factor in additional administrative cost to the practice of manually entering information for **2,079** virtual credit cards and manually posting payment information
- Practice reports receiving virtual card payments from **48** different vendors; extremely labor intensive to opt out of all programs

ACH EFT Concerns

- AMA promoting ACH EFT as preferred payment form vs. virtual credit cards
- Alarming reports of providers being charged percentage-based fees (1.8% -1.9%) for ACH EFT
  - Fees charged by health plans' payment solution vendors
  - Vendors claim fees are for "value-added services"
  - Communication to providers contains no indication that no-charge ACH EFT option is available
- Physicians are again paying to be paid!

Virtual Credit Cards and Standard Electronic Transactions

- ASC X12 835 v 5010 does not support credit card payment
  - RFIs 1631 and 1887 both stated that transaction cannot carry all of the necessary information
- CR [change request] 1265 updates ASC X12 835 to support credit card payments
  - Discussion on CR 1265 to continue after June 2014 ASC X12 meeting
  - AMA does not support CR 1265 unless provider protections (e.g., opt-in verbiage) are added
- Even if CR 1265 is approved, it will be years until virtual card information can be used in X12 835
  - Guide development, pilot testing, and regulation process could mean 6 years until new HIPAA-mandated version of X12 835 is in place

Virtual Credit Card Guidance

- CMS issued FAQ 9778 on March 28, 2014, which states:
  - Health plans must comply with provider request for payment via ACH EFT
  - Health plan cannot delay or reject standard transaction
  - Providers cannot be incentivized for using alternate payment method or adversely affected for using standard transaction (i.e., **charged excessive fees**)
  - Providers should carefully analyze agreements for any added fees



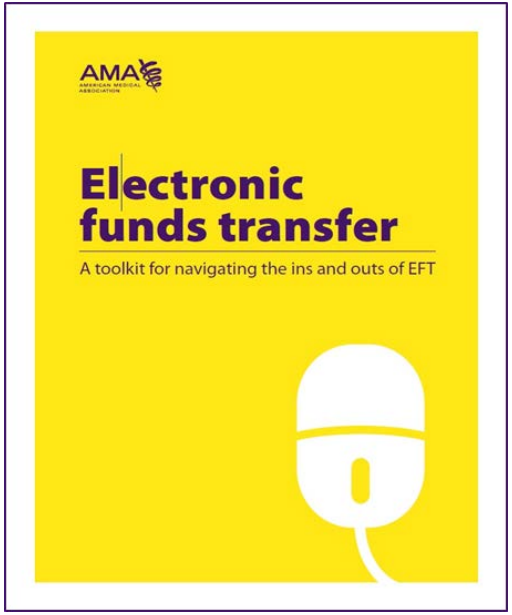


AMA Resources on Virtual Credit Cards and EFT

AMA EFT Toolkit additions:

- "The effect of health plan virtual credit card payments on physician practices"
- "Know your rights and make ACH EFT work for your practice"
- Upcoming educational webinar (will be live and archived)

All available at www.ama-assn.org/go/eft



Recommendations

- Additional guidance required on virtual credit cards to directly address transparency on fees and provider choice
- Health plans should not be incentivized to use virtual credit cards at provider expense
- Percentage-based fees for ACH EFT improper and an enforcement issue
- No-cost ACH EFT option should be available and clearly communicated to providers

Thank You

Heather McComas

Director, Administrative Simplification Initiatives

AMA

heather.mccomas@ama-assn.org


AMA
AMERICAN MEDICAL
ASSOCIATION

NACHA
The Electronic Payments Association®

Leading the payments industry through rulemaking, dialogue, advocacy and education

December 7, 2018

Subcommittee on Standards
National Committee on Vital and Health Statistics
Via email

Re: Request for Comment on Predictability Roadmap Draft Recommendations

Dear NCVHS Members,

NACHA appreciates this opportunity to comment on the draft recommendations for the NCVHS Predictability Roadmap. We appreciate the work of HHS, NCVHS, and the entire industry in the movement toward electronic transactions and administrative simplification.

NACHA fully supports the Predictability Roadmap outcome goals of:

- Improved education, outreach and enforcement of HIPAA standards and operating rules
- Support of industry process improvement changes; and
- Timely adoption, testing and implementation of updated or new standards and operating rules.

With actionable recommendations and clearly defined calls to action, these goals can be attained.

While NACHA has strong interest in the overall success of this effort, we are only a small part of the effort, and will continue to work with the industry and provide input and resources where appropriate. Most of our specific comments below apply to the healthcare Electronic Funds Transfer (EFT) standard transaction, for which we are designated the Standard Development Organization; and to experiences and lessons from the financial services industry with electronic transactions that could be applicable to the healthcare industry.

NACHA, the ACH Network, and the NACHA Operating Rules[1]

NACHA is the financial services industry's governance and administrative organization for the Automated Clearing House (ACH) electronic payments system. NACHA is responsible for the development, adoption, and maintenance of the *NACHA Operating Rules* that govern the use of ACH payments. In addition to the healthcare EFT standard, the ACH Network is commonly used for the Direct Deposit of payroll and benefit payments and tax refunds;

[1] A comprehensive overview of NACHA, the ACH Network, and NACHA;s rulemaking process for the NAHCA Operating Rules was given in testimony to the NCVHS Subcommittee on Standards on July 20, 2010 - https://healthcare.nacha.org/sites/healthcare.nacha.org/files/files/20100709%20NACHA%20Testimony%20on%20Operating%20Rules%20NCVHS%20Hearing.pdf

recurring and online electronic bill payment; and business-to business payments. NACHA estimates that in 2018 there will be a total of 23 billion ACH payments, transferring $50 trillion.

Requests and proposals to amend the *NACHA Operating Rules* are evaluated through an inclusive and transparent rulemaking process that develops and assesses the business case and justification for the proposal. Each change that is approved has a defined effective date, at which time all covered parties are required to be compliant. NACHA takes a flexible approach to such effective dates. Relatively simple ones that do not involve significant technology or business process changes can become effective within 6 months of approval. Major changes may take as long as 18 months to become effective.

Requests for changes to the healthcare EFT standard transaction[2] may be made by any interested party, and would be evaluated through NACHA's existing rulemaking process. To date, we have not received any requests to modify the healthcare EFT standard.

The Healthcare EFT Standard

Since the designation of the NACHA "CCD+Addenda" as the healthcare EFT standard on January 10, 2012, the adoption of this standard transaction by the industry has been robust. Measured by the number of payments, its use has more than doubled since 2014 (the first full year of use after the effective date) to more than 300 million payments in 2018, and will transfer approximately $1.6 trillion in value in 2018. (See chart below.) According to the CAQH Index[3], 60 percent of medical claim payments in 2017 were made using the standard EFT.

Despite this success, some in the industry have experienced pain points in adopting or using the standard EFT, as described below. The same CAQH Index shows that only 9 percent of dental claim payments in 2017 were made using the standard EFT. NACHA commends the American Dental Association for recently launching an industry-wide effort to promote and increase adoption of standard transactions by dental practices, and we are committed to participating in and supporting that initiative.

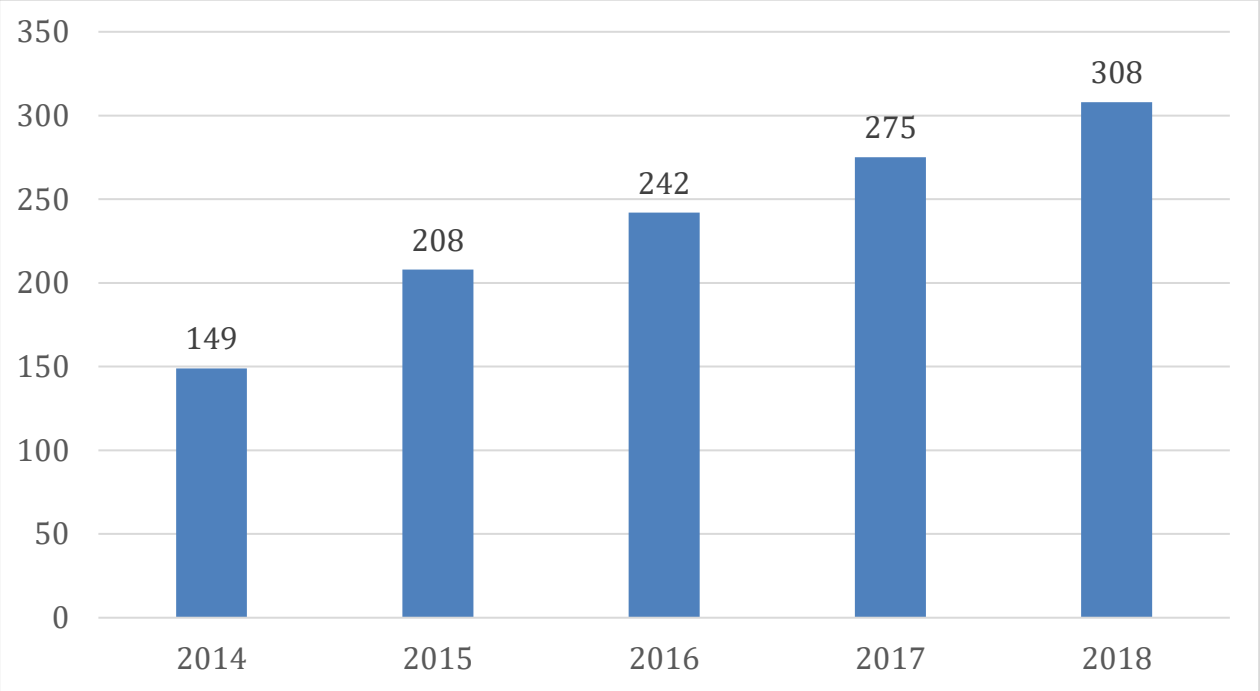
Another industry pain point is the effort required by providers to reassociate separate EFT and ERA transactions. This is a natural result of HHS' decision in 2012 that these two standard transactions would travel separate paths. Both the CAQH CORE operating rules (Phase III CORE 370 EFT & ERA Reassociation (CCD+/835) Rule) and the NACHA Operating Rules address reassociation requirements in order to ease its accomplishment by providers. Nevertheless, provider pain points generally result from: 1) a lack of automation in internal practice management or treasury management systems; 2) incorrect, non-standard, or missing data elements in one of the standard transactions; and 3) a lengthy gap in timing between the receipts of the two transactions.

[2] See https://healthcare.nacha.org/EFTStandardEnhancementSubmissionForm
[3] See https://www.caqh.org/sites/default/files/explorations/index/report/2017-caqh-index-report.pdf

A different type of pain point experienced by providers regards business practices by some payers or their vendors. In many instances, NACHA has heard that some providers have experienced difficulties in enrolling in EFT; that payers or their vendors are charging fees to use the standard transaction; or that they are paid involuntarily by virtual credit cards.

Addressing these existing pain points could go a long way toward increasing adoption of the standard EFT transaction, even absent any other actions pursuant to the Predictability Roadmap.

Chart - Healthcare EFT Standard Transactions (in millions)



Goal 1 - Education, Outreach and Enforcement

NACHA strongly supports draft recommendations 1 and 2 (as well as measurement step M1) regarding enforcement. In our experience with the governance of electronic payments, clear and consistent enforcement is inherent to compliance with standards, operating rules and other business practices. The knowledge and expectation of scrutiny provides an incentive for compliance. We have direct experience of this with the *NACHA Operating Rules*, in which compliance is achieved via adherence to contracts, a requirement to audit compliance with the Rules annually, and a NACHA-administered enforcement process.

NACHA also strongly supports draft recommendation 7 that "the HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules." We would note, however, that specific to the standard EFT transaction, HHS' performance so far in this regard has not been successful. A substantial number of providers and industry organizations have been requesting that HHS issue

guidance on: 1) the involuntary payments by virtual credit cards; and 2) the practice of payers or their vendors charging providers fees to use the standard transaction. In several instances, FAQs published by CMS on these topics have been rescinded, most recently in February 2018.

As far back as September 2014, NCVHS recommended[4] that HHS should issue guidance that "defines whether, when, and how VCCs and CCs comply with national HIPAA-adopted standards for Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA)," and "clarifies and emphasizes the current provisions that prohibit practices that discourage or prevent the use of a national HIPAA-adopted standard." As of the date of these comments, no such guidance is available from HHS.

NACHA is in full agreement with the Medical Group Management Association's (MGMA) most recent letter of April 2, 2018 to CMS Administrator Verma regarding Reinstatement of Electronic Payments Guidance on the CMS Website[5] calling for CMS "to expeditiously re-post these critical FAQs."

NACHA also is in full agreement with WEDI's industry best practices, entitled *Electronic Payments: Guiding Principles*.[6] As WEDI has an official advisory role to the Secretary, it would be straightforward for HHS to adopt WEDI's industry-consensus guidance as its "guidance on appropriate and correct use" of the standard EFT. In this regard, WEDI has already accomplished "Call to Action B" to publish white papers on agreed upon best practice regarding the use of the EFT standard.

Goal 2 - Process Improvement

NACHA strongly supports the goal of efficient and effective process improvements. We are skeptical, however, that the creation of a new industry governance entity, as outlined in recommendations 4 and 5, is necessary to achieve meaningful process improvements. In fact, it is possible that the resources and attention that would be required to be devoted to the establishment of a new governance entity could have the unintended consequence of diverting resources and attention from other process improvements and updates to standards. We would encourage NCVHS to explore process improvements that do not involve the establishment of a new industry governance entity.

Goal 3 - Timely adoption, testing and implementation of updated or new standards and operating rules

NACHA agrees that there should be reasonable timelines for updating or adopting standards and operating rules, but cautions against arbitrary timelines or one-size-fits-all approaches when not justified by a business case. With respect to the standards and operating rules other

[4] See https://www.ncvhs.hhs.gov/wp-content/uploads/2014/10/140923lt2.pdf
[5] See https://www.mgma.com/advocacy/advocacy-statements-letters/advocacy-letters/mgma-sends-letter-to-cms-urging-an-end-electronic
[6] See https://www.wedi.org/news/press-releases/2016/09/07/wedi-issues-electronic-payments-guidance-to-address-industry-concerns-with-ach-eft-transactions-virtual-credit-cards

than for the EFT, we defer to others in the industry. With respect to the standard EFT, NACHA thinks that it is premature to adopt recommendations about potential future updates when the industry should be focused on full adoption of the existing standard and compliance with the existing CORE operating rules.

Calls to Action

NACHA agrees with Call to Action A, that "health plans and vendors should identify and incorporate best practices for mitigating barriers to the effective use of the transactions, determining which issues are the most critical and prioritizing use cases." Identifying and mitigating barriers to the effective use of the EFT standard is critical to faster claim settlement and efficient payment processing. Fortunately, industry groups have conducted much work here already. WEDI's best practices white paper, *Electronic Payments: Guiding Principles*, should serve as a model for all plans and their vendors. Plans and vendors needing in-depth and customized advice can consult with NACHA's Elevation consulting group, which recently has assisted two large health plans in evaluating their ACH payments practices.

NACHA supports the work of WEDI on industry best practices (Call to Action B). WEDI's best practices white paper, *Electronic Payments: Guiding Principles*, should serve as a model for all plans and vendors, and should be adopted by HHS as official guidance.

NACHA supports Call to Action C regarding certification and validation to the extent that such new tools or programs are not duplicative of existing initiatives. Similarly, NACHA supports Call to Action D regarding cost-benefit analyses, including through collaboration or support of existing analyses.

* * * * *

NACHA appreciates the opportunity to provide comments in response to the Request. If you have any questions regarding our comments, please do not hesitate to contact me at (703) 561-3924 or mherd@nacha.org.

Sincerely,

Michael Herd
Senior Vice President, ACH Network Administration

Medical Group Management Association®

April 2, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Reinstatement of Electronic Payments Guidance on the CMS Website

Dear Administrator Verma:

We write today to convey our great concern regarding the recent removal from the Centers for Medicare & Medicaid Services (CMS) website several frequently asked questions (FAQs) instructing providers of their rights and prohibiting unfair business practices regarding electronic payments (e-payments) from health plans to providers. We urge you to expeditiously re-post these FAQs.

MGMA is the premier association for professionals who lead medical practices. Since 1926, through data, advocacy and education, MGMA empowers medical group practices to create meaningful change in healthcare. With a membership of more than 40,000 medical practice administrators, executives, and leaders, MGMA represents more than 12,500 organizations of all sizes, types, structures, and specialties that deliver almost half of the healthcare in the United States.

At issue are the unfair business practices related to two forms of payments made from health plans to providers, “virtual” credit cards (VCCs) and electronic funds transfer (EFT), and the various impediments health plans and third-party payment vendors have implemented that discourage provider adoption of EFT. Health plan use of third-party payment vendors has become a significant issue in the payment environment. A March 20, 2018 MGMA poll with over 850 responses found that nearly 3 in 10 respondents (29%) report that their payment from the health plan is routed through a third-party payment vendor. Of these, 58% reported being charged a fee by the vendor to receive their payment. Less than one quarter of respondents (24%) stated that no fee was attached to their payment and an additional 18% were unsure.

In a VCC payment, a health plan or its payment vendor sends a single-use credit card number to a provider by mail, fax, or email which the provider must then manually enter. This is known as a “virtual” card because a physical credit card is never created or presented to the provider. For these authorizations, providers are required to pay credit card interchange fees, typically ranging from 3 to 5% of the value of the payment.

Not only are these fees unwarranted and unfair, but in the vast majority of cases, the practice did not choose this payment method. Opting out of VCCs and receiving payments via EFT from a reluctant payer or vendor is a manual, burdensome process that further delays payment. Even more disconcerting, the use of VCCs is contrary to the agency's stated priority of putting "patients over paperwork" and reducing physician administrative burden and cost. Importantly, VCCs do not meet the national EFT standard established by the Department of Health and Human Services (HHS) in the 2012 interim final regulation, nor do they support the Health Information Portability and Accountability Act (HIPAA) standard transaction for Electronic Remittance Advice (ERA), resulting in additional manual processing for practices along with significant associated costs.

The Automated Clearinghouse "CCD+Addenda" standard was adopted as the HIPAA standard transaction for EFT and took effect January 1, 2014. The regulation specified that "if a covered entity conducts with another covered entity (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction." In requiring the adoption of a standard for EFT, the 2012 rule clearly states a cost savings intent when utilizing EFT over traditional paper payments. The Impact Analysis from the rule, for example, states that the issuance of an EFT standard: "is based on the assumption that the health care EFT standards will make health care claim payments via EFT more cost effective and will therefore incentivize increased usage of EFT by physician practices and hospitals" (77 FR 1575). The final rule goes on to say "[e]ach move from a non-electronic, manual exchange of information to an electronic transaction brings with it material savings in terms of less money spent on paper, postage, and equipment required for paper-based transactions, as well as cost avoidance in terms of time savings for staff. For health plans, we expect direct savings from the transition from a paper-based payment system (for example, paper checks) to EFT. These savings are found in the amount of staff time saved, as well as material savings such postage, paper, and printing" (77 FR 1582-83).

With industry cost savings as the primary motivation for adopting the EFT standard, it is very disappointing that some unscrupulous health plans and payment vendors have begun to take advantage of providers by charging them a percentage-based fee (typically 2-5%) on every EFT transaction. Providers unwilling to pay these fees are typically offered a VCC as the only other payment option, forcing them to incur fees no matter which option they choose.

Other unfair practices employed by health plans and payment vendors to discourage adoption of EFT by providers include:

- Automatic opt-in for virtual card payments, forcing the provider to opt out to receive payment by another method, including EFT;
- Informing providers wanting to opt out of VCC payments that it takes 60 days or more to reissue the claims payment as either a check or ACH EFT payment, thus negatively impacting business cash flow;
- Creating unnecessarily burdensome processes for opting out of VCC payments, such as not including payer contact information when issuing the VCC number;

- Creating unnecessarily burdensome EFT enrollment processes, such as refusing to permit enrolling all physicians in a group at the same time, to deter use of the EFT standard transaction;
- Communicating inaccuracies about the lack of safety of banking information used in EFT transactions;
- Misrepresenting card system rules such as informing providers that they must accept VCCs for claims payment if they accept patient credit cards; and
- Requiring VCC payments as part of provider contracts by telling providers they are exempt from the requirement or that a VCC payment meets the definition of "electronic payment.".

The National Committee on Vital and Health statistics (NCVHS), the statutory advisory committee with responsibility for providing recommendations on health information policy and standards to the HHS Secretary, has weighed in on the need for e-payments guidance. In its 2014 letter to the Secretary, NCVHS made the following recommendations:

"*HHS should issue guidance that:*

- *Defines whether, when, and how VCCs and CCs comply with national HIPAA-adopted standards for Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA), and are valid options for health care claim payments.*
- *Clarifies and emphasizes the current provisions that prohibit practices that discourage or prevent the use of a national HIPAA adopted standard, in lieu of other transaction methods.*

HHS should work with the health care industry and other appropriate agencies to:

- *Encourage the increased adoption of EFT and ERA by identifying and disseminating best practices.*
- *Ensure there is full transparency, disclosure, and informed optionality between trading partners regarding the use of VCCs and CCs.*
- *Identify and encourage the use of nationally accepted good business practices in the financial sector with respect to the use of VCCs and CCs.*
- *Ensure that health care providers understand their rights with respect to acceptance or declining to accept VCCs and CCs as payment methods for their services.*

HHS should work with the health care industry and other appropriate agencies to identify market-driven solutions that support the industry as it:

- *Continues to innovate and improve administrative efficiency.*
- *Educates itself on the use of health care administrative transaction standards as it relates to VCCs and CCs.*
- *Identifies and emphasizes generally accepted best practices of electronic payment and VCC and CC use.*
- *Seeks to eliminate coercive business practices in the use of VCCs and CCs.*
- *Develops mechanisms to monitor and resolve inappropriate and unfair payment practices."*

Based in part on the NCVHS recommendations, CMS issued FAQs in fall 2017 to address several important payment issues. The following FAQs, now removed from the agency's website, provided critical industry guidance prohibiting unfair business practices and encouraging the widespread adoption of cost-saving EFT payments.

FAQ 22285 made it clear that providers were not required to accept VCCs from health plans and that they had "…the right to request that a health plan use the EFT transaction." This was important guidance, as many of our members have told us that health plans and their business associates send a VCC to the provider for payment of a claim (i) without prior notice of this method of payment; (ii) without offering that the payment be sent via EFT; (iii) using language that suggests that this VCCs qualify as e-payments; and (iv) that the provider has no choice but to accept this payment method.

FAQ 22281 definitively stated that a VCC is not considered a HIPAA standard transaction because the payment is made outside the ACH network and that health plans "must comply" with requests to receive claims payments via EFT. Most importantly, FAQ 22281 stated explicitly that fees may not be imposed on a provider for this transaction by either the health plan or their payment vendor. "Health plans should not charge providers communications fees for the use of the HIPAA EFT transaction, nor should health plans' payment vendors, which are business associates of the health plans, do so." The FAQ went on to state that "[a]ny fees charged to a provider for an EFT transaction are banking transaction fees, which should be applied only by the provider's financial institution…[and] are typically around $.034 per transaction nationally."

FAQ 22297 addressed four important and related issues. First, the FAQ reminded the industry that non-banking fees cannot be assigned to EFT transactions. Second, it stipulated that providers are not required to contract with payment vendors for "value-added services." Third, providers were reminded that they should closely review all vendor contracts and agreements. Finally, health plans functioning as clearinghouses were instructed not to charge fees or costs for normal telecommunications that exceed the fees they incur when they directly transmit or receive a standard transaction.

Most importantly, the guidance clarifying value-added fees was critical, as providers are often instructed by their health plans that they are required to receive their payment via the plan's designated third-party vendor, who in turn charges the provider a percentage fee on the EFT transaction. These "value-added" services are typically not offered as an option, but rather a requirement of payment, regardless of whether the provider wishes to take advantage of these services or not. While we do not oppose the ability of a payment vendor to offer these services, we contend that there needs to be full transparency regarding the specifics of these services and any associated fees. Further, these fees should be optional, and providers must be given the option of free EFT transactions.

FAQ 22385 provided important guidance to providers regarding updating, renewing, or signing e-payments-related contracts. We were pleased to see CMS reference the Workgroup for Electronic Data Interchange's (WEDI's) Electronic Payments: Guiding

Principles white paper in the FAQ. MGMA served as co-chair of the broad industry coalition that developed this white paper, an effort that included health plans, payment vendors, credit card companies, clearinghouses, hospitals, physicians, and CMS itself. This set of core principles were developed with the goal of advancing the adoption and use of the EFT transaction, and many of the principles mirrored the four CMS FAQs referenced above.

In concert, these FAQs provided clear guidance to the industry regarding e-payments, served as an incentive for providers to embrace EFT and ERA, and further encouraged implementation of the full suite of cost-saving administrative simplification transactions. They informed health plans and third-party payment vendors of their legal obligations, barred unfair business practices, and educated providers about their rights under the law. They are critical if the healthcare industry is to successfully drive out needless administrative waste.

We appreciate the opportunity to share our concerns regarding the removal of this important industry guidance and urge you to expeditiously re-post these critical FAQs. This action would communicate your commitment to simplifying the nation's healthcare system and prohibiting VCC abuses and unjust EFT fees imposed on physician practices. Thank you for your consideration of this request and please contact Robert Tennant at rtennant@mgma.org or 202-293-3450 should you have any questions.

Sincerely,

/s/

Anders Gilberg, MGA, Senior Vice President, Government Affairs

CC: Madhusudhan Annadata, Director, Division of National Standards, CMS

U.S. Department of Veterans Affairs

Veterans Health Administration
VHA FOIA Office (105HIG)
810 Vermont Avenue NW
Washington, DC 20420

In Reply Refer To: **FOIA Request 22-08382-F**

09/29/2022

Alex Shteynshlyuger
New York Urology Specialist
33 W. 46th St. 5th Fl
New York, NY 10036
dralex@newyorkurologyspecialists.com

Dear Dr. Shteynshlyuger:

This letter is the initial agency decision (IAD) on your July 26, 2022, request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, submitted to the Department of Veterans Affairs (VA), Veterans Health Administration (VHA) Central Office FOIA Office

Search:

It is noted that this is a duplicate request to 22-05334-F that was received in the VHA FOIA Office on April 28th, 2022. Your April 28th, 2022, request (22-05334-F) was administratively closed on July 5, 2022, for failure to clarify. In a good faith effort to address your request for records, we've conducted a new search for records.

It is also important to note, the U.S. Department of Treasury performs all of the "clearinghouse" efforts for ERAs and EFTs. The VA, through the

Department of Treasury, does not receive, and will not accept, credit cards, virtual credit and debit cards for health care third party payer payments.

Determination:

My review of the documents revealed that they contained information that falls within the disclosure protections of FOIA Exemption

If you disagree with my determination to withhold the information under FOIA Exemption 6, please be advised you may appeal to:

Office of the General Counsel (024)
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420
Fax: (202) 273-6388
Email: ogcfoiaappeals@va.gov

If you should choose to file an appeal, your appeal must be postmarked or electronically transmitted no later than ninety (90) calendar days from the date of this letter. Please include a copy of this letter with your written appeal and clearly state why you disagree with the determinations set forth in this response.

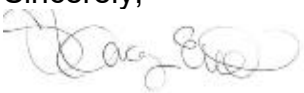
You may also seek assistance and/or dispute resolution services for any other aspect of your FOIA request, excluding the release determination, from VHA's FOIA Public Liaison and or Office of Government Information Services (OGIS) as provided below:

VHA FOIA Public Liaison:
Email Address: vhafoia2@va.gov
Phone Number: (877) 461-5038

Office of Government Information Services (OGIS)
Email: ogis@nara.gov
Fax: (202) 741-5769
Mailing address:
Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road
College Park, MD 20740-6001

Thank you for your interest in VA. If you have any further questions, please feel free to contact me at (785) 230-8430 or via email at stacy.ekis@va.gov.

Sincerely,



Stacy Ekis
VHA FOIA Officer

Enclosure:

Transcript of Phone Conversation on 8/12/2019 between Echo Health and Dr. Alex Shteynshlyuger: ERA Delivery and ERA Fees; EFT Fees. (Part 2)

Phone Number Dialed: (440) 835-3511
Date: 8/12/2019
File recording length: 0:17:43 minutes Part 2 (30 minutes total)
Caller 1: Dr. Alex Shteynshlyuger – New York Urology Specialists
Caller 2: Brittney – **ECHO Health Representative**
Caller 3: Courtney **– ECHO Health Representative**
Caller 4: **Angie – ECHO Health Supervisor:**
File name: part-2-split-EchoHealth2-8-12-2019-20190812-130742_1_1_Outgoing_Auto_1189944300007

Courtney – ECHO Health Representative: Okay. Dr. Alex. I can see what the problem was. So I spoke to a team member that is just a little – has been here a little bit more amount of time than I have been, but they directed me. I can see that **Meritain was removed because you didn't receive a payment for 90 days.** [0:00:30]

Dr. Alex Shteynshlyuger: What are you talking about? I'm confused.

Courtney – ECHO Health Representative: Sure. So let's go to the Meritain issue, the ESP issue. So, you said that you were like unenrolled in November, right? Or just enrolled I do apologize.

Dr. Alex Shteynshlyuger: What do you mean dis-enrolled?

Courtney – ECHO Health Representative: That's what you said, right? You said you are no longer – you gave me a November date I thought, but-.

Dr. Alex Shteynshlyuger: No.

Courtney – ECHO Health Representative: What happened-.

Dr. Alex Shteynshlyuger: [0:01:00] On January 5, 2018, **Angela Cascone** emailed me to confirm that I'm enrolled in EFT. Do we have an enrollment date for EFT for Meritain Health in your system for me?

Courtney – ECHO Health Representative: So I do see those forms were saved on January 5th, 2018 and at the end [crosstalk] [0:01:24] of the year-.

Dr. Alex Shteynshlyuger: Was I enrolled in EFT?

Courtney – ECHO Health Representative: You [0:01:30] were enrolled in EFT, January 5th 20018.

Dr. Alex Shteynshlyuger: Okay, and what happened?

Courtney – ECHO Health Representative: Well towards the end of the year after – for one reason or another, you didn't receive a payment issued by Meritain Health for 90 days, for a period of 90 days. Meritain did not issue you any payments. **So after 90 days that EFT goes stale [0:02:00] because they had no activity for 90 days. So we can just get you re-signed up, we can get you the forms and you can fill them out and just – you may want that [crosstal**k] [0:02:11]-.

Dr. Alex Shteynshlyuger: You unenrolled me from EFT? That's what you're telling me, after 90 days?

Courtney – ECHO Health Representative: We didn't unroll you after 90 days, **the system un-enrolled you because of inactivity for 90 days.** So for 90 days, at some point 90 days last year, [0:02:30] Meritain did not issue you any payments. So because of that-.

Dr. Alex Shteynshlyuger: So each time you don't have the payment for 90 days you un-enroll from EFT. And what do you do next? [Crosstalk] [0:02:43] and this is your settings. This is for all payors [0:02:49] or just Meritain? You won't [crosstalk] [0:02:52]-.

Courtney – ECHO Health Representative: This is the first [crosstalk] [0:02:53]-.

Dr. Alex Shteynshlyuger: Are you sure I'm not a [indiscernible] [0:02:56]. Do you know the answer for sure, 100% [0:03:00] to this question?

Courtney – ECHO Health Representative: Yes.

Dr. Alex Shteynshlyuger: Are you sure?

Courtney – ECHO Health Representative: Yes.

Dr. Alex Shteynshlyuger: Because this is going to a federal agency, so you need to provide a very – I need to talk to a supervisor. I'm sorry if you spoke – if you've been there for a month, I don't think you can provide a reliable answer. I need to speak to a supervisor who has been here at least a year or two. Who is, [indiscernible] [0:03:26]-.

Courtney – ECHO Health Representative: Okay, fine. Okay, hold on. [0:03:30] Alex, do you need me to still be on the phone?

Dr. Alex Shteynshlyuger: Yeah. I want [inaudible] [0:03:36] problem. This is becoming more and more complicated. It's not [indiscernible] [0:03:43] and I don't want to [inaudible] [0:03:49]

that's it. [0:04:00] But I didn't create this mess [indiscernible] [0:04:03] is creating the complicated system, enrolls and un-enrolls providers without asking them-.

Courtney – ECHO Health Representative: So what I could do for you, I could go in and put you as unenrolled, would you like me to do that?

Dr. Alex Shteynshlyuger: No, hold on for now, let's get to the bottom of this. I already am enrolled once. This is you know, I cannot be calling every night and day [inaudible] [0:04:35] credit card and still [inaudible] [0:04:38], this is a joke.

Courtney – ECHO Health Representative: [indiscernible] [0:04:47] Okay, I'm going to transfer you.

Dr. Alex Shteynshlyuger: Okay, thank you Courtney.

Angie – ECHO Health Supervisor: ECHO Health, this is Angie, how can I help you?

Dr. Alex Shteynshlyuger: I'm sorry, what's your name?

Angie – ECHO Health Supervisor: My name is Angie.

Dr. Alex Shteynshlyuger: Angie, how are you doing? My Name is Dr. Alex Shteynshlyuger. I'm a physician in New York City. I'm calling about [0:05:30] ECHO Health. Do you need my tax ID?

Angie – ECHO Health Supervisor: Yes, please.

Dr. Alex Shteynshlyuger: It's XXXX73615.

Angie – ECHO Health Supervisor: Okay. And how can I help you?

Dr. Alex Shteynshlyuger: Okay. Before we get started are you a supervisor? What is your position?

Angie – ECHO Health Supervisor: Yes, I'm a lead.

Dr. Alex Shteynshlyuger: You're a lead. How long have you been with ECHO Health?

Angie – ECHO Health Supervisor: This will be **three years in December.**

Dr. Alex Shteynshlyuger: So you know, quite a bit. [0:06:00] all right, so here -.

Angie – ECHO Health Supervisor: Yeah, a little bit.

Dr. Alex Shteynshlyuger: You know I spoke to Courtney and no offense; she's been only here for a month. So I was asking very detailed and complicated questions and I didn't want to get wrong information. I've been calling you multiple times before and I don't want to get incorrect

information. Now, here's the situation. I enrolled in EFT on January 5, 2018, [0:06:30] through ECHO Health with Meritain. Do you have that in your system? Is that correct?

Angie – ECHO Health Supervisor: I see that we did process an enrollment for you, but I also see that it was removed for stale banking.

Dr. Alex Shteynshlyuger: Why was it removed?

Angie – ECHO Health Supervisor: So **we implemented a new system, where if you don't receive a payment for 90 days from that particular payer, the banking is removed** [0:07:00] from our system.

Dr. Alex Shteynshlyuger: That's not just for Meritains, it's for every payer?

Angie – ECHO Health Supervisor: Right. It's for all the ECHO payers, so any payers that are processed through our system.

Dr. Alex Shteynshlyuger: So after 90 days, if I don't receive EFT, the EFT is deleted.

Angie – ECHO Health Supervisor: Correct.

Dr. Alex Shteynshlyuger: And what happens next? How do I get payments?

Angie – ECHO Health Supervisor: If you did happen not to get a payment after that 90 days, you would revert back [0:07:30] to our default payment method, which could be a virtual card, paper check, we have something called Medpay where you can print out your paper checks; it sort-of funnels through the system.

Dr. Alex Shteynshlyuger: What is the default payment for me?

Angie – ECHO Health Supervisor: I can take a look and see what your most recent email was sent as.

Dr. Alex Shteynshlyuger: How do you determine what is the default payment for a particular account?

Angie – ECHO Health Supervisor: So we started the talk with EFT and we checked to see if you're enrolled for EFT. If you're not [0:08:00] the next default method would be virtual card. After that, is something called Elavon, which if you're enrolled in Elavon, you would be offered Elavon payments. After that would be MedPay. And then after that would be paper check.

Dr. Alex Shteynshlyuger: What is Elavon?

Angie – ECHO Health Supervisor: That's just a company that we work with to process payments. Some providers use them for their merchant terminals. Like what you would swipe your credit card through. Some don't, but you would know if you had them. Let me see where you're at here.

Dr. Alex Shteynshlyuger: And how [0:08:30] do you know which method payment to use?

Angie – ECHO Health Supervisor: Like I said, we start at the top and we just work our way down depending on your opt-out. So if you're enrolled in EFT that would be the first way we would try to pay. And then the next way we would try to pay with the virtual card, which if you opt-out of a virtual card, then we would pay Elavon, if you don't work with Elavon, we would pay MedPay. If you opt out of MedPay, we would pay paper check.

Dr. Alex Shteynshlyuger: What is MedPay? Is this also a credit card?

Angie – ECHO Health Supervisor: No, that's a paper check [0:09:00] option. It's kind of cool. We recently introduced it. You can print your paper check online and then take that to the bank so that you don't have to wait for it to come in the mail.

Dr. Alex Shteynshlyuger: What about Elavon? Elavon, is it a credit card?

Angie – ECHO Health Supervisor: Yeah, that's a company that you would be contracted with for credit card payments, but they also do direct deposit and we work with them in regards to direct deposits. So if you happen to sign a contract with Elavon to like install their credit card terminals in your office [0:09:30], in there, in that contract that you sign with Elavon, is an option for you to get direct deposit.

Dr. Alex Shteynshlyuger: And with MedPay, is there a cost to using MedPay?

Angie – ECHO Health Supervisor: No, not to put your payments out, there's no fee. On the MedPay website, if you want to convert into like an instant deposit right there on the website, I think they do charge a fee, but if you want to just print out your check and take it to the bank, there is no fee.

Dr. Alex Shteynshlyuger: And if I don’t choose MedPay, then what's the next payment method?

Angie – ECHO Health Supervisor: After that would just be a regular paper [0:10:00] check.

Dr. Alex Shteynshlyuger: Paper check. Now, did I previously opt out of a virtual credit card?

Angie – ECHO Health Supervisor: I'm not saying that you opted out for Meritain. That's what I have pulled up here. I'm showing that you're currently receiving Meritain virtual cards.

Dr. Alex Shteynshlyuger: Yeah, we did it – this is how it works, when I enroll in EFT, **I also opted out of virtual credit cards and I'm still getting virtual credit cards. So the question is why**?

Angie – ECHO Health Supervisor: Let me take a look at your opt-out history [0:10:30] for all payers to see if I can see what happened.

Dr. Alex Shteynshlyuger: That would be good.

Angie – ECHO Health Supervisor: Okay. I think I see what's happening here. **We have more than one virtual card offering. And you received card ID two which is our second card offering [0:11:00] that's offered 300 days after the initial opt-out of our first card offering.**

Dr. Alex Shteynshlyuger: I'm sorry, how does it work? Card ID two, what does it do?

Angie – ECHO Health Supervisor: So we have more than one card offering, the card offering that you received is our secondary card offering and it's offered to you 300 days after your initial opt-out.

Dr. Alex Shteynshlyuger: So after I opt out of card ID one, 300 days after; I'm automatically enrolled in card ID two, right?

Angie – ECHO Health Supervisor: [0:11:30] **Correct**.

Dr. Alex Shteynshlyuger: How many different cards IDs do you have?

Angie – ECHO Health Supervisor: We have three.

Dr. Alex Shteynshlyuger: And if I opt out of card ID two, will I be automatically enrolled in card ID three after some period of time?

Angie – ECHO Health Supervisor: No, the third card offering is only sent to you if you run a card payment from like a different payer. So if you start accepting cards again, then we re-enroll you. But if you don't accept cards and you never run the cards, then [0:12:00] you're not going to be offered another one.

Dr. Alex Shteynshlyuger: How am I supposed to know that you have two card IDs? Did I enroll specifically from card ID one? Did you tell me that there are two cards and I need to un-enroll from two of them?

Angie – ECHO Health Supervisor: We do let you know in a letter that goes out, that there are – that the default method of payment is the virtual card.

Dr. Alex Shteynshlyuger: Right.

Angie – ECHO Health Supervisor: So **we're going to try to pay you by virtual card as many times as we can** [crosstalk] [0:12:24]-.

Dr. Alex Shteynshlyuger: First of all, I enrolled in EFT. Second of all I unenrolled from virtual [0:12:30] card. I did not specify whether it's virtual card one or two because you didn't give me an option. So I un-enrolled from virtual card and 300 days later your policies choose to send me a different virtual card despite the fact that I opted out of it as a payment option.

Angie – ECHO Health Supervisor: Right. Be sure that a lot of providers end up installing merchant terminals [0:12:51] and they get [indiscernible] [0:12:52] at a later date.

Dr. Alex Shteynshlyuger: Okay, all right. So basically to summarize, [0:13:00] **I enrolled in EFT, you automatically un-enrolled EFT after 90 days if there is no payment for all providers, for all insurance companies. That's the ECHO Health policy.** Second, **I opted out of virtual credit card, more than a year ago but your policy is to opt me back in into a different type of virtual credit card called [0:13:30] card ID number two, despite the fact that I already opted out from a virtual credit card previously. Anything is incorrect?**

Angie – ECHO Health Supervisor: On that first part we would remove the banking for just Meritain. We wouldn't remove the banking for any other payers.

Dr. Alex Shteynshlyuger: Well if I didn't-.

Angie – ECHO Health Supervisor: You have to have a payment for 90 days from that particular payer or else we remove the banking.

Dr. Alex Shteynshlyuger: So **for any payer that I didn't get a payment in 90 days [0:14:00], you remove the EFT as an option, right?**

Angie – ECHO Health Supervisor: Right, yes.

Dr. Alex Shteynshlyuger: That sounds like a wonderful business plan. All right, so you should probably bring this conversation up to your supervisor because I'm going to file a complaint with Centers of Medicare and Medicaid who regulate EFT and ERA. And your lawyers for ECHO Health should probably review this recording because they will need to provide an answer to the federal government about your policy.

Angie – ECHO Health Supervisor: Okay.

Dr. Alex Shteynshlyuger: Okay?

Angie – ECHO Health Supervisor: All right, sounds good.

Dr. Alex Shteynshlyuger: So how do I opt out of payment for credit card number two?

Angie – ECHO Health Supervisor: I can opt you out now. That's not a problem. If you're not interested in the virtual cards, if you didn't get a terminal, if you're still not on the card acceptor, I can go ahead and get you opted out. [0:15:00]

Dr. Alex Shteynshlyuger: Wonderful. And how do I enroll in EFT?

Angie – ECHO Health Supervisor: I can send you the paperwork, you will fill out the-.

Dr. Alex Shteynshlyuger: I already filled out the paperwork a year ago.

Angie – ECHO Health Supervisor: Right. But we need you to revalidate since the draft information on there would have expired. It's just part of our procedure to prevent fraud.

Dr. Alex Shteynshlyuger: Did you inform me that you are un-enrolling me from EFT for Meritain Health?

Angie – ECHO Health Supervisor: I'm not sure if a letter goes out or not, [0:15:30] but I can look into that for you.

Dr. Alex Shteynshlyuger: Can you look it up? Did a letter go out to me?

Angie – ECHO Health Supervisor: That would have to be something that I would have to look up. I'm not sure if a letter was sent or not. I'm not aware of one. But I can take a look.

Dr. Alex Shteynshlyuger: Well, you've been working there for three years. If letters were going out, you would be aware of it, right?

Angie – ECHO Health Supervisor: Not always. It's not my specific department, but I can definitely take a look for you.

Dr. Alex Shteynshlyuger: Well it would be in my account, right? All the communication is saved under my tax ID [0:16:00] right? So, can you see [crosstalk] [0:16:02]-?

Angie – ECHO Health Supervisor: No, we don’t keep provider records like that, no.

Dr. Alex Shteynshlyuger: [Inaudible] [0:16:05]. Well I can tell you this much, I was not informed. You have my email; you have my mailing address. **I did not get a letter from you informing that my tax id or EFT is being removed.** Okay.

Angie – ECHO Health Supervisor: Okay. I'll go ahead and make a note of that and I'll let our team know to see if that's something that we can start doing [0:16:30], sending out a letter, because I'm not aware of any letters right now that go out. So I'll see if there is a letter, but if not, I'll definitely raise that concern and say that providers are wanting a letter letting them know that the banking is going to be removed.

Dr. Alex Shteynshlyuger: Okay Angie. There are federal laws that regulate the requirements for EFT and ERA. And one of the requirements is if I ask for EFT to get me an EFT, **there is no rule allowing you to expire EFT within 90 days and opting me in into a virtual credit card.** But that's not something you know, you need to worry about. This is your management that needs to worry about it. I think Brittney is still on the line and I appreciate Brittney for being there and I think you probably learned a little bit on how the payments and virtual credit cards work.

Brittney – ECHO Health Representative: Yes, thank you.

Dr. Alex Shteynshlyuger: Okay. All right, Angie, thank you for your help as well. Thank you Brittney and have a good day.

Angie – ECHO Health Supervisor: Thanks, you too. Bye-.

Brittney – ECHO Health Representative: Okay, thank you for calling ECHO Health Dr. Alex. Have a nice day.

Dr. Alex Shteynshlyuger: Bye.

Operator: All parties have disconnected the line.

[Audio Ends] [0:17:43]

Testimony of Sajid Imam
Senior Director, Global Vertical Solutions (Commercial & Prepaid) – Healthcare & Insurance
Visa Inc.

National Committee on Vital and Health Statistics (NCVHS)
Subcommittee on Privacy, Confidentiality & Security

Open Meeting: Section 1179 of the Health Insurance Portability and Accountability Act

May 6, 2015

I. Introduction

Members of the Subcommittee, thank you for inviting me to speak with you today. My name is Sajid Imam, and I am the Senior Director for Global Vertical Solutions (Commercial and Prepaid) – Healthcare & Insurance, at Visa Inc.

Visa is a global payments technology company. It has been a pioneer in electronic payments since 1958. As a premier payments technology company, Visa's global network connects thousands of financial institutions with millions of merchants and cardholders every day. Visa does not itself issue payment cards to consumers or businesses, but rather Visa's network supports the Visa-branded credit, debit, and prepaid products designed by issuing banks to enable cardholders to make purchases at merchants and retailers globally and receive funds in a convenient, secure and reliable manner. The transactions carried over Visa's network include consumer transactions, as well as business to business (B2B) and government to business (G2B) transactions. Each of these transaction use cases can be supported by payment card solutions.

Visa supports multiple types of electronic payment or electronic funds transfer (EFT) transactions types through its network. Its innovation in EFT enables new channels and/or form factors, such as mobile payments, near field communications (NFC) and virtual cards (described further below), among others, that utilize the card platform in the background.[1] As payments increasingly move to the digital environment, Visa is investing in mobile platforms, technologies and capabilities to enable consumers and businesses to continue to pay and get paid, with the same convenience, security, reliability, and global acceptance that Visa has achieved in the physical world.

II. Use of Payment Cards for Consumer Health Care Transactions

As consumers, we are an increasingly electronic society, with transactions by payment card – credit or debit (which includes prepaid) – often replacing cash or check as the preferred means of payment. Payment by debit and credit card has become a nearly universal means by which consumers, including consumers of health care, pay merchants (including health care providers and health insurance issuers) for goods and services, with such payments constituting approximately 46% of the dollar volume of all U.S. consumer spending in

[1] The U.S. Department of Health and Human Services (HHS) and the National Committee on Vital and Health Statistics has recognized that EFT transactions can encompass transactions conducted by ACH, FedWire, or payment card network. *See* Adoption of Standards for Health Care Electronic Funds Transfers (EFTs) and Remittance Advice, 77 Fed. Reg. 1556, 1567 (Jan. 20, 2012); NCVHS Letter to Secretary of HHS at 3 and App. A at 3 (February 17, 2011).

2010 and projected to constitute approximately 56% of such total dollar volume in 2015.[2] This is especially true with respect to younger consumers. An overwhelming number of individuals under the age of 30 cite debit cards as their preferred method of payment.[3] But this is the case not only for young or affluent consumers, but also for the unbanked and underbanked population that disproportionately relies on general use prepaid cards for purchase transactions because the absence of a bank account renders them unable to write traditional checks or to use direct electronic transfers.[4]

This trend also encompasses payment for health care and health insurance. Payment cards are ubiquitous as a form of payment. Accordingly, most health care providers accept payment cards as a means of payment.[5] The trend can also be seen in the insurance purchase market where:

- Consumer use of credit or debit cards to pay for insurance has more than doubled since 2003;[6]
- Fees associated with prepaid cards are typically less than fees associated with traditional checking accounts;[7]
- Cards complement other payment options, with increased card acceptance not expected to result in fewer Automated Clearing House (ACH) payments;[8] and

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[2] Nilson Report No. 985 (Dec. 2011), p. 1. Specifically, debit payments constituted 21% of such dollar volume in 2010 and are projected to constitute 25% of such dollar volume in 2015, while credit card payments constituted approximately 25% of such dollar volume in 2010 and are projected to constitute 31% of such dollar volume in 2015. *Id.* In terms of number of transactions, debit cards are now the most prevalent card payment option, constituting roughly 60% of card payment transactions. J. Miller, "Paying with Plastic," *Public Utilities Fortnightly* (Dec. 2009), *available at* http://www.fortnightly.com/fortnightly/2009/12/paying-plastic (full article accessible to subscribers).

[3] Visa US Consumer Issues Monitor (January 2010); Younger Insurance Consumers Expect Online Insurance Options, Insurance Journal (January 2011); *see also* Visa US Payments Tracker (2011) (showing that consumers in the 18-24 age group prefer debit cards to any other payment options and consumers in the 25-34 age group prefer debit nearly as much as online banking payments).

[4] This segment of the population is substantial: the Federal Deposit Insurance Corporation estimates that 7.7% of U.S. households (roughly 9 million) are "unbanked," while an estimated 17.9% of U.S. households (roughly 21 million) are "underbanked." FDIC National Survey of Unbanked and Underbanked Households (Dec. 2009), http://www.fdic.gov/householdsurvey/full_report.pdf. Together, at least 25.6% of U.S. households (nearly 30 million households, in which approximately 60 million U.S. adults reside) are either "unbanked" or "underbanked." *Id.*

[5] According to a 2009 study conducted by Medical Group Management Association of its members, 98% of survey respondents accept payment cards. 2009 Visa/MGMA Practice Perspectives on Patient Payments. This reflects general consumer preference for card-based payments, as well as the recent migration of payments tied to health and welfare benefit accounts (e.g., HSA, FSA) away from paper checks to cards and card-based solutions. *See* IRS Revenue Ruling 2003-43 and IRS Notice 2006-69.

[6] Visa Payment Panel (2011).

[7] See Checking vs. Prepaid: Threat or Opportunity, https://www.javelinstrategy.com/brochure/286.

[8] How Americans Pay Their Bills: Sizing and Forecasting Bill Pay Channels and Methods, 2010-2013 (October 2010).

- 79% of all insurance purchasers want multiple online payment options.[9]

HHS has recognized this trend in a number of ways, including by requiring the issuers of qualified health plans at a minimum to accept, for all payments in the individual market, paper checks, cashier's checks, money orders, EFT, and all general-purpose prepaid debit cards as methods of payment and to present all payment method options equally for a consumer to select their preferred payment method.[10]

On the consumer side, payment card technology is used to enable the payment of provider bills, insurance premiums, and certain select IRS-approved health transactions for health and dependent care flexible spending arrangements[11] safely and securely. Card technology is also used to allow access to health savings account (HSA) funds even though IRS limitations on withdrawals do not apply.

In a typical consumer transaction, the following types of information may flow through the payment card system/network: cardholder name, card number, card verification code (CVV2), card expiration date, transaction date, transaction amount, merchant name, merchant id, terminal id, and merchant category code (MCC). However, the payment transaction contains no information that identifies the specific product(s) and/or service(s) being purchased by the cardholder. Even in the processing of transactions related to health-care specific payment cards associated with health flexible spending arrangements (FSAs), health reimbursement arrangements (HRAs) and HSAs, individual item level detail and/or details of goods and services being paid for by the cardholder do not form part of the transaction flow, and are not visible or captured by the card networks.

III. Use of Payment Card for Health Care B2B and G2B Transactions

On the commercial side, one type of EFT transaction increasingly being used in the health care industry today is "virtual card payment" whereby providers can be paid by payors, such as health plans, using a credit or prepaid card, that is virtual in nature (i.e., without the plastic), over the payment card networks through the use of an electronic authorization. Reasons for growth in the use of virtual card payments include: ease of acceptance, elimination of need to reconfigure systems or enroll with separate health plans to accept EFT payments, no need to provide banking information to health plans, and facilitation of payment re-association and reconciliation for EFT transactions.[12] When coupled with

[9] Visa US Consumer Issues Monitor (January 2010); Younger Insurance Consumers Expect Online Insurance Options, Insurance Journal (January 2011).

[10] 45 C.F.R. § 156.1240(a)(2).

[11] See IRS Rev. Rul. 2003-43.

[12] The Accredited Standards Committee X12 is currently engaged in efforts – which we support – to include, in the HIPAA ERA transaction standard, an identifier for payment cards in the BPR (financial information) and TRN (re-association trace number) segments to facilitate the use and re-association of payment card EFTs with the ERA. Although X12 has made significant progress, and has voted to adopt a

additional information separately maintained in an accounts payable automation system, virtual card EFT payment solutions can meet all of the core requirements under HIPAA for administrative simplification: (1) automated reconciliation; (2) addressing acknowledgments; (3) reducing manual effort; and (4) describing data elements in unambiguous terms.[13]

The typical commercial health care payment transaction contains many of the same categories of information as noted above for consumer transactions. Additionally, a commercial health care payment transaction may also include: health plan/payor name, health plan/payor identification number, health care provider/payee/merchant name and number, and trace re-association number. However, no information related to the actual health care claim, for which the payor is paying the provider, flows through and/or is captured by the payment network in a payment card EFT transaction. Thus, for example, the payment card EFT transaction would not include the name of, or any identifiable information about, any individual patient(s) for whose health care payment is being made, or any information on the products or services for which payment is made.

IV. Health Care Payment Card Transactions Are Exempt from HIPAA under Social Security Act § 1179

When processing consumer or commercial health care payment card transactions, financial institutions (including card issuers and their agents) are exempt from meeting HIPAA requirements, including the business associate provisions, under an exemption provided in Social Security Act § 1179. This exemption provides, in part, that

> To the extent that an entity is engaged in *activities of a financial institution* (as defined in section 3401 of title 12),[14] or is engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments, for a financial institution, *this part, and any standard adopted under this part, shall not apply to the entity with respect to such activities*, including the following:
>
> (1) The use or disclosure of information by the entity for authorizing, *processing, clearing, settling, billing, transferring, reconciling or collecting, a payment for, or related to, health plan premiums or health care*, *where such payment is made by any means*, including a

completed Business Requirements Technical Solution document (BRTS #1265) for introducing a code for Card Payment Type in the 835 transaction standard, the process is lengthy and far from conclusion.

[13] HIPAA Title II, Subtitle F. Pub. L. 103-191.

[14] As defined there, "financial institution" means "any office of a bank, savings bank, *card issuer* as defined in section 1602(n) [now 1602(o)] of title 15, industrial loan company, trust company, savings association, building and loan, or homestead association (including cooperative banks), credit union, or consumer finance institution, located in any State or territory of the United States, the District of Columbia, Puerto Rico, Guam, American Samoa, or the Virgin Islands." 12 U.S.C. § 3401(1) (emphasis added).

> *credit, debit, or other payment card*, an account, check, or *electronic funds transfer*.[15]

There is nothing in the language of this provision that would limit the exemption for financial institutions to consumer-conducted transactions.[16]

V. Health Care Payment Card Transaction Generally Do Not Include PHI Other Than as Necessary to Effectuate the Transaction and As Permitted by HHS

Consistent with the exemption in Social Security Act § 1179, health care payment card transactions do not include protected health information (PHI) – other than as may be necessary to effectuate the transaction. This is true for both consumer payment cards and business payment cards. As noted above, although a consumer payment card transaction may include the name of a consumer and the name of a health care provider (or health insurance issuer), it does not contain any medical/health care information, such as medical diagnosis, condition, or treatment. Similarly, a transaction involving a business payment card aligns with the CCD+ format to provide a similar flow of payment and transaction information, as is associated with an ACH payment today, with no PHI being transmitted in the transaction.[17]

HHS has previously recognized that, consistent with Section 1179, a limited amount of PHI may be included in a health care payment transaction involving a financial institution, without triggering HIPAA coverage:

> We seek to achieve a balance between protecting patient privacy and facilitating the efficient operation of the health care system. While we agree that financial institutions should not have access to extensive information about individuals' health, we recognize that even the minimal information required for processing of payments may effectively reveal a patient's health condition; for example, the fact that a person has written a check to a provider suggests that services were rendered to the person or a family member. Requiring authorization for disclosure of protected health information to a financial institution in order to process every payment transaction would make it difficult, if not impossible for the health care system to operate effectively.[18]

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[15] SSA § 1179, 42 U.S.C. § 1320d-8 (emphasis added).

[16] *See*, e.g., 77 Fed. Reg. at 1567 (recognizing that financial institutions conducting health care EFT transactions would be exempt, under section 1179, from compliance with the adopted HIPAA standard).

[17] HHS has recognized that the ACH CCD+ EFT transaction does not include individually identifiable health information, although it may contain health information. 77 Fed. Reg. at 1567. Because the payment card EFT transaction aligns with the CCD+ format, it too would not contain individually identifiable health information and, thus, not contain PHI.

[18] 65 Fed. Reg. at 82616.

Similarly, financial institutions may submit payment transactions and disclose PHI (or otherwise individually identifiable health information) to intermediary payment processors under Section 1179 without an authorization (or business associate agreement with health plan or provider clients) for health care payment transactions.[19]

Any identifiable information transmitted in the processing of health care payment card EFT transactions – whether on the consumer or commercial side – is consistent with these limitations.

VI. Health Care Payment Card Transaction Information Is Secure

Payment card networks and the payment card system employ a number of features that protect any identifiable information contained in payment card transactions. Any merchant – including health care providers and health insurance issuers – that accepts card payments must comply with the PCI Security Council information security standards with respect to such payment transactions. Visa and the other payment card brands enforce these standards with respect to merchants (including health care providers and health insurance issuers) accepting their branded payment cards to safeguard consumers' information. And, if consumer payment card information is nevertheless compromised, and fraudulent or unauthorized transactions occur, the consumer is not liable to pay such charges under the payment card brands' respective Zero Liability policies.

With respect to B2B transactions, payment card EFT transactions provide a safe method of electronic payment. First, if the payment card EFT is a Straight Through Processing (STP) payment, the funds are directly deposited into the provider's merchant banking account, and there is no possibility of diversion.[20] Second, in most cases, the information necessary to process the card transaction (e.g., card number, expiration date, etc.) are generally transmitted to providers by secure email. Third, payment card numbers can be restricted to specific MCCs, which means that such payment cards can only be used by a specific type of merchant (e.g., doctors, hospitals, etc.). Finally, in most cases, the payment card can only be negotiated for the exact payment amount that the payor authorizes, another protection against diversion of payment.

* * * *

Visa looks forward to working with NCVHS and other stakeholders on issues relating to the involvement of financial institutions in health care transactions and to the section

[19] *See* 65 Fed. Reg. at 82495; *see also* 65 Fed. Reg. at 82535, 82617 (recognizing that, under the minimum necessary rule, certain information is generally necessary for certain payment processing activities of financial institutions, including name and address of the individual; name and address of the payor or provider; amount of charge for health services; date on which health services were rendered; the expiration date for the payment mechanism (i.e., credit card expiration date); individual's signature; and relevant identification and account numbers).

[20] With "Straight Through Processing" (STP), the automated payment card transaction processing service available to providers, a health plan/payor can submit a payment directly to the provider's acquiring institution for disbursement to the provider's bank account, without the need for a provider to manually key enter the card number into a Point of Sale terminal to process the payment card EFT transaction.

1179 exemption applicable to financial institutions engaged in payment processing activities.

If you have any questions or would like to discuss these issues further, I would be happy to do so.

Thank you.

Sajid Imam
Senior Director
Visa Inc.
Tel: 650 432 1646

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Initial Complaint
11/09/2022

Initiated assistance with Zelis payments on 07/21/22 to get our admin changed on our portal so we could access the system. It is now 11/8/22 and this issue has yet to be resolved. I have called over 20 times and sent multiple emails trying to get this resolved and never receive a response. When I call in, I can only speak with the "payments customer service" department and I'm told this is an "IT issue" and IT will have to reach out to me; yet they never do. On my most recent call, I was told by the payments customer service rep that they don't have any access to the IT team aside from sending them a message.

Business response
11/10/2022

**********,

I reviewed your account with Zelis' Technical Support Team and they did confirm your account was linked to larger issue impacting more than one client. I apologize for the delay and the inconvenience. It appears Zelis was able to resolve the issue with you on 11/08/2022 at 03:05 PM. If you continue to experience issues, please let me know.

Regards,

Zelis Payments

Customer response
11/11/2022

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Sincerely,

****

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
10/21/2022

I am a behavioral health care provider contracted with **********, who uses Zelis/Epayment Center as their electronic funds transfer partner. I have been endeavoring to set up EFT since August 1st. It is now October 20th and I am still being told that my verification has not been completed, even though I completed verification and provided bank account information multiple times, including most recently on September 16th, when I was repeatedly assured (by *****, who was helpful) that I was verified. Every rep I have spoken with tells me they need to have their "verifications specialist" complete verification, but he is never in the office. They tell me that he has "repeatedly tried to contact me", but I have records of all incoming phone calls and he has never once contacted me, by phone or email. Their lack of follow up and blatant false information has been costing me and my practice money, and

hurting my relationship with the insurer. I am happy to provide a record of my interactions and lack of follow up with this company and their reps, but I have run out of characters to provide this in full.

Business response
10/27/2022

Hello **********,

Zelis reached out and spoke to you on 10/26/22. Your account information was verified and your ACH enrollment is complete. Please let us know if you need further assistance.

Regards,

Zelis Payments

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
10/19/2022

Zelis needs to STOP stealing my already limited medical visit payments ! ASAP!! I will report each payment Zelis has illegally obtained from my practice to each insurance company ! We have spoke with Zelis mutltiple times, but keep receiving unauthorized, negotiated checks and virtual payments. Payments need to come directly from the insurance carrier!

Business response
10/24/2022

Hello **********,

We have received and actioned your request.

Please contact your payer if you do not agree with a previous claim payment amount that you received by check.

Checks and remittance are printed and delivered as instructed by the carrier.

Respectfully, Zelis

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
10/19/2022

I am a provider at a sole-proprietor mental health practice . An insurance company who I am contracted with started using Zelis payments for provided services, and I have struggled to be paid ever since. I was authorized to be paid by the insurance company on July 10. It is October and I still haven't been paid, in spite of many phone calls. I am constantly told I will be put in touch with someone who can get to the bottom of the delay, and am never called back. They said they sent a check, but it never arrived. At this point, Zelis has thousands of dollars in my payments for services that they have not paid me, and that I require to effectively run my business. Zelis has been completely ineffective and uncommunicative. I have not been contacted once about this issue, in spite of ***** phone calls I have made to them to resolve this matter.

Business response
10/21/2022

**********,

Your issue was escalated. Our records indicate a Zelis associate reached out to you and your ACH enrollment has been completed. All past and future payments will be processed via ACH.

Regards,

****

Customer response
10/21/2022

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Sincerely,

****

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
10/11/2022

Unfortunately, it appears filing a complaint with the BBB is the only way to opt out of these virtual cards. You will wait on hold for over an hour - our staff has done this more times than our payroll can allow - sadly it is usually for an $18.00 check. No option to opt out online - you have to actually sit on hold in their que. Then their representative rudely gives you push back for wanting out of the cards. IF you want to get EFT, there are fees with this as well (almost equivalent to CC Merchant fees) - which is not disclosed until you have completed a crapload of data entry for their enrollment documents. We want a paper check mailed to us. Period. Why do they make this so miserable? Hopefully the receive enough complaints to make a more streamlined option. They should take a ****** from ECHO QuicRemit - easy opt out online and takes 30 seconds. These insurance carriers have no clue how poorly Zelis reflects upon the insurance carrier.

Business response
10/14/2022

Poppy,

Thank you for contacting Zelis Payments. Your request to opt-out your account ending in **** has been processed. Your account has also been flagged and you will not longer received virtual credit card payments. Please let us know if you have any additional questions.

Thank you
Zelis Payments

Customer response
10/21/2022

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Sincerely,

Poppy ******

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
09/23/2022

We use are a dental office & use Zelis payment portal for some of our providers payments. I have contacted Zelis three times & also sent an email. The first contact was on 9/13/2022 because I have been unable to access the portal or unable to reset my password. I was told someone would contact me between 5-7 days to help with my issue. My second phone call was 9/19/22 & an email was also sent requesting help. My third call was today because I have yet to get a phone call or email response to my issue. If I cant have access to the portal I'm unable to do my job.

Business response
09/27/2022

**********, Upon receipt of your complaint, an escalation request was sent to the proper department. Our records indicate that your issue was resolved and your account has been updated. Please let us know if you require further assistance. Thank you.

Customer response
10/03/2022

Complaint: 18062302

I am rejecting this response because: although I received a call from Zelis, my issue is still not resolved. I am still unable to log onto the portal for payments. I was told another department would have to help me fix the issue. I am currently waiting to hear from that department.

Sincerely,

****

Business response
10/05/2022

**********, I escalated your issue with our technical support team and I received confirmation today that your password has been reset. They also advised that your office

confirmed that they can login, have access to the data they require and that everything is working as intended. Thank you, **********

Customer response
10/06/2022

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Sincerely,

****

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
09/21/2022

My office begin receiving virtual credit card payments from insurance companies that we have never signed up for. I first thought that's how the insurance companies were paying claims until I looked at our CC fees. I called the insurance companies to receive paper checks and at that point was told I needed to call Zelis and opt out of the virtual CC payments. I have called for the past 2 months trying to opt out and every time a rep says a customer care rep will call us and assist with opting out but we never receive a call. We pay fees for each transaction and how is this legal!!!!! How did they receive our information to just intercept OUR payments and take some for themselves without OUR permission!!!!! Asked for a copy of the signed agreement between our office and Zelis and was hung up on. They are PURE THEIVES!!!!!!

Business response
09/21/2022

*******,

As discussed in our recent telephone conversation, your account has been opted out of the Virtual Card product and future payments will be sent as checks. I added you to our Do Not Call List.

Please let me know if you need further assistance.

Regards, **********

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
09/13/2022

Zelis Payments, LLC is fraudulently receiving payments that belong to our business. I have attempted to get paid through Zelis Payments since they fraudulently took over. I do not ever want to have have any agreement or contract with Zelis Payments. I had never heard of Zelis Payments until somehow they started collecting my payments from insurance reimbursements. . Today, I contacted the insurance companies (1) ILWU-PMA Zenith American, (2) Blue Shield of CA and (UMR)., but of the insurance companies advised me that They did not provide our information to Zelis Payments, (2) Zelis Payments added our business and Federal Tax ID #XXXXXXXXX to ********** "Provider List." In doing so, Zelis Payments has fraudulently instructed insurance companies to send payments due to our business to Zelis Payments instead of sending the payments directly to us. I have contacted Zelis Payments to attempt to receive my payments but Zelis s holding several payments that belong to my business, in a nonredeemable virtual credit cards, and are not able to covert payments to paper checks. I told the Zelis Payments representative, to convert to paper check on at least ten occasions with no result, they are still holding a virtual credit card that caused my Square merchant dump ME as a client.t I will have no relationship whatsoever with Zelis Payments! I never agreed to or authorized Zelis Payments to collect payments on my behalf. I instructed the Zelis Payments representative to return our payments to the Insurance Companies and to REMOVE our business name and Tax ID from their "provider list" and data base. The Zelis Payments representative asked me to contact the insurance companies. I explained each insurance company told me they were instructed by Zelis Payments to send our payments to Zelis Payments stated this error can only be corrected by Zelis Payments. I did a ****** search of Zelis Payments; there are many complaints about Zelis Payments from other doctors.

Business response
09/21/2022

Zelis partners with multiple payers to help facilitate electronic payments. We have processed your request to have your account removed from our database and will convert any outstanding virtual credit card payments that were received to checks. Please let us know if you have any further questions or comments on this matter.
Sincerely
Zelis

Customer response
09/21/2022

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.
My complaint remains as a warning to the business to do better. Much much better. This is an unacceptably poorly operated schemlike business, but with multiple corrections it could be a good solution for some clients.

My score for now is an F.

Sincerely,

**** Back

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
08/30/2022

Our dental office has been receiving multiple virtual credit card payments that we have never opted into or authorized. I have tried contacting Zelis multiple times and I am unable to get through to anyone. I would like for all of the virtual credit cards to be re-issued as checks, and to be opted out of all future virtual card payments.

Business response
09/09/2022

Zelis contacted the provider office on September 9, 2022 and addressed the provider's concerns and proceeded with opting out the account and reissuing the outstanding virtual credit cards as checks. Please feel free to contact Zelis if there is anything outstanding that we can assist with. Thank you

Customer response
09/10/2022

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Sincerely,

****

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
08/30/2022

I,ve been trying to contact Zelis CS for more then a week. like everybody in here are in disbelieve about about the lack of disclosure and the way Zelis is doing business with providers. I just talked to ******** from their call center, she gave me the name of her supervisor ******. I'm hoping this time I can get solutions to this problem with Zelis. No supervisor we can talk to, I was told that it can take a months to get them on the phone!! We are requesting the following through this outlet since looks like Zelis is more diligent to responding here!1- We are opting-out from V-payments 2- We are opting out from ACH with fees.3- If we can't have EFT without a fees then and Only then#4 (I will need to get an explanation of why this option is not available since all payers are doing that at no cost.4- Paper check will be our prefer payment method. Our company is loosing money and can't allowed under my watch to witness this everyday, this is simply so wrong!

Business response
09/13/2022

Hello *********,
We apologize for any breakdown in communication, upon review of the telephone interaction with our associate ********, we found that you were advised a supervisor callback should be expected within a few hours.
Our records then indicate that ****** made contact the next business day and completed the termination of services as per the terms of our agreement.
The added value products and services that Zelis offers, allow providers such as SBH Labs, to realize efficiencies in the health care system by significantly reducing billing and insurance related tasks beyond the scope of free solutions that *** be offered by a health plan or payor. ********** itself is not a health plan or claim payor and charges a fee for these added value solutions and the intrinsic value they *** provide.
We appreciate the opportunity to respond to your complaint.Please let us know if you have any further questions or comments.
Sincerely
Zelis

Next >

Customer Complaints Summary

Business's Response Rate: 100%

32 total complaints in the last 3 years.

24 complaints closed in the last 12 months.

Contact Information

570 Carillon Pkwy STE 500
Saint Petersburg, FL 33716-1343

Visit Website

(877) 828-8770

BBB Rating & Accreditation

ACCREDITED BUSINESS BBB®

A+

Accredited Since: 9/7/2012

Years in Business: 11

Customer Reviews are not used in the calculation of BBB Rating

Reasons for BBB Rating

understand that the nature of complaints and a firm's responses to them are often more important than the number of complaints.

BBB Business Profiles generally cover a three-year reporting period. BBB Business Profiles are subject to change at any time. If you choose to do business with this business, please let the business know that you contacted BBB for a BBB Business Profile.

As a matter of policy, BBB does not endorse any product, service or business.

Better Business Bureau®

Complaints

Zelis Payments, LLC

Payment Processing Services

View Business profile >

ACCREDITED BUSINESS

Need to file a complaint?
BBB is here to help. We'll guide you through the process.

File a Complaint

Complaint Details

Note that complaint text that is displayed might not represent all complaints filed with BBB – some consumers may elect to not publish the details of their complaints, some complaints may not meet BBB's standards for publication, or BBB may display a portion of complaints when a high volum received for a particular business.

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
08/29/2022

I am a practice owner participating in various different insurance plans. For years we have been always receiving payments via EFT and/or paper checks. One day we started to receive virtual cards and my credit card processing fee has gone up 300%. We never gave anyone authorization to use Zelis nor do we desire Zelis to double dip in the already reduced insurance reimbursement. In the past few months we have requested to switch back to EFT or paper checks. It was working for a while until we started to receive virtual checks again this past weekend. When we contacted Zelis we were told that the EFT/paper checks will

automatically revert back to Zelis every 300 days. Who gave you the right to do so? There was no where indicated in any underwriting that we are being charged additional cc processing fee. Another way for third party to make money out of providers.

Business response
08/31/2022

Zelis contacted your office on 8/30/22 and spoke to office manager *****. I was able to locate your account with the information she provided. I left a message with her with my direct contact number should you want to reach back out to me directly. The account was already cancelled. The payments will be sent to you in the form of paper checks. These actions were taken earlier that day when your office manager ***** called our ********** To ensure this issue does not impact your office in the future, I have added you to our Do Not Call List. If you need further assistance, please feel free to reach out to me directly at the number I provided to your office manager.

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
08/07/2022

I am a business who files claims with insurance companies, such as Medcost. I was previsouly recieved reimbursements directly from Medcost but am not getting virtual payment cards, which I never signed up for. I have requested to sign up for direct EFT payments to my business account but I continue to receive error messages from Zelis that they cannot sign r TIN up, but yet they are sending me claim reimbursments by payment card, These cards are inconvenient to use and unwarranted. Not only that, they give no directive, except an enrollment contact number that you cannot get through to anyone. I now have 3 claim reimbursements in the form of virtual mastercards: $216.16, $216.16 and $54.04 that I cannot use since it says the exact amount needs to be entered. I have been trying to get through to Zelis regarding ACH payments through insurance payers for a year, correspondence starting in July 2021. I continue to have the same cycle: email with issues, number to call or directives to attempt to enroll again, then a message that someone with call me, then an email with issues and a number to call but I cannot get a hold of anyone and again and again.

Business response
08/26/2022

Business Response /* (1000, 5, 2022/08/12) */ Hi *******, Thank you for your time today, we confirmed the contact phone numbers provided in email replies and virtual card pages are correct, we regret that you experienced long wait times on the occasions you called. Your payments are being delivered as paper checks and will continue to be sent via that method. We hope that we have addressed your complaint adequately. Sincerely Zelis

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
06/29/2022

Zelis Payments, LLC is fraudulently receiving payments that belong to our business. We are not and have never been affiliated with Zelis Payments. We do not and have never had any agreement or contract with Zelis Payments. In fact, before today, we had never heard of Zelis Payments. Today, I contacted 3 separate insurance companies (1) ILWU-PMA Zenith American, (2) Blue Shield of CA and (3) Health Comp to check on the status of payments due to our business. Each of the insurance companies advised me that (1) They did not provide our information to Zelis Payments, (2) Zelis Payments added our business and Federal Tax ID #XXXXXXXXX to Zelis Payments' "Provider List." In doing so, Zelis Payments has fraudulently instructed insurance companies to send payments due to our business to Zelis Payments instead of sending the payments directly to us. I contacted Zelis Payments today by phone; their representative confirmed to me Zelis Payments received and is holding several payments that belong to our business. I told the Zelis Payments representative, this is an error, we have no relationship whatsoever with Zelis Payments and we never asked, agreed or authorized Zelis Payments to collect payments on our behalf. I instructed the Zelis Payments representative to return our payments to the Insurance Companies and to REMOVE our business name and Tax ID from their "provider list" and data base. The Zelis Payments representative asked me to contact the insurance companies. I explained each insurance company told me they were instructed by Zelis Payments to send our payments to Zelis Payments AND, each insurance company stated this error can only be corrected by Zelis Payments. I sent an email today to Zelis Payments as a follow up. Zelis Payments provided a generic response to my email and provided a "case number" XXXXXXXX. I did a Google search of Zelis Payments; there are many complaints about Zelis Payments from other doctors & healthcare businesses.

Business response
07/21/2022

Business Response /* (1000, 5, 2022/07/07) */ Zelis contacted the provider office on July 5th and assisted with any outstanding payments. The provider has been opted-out and added to our Do Not Contact list. The provider will not receive virtual credit card payments from Zelis in the future.

Complaint Type:
Billing/Collection Issues

Status:
Resolved

Initial Complaint
05/31/2022

I have told this company more than once that we do not accept credit card payments from insurance companies. They will stop sending them for a few months then start sending them again. They are costing us money due to the fees associated with the credit card payments.

Business response
06/08/2022

Business Response /* (1000, 5, 2022/06/01) */ The request to opt-out the provider's account was received on June 1, 2022 via the BBB and has been processed. Along with this action the provider has been placed on a do not call list and no other virtual credit card payments will be issued. All outstanding and in progress cards have been cancelled and converted to check payments. **Consumer Response** /* (2000, 7, 2022/06/06) */ (The consumer indicated he/she ACCEPTED the response from the business.)

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
05/31/2022

We have requested this company to unlock our account several times with no resolve. We were asked to send emails to get copies of EOB's sent to us with no response. This has been over 30 days with no response or issue fixed. We can not post payments without these eobs.

Business response
07/01/2022

Consumer Response /* (3000, 10, 2022/06/28) */ No, the issue is not yet resolved. They responded saying they sent an email to fix my account but in fact they have not. **Business Response** /* (4000, 12, 2022/06/29) */ ****** ********** - Our records indicate Zelis performed a client identification process to ensure proper access to your provider portal. That verification was completed on 6/28/22 around 3 pm EST. A Portal Registration was sent to the Administrator on file. On 6/29/22, a member of our Client Experience Team reached out to your office. Your Office Manager, Sharon, was out of the country but we were able to verify they were able to log in and have access. Thank you for your business and please let us know if we can further assist you. **Consumer Response** /* (2000, 14, 2022/07/01) */ (The consumer indicated he/she ACCEPTED the response from the business.) A solutions has finally been achieved and permission has been reset

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
05/19/2022

We were contacted by Steve at Zelis payments and told one patient had EOB set up for virtual credit card payment, we gave our fax number. Steve proceeded to enroll us in Zelis virtual credit card payments. We do not want this, we want our checks to continue coming regular mail and check form only. If we were to transfer Excellus to any form of electronic payments, we would use our already existing business, Availity. We have tried unsuccessfully since May 9th to stop this. Numerous phone calls, ticket numbers generated, complaints called in, emailed to provider portal. We are hung up on, left on hold, or just plain ignored. If the option exists to continue paper checks, as Excellus stated on phone today, why are we not able to obtain these checks and cash them? They will only provide payment in form of credit card. We have filed a complaint with the Attorney General's Office as well today. Excellus is no help, they give me same 800 number that gets us no where. Either we are left on hold, hung up on, or just plain ignored. We have not registered or signed any contract with them. We do not want to register with them. We do not want anything to do with a company that literally ignores its customers. They have dozens of complaints filed against them in Florida, they have lost BBB accreditation in Florida, for literally ignoring ALL complaints filed against them. We are within our legal rights to request these payments to come via regular check. We are not cashing virtual credit card payments because that in itself is consent to virtual check payment. Please advise. Kim L **********

Business response
06/06/2022

Business Response /* (1000, 5, 2022/05/20) */ I have tried to reach individual, office closed on Friday. All payments have been moved to check and all future payments will be processed as check. Individual will be contacted on Monday 5/23 to confirm resolution

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
04/06/2022

I am a private duty nurse that bulls Excellus. Excellus in turn has Zellis for our paychecks...a number of nurses are missing payments, the company holds our checks and splits our claim so we only get paid for a partial claim. Also they are more than a month behind in payments. Excellus says our claims are sent to Zellis within 2 weeks receiving them but we do not get a check until a month later. We have called Zellis and Excellus. My bills are late and my credit score has dropped dramatically. It's not fair that I work so many hours and I cannot pay my bills on time. It would be different if we were getting our full claim amount as we are waiting for a month...but we are only receiving partial payment. Is there anything that we can do. We need to pay our mortgages and our health insurance and our taxes just like everyone else. It's not right!

Business response
04/28/2022

Business Response /* (1000, 5, 2022/04/13) */ Zelis has printed a total of 32 checks for this provider Tax ID since 11/24/2020 on behalf of the claim payer in question. The latest payment collected today on 4/13/22 is due to be printed tomorrow on 4/14/2022. Claim payments are paid as instructed by the claim payer, Zelis prints and mails checks and remittance according to the payer's instructions and amount. In this instance, check payments received by Zelis are printed the next business day and are then collected by USPS within 1 business day of printing.

Complaint Type:
Advertising/Sales Issues
Status:
Answered

Initial Complaint
12/29/2021

This is repeat complaint filed by many other dental service providers in the area. We are a fee for service denta provider that files insurance claims for our patient's reimbursement only. Since February of this year we have been receiving payments from Zelis (a third party). We NEVER contracted and authorized either Zelis or any insurance company to pay Zelis or Zelis to collect payment on our behalf., We have had multiple requests sent to Zelis to remove our contacts and send payments back to insurance company so us to get our claims cleared in timely manner. Requests to remove us from their provider list have gone unanswered. Also, email requests are returned as undeliverable. To reiterate, Zelis has been collecting payments fraudulently for our claims with insurance companies without any authorization from us and then use predatory tactives to collect undue fees for releasing payments owed for the claims. This is our last attempt to resolve issues created by Zelis before we escalate this matter further.

Business response
05/23/2022

Business Response /* (1000, 14, 2022/05/23) */ On October 19, 2021, Zelis contacted Alivio Dental Care LLC and spoke to Zack M Office Coordinator regarding a claim payment which Zack advised could be faxed over to the office as a virtual credit card. On November 24, 2021, Zelis followed up with Zack to ensure payments were being received and the office did not know as their leadership only works "offsite". On December 6, 2021, Zelis followed up with Zach to ensure Alivio was receiving payments and we enquired if payments were being received and Zach advised that he did not know and that the only person who would know is a gentleman named San who is only reachable by email. We asked Zach if there was another method of payment that the office would like to have and Zach replied, "not that he was aware of at this point". Zelis' award-winning Provider Customer Service team is available by phone Monday-Friday from 8am-7pm Eastern. The contact phone number is posted on every payment that was sent to Alivio Dental. On December 29, 2021, Zelis learned about Alivio's complaint via the BBB and updated the office's payment delivery preferences were updated within 3 business days. It is regrettable that Alivio Dental was unable to communicate directly with Zelis despite three separate phone conversations with an ****** employee each initiated by Zelis. **Consumer Response** /* (3000, 16, 2022/05/24) */ (The consumer indicated he/she DID NOT accept the response from the business.) This company is full of lies. Here below is the communication which was NOT returned before FTC and BBB complaint was filed for this company which should not even exist. BTW who gave you this award "Zelis' award-winning Provider"?? Forward all following communication to who gave you this award. ========== Alivio Dental - DG Tue, Oct 19, 2021, 4:30 PM to Zelis Payments <****@zelispayments.com> WE DID NOT SIGN UP FOR ANY PORTAL FOR YOUR COMPANY. DELETE THIS ACCOUNT BEFORE WE FILE COMPLAINT AGAINST THE SCAM AND PREDATORY PRACTICES AT YOUR COMPANY. REMOVE THIS EMAIL ADDRESS AND WE DID NOT SIGN UP AND REFUSE PAY FOR ANY PAYMENTS TO YOUR COMPANY. WE RECEIVE DIRECT CHECK FROM INSURANCE COMPANIES. ========== Alivio Dental - DG Sep 17, 2021, 1:17 PM to Ashley Demarco <**********@zelis.com> Which insurance company and patient are you trying to send payment for? ========== Alivio Dental - DG Mon, Dec 6, 2021, 10:02 AM to Zelis Payments <**********@zelispayments.com>, *******@zelispayments.com STOP SPAMMING OUR EMAIL AND FAX ACCOUNTS. THIS IS THE LAST REQUEST FROM US OF MANY SENT BEFORE. ========== **Business Response** /* (4000, 18, 2022/05/27) */ On December 15, 2021 email notifications from our portal were disabled as requested. No other electronic payments will be delivered to Alivio from Zelis. Contact information has been removed and your practice has been placed on a do not call list. Respectfully, Zelis

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
11/09/2021

On June 15th, 2021 I Had A Skin Graft Done At Mountaineer Periodontics With Dr. ****** I Paid

$1,200 For My Skin Graft & I Was Suppose To Reimbursed For $586.60. I've Spoke With My Insurance ****** ***** & ****** Payments Numerous Times In Reference To Trying To Get My Reimbursement Check. I've Been Told It Was Processed & Mailed Out; But, I Never Received It. I've Had To Stop Payment The First Time Because I Never Received It. Now, I'm Still Waiting Again Since I Was Told My Reimbursement Check Was Processed & Mailed Out Again. I Want My Reimbursement Check. This Is Ridiculous. I've Never Had Any Issues With Getting My Mail or A Check In The Mail Before; Until Now. Please Respond To My Complaint & Help Me Get This Resolved. I Would Really Appreciate It. Thanks, ******* *. ******

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
10/25/2021

I am a health care professional and I have twice spoken with a representative at Zelis payments requesting that all future payments be via check, not virtual credit card. However, I continue to receive virtual credit cards from this company. Each time I have had to spend 15-30 minutes on hold. I am able to get checks for past claims, but future claims continue to result in virtual credit cards, which then require another call to customer services.

Business response
05/23/2022

Business Response /* (1000, 24, 2022/05/23) */ Zelis Payments spoke with the provider on 10/11/21 and assisted Dr. ******** with opting his account at that time. **Consumer Response** /* (2000, 26, 2022/05/26) */ (The consumer indicated he/she ACCEPTED the response from the business.)

‹ Previous

1 2 3

Next ›

Customer Complaints Summary

Business's Response Rate: 100%

32 total complaints in the last 3 years.

24 complaints closed in the last 12 months.

Contact Information

570 Carillon Pkwy STE 500
Saint Petersburg, FL 33716-1343

Visit Website

(877) 828-8770

BBB Rating & Accreditation

ACCREDITED BUSINESS BBB ®

A+

Accredited Since: 9/7/2012
Years in Business: 11

Customer Reviews are not used in the calculation of BBB Rating

Reasons for BBB Rating

Better Business Bureau®

Complaints

ECHO Health, Inc.

Payment Processing Services

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ACCREDITED BUSINESS

Need to file a complaint?
BBB is here to help. We'll guide you through the process.

File a Complaint

Complaint Details

Note that complaint text that is displayed might not represent all complaints filed with BBB – some consumers may elect to not publish the details of their complaints, some complaints may not meet BBB's standards for publication, or BBB may display a portion of complaints when a high volume is received for a particular business.

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
10/10/2022

I have opted out from virtual credit card payments from Echo Health numerous times! and now I am receiving VCC once again! When I have called in the past the customer service reps at Echo pressure me as to why I do not want VCC payments. I get charged a fee for processing credit card transactions therefore not getting the full insurance reimbursement for the services rendered. It is a headache to be going online everytime to cancel the VCC payment and request a live check! When I OPT OUT it means OPT OUT! I never authorized any virtual credit card payments for my business!

Business response
10/13/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department has opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you

Customer response
10/13/2022

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Regards,

***** *********

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
09/21/2022

I have been a counselor in private practice and complete my own billing. Now, against my will and without my request I am receiving virtual credit cards for payment in place of paper checks. Echo Health is not giving providers the option to opt out, and instead we have to go to their website and cancel every virtual credit card and then request a paper check which adds several more weeks to payment time. The inability to opt out entirely and just receive paper checks is unacceptable. I have spent multiple hours with different customer service agents and as a practitioner I do not have the time to sit on the phone for hours on end dealing with errors not caused by me. To add salt to the wound, they provided the wrong address and now I have to independently contact each insurance agency with a new W9 with an updated address. This is beyond frustrating. I have been in my field for many years and this is singlehandedly the worst, mindless thing I have encountered from a business.

Business response
09/23/2022

ECHO's Customer Service manager reached out to provider's office and discussed our payment options. As a
result of that conversation, we updated the provider's payment preferences and sent an email to confirm this selection.
We believe this matter is now resolved. Thank you for giving us the opportunity to resolve this issue

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
08/17/2022

Our office has never opted-in for virtual credit card payments from Echo Health. They simply appear on our fax machine. I have attempted to opt-out of virtual credit card payments from Echo Health on multiple occasions. The wait time on hold is completely unacceptable, and I am told I have to call back on each occurrence. As a busy dental office, there is not enough time in a day to devote to their required opt-out procedures. They require our TIN for each call. Our TIN, and our desire to opt-out, should suffice for opting out of ALL virtual credit card payments.

Business response
08/18/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department has opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you

Customer response
08/18/2022

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Regards,

****** *****

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
08/11/2022

Have tried on numerous occasions to get my company out of their system. They have refused. I emailed them, send mail to them, as well as faxed them. I do not want them processing my dental checks for my company, ******** ****** **********

Business response
08/12/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department ha opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you

Customer response
08/30/2022

CONSUMER FILED ANOTHER COMPLAINT RELATED TO THE ORIGINAL COMPLAINT. HERE ARE THE DETAILS:

I filed a complaint that was closed after echo stated to the BBB that they would not longer be processing payments at a fee for my practice. I never signed up for them and have reached out them on numerous occasions to have this resolved. the original complaint number was ********* They have not stopped filing my claims and are still charging fees even though they told you they are not. Below is an image of them still filing my claims after they told you they are not.

Business response
09/12/2022

ECHO's Customer Service manager reached out to provider's office and discussed our payment options. As a
result of that conversation, we updated the provider's payment preferences and sent an email to confirm this selection.
We believe this matter is now resolved. Thank you for giving us the opportunity to resolve this issue.

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
06/20/2022

We have repeatedly called Echo Health from the dental office to opt out of Virtual Card payment on our patients. We have been told they will indicate we are not wanting to receive virtual payments but rather hard copy checks but we continue to get these virtual card payments. What we have been doing is having to wait on payment when we have to call on each individual patient to cancel the virtual payment.

Business response
06/29/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department has opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
05/18/2022

We are dental services provider and we have attempted to opt out of Echo Virtual Card with payments multiple times and have notified the business via phone. Echo Virtual cards refuses and has not stop predatory practices to steal fees from claims due by insurance companies to the providers in the area. Upon multiple requests Echo Health is still refusing to comply with optout request and thus violating laws. We have not signed any contract or authorized any company including Echo Health or its subsidiaries to collect, pay or represent us to receive payment on our behalf for dues/claims payable to us for the services provided to any of our patients. Complaints although Echo remains out of compliance with the laws and are essentially threatening access to care for their members by causing waste/abuse time as claims that cannot be processed in a timely fashion create payment issues for their members and reduce willing providers to provide care for these insured patients.

Business response
05/19/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department has opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
05/17/2022

We were never given an option to "opt in" for electronic credit card payments rather than paper checks but we continue to receive payments for insurance claims in this manner. Every time I get one I have to go online to their site and enter all of the information to get it canceled and then our office has to wait up to an additional 4 weeks to receive our payment in the form of a paper check. In order to "opt out" I am expected to download a spreadsheet and fill it our with each payment. This is all very time consuming and frustrating.

Business response
05/18/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department has opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
04/16/2022

I am an independent care provider for the state of Ohio getting paid through an insurance company who outsources my pay to echo health inc. my first day with the state was feb23,2022. I finalized and submitted my pay info march14,2022. My pay was supposedly mailed March 21,2022. It is April 16,2022 and they are supposedly in the mail. Like four pays. They pay on debit card which I was told I should get two paper checks and then be unrolled in direct deposit. We'd. 4/13/2022 I had them cancel the debit card and mail paper check and I should get in 7-10 business days. Stay tuned..... $3000 in pay not being sent out. And my bills need payed... I am curious to know if I will ever get these so called cards. One employee told me I can have the pay stubs faxed but failed to tell me if I don't have a fax that I can set up for my pay to be faxed to a certain place like fedex store or or ups.

Business response
05/05/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department has opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
04/13/2022

Terrible customer service! We are forced to use this company because this is who my parent's long term health insurance provider uses. Why they continue to use this company I don't know!! They are making our lives difficult!! Our caregiver signed up for Direct Deposit about 4 weeks ago and she still hasn't gotten paid. We spent weeks going back and forth with Echo trying to get her signed up for Direct Deposit. I'd ask if they needed any more info ... then they'd add something else they needed. It seemed like everyone was giving us a different answer. It was ridiculous!! Then our caregiver received a "Virtual Credit Card" that we had no idea was coming (we were told it would be a check) and she didn't know what to do with it. I spent hours and hours on the phone with Echo, banks, friends, etc. trying to figure out if we can cash these virtual cards. No one had ever heard of them. Our caregiver just wants her paycheck!!! It has now been 10 days since they told us everything was processed for Direct Deposit and she still hasn't received money in her account. They told us it would be 7-10 business days. I don't even know what to do at this point!!

Business response
04/15/2022

Thank you for bringing this matter to our attention. As we have discussed, we believe the issue is now resolved. We sincerely apologize for the inconvenience, and appreciate your assistance in getting the matter resolved!

Customer response
04/18/2022

Our caregiver received her first paychecks in the mail today so our complaint seems to be resolved at this time. We are expecting more EFT payments in her account for the past 3-4 weeks that she worked. If this does not happen, we will be back in touch with you. Thank you for your help!

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
04/11/2022

This company profits by having providers select virtual payments or EFT payments. I believe this company is intentionally making their paper remittances (checks) difficult to read for electronic deposit banking apps in order to encourage more people to sign up for their paid services. I have consistently had difficulty depositing their checks electronically and they are the only company that uses such small font sizes and unnecessary asterixis before the payment amount. I suggest that this amount to bad business practices and requires correction.

Business response
04/20/2022

Thank you for bringing this matter to our attention. We have confirmed your enrollment in EFT. We sincerely apologize for the inconvenience, and appreciate your assistance in getting the matter resolved.

Customer response
04/20/2022

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Regards,

****** *****

1 2 ... 17

Next >

Customer Complaints Summary

Business's Response Rate: 100%

172 total complaints in the last 3 years.

21 complaints closed in the last 12 months.

Contact Information

810 Sharon Dr
Westlake, OH 44145-1521

Visit Website

(888) 834-3511

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ACCREDITED BUSINESS BBB ®

A+

Accredited Since: 9/29/2014

Years in Business: 25

Customer Reviews are not used in the calculation of BBB Rating

Overview of BBB Rating

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Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
03/30/2022

I am the billing manager for multiple healthcare providers. For the past several months we continue to get insurance payments due to our providers through Echo Health using VCP. Our office does not accept these type of payments. I cannot count the multiple times this company has been called requesting them to no longer send us VCP payments or the time they have wasted of myself and my staff. I am not sure how this service can be legal. Why would I want to pay a service fee for money that is owed to my providers. Each call they tell us that we will no longer receive this type of payment and within a couple weeks we start receiving them again. For one of my providers, they are also taking additional 2 % of each payment in which they reference contract # ****. I have requested several times to receive a copy of that contract and

what i need to do to cancel that contract and my request are ignored. How are they allowed to advertise there are no fees to use their services.

Business response
04/08/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department has opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you

Customer response
04/08/2022

[**A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.**]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Regards,

***** *******

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
02/24/2022

Our private medical practice does NOT accept VCC virtual credit card payments from insurance companies. Insurance is required by contract to provide our payments free of charge. VCC payments cost the medial practice via terminal fees. Within the last year we have seen a vast increase in the amount of VCC payments mailed and faxed to our office. ********* is the company sending out the VCC payments to our office. When we receive a VCC payment from ********* we call ********* and have the card cancelled and request that a paper check be mailed to us or sent via EFT, if we are already enrolled. I have asked the representative on each occasion to opt our business out of receiving any and all VCC payments from *********

regardless of who the payer is. ********* always states that we must call on each VCC payment to opt out. I called the corporate office today at ********** and spoke with ***. *** confirmed that we cannot completely and permanently opt our office out of receiving VCC payments. This is not acceptable! ********* is costing our office time and money. We demand to be opted out completely and permanently from receiving any and all VCC payments from *********. Our TIN is **********

Business response
03/03/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department has opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you

Customer response
03/03/2022

[**A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.**]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Regards,

****** *******|

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
01/18/2022

On Jan 14, our office received a fax from Echo Health re: a payment for another party/dental provider (who is at a different location and has a completely different tax ID) which we had been receiving for the past 4~6months at least. Previously we would just forward any comm to

this other provider's office but because it kept happening, I reached out to Echo to see what the issue was and to have a conversation about compensation - unbeknownst to our office, Echo had switched our fax number with this other provider's and had been sending all faxes which were including payment info, tax ID info, patient personal info, etc to our office by mistake even though we had reached out to the other provider re: this. She had assured us that she had reported them and yet we continued to receive these faxes. My concern is two fold - First is the complete HIPAA violation of sending the wrong office's faxes with personal info, explanation of benefits and payment info to a third party without having any confirmation of who they are sending these faxes to. (Got that info from the last person I spoke to at Echo - more on that later). And secondly, when I called for information on reimbursement because for months they have been using our resources and energy by sending unsolicited faxes, no one could help - spoke to at least 6 people but the last person, ****** was extremely rude, stated that her company does not reimburse for paper and yet when I came across the BBB, this was coming from the company who states: "ECHO Health, Inc. Response 09/30/2021 We are sorry to hear that you have not had a good experience. We pride ourselves on our customer satisfaction. If you would like to reach out to us directly, we would be happy to assist you. We also offer the ability to update payment preference online at www.ECHOVCards.com" This should NOT be that difficult - they were in the wrong and I have yet to hear an apology from their company's employees...

Business response
02/18/2022

RECEIVED VIA EMAIL BY BBB STAFF MEMBER:

I apologize for the tardiness of this response.

The initial report of this issue came in on a Friday afternoon (1/14/22), and on Monday morning (1/17/22) the team began researching the issue. The caller's fax number had been associated with the other provider's office for years, but the call on 1/14 was the first record we have of anyone contacting ECHO about the issue.

On 9/27/2021 ECHO sent a standard HIPAA Fax Verification letter to the receiving fax. The purpose of this letter is to proactively identify any fax numbers that are incorrect, to prevent sending Protected Health Information to the wrong recipient. We received no response to this notice telling us we had the wrong fax number for that provider.

The fax number was removed as a result of this call, so no further faxes for the wrong provider will be received.

Megan Sroka

Compliance Manager

Business response
02/18/2022

This issue has been escalated to ECHO's Compliance Department for review.

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
01/17/2022

We have made several attempts with Echo Health, over the last year or so, regarding opting out of credit card payments for insurance payments! There is still no resolution to this matter. Our office does not accept credit payment from any health insurance companies, we are a small private practice. We have been assured many times that this issue will be resolved. We are told the same thing every time! They are trying to force us to use their virtual V-card or the EFT deposit, that put an extra expenses on our office. Please help with this issue, it is absolutely unacceptable.

Business response
02/21/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department ha opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you

Customer response
02/22/2022

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********* and find that this resolution is satisfactory to me.

Thank you & Regards,

****** *********

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
01/13/2022

I am a healthcare provider and we have attempted to opt out of Echo V Card with ******** ********* payments multiple times and have notified the business via phone (they say you can't send more than 1 opt out request per day per plan), and I've also sent multiple faxes to their provider payment number to opt out of V Card which our office does not accept. Per Arizona bill HB 2494 passed in 2019 and per CMS Guidelines, providers are given the legal right to opt OUT of Vards into perpetuity. Echo Vcards resfuses to acknowledge this law and has not responded in a timely fashion. I am attempting to resolve this issue permanently and have also filed an official complaint with the AZ Board of Insurance and Consumer Complaints although Echo remains out of compliance with the laws and are essentially threatening access to care for their members by causing waste/abuse time as claims that cannot be processed in a timely fashion create payment issues for their members and reduce willing providers to provide care for these insured patients.

Business response
02/22/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunicatio that has taken place in the
past, and any frustration that has caused. At this time, our customer service department has opted this Tax ID out of the
virtual card program, and has provided our EFT enrollment form, for an alternate payment option. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you.

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
12/21/2021

Like other complaints filed, we cannot stop Echo Virtual card payments to stop. It has been

going on for a year and they keep sending virtual credit cards for insurance payments so not only do you have to write off money for the insurance but, now you also have to lose another 4% of the payment for credit card fees. This has got to stop. It's not just once in a while, it is all the time. We have opted out several times and called and they tell us we have to call the insurance company and the insurance company tells us we have to opt out through ECHO so they just bounce us back and forth. We go on the echovcards to cancel the individual cards and they just send a new one. There is no way to put an end to this. WE do not accept credit card payments from insurance companies on top of all the write offs. If they want to send a credit card, they need to pay the 4% fee, not us. WE want the virtual cards to stop for all insurance payments and there has to be a way through ECHO to opt out of all of them.

Business response
01/17/2022

Thank you for bringing this matter to our attention. We apologize for the miscommunication that has taken place in the
past, and any frustration that has caused. At this time, our customer service department has opted this Tax ID out of the
virtual card program. We believe this matter
is now resolved – thank you for giving us the opportunity to address this for you.

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
12/01/2021

Our office is has been trying for months to try to opt out of virtual credit card & have spoken to many representatives & are continually been told that we are opted out however we are still receiving the virtual credit cards after months of getting this resolved. We never opted into this program. I have faxed a letter to opt out all of our offices from this with no resolution.

Business response
12/13/2021

All TINs provided were opted out of ECHOs virtual card offerings for all payers. The provider was notified by email.

Complaint Type:
Billing/Collection Issues

Status:
Answered

Initial Complaint
11/18/2021

We have made several attempts with Echo Health, over the last 90 days, regarding opting out of credit card payments for insurance payments! There is still no resolution to this matter. Our office does not accept credit payment from any health insurance companies. We have been assured many times that this issue will be resolved. We are told the same thing everytime! They are trying to force us to use their virtual V-card or the EFT deposit, that put an extra expenses on our office. This needs to stop immediately!! Attached is the latest that was faxed yesterday (11/17/2021)

Business response
11/18/2021

Provider TIN has been opted out of VCP. An email was sent to the provider letting them know what action had been taken.

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
11/03/2021

We have made several attempts with Echo Health, over the last 60 days, regarding opting out of credit card payments for insurance payments! There is still no resolution to this matter. Our office does not accept credit payment from any health insurance companies. We have been assured many times that this issue will be resolved. We are told the same thing everytime! They are trying to force us to use their virtual V-card or the EFT deposit, that put an extra expenses on our office. This needs to stop immediately!!

Business response
11/09/2021

Provider has been opted out effective 11/09/21 and notified.

Customer response
11/09/2021

[A default letter is provided here which indicates your acceptance of the business's

response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Regards,

******** ***

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
10/13/2021

We called trying to locate a fax payment for a specific claim for one of our patients. When they informed us the payment had already been faxed several weeks before, we informed them the payment never made it to us and we needed it resent. The rep stated they could only MAIL the credit card information, so we agreed to wait 7-10 more days for it to come in the mail and it never came. Called again last week and a rep told me she would fax it to me right then, and I never received it. We've received claim payments from the company with zero problems before and after this incident, so the issue was not with our fax machine. The payment for claim is nearly 4 months overdue now, and in a busy practice we don't have time to wait on hold to be told something will be resolved when it won't be. Our office would like this company to reach out to us immediately to resolve the issue and send us the fax payment information.

Business response
10/15/2021

VCC refax submitted on 10/15. Provider informed to allow until end of business day, Monday.

Customer response
10/15/2021

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ******** and find that this resolution is satisfactory to me as long as we do in fact receive payment information by the end of the day on Monday 10/18.

Regards,

******** ********

Previous

1 2 3 ... 17

Next

Customer Complaints Summary

Business's Response Rate: 100%

172 total complaints in the last 3 years.

21 complaints closed in the last 12 months.

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810 Sharon Dr
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Visit Website

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ACCREDITED BUSINESS

A+

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Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
10/12/2021

The just seem to add you back into the system. Hold times are abysmal - if you can even get a hold of someone

Business response
10/13/2021

Email sent to provider and is pending a response.

Business response
11/09/2021

A follow up email was to the doctor this morning. I offered to call at 3 pm EST to resolve or to resolve via email.

Customer response
11/09/2021

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and have determined that this does not resolve my complaint. For your reference, details of the offer I reviewed appear below.

[To assist us in bringing this matter to a close, we would like to know your view on the matter.]

Regards,

**** ******

I asked that Echo respond to my e-mails rather then call and still have not received a response to the e-mails sent

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
10/08/2021

I am a healthcare provider who has opted out of virtual paper card payments for years. They continue to send them to me. They don't answer their phone. The online option doesn't work. It will NOT SUBMIT the request. I tried to enter draft and card number this won't work either. PLEASE HELP I just want a paper check.

Business response
10/11/2021

Email sent to provider and pending response.

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
10/05/2021

Our office is has been trying for months to try to opt out of virtual credit card & have spoken to many representatives & are continually been told that we are opted out however we are still receiving the virtual credit cards after months of getting this resolved. We never opted into this program. I cancel the credit card & I have multiple checks that I have been waiting on payment on. I keep getting the run around from Echo and are told it take awhile to get this program cancelled. It has been over a year.

Business response
10/25/2021

Provider was opted out and notified of opt out on 10/11.

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
10/04/2021

Our office receives numerous credit card deposits from insurance companies for payment. We receive these through EchoVcards. We never signed up for their service to receive these cards. Not only do they charge the credit card fees, they cannot split up payments between patients. We have asked repeatedly for these cards to be cancelled and to start receiving paper checks like we are used to having. They have told me, and other front office staff, that we have been opted out yet we still continue to get credit card deposits. This has been going on since late spring of 2021 and it's now fall of 2021. We have had it. We need this cleared up to help us cut down on cost as well as operate more efficiently.

Business response
10/25/2021

TIN has been opted out of VCP. Payment was canceled and reissued as a check. Provider notified on 10/25.

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
09/30/2021

Spoke with multiple representatives (over the past 30 days) at ECHO regarding opting out of credit card payments! I still have no resolution to this matter. Our office does not accept credit payment from any health insurance companies. The process to opt of of the v-card payments is not efficient. I was on hold for over an hour and no one answer. Contacted the insurance company. The insurance company told me to contact ECHO! We are getting the run around. We did not sign up for this services. They keep telling us to allow 90 days for a paper check to be mailed to our office. Our office wants to opt into auto deposit - EFT, like all major insurances, but we would have to pay for that service. They are forcing us to to use their virtual V-card or the EFT deposit, that put an extra expenses on our office. Definitely they are getting a cut on doing so.

Business response
10/04/2021

Emailed provider on 10/04/21 and pending response to complete opt out of virtual credit card.

Customer response
10/04/2021

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********* and find that this resolution is satisfactory to me.

Regards,

***** ******

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/29/2021

Our office has been receiving virtual credit cards through ECHO card service. We did not sign up for this service and I have contacted them multiple times to opt out of the service. I have spent hours on the phone trying to talk to a representative. Every time they tell me they are opting us out-we receive another virtual check. We then have to call-yes another 35 minutes on hold-and the check takes 30 days to arrive. We should be able to choose to opt out on a one time basis. The company is terrible!!!!!

Business response
09/30/2021

Email sent to provider and pending response.

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
09/29/2021

I am a private practice mental health counselor. I have not been paid after submitting bills for services rendered since July. After I called the health plan administrator to report this, I was informed I should have received virtual credit cards in the mail to run through my credit card terminal. They did eventually arrive, but I don't have a credit card terminal - I cannot accept virtual credit cards for insurance payouts. The representative directed me to contact Echo Health to speak with them about it in order for the payment to switch to paper checks, etc. I've tried calling Echo Health at their number they list for opting out of v-card payments. I've been on hold for over 30 minutes each time with no answer. I tried using their website to opt out of virtual cards - the website is broken as I input my information and it gave me an error message each time I tried. I need resolution to this soon as dates of service go back to July 2021.

Business response
09/30/2021

Email sent to provider and pending response.

Business response
11/01/2021

A email was sent to the provider on 10/25/21, requesting the TIN and Draft and is still pending a response. Additional information is needed to resolve the inquiry. A follow-up email will be sent today, 11/01/21.

Customer response
11/09/2021

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me.

Regards,

********** ****

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
09/27/2021

We are a dental office that continues to receive virtual credit card payments from Echo Vcards clearinghouse. We have called numerous times, spoke to representatives, and also faxed requests as instructed to Opt out of receiving the vcards for insurance payments. We have been told by representatives that we have been opted out, yet still receive virtual card payments. Examples of the insurance companies are ******** and *******. We have also requested, and never received, any form of confirmation that we successfully opted out. We would prefer paper checks as there is a fee for the vcards we do not wish to incur. We never agreed to receive payments this way. Our office registered on the website ********** to try to opt out also, but there is not option to do so on the site. So phone calls, faxes, and on-line methods have all failed as methods to opt out.

Business response

09/28/2021

*email sent to provider on ****** and pending a response.*

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
09/27/2021

Like Sooooo many others here: I have received multiple EchoVCards for payment of patient services from insurance companies. I never opted-in to this service. I have called customer service and sat on hold for HOURS, taking time away from my patients and family to resolve this. I have been told that I can only opt-out of EACH individual v card that is sent and there is no way to opt-out from ever receiving V cards again. This is unacceptable and leads to lost revenue and delayed payments for those that are processed. I do not want to ever receive a v card again. I did not ask for this and between EchoVCards and the insurance companies, I am getting the run around about ending this schema they have worked up to defraud providers of their payments. Even charging visa fees to use the card!

Business response
10/13/2021

Original email sent on 09/27 to provider and a follow-up sent 10/13. Still pending provider response.

Customer response
10/17/2021

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and have determined that this does not resolve my complaint. For your reference, details of the offer I reviewed appear below.

When submitting the complaint I provided two files for the business to review. They instead responded with a request for the very type of document that I uploaded.

Their response over the phone was for me to take the time to go online for every vcard that I receive and opt of of receiving vcards for that particular company. The business admits to having a partnership currently with over 200 companies. This is not acceptable. EchoVCard should have a database of clients such as myself who have called and explicitly declined to NEVER receiving vcards such that when any of the 200 companies chooses EchoVCard as a

payment option, it is immediately rejected and that client is directed to send payment in an alternative manner.

Still awaiting the desired response from EchoVCard.

[To assist us in bringing this matter to a close, we would like to know your view on the matter.]

Regards,

***** *********

Business response
10/25/2021

Opt out was completed on 10/25. Provider was notified.

Customer response
11/02/2021

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********. I was told that my tax ID was unenrolled from ECHO vCard which I understand to mean that I will no longer receive any payments through them from the 200+ companies they've partnered with. Should this not be the case, the complaint will be updated.

Regards,

***** *********

Complaint Type:
Billing/Collection Issues
Status:

Answered

Initial Complaint
09/27/2021

Our office is trying to opt out of Echo health vitual credit card. I have tried numerous times to comtact the company regarding some payments but have been on hold for over 30 minutes. I have never been able to speak to anyone. The number that is listed for this company is busy and you cannot even get through. I have 5 Claims I would like to talk to someone about . Please help us get opted out of this terrible company.

Business response
09/29/2021

Provider was opted out of VCP and notified on 09/29/21.

Previous

1 2 3 4 ... 17

Next

Customer Complaints Summary

Business's Response Rate: 100%

172 total complaints in the last 3 years.

21 complaints closed in the last 12 months.

Contact Information

810 Sharon Dr
Westlake, OH 44145-1521

Visit Website

(888) 834-3511

BBB Rating & Accreditation

ACCREDITED BUSINESS BBB®

A+

Accredited Since: 9/29/2014
Years in Business: 25

Customer Reviews are not used in the calculation of BBB Rating

Overview of BBB Rating

Better Business Bureau®

Complaints

ECHO Health, Inc.

Payment Processing Services

View Business profile >

ACCREDITED BUSINESS

Need to file a complaint?
BBB is here to help. We'll guide you through the process.

File a Complaint

Complaint Details

Note that complaint text that is displayed might not represent all complaints filed with BBB – some consumers may elect to not publish the details of their complaints, some complaints may not meet BBB's standards for publication, or BBB may display a portion of complaints when a high volume is received for a particular business.

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
09/24/2021

Echo vcards are used for healthcare provider reimbursements, putting the burden of transaction fees on the provider. This is not acceptable and places the responsibility of the recipient to cancel each vcard payment and request paper reimbursements. There is no provision to opt out of this form of payment. This is an illegal practice in the state of NJ, and violates payment laws.

Business response
09/27/2021

Email sent to provider on 09/27/21.

Customer response
09/30/2021

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********* and have determined that this does not resolve my complaint. For your reference, details of the offer I reviewed appear below.

I have made several attempts to contact the representative on her direct number as well as the general customer service line, and left messages, but have not been successful in reaching her, nor of resolving this issue.

Regards,

******* ****

Business response
10/13/2021

*I spoke with ******* on the phone on 09/30. ****** opt out was completed. ******* advised at that time the complaint could be closed.*

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
09/23/2021

I have been trying for months to try to opt out of virtual credit card and have spoken to many representatives and have been told that we are opted out however we are still receiving the virtual credit cards. We never opted into this. As of right now I cancel the credit card and I have multiple checks that I have been waiting on. I keep getting the run around from ESIS and Echo and there is not enough time in the day to be arguing back and forth with the carrier as well as ECHO,.

Business response
09/27/2021

Reached out to provider and provider advised they have already been assisted.

Customer response
09/27/2021

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me. If the problem still persists then I will be updating again.

Regards,

********* *********

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/22/2021

This business is a joke! I have called every day for over a week to have a very important matter handled and each time I call I a told there is only 1 individual who can resolve my issue and he/she is out of the office. Echo has been instructed by ********** to remove a block on our payments and immediately pay us. This has taken over a week and no one on the phone knows anything. Very unprofessional and I will definitely be filing a lawsuit in court against this company.

Business response
10/14/2021

To my knowledge this has been resolved. The provider worked directly with our Chief Financial Officer on her concerns. If further assistance is needed, please let me know.

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/21/2021

I have contacted this company multiple times requesting to opt out of their automatic credit card payments. I've received differing responses from different representatives. They usually claim that Echo "does not offer" the option for healthcare providers to opt out of their credit card payments. They state we must go through a time consuming process for EACH payment received to opt out, one at a time. The last representative I chatted with provided a lengthy explanation about how I could sign up for EFT, for an added fee of 1.99% per payment. When I was confused about the extensive, multi-step, Excel spreadsheet process, she abruptly ended the chat with me. This company is out to make a buck by making opting out of credit card payments as laborious and ineffcient as possible. It's a racket. I never agreed to automatic credit card payments.

Business response
09/27/2021

Provider was opted out on 09/27/21 and notified.

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/20/2021

I am a health care provider. ECHO Health, Inc. Sent me a check for $22.84. They won't tell me which patient account to allocate this to until and unless I sign up with their echo check program.

Business response
09/21/2021

Informed provider to ensure HIPAA compliance and the protection of providers and patients we do not patient information. This information can be obtained on our provider portal. Provider portal registration instructions were provided.

Customer response
09/22/2021

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********* and have determined that this does not resolve my complaint. For your reference, details of the offer I reviewed appear below.

[To assist us in bringing this matter to a close, we would like to know your view on the matter.]

Regards,

******** *****

Complaint Type:
Billing/Collection Issues
Status:
Resolved

Initial Complaint
09/20/2021

We continue to receive virtual credit card payments that we don't accept and I have continuously responded back to Echovcards.com and opted out of this service many times. We have 22 different NPI numbers and I spend at least 2 hours a day opting out of this service and continue to get these credit card payments that we do not accept. Why doesn't this issue resolve once I opt out?

Business response
09/29/2021

All TINs requested have been opted out and provider notified.

Customer response
10/15/2021

RECEIVED VIA EMAIL BY BBB STAFF MEMBER:

The issue has been resolved!

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/18/2021

ECHO INC. HIJACKING MY ****** ******/*** ****** REIMBURSEMENTS HAVING OPTED OUT AND CALLED SEVERALTIMES! I WANT ANY RELATIONSHIP BETWEEN ECHO , MY DENTAL PRACTICE AND SOLELY ****** ****** TO CEASE IMMEDIATELY *** HAS NOT YET BEEN ABLE TO INTERVENE YET I AM SEEKING PAYMENTS GOING AS FAR BACK AS JAN2021 I AM NOT CONFIDENT AT THIS TIME THAT ****** ****** CAN BE INSTRUMENTAL IN THIS PROBLEM SINCE THEY ALSO HAVE BEEN INCOMPETENT AND DERELICT IN THEIR DUTIES THANK YOU

Business response
09/27/2021

Provider was opted out of VCP on 09/27/21 and notified.

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
09/15/2021

I spoke with multiple representatives (10 to be exact over the past two days) at ECHO regarding opting out of credit card payments! I still have no resolution to this matter. Our office does NOT want to receive this type of payment from ANY insurance companies. The process to opt of of the vcard payments is not efficient. I was on hold for over an hour yesterday and then was told to contact the insurance company. The insurance company told me to contact ECHO! I am getting the run around. I did not sign up for this service nor do I want it!. I currently have 11 card payments on my desk waiting for check to be issued for which I was told it would take 90days. I was also informed that if our office wants to opt into auto deposit - EFT, we would have to pay for that service. I was sent an e-mail to fill out the paper work for single payer EFT option, but the e-mail included 4 attachments, but not the one requested. I called again and was put on hold. After an additional hour no resolution.

Business response
09/15/2021

Provider opt out completed and provider notified.

Customer response
09/15/2021

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********* and find that this resolution is satisfactory to me.

Regards,

******* *******

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/13/2021

I received a *** ********** dated 8/30/21 from *** **** * echovcards. I did not authorize them to pay by ***. card # **** **** **** ***** ***** **********. I want to completely & permanently opt out of the *** virtual card. Please pay by check. They kept me on hold for 14 minutes before answering and gave a wrong website name [echovcards] to manage this issue. but that website did not offer a resolution option; it was just for their sales. ** ****** ** ***** ******* ****** ***** *** ** ***** *** ** *********

Business response
09/28/2021

Email sent on 09/15/21 and still pending a response from the provider.

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/08/2021

I have repeatedly asked Echo Health for physical checks for dental claim payments and to opt our office out for virtual credit card payments. We are a small office and already accept a reduced fee for many of our services, we cannot afford to pay a fee to process these payments in order to receive payment. Thank you.

Business response
09/15/2021

Provider opt out completed and provider notified.

Previous

1 ... 3 4 5 ... 17

Next

Customer Complaints Summary

Business's Response Rate: 100%

172 total complaints in the last 3 years.

21 complaints closed in the last 12 months.

Contact Information

810 Sharon Dr
Westlake, OH 44145-1521

Visit Website

Visit Website

(888) 834-3511

BBB Rating & Accreditation

ACCREDITED BUSINESS BBB®

A+

Accredited Since: 9/29/2014
Years in Business: 25

Customer Reviews are not used in the calculation of BBB Rating

Overview of BBB Rating

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ECHO Health, Inc.

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File a Complaint

Complaint Details

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Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/07/2021

We received several virtual credit cards from ECHO Health and the message we receive when trying to process the card is : Declined: TRANS NOT ALLOW TRANSACTION NOT ALLOWED TO CARDHOLDER Please Try Again. I have called several times and been on hold over 30 minutes. I have yet to speak to anyone. I have had to hang up to handle other business and have tried different times a day. I have looked on the website for help and can not find any help there either. One of the *** payments that we are trying to resolve is for $720.00 dated 07/28/2021. The EPC Draft# is *********. We are ******* ** **** ****** and our Tax ID# is *********. The odd thing is that for one of the VCC received that we could not process, we received a check on August 24, 2021 that had the same draft # (*********) and dated the same day (7/21/2021) as

the information on the *** without any notification, explanation, or warning. We would prefer checks because obviously the *** is not processable.

Business response
09/08/2021

Provider opt out completed and provider notified.

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
09/07/2021

Echo Health send virtual credit cards to you to pay for dental claims that have been submitted. They give you an option to opt out, but as you can see by the complaints filed, they DO NOT opt you out. We continue to receive virtual credit cards even after opting out time and time again. Please just opt us out!! ********** and TID **********

Business response
09/09/2021

Provider opt out has been completed and the provider was notified.

Customer response
09/13/2021

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********, and find that this resolution is satisfactory to me. They stated they have opted us out of virtual payments, time will tell if this occurs. I appreciate your help and if I have further issues i will be sure to contact you again.

Regards,

***** ********

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/02/2021

I have been trying to opt out of virtual credit card payments in order to receive a paper check. Every time I speak with a representative, I am told I have been opted out. I keep receiving v-cards, obviously not being opted out. Yesterday I was informed I need to speak with the insurance company to opt out. I call the insurance company, and they tell me I have to call Echo to opt out. I need to have this issue resolved!

Business response
09/03/2021

*Provider has been opted out of *** and notified.*

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/02/2021

I have a complaint against this company, Echo Health, Inc. I continue to receive virtual cards after having requested time and again to receive paper checks. They are impossible to get in touch with. When you call their phone number listed they indicate EVERY time that wait time is 10 minutes. I've never been able to wait long enough to talk to someone. The web page indicates you are requesting a check, but does not formally ask you if you want to opt out. They do have an online chat. I started a chat with someone named Matt Brack, but like the phone call, he never responded. PLEASE do something about this company. Doctors do not want to pay fees in order to get their full payment for services. It is not right. Jeanine Roquet, Office Manager for ** **** ******* *** ****** TX

Business response
09/27/2021

Opt out was completed on 09/27/21 and provider was notified.

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
09/01/2021

On the most recent date 9-1-2021, a virtual credit card (***) was issued to our business. ECHO Health is a third-party vendor for medical insurance carriers; ECHO Health forwards (via fax) a virtual credit card payment from the issuing insurance carrier to medical providers in order to pay a medical claim for their insured. The issue we have with this process is that we lose a percentage based on the transaction fees for using a credit card. We want a regular, old fashioned paper check. In order to "opt out", ECHO health requires that a call be made each time a *** is issued. We want to "opt out" forever! We no longer want to receive ***'s, sit on hold for 30 plus minutes to opt out, or go online to opt out. Please look up our tax id in your system and remove it or block it from getting any future ***'s. I would like confirmation that my request has been heard and with any luck, we will no longer be active in ECHO Health *** pay system. See attached.

Business response
09/27/2021

A email was to the provider on 09/21/21 and pending a response.

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
08/31/2021

I want to stop receiving virtual checks. No matter how many times I speak to an agent, no matter how I remain on hold for hours at a time I still receive these checks. How do I stop this?????

Business response
10/25/2021

Email was sent on 09/02 and 10/25. Provider has not responded with the required details to take action.

Complaint Type:
Billing/Collection Issues
Status:
Answered

Initial Complaint
08/31/2021

***** contracted with Echovcards for its payments to healthcare providers. I do not want Vcard, and there is an opt out phone to contact. I contacted them and after a 35 minute wait, was able to speak with representative that indicated my name was removed from vcard reimbursements, and they would send paper check remittances instead. This did not happen, and I continue to get Echovcard payments. So, I called again today (8/31/21), and after another 35+ minute wait, spoke with representative who took information and dropped call before I could get confirmation that paper checks would be sent. I simply don't have the time for this type of incompetence. Also, ***** should have surveyed providers for remittance preferences before they moved data to Echovcard. Echovcard is incompetent at ensuring provider preferences are met and ***** acted without due consideration to provider preferences.

Business response
09/03/2021

Email was sent to provider and provider stated that they had already received assistance from the call center.

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
08/26/2021

I have opted out of ECO health V card payments on multiple occasions and I still keep getting the V Payments . We are a small medical practice and do not want these credit card payments we wish to receive paper check for all insurance payments . This company puts you on hold for over an hour and still no answer.

Business response
09/21/2021

Opt out was completed on 09/02 and provider was informed.

Complaint Type:
Problems with Product/Service
Status:
Resolved

Initial Complaint
08/24/2021

Echo Health Inc. ***** ***** No matter how many times I opt out of the program for our dental office I still continue to get these virtual credit cards. This has been going on for over 3 years and it is unacceptable. I do not have 20 mins to spend on hold to get this resolved for every patient they decide to send to us like this. We never opted into this program, but I spend hours trying to opt out and it is ridiculous. There must be something the BBB can do about this.

Business response
08/27/2021

Provider was opted out of VCP and notified.

Customer response
08/30/2021

[A default letter is provided here which indicates your acceptance of the business's response. If you wish, you may update it before sending it.]

Better Business Bureau:

I have reviewed the response made by the business in reference to complaint ID ********* and find that this resolution is satisfactory to me if they follow through with what they said they will do.

Regards,

****** *******

Complaint Type:
Problems with Product/Service
Status:
Answered

Initial Complaint
08/23/2021

I manage dental practice in Bergen County and the insurance companies are now having "qiuick remit" payments issued to us. I have tried to reach them via their 888 phone number and their web address to stop all QR payments. To no avail. They are impossible to reach to cancel these VISA payments. We pay a fee to process them and it is not fair we can not make contact to discontinue this type of payment.

Business response
09/15/2021

A email was sent to the provider on 08/25 and 09/15 and is pending a response.

Previous

1 ... 4 5 6 ... 17

Next

Customer Complaints Summary

Business's Response Rate: 100%

172 total complaints in the last 3 years.

21 complaints closed in the last 12 months.

Contact Information

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A+

Accredited Since: 9/29/2014

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Customer Reviews are not used in the calculation of BBB Rating

Overview of BBB Rating

From: ssanderson@peerlesspediatrics.com NCVHS
To: Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Thursday, December 15, 2022 10:56:23 AM

Please vote down these proposals. These are so detrimental to medical practices. Most of us are already struggling financially and this is just another abuse by the big insurance companies. It's rape and pillage of the doctors actually caring for the patients and doing their best to do the right thing. Please help us continue to provide high quality care and keep our office operating. I know these proposals are universally condemned by practitioners,practices,doctors….anyone running a medical practice! They are truly detrimental and are actually usurious. It's another shameful act of great by insurance providers.
Sincerely ,
Stephanie Sanderson MD
PEERLESS PEDIATRICS

From: Kim Steffenhagen
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals by December 15, 2022
Date: Thursday, December 15, 2022 7:31:00 AM
Attachments:

Good Morning,

We are against the X12 proposed addition of the "card payments" remittance information to 835 ERA. These VCC are not only difficult to review and track but are also costly to physician practices. Physician practices lose revenue when health insurers make payments using virtual credit cards, often costing 3%+ of revenue and 6-8% of gross profit. EFT and ERA are more cost effective and efficient.

Please reconsider your new standard and protect the ability of physician practices to receive electronic payments and remittances from health insurers without charges or fees.

Kim Steffenhagen, CPC, CEMC, COPM
Central Billing Liaison
Pinnacle Ear Nose & Throat Associates, LLC
994 Old Eagle School Rd
Suite 1017
Wayne, PA 19087

Point32Health
1 Wellness Way
Canton, MA 02021
point32health.org

December 14, 2022

NCVHSmail@cdc.gov

RE: RFC on CAQH CORE Proposal

Point32Health appreciates the opportunity to share input on the proposed new and updated CAQH Committee on Operating Rules for Information Exchange (CORE) Operating Rules currently under consideration by the National Committee on Vital and Health Statistics (NCVHS) for federal adoption. Point32Health is at the forefront of technical advancements that promote automation of healthcare transactions and information sharing. We strongly support the proposed operating rule package for its ability to compel industry stakeholders to adopt best practices, simultaneously supporting assurance that our trading partners are using modern, secure methods to do business and ensuring we can quickly address critical use cases for our beneficiaries and provider partners.

Point32Health represents the coming together of two of New England's most iconic nonprofit health care companies and is the combination of Tufts Health Plan and Harvard Pilgrim Health Care. Representing nearly 90 years of combined service to our members and the community, together we are building upon our diverse legacies and innovative collaboration by making it our purpose to guide and empower healthier lives for everyone — no matter their age, health, race, identity, or income. As Point32Health, we strive to be a different kind of nonprofit health and well-being company, with a broad range of health plans, and innovative tools that make navigating health and well-being easier, guiding our members at every step of their health care journey to better health outcomes. We are committed to providing high-quality and affordable health care, improving the health and wellness of our members, and creating healthier communities across the country.

Point32Health acknowledges the important and wide-reaching scope of the proposed new and updated CAQH CORE Operating Rules. The updated operating rules better reflect the 24/7 nature of healthcare while contemplating modern security requirements, the growing complexity of benefit design, and the need for granular information at the point of care. The framework supported by this proposed rule set enables industry-wide automation leading to greater efficiency and downstream benefits to patients and providers by reducing delays in care and clearly outlining financial responsibility. Importantly, CAQH CORE proposes to extend the benefit of operating rules to workflows governing the exchange of attachments for claims and prior authorization.

The proposed CAQH CORE Attachments Operating Rules are specifically designed to be standard-agnostic and can serve as a framework for uniform expectations for the electronic exchange of attachments using X12 275, HL7 CCDA, or HL7 FHIR, all standards under consideration for federal adoption. Point32Health supports regulatory action to establish standards for the exchange of attachments, but further recognizes the need for additional guidance that minimizes implementation variability and content gaps. Therefore, we strongly recommend that the Attachments Operating Rules be adopted concurrently with federal action establishing attachment standards.

We have provided detailed responses to each of the questions posed in the NCVHS Request for Comment. Point32Health is pleased to recommend federal adoption for the complete rule set. Should you have any questions or wish to discuss further, please contact me at Michael.Sherman@Point32Health.org.

Sincerely,

Michael S. Sherman, MD, MBA, MS
Chief Medical Officer
Point32Health

1. Infrastructure updates to the adopted Eligibility and Benefits and Claim Status Operating Rules: Point32Health maintains a robust technical infrastructure that represents the best practices necessary to automate electronic data exchange; however, we recognize adoption of these mechanisms and methods has not been implemented equally across the industry. We strongly support federal adoption of the proposed updates to the mandated CAQH CORE Infrastructure Operating Rules for their role in compelling stakeholder alignment around modern security and exchange standards, more rigorous system availability requirements, and support for emerging data exchange standards, such as HL7 FHIR. We further recognize their role at our organization in supporting initiatives to further streamline and strengthen operations.

We support requirements to increase overall weekly system availability from 86% to 90% for claim status and eligibility and benefits transactions. Already Point32Health maintains greater than 90% system availability, but we note that this is not applied equally across the industry. Mandating this requirement aids all stakeholders in maintaining reliable, automated exchanges that are available on a consistent schedule. Point32Health specifically benefits from these enhancements through the updated accommodation allowing an optional 24 hours of additional downtime per quarter. As Point32Health seeks to integrate the disparate systems of our founding health plans, this additional downtime allows us to perform major updates predictably, minimizing impact on our provider and vendor partners, and our beneficiaries.

Point32Health also acknowledges the positive impact that the inclusion of the latest version of the CAQH CORE Connectivity Rule has on the updated infrastructure requirements. The update ensures that Point32Health and its trading partners are held accountable to the latest security protocols while simultaneously advancing industry-wide efforts to modernize and implement updated and emerging exchange standards, such as newer versions of X12 or the HL7 FHIR Standards. We welcome this dual recognition of security threats and a need to foster technological growth throughout our industry. We further address the benefit of the updated CORE Connectivity Rule later in this document.

2. Data Content Updates for Eligibility and Benefits Operating Rule: Updates to the CAQH CORE Eligibility and Benefits Data Content Operating Rule address gaps in the mandated version to better contemplate crucial business scenarios arising from changing care settings, complex benefit designs, and the influence of regulatory priorities over the past ten years. The necessity of these changes is well-exhibited in the 2021 CAQH Index, which shows that 89% of eligibility and benefit transactions are automated but, counter to this high adoption rate, the remaining 11% of transactions contribute to nearly $9.8 billion worth of avoidable expenditures. Without adoption of the updates proposed by CAQH CORE, costly manual workflows will persist throughout the industry.

Point32Health was an active participant in the development and publication of the enhanced operating rule, and we believe our organizational best practices are well represented in the updated structure. Expansion of the covered service-type codes and inclusion of procedure codes for which health plans are required to return patient financial information, as well as requirements to return telehealth eligibility, information about tiered benefit structures, and the need for prior authorization combine to promote automation across a range of use cases and business scenarios. At Point32Health, many of the requirements have already been implemented, allowing us to automate greater than 99% of our 40 million eligibility and benefit transactions in 2021. The positive financial impact of automation is significant, only costing health plans about $0.03 per transaction according to the CAQH index rather than upwards of $15.09 per manual transaction.

We would also like to address the application that the updated Eligibility and Benefits Data Content Rule has on emerging regulatory requirements. The enhanced granularity the rule provides helps industry stakeholders meet Good Faith Estimate and Advanced Explanation of Benefits requirements outlined under the No Surprises Act.

We strongly urge the Subcommittee to recommend for adoption the updated CAQH CORE Eligibility and Benefit Data Content Operating Rule in recognition of its ability to fulfill emerging business scenarios and use cases in the industry, driving automation. As chronicled, Point32Health has implemented many of the data content requirements in these new and updated rules to good effect and encourage adoption to align the industry around a uniform set of requirements.

3. New: Single Patient Attribution: Point32Health is strongly committed to advancing value-based care. We actively steward value-based models and incentives for our partner providers, and through our founding plans Harvard Pilgrim and Tufts Health Plan, we remain an active participant in the MassHealth Medicaid Accountable Care Organizations. We recognize the difficulties that providers sometimes encounter when participating in value-based contracts in having to navigate complex methodologies that vary between health plans. One of these methodologies, patient attribution, is particularly troublesome in that health plans and other stewards of value-based care often utilize proprietary models, making it difficult for providers to consistently identify which of their patients are attributed to a model. Additionally, health plans use a variety of mechanisms to share attribution data with providers including web portals, email, and spreadsheets.

CAQH CORE has provided an eloquent solution to this challenge through the creation of the Single Patient Attribution Operating Rule. At the time of eligibility verification, health plans must return the patient's attribution status to a value-based contract using a standardized format. We strongly support adoption of this operating rule for its role in advancing value-based care operations by clarifying disparate methodologies and empowering providers to address care gaps and fulfill contractual obligations proactively. This rule directly supports increased quality and reduced costs through its support of value-based payment operations.

4. Companion Guide Template: The updated infrastructure rules proposed for adoption reference an updated CAQH CORE Master Companion Guide Template that allows implementers to indicate other versions of the X12 standard, beyond the current HIPAA-mandated v5010. This update directly supports the proposed CAQH CORE Attachments Operating Rules that reference v6020 and is also reflective of concurrent proposals from X12 to update the referenced standard for several transactions. We would also acknowledge that the Master Companion Guide Template can be used as a starting format to unify companion guides for non-X12 standards.

Point32Health supports the inclusion of the updated Master Companion Guide Template in the CAQH CORE Infrastructure Rules. The template provides a uniform, predictable approach to the development of companion guides that can cleanly, and easily, fit into our workflows, and those of our industry partners.

5a. Updated Connectivity Rule: Impact and changes to organizational infrastructure: Point32Health strongly supports adoption of vC4.0.0 of the CAQH CORE Connectivity Rule. The updated rule enhances security and communication protocols, while better accommodating emerging technologies and standards by integrating support for APIs. Adoption of this rule "future proofs" our ability to securely automate the exchange of electronic information using multiple standards and formats.

As a HIPAA-covered entity, Point32Health conforms with the currently mandated Phase I and II CORE Connectivity Rules. Though provisions of these rules are still relevant, many of the security and exchange mechanisms are outdated, exposing Point32Health and its trading partners to potential security threats.

Point32Health must update its systems to conform with the new requirements, but we do not foresee devoting significant resources to these changes. As previously mentioned, vC4.0.0 carries forward several key requirements of the currently mandated Connectivity Rules, including safe harbor requirements. This means that we do not need to overhaul mutually agreed upon connections with trading partners to conform with the updated requirements. Additionally, expanded support for communication and exchange protocols, such as APIs, allows us automate connections with a greater number of trading partners, driving a more efficient infrastructure. Second, vC4.0.0 of the Connectivity Rule includes technological advancements that are largely considered to be industry best practices. This includes the incorporation of digital certification using an X.509 standard, which aligns requirements with modern web-based traffic and helps save time and money by removing the need to maintain outdated and administratively costly mechanisms like the username and password authentication.

As referenced previously, through our founding health plans, Point32Health is a CORE-certified organization. We value this certification as it demonstrates the rigorous attention Point32Health gives to its technology infrastructure. We intend to maintain this certification and, to do so, must demonstrate conformance with the requirements laid out in vC4.0.0 of the CAQH CORE Connectivity Rule during our re-certification. These changes represent current industry best practices, and we will not hesitate to devote the resources to meeting these requirements. Because all entities are not required to be CORE-certified entities, we strongly urge the Subcommittee to recommend this updated rule for federal adoption to ensure best practices are equally disseminated across the industry.

5b. Updated Connectivity: Scope: Point32Health believes that the updated Connectivity Rule is representative of current industry best practices and that it establishes a durable framework for the secure transfer of health information using a variety of payloads and formats. The rule provides a standard agnostic approach that harmonizes disparate technologies and standards. In addition, the updated rule optimizes connections with our existing trading partners while maximizing our ability to make new connections throughout the industry. The technologic updates and flexibility this updated rule provides allow implementers to accommodate a robust framework for the automated exchange of health information using existing and emerging standards.

6. Costs: The benefits of the updated CAQH CORE Data Content and Infrastructure Operating Rules have been discussed at length in this response. In short, the updates drive greater adoption of electronic transactions across the industry by addressing more use cases, promoting the use of modern standards and technologies, and enhancing security and exchange workflows. We also note the positive impact adopting these updates has on the healthcare revenue cycle. Automating eligibility verification de-burdens provider workflows by clarifying point-of-service collections, leading to less health plan time spent manually responding to phone inquiries. Similarly, increased granularity facilitates higher accuracy of claim submissions, resulting in fewer denials and less staff time spent resolving appeals or resubmissions – a benefit to the providers we serve and to our internal operations.

As previously highlighted, Point32Health has demonstrated great success automating eligibility verification, carrying out over 99% of requests fully electronically and only contributing $0.03 of expenditures per transaction;

however, we do not think these efficiencies are applied equally across the industry, particularly as business scenarios and care settings continue to evolve.

This point is illustrated by the pandemic-related growth of telehealth. Industry-wide, usage of telehealth usage increased to promote safe care continuity. During this time, Point32Health saw requests for telehealth eligibility verification increase significantly. Though we automate eligibility for telehealth in a way that aligns with the updated CAQH CORE Operating Rule requirements, this practice was not applied universally, and many providers and health plans devote time and resources to manually carry out these transactions. We submit that mandating the updated operating rule requirements provides a pathway for automating more eligibility verifications, including for telehealth services, and aids the industry in saving nearly $15.09 and 21 minutes of provider time per eliminated manual transaction.

We also acknowledge that adoption of the infrastructure rules, while not directly fulfilling critical business scenarios in the way that the updated CAQH CORE Eligibility and Benefits Data Content Operating Rule does, drives greater automation of claim status and ERA processes. This is primarily achieved through enhanced security and technical requirements that engender increased access to and comfort with automation. Respectively, according to the 2021 CAQH Index, conducting automating claim status and ERA transactions could save up to $16.65 and 22 minutes of provider time and up to $4.06 and 7 minutes of provider time.

7. Alternatives: Point32Health views the adoption of the updated rule set as extremely positive. Though our organization is at the cutting edge of technology, we recognize the importance of these operating rules in driving industry uniformity, advancing alignment around best practices, and optimizing our ability to do business with other stakeholders by guaranteeing common expectations for data exchange and connectivity methods. We do not believe there is a reasonable alternative to mandating the updated operating rules. The proposed package empowers the maintenance and adoption of standards by setting a foundation for uniform implementation thus minimizing industry fragmentation and burden. We would also recognize the negative consequence of not adopting the updates that would arise from maintaining outdated security and exchange technologies and through a failure to address critical business scenarios.

8. Attachments: The exchange of supplementary clinical information to support claims and prior authorization using attachments is rarely automated and can be a burdensome process for both providers and health plans. Industry-wide only 21% of attachments are exchanged fully electronically, with the remaining 79% transferred using proprietary portals or insecure methods such as fax or email according to the 2021 CAQH Index. At Point32Health we exchange a high percentage of attachments fully electronically but similarly see room for improvement. Attachments shared through email, fax or other formats are, at times, difficult to reassociate with the claim submission or prior authorization request they support because the formats being used, and the type of included information, can differ between submissions.

This issue is exacerbated when providers, who often anticipate our requests for additional information, send unsolicited attachments. These attachments can easily be separated from the transactions they support; at worst, they can be ignored if there is not a corresponding request for additional information. At the root of these difficulties is the lack of a named standard under HIPAA for the electronic attachments that would help unify exchange workflows. Point32Health believes the CAQH CORE Attachments Operating Rules can drive more

uniform exchange of attachments by establishing minimum data content and infrastructure requirements for the standard agnostic exchange of information.

Many health plans, including Point32Health, use myriad approaches to facilitate the exchange of attachments. The proposed CAQH CORE Operating Rules allow these practices to continue but establish minimum data content and infrastructure requirements that aid in reassociating an attachment with the claim or prior authorization request it is supporting. Together, this means that regardless of the format or the approach required at a health plan, an attachment can be easily integrated with a request. At Point32Health, this integration speeds workflows and helps avoid lags in adjudication that could lead to harmful care delays or impacts to the revenue cycle.

We also highlight the obvious synergistic advantage the operating rules have with the imminent release of an attachment standard which may include the X12 275, HL7 CCDA, or HL7 FHIR, among other options. Standards, while beneficial in establishing expectations and consistent formats for the industry to draw upon, are not always implemented in a uniform manner especially when multiple standards are under consideration for adoption. The operating rules provide a pathway for uniform implementation across standards that helps speed conformance and minimize proprietary methods that perpetuate industry fragmentation. Without the guiding hand of the operating rules, it is possible many of the same burdens that impact the industry today will persist. Therefore, we recommend that the CAQH CORE Attachment Operating Rules be adopted concurrently with regulated attachment standards so implementation can be guided using a common set of principles.

9. General Questions: Point32Health strongly recommends the simultaneous adoption of CAQH CORE Attachments Operating Rules and named standards. Doing so will drive uniformity in a way a standard alone cannot. The industry has awaited a standard exchange for over 20 years and has functioned without promised operating rules for over a decade. We believe concurrent adoption of a named standard and operating rules creates a framework that allows implementers to scale resources and meet regulated requirements more efficiently.

Additionally, simultaneous adoption prevents stakeholders from operating on multiple timelines. Typical conformance timelines already extend into 2026 and delaying proposal and adoption of operating rules would push uniform implementation even further. We recommend that the Subcommittee not delay adoption of operating rules if anticipated regulatory action establishing named standards does not come to pass. As has been proven for other transactions, operating rules can function effectively with or without a standard and would be a viable stand-in to promote uniformity if the federal government chooses not to act.

To: The National Committee on Vital Health and Statistics

Re: National Committee on Vital and Health Statistics Request for Public Comment on Proposal for Updates to X-12 Transactions and New and Updated CORE Operating Rules

Date: December 15, 2022

Submitted electronically to: NCVHSmail@cdc.gov

Premier Inc. appreciates the opportunity to submit comments to the National Committee on Vital Health and Statistics (NCVHS) in response to the Request for Comment (RFC) on Proposals for Updates to X12 Transactions and New and Updated CORE1 Operating Rules Version 3 – November 28, 2022.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,300 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to ensure access to the highest quality products.

Premier's comments focus on the request for comments related to NCVHS' question **"Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction."**

Premier strongly supports including unique device identification (UDI) in the updated version of the X12 claim transaction. The addition of medical device identifiers to claims data will help ensure more accurate adverse event reporting, enable improved evaluations of marketed devices, reduce medical errors through improved device identification, streamline payment processes, decrease healthcare supply chain costs, and facilitate more comprehensive recall resolution. Through the adoption of UDI data elements, patients, clinicians, providers, policymakers, regulators and researchers will have better data to help ensure high-quality care, prevent harm and reduce cost.

The unique device identification system was established by the Food and Drug Administration (FDA) to identify and track medical devices from manufacturing through patient use. Manufacturers are now required to print UDI data in both human and machine-readable formats on device packaging.

The benefits of UDI are already far reaching. Healthcare providers must satisfy the requirements of the FDA's UDI system and demonstrate meaningful use of certified electronic health record (EHR) technology through the capture of UDIs in EHRs. Healthcare systems are now able to scan UDI barcodes of implants into patient records and clinical inventory systems. In addition, UDIs are incorporated in the official medical device recall notices from manufacturers, providing an additional level of accuracy for healthcare providers. The presence of the identifiers in recall notices drives adoption as provider inventory systems update to include them in operational tasks. However, ***the UDI system can only achieve its full potential to improve patient safety and achieve greater efficiency once it is included in claims***. Claims provide longitudinal information on patient care delivery and outcomes across the continuum of care, sites and providers. Unlike many other information sources, claims also offer large, standardized data sets for analysis. For example, patients often seek follow-up care for implanted devices from providers that did not implant the device. Claims data would capture both the procedure and the patient outcome. Incorporating device identifiers into the electronic claims forms will provide an efficient way to understand the long-term safety and performance of different devices and enable comparative effectiveness evaluations. Particularly

in an era of value-based care, healthcare providers need this information to make informed decisions about the products they use.

Premier shares the vision of enabling healthcare providers to track medical devices electronically within the supply chain and across the care continuum. ***It is imperative that the NCVHS support the adoption of UDI as data elements in the updated version of the X12 claim transaction.***

We hope these comments are helpful as you continue this important work. If you have any questions regarding our comments or need more information, please feel free to contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.

From: Roger Puckett
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Thursday, December 15, 2022 10:16:50 AM
Attachments:

We are against the X12 proposed addition of the "card payments" remittance information to 835 ERA.

We should not have to absorb processing fees in order to get paid.

RP

Roger Puckett, CPA
Administrator, Quail Creek ENT

www.quailcreekent.com
6830 Plum Creek Drive
Amarillo, TX 79124

From: Robert Weiser
To: NCVHS Mail (CDC)
Subject: No virtual credit card payments Thursday,
Date: December 15, 2022 7:47:54 AM

I am a sole practitioner. Please do not allow virtual credit card payments. They are costly and time-consuming to my small practice and will hasten my exit from practicing medicine

From: Alicia Myrick
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Tuesday, December 13, 2022 10:07:57 AM

We are against the X12 proposed addition of the "card payments" remittance information to 835 ERA. Our providers in independent practice have seen a decline in payments for Medicare and Medicaid already and making VCC allowed to charge a fee against the fee for service the providers are suppose to make is unconstitutional.

Alicia Myrick
Administrator
Rogue Valley Physicians, P.C.

From: san san wynn
To: NCVHS Mail (CDC)
Subject: RFC ON X12 & CAQH CORE PROPOSALS BY DECEMBER 15, 2022
Date: Thursday, December 8, 2022 5:27:54 PM

To Whom It May Concern,
i am a community BASED Solo practitioner as Hematologist & Medical Oncologist. Recently, I started to receive so called paper credit card or virtual credit card from commercial insurances. When I go for grocery shopping or other shopping, no one accepted the virtual credit card. When I used it online @ Amazon which took the card but remaining balance which is not enough to buy another item. Besides the expiration date is in 3 months.
I felt that I got paid for my service rendered to my patients BUT I can't use it. as if we did not get pay for the services. Why? We, doctor professions are just like other professions, we have family, we have staffs, we have bills to pay. We have our personal lives too. We deserved and entitled to get paid for the services we have rendered to our patients
Now, CMS proposed to add credit payment and decided to cut 8.7% payment in 2023. With inflation, everybody gets increased payment EXCEPT PHYSICIANS. WHY?
We were called "HEROES" during Covid-19 pandemic. What are we now? Forget us so fast.
We are going to do it & save people's lives again & again & again if needed.
Another issue is: CMS started not to give office visit, if we give another services on the same day. For me, as hematologist/ medical oncologist, most of my patients are advance stage cancer. I cannot give chemotherapy Without evaluating them first. Cancer patients are already suffered enough, why ask them to come one day for evaluation & another day for chemo or immunization especially when the weather is bad.
Many doctors are thinking to retire prematurely. During Covid-19 pandemic, because of physician shortage, my colleagues came back from retirement & help to save patients & 2 colleagues died from Covid-19.
Please be considerate to the kind hearted physicians.
Thank you very much for your kind attention to this matter.
Truly,
San San Wynn, MD
Hematologist/Oncologist

NCVHSMAIL@CDC.GOV

immediately if you have received this message by mistake and delete it from your system.

December 15, 2022

Denise E. Love
Richard W. Landen
Co-Chairs
Subcommittee on Standards
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: RFC CAQH CORE Proposal

Submitted electronically to NCVHSmail@cdc.gov

Dear Ms. Love and Mr. Landen:

Thank you in advance for considering St. Joseph's Health's comments on the new and updated CAQH Committee on Operating Rules for Information Exchange (CORE) Operating Rules proposed for federal adoption. The proposed new and updated operating rules provide modernity to security and exchange protocols and address critical business scenarios that have arisen in the decade since the currently mandated operating rules were adopted. We urge the National Committee on Vital and Health Statistics (NCVHS) to recommend the full set of operating rules for federal adoption to the Secretary of the Department of Health and Human Services (HHS).

Established more than 154 years ago by the Sisters of Charity of Saint Elizabeth, Paterson New Jersey's first hospital has evolved into St. Joseph's Health, a multi-faceted integrated healthcare organization and the largest employer in Passaic County. With a "patients first" approach to healthcare excellence, St. Joseph's is fully committed to providing top-quality services designed to heal the minds, bodies, and spirits of those in need. St. Joseph's is a dynamic healthcare system recognized as one of the leading providers in Northern New Jersey for comprehensive medical and surgical services, innovative treatments and procedures, and a wide range of ambulatory and post-acute care options. As an academic organization with multiple teaching affiliations, St. Joseph's not only utilizes but also teaches leading-edge medicine and best clinical practice to future clinicians.

As a safety net health system specializing in the care of underserved populations, we are continuously challenged to identify operational efficiencies that help accomplish this mission and best serve our community. The CAQH CORE Operating Rules are central to fulfilling these goals by accelerating interoperability and aligning administrative and clinical activities to the benefit of providers, health plans, and patients.

The proposed updates to the mandated CAQH CORE Operating Rules accommodate essential infrastructure advancements to security and connectivity requirements and address critical business scenarios not contemplated in the currently adopted versions. The newly proposed operating rules provide, among other efficiencies, welcome uniformity to the exchange of attachments that accelerate the adoption of electronic methods and reduce the reliance on time-consuming and costly manual processes. These changes drive automation and efficiency at every level of our organization, empowering our ability to effectively provide for the community we serve.

St. Joseph's Health is honored to be a CAQH CORE Participating Organization and to be represented on the multi-stakeholder CAQH CORE Board. The development of these rules is the result of a collaborative, consensus-based process with over 100 other CAQH CORE Participating Organizations. We believe the proposed new and updated CAQH CORE Operating Rules represent industry best practices and adeptly fulfill complex business scenarios and, as such, we strongly urge NCVHS to recommend the proposed operating rules to HHS for federal adoption.

Sincerely,

Linda Reed, RN, MBA, CHCIO, FCHIME
Senior Vice President, Chief Information Officer
St. Joseph's Health

1. Improved Efficiency to the Adopted CAQH CORE Eligibility & Benefits and Claim Status Infrastructure Operating Rules

Updates to the CAQH CORE Infrastructure Rules meet modern technology needs by referencing best-practice security and connectivity standards, better representing the full-time nature of healthcare operations, and cementing support for updated and emerging standards. These updates are crucial to efficient operations at St. Joseph's Health, allowing us to securely automate workflows for the mandated eligibility & benefits, claim status, and electronic remittance advice (ERA) transactions. Several key updates and their impact on our operations are highlighted below.

System availability updates improve predictable, automated communication and exchange with health plans. The updated CAQH CORE Eligibility & Benefits and Claim Status Infrastructure Operating Rules increase weekly system availability requirements from 86% to 90%. To offset this increase, health plans can use an optional 24 hours of additional downtime per quarter to facilitate larger system updates and maintenance. These changes result in an additional 364 hours of annual system uptime. Enhancements to system availability benefits St. Joseph's Health by allowing us to extend the benefits of automation across a greater number of encounters, including those occurring during weekends and off-hours. Additionally, accommodating health plans with optional, additional downtime ensures that our systems remain cutting-edge and durable.

References to the CAQH CORE Connectivity Rule modernize technical infrastructures. The CAQH CORE Infrastructure Rules reference the latest version of the CAQH CORE Connectivity Rule, currently vC4.0.0. This update strengthens security and exchange protocols while maintaining key requirements of past versions of the Connectivity Rule. The updates further set a pathway for the adoption of updated and emerging standards by adding support for the APIs. St. Joseph's Health details the advantages and impacts of this proposed update later in our response; however, we acknowledge that these changes benefit our organization by reducing security threats and by facilitating our ability to efficiently connect with industry trading partners using a variety of payloads and methods.

Updates to the CAQH CORE Master Companion Guide Template add necessary flexibility for an evolving industry. The updated CAQH CORE Master Companion Guide Template has been updated

allowing implementers to indicate non-5010 versions of the X12 standard and use the template as an example to generate companion guides for non-X12 standards. We further detail the benefit of this change later in this response but recognize that the uniform companion guide template allows us to easily, and efficiently, integrate requirements into our workflows.

For the above reasons, St. Joseph's Health encourages NCVHS to recommend the updated Infrastructure Rules for eligibility, claim status, and ERA to HHS for federal adoption.

2. Modernization of the Adopted CAQH CORE Eligibility & Benefits Data Content Operating Rule

During the development of the updated CAQH CORE Eligibility & Benefits Data Content Rule, CAQH CORE participants sought to address critical data content gaps in the mandated version of the operating rule that emerged over the past decade and limit full automation of eligibility verifications. As a result of this work, the operating rule expanded the service type code lists, and added procedure codes, for which health plans must return detailed patient financial responsibility. The updates further added new requirements to facilitate the return of detailed coverage information for complex benefit designs, telehealth eligibility, and indications of whether prior authorization is required. These changes address a greater number of automation gaps for St. Joseph's, driving efficiency.

At St. Joseph's Health, approximately 60% of our eligibility verifications are automated. The remaining 40% are performed using a combination of methods, including proprietary portals that vary by health plan and manual phone calls. Changes to the operating rule, such as the requirement to return telehealth eligibility, helps us automate more of these transactions. We highlight this example because, during the pandemic, telehealth visits increased by 1000% at St. Joseph's Health and many of our health plan partners had not yet automated eligibility verification for these services. Given that the use of remote care for select services persists, this enhancement significantly benefits our operations by reducing the manual workflows to confirm telehealth benefits. According to the 2021 CAQH Index, this could result in cost reductions of up to $15.09 and time-savings of nearly 21 minutes per eligibility transaction.

We would also like to address the positive, synergistic impact the updated operating rule has on price transparency initiatives. The requirement for health plans to return detailed patient financial responsibility for a robust list of service and procedure codes, as well as for complex benefit designs, arms St. Joseph's Health with the information necessary to support the Good Faith Estimate (GFE) requirements of the No Surprises Act. Though we are still awaiting clarifying regulations detailing exactly what the requirements entail, having detailed information available at the point of care is a powerful tool in conforming with regulatory requirements.

Given the palpable time and cost savings that enhancements to the CAQH CORE Eligibility & Benefits Data Content Operating Rule will have across the healthcare industry, St. Joseph's Health urges NCVHS recommend the updated rule for federal mandate.

3. Advancement of Patient Attribution Transparency through Updates to CAQH CORE Eligibility & Benefits Data Content Operating Rule

Many providers at St. Joseph's Health are active participants in alternative payment models (APM), engaging in contracts stewarded across a variety of health plans. Though committed to the purpose of value-based care, our providers report frustration when attempting to reconcile methodologies across APMs. One often repeated pain point revolves around determining patient attribution. Health plans employ slightly different patient attribution methodologies and approaches for sharing this information

with providers. We receive attribution data at varying intervals through a variety of exchange methods, most of which are proprietary and require manual review. In practice, this makes it difficult for providers to easily identify what patients are assigned to their practice; a substantial headache as they try to establish workflows to meet varying reporting and performance requirements.

The CAQH CORE Single Patient Attribution Data Content Rule provides a framework for our providers to easily identify patients that are attributed to them by leveraging existing eligibility verification workflows. The operating rule additionally supports data standardization by requiring that the information is returned using defined content in a uniform format. This change is an important one and advances the goals of value-based care by clarifying opaque methodologies and allowing providers to identify and close care gaps and proactively meet contractual requirements.

We encourage the NCVHS to recommend the CAQH CORE Single Patient Attribution Data Content Operating Rule for federal adoption.

4. Simplified Business Processes with Updated Companion Guide Template

The CAQH CORE Master Companion Guide Template organizes information into consistent sections and provides a common flow and format across health plan guides that can be easily integrated into our procedures and workflows governing transactions and information exchange. Updates to the Master Companion Guide Template allow implementers to indicate versions of the X12 standards beyond v5010 and can inform template structures for non-X12 transactions. Additionally, these updates accommodate implementation of the CAQH CORE Infrastructure and Data Content Attachment Operating Rules that reference X12 v6020.

St. Joseph's Health fully supports federal adoption of the CAQH CORE Infrastructure Operating Rules in which the Master Companion Guide Template is referenced.

5a. Common, Trusted, and Secure Method to Exchange Administrative Data with the Updated CAQH CORE Connectivity Rule

Technology is rapidly advancing across the healthcare industry and St. Joseph's Health is eager to implement solutions that facilitate the secure, and efficient, transfer of information. As a HIPAA-covered entity, we actively conform with the requirements of the decade old Phase I and II CAQH CORE Connectivity Rules. Though these rules empower the safe exchange of information with multiple industry trading partners, they must periodically be refreshed to ensure they meet current best practices for the secure exchange of health information. The updates included in vC4.0.0 of the CAQH CORE Connectivity Rule provide essential modernity while carrying forward existing, relevant requirements that reduce the cost burden of implementation.

As we have referred to at several points in our response, St. Joseph's Health is a safety net provider, and therefore must evaluate planned infrastructure investments against their potential impact on our ability to deliver care for our underserved community. As a HIPAA-covered entity, we are required to comply with mandated updates to the CAQH CORE Connectivity Rule either internally or through our vendor and industry partners. When evaluating the impact of the updates included in vC4.0.0, we conclude that the modest financial investment required to conform with these requirements are justified by the promised improvements to our security infrastructure, and through the ability to connect to a wider array of industry stakeholders. This expands our capacity to automate exchanges using a variety of formats, including HL7 FHIR-driven APIs.

Several features of vC4.0.0 of the CAQH CORE Connectivity Rule facilitate an efficient implementation. For one, the updated operating rule carries forward Safe Harbor Connectivity requirements from previous versions, ensuring that St. Joseph's Health and its vendor partners can continue using mutually agreed upon connections with trading partners, without the need undertake expensive system overhauls. Second, inclusion of digital certification requirements represents a more widely accepted and modern solution than username and password authentication. Though resources must be devoted to implementing this new requirement, it ultimately represents cost-savings relative to maintaining and administering outdated methods.

For the reasons stated above, we strongly urge that vC4.0.0 of the CAQH CORE Connectivity Rule be recommended for federal adoption by NCVHS.

5b. Updated Connectivity: Scope

As above, the updated CAQH CORE Connectivity Rule is inclusive of current industry best practices for the secure exchange of health information. While the proposal for federal adoption only includes use for the eligibility, claim status, and ERA transactions, the rule supports a standard agnostic approach, simultaneously supporting existing and emerging standards – this benefits St. Joseph's Health by expanding our pool of potential trading partners and enhancing our ability to automate common healthcare transactions. The robust security requirements additionally benefit our operations by providing assurance that information can not only be exchanged quickly, but also securely. Hospitals like St. Joseph's are increasingly becoming the target of hackers and phishing scams as the nefarious exchange of personal information by bad actors gains capital. We welcome any mandated requirements that strengthen industry-wide security protocols and ensure the safe handling of our patients' sensitive information. To reiterate our support, St. Joseph's Health urges NCVHS to recommend the updated operating rule for federal adoption.

6. Implementation Costs

St. Joseph's Health highlights the significant benefits that can be realized at our organization and industry-wide by federally mandating updates to the proposed CAQH CORE Data Content and Infrastructure Operating Rules. The updates optimize the healthcare revenue cycle and align requirements with use cases and critical business scenarios that emerged in the decade since the current versions of the operating rules were mandated. All together, these improvements help us realize greater automation – and efficiency – of HIPAA-mandated and voluntary transactions.

Though we acknowledge the necessary expenditures associated with implementation, we believe they are modest when considered against the cost and time savings of automation. For example, St. Joseph's Health commits, on average, 60 – 120 minutes to adjudicate a prior authorization request; this includes the time it takes to determine if a service even *requires* prior authorization. It does not include the time required to review, rework and re-submit queries and denials, which are an additional administrative burden that subsequently delays the vital care needed by our patients. The updated CAQH CORE Eligibility & Benefits Data Content Rule requires health plans to return whether prior authorization is necessary during eligibility verification. By automating this workflow, manual processes can be eliminated and, according to the 2021 CAQH Index, upwards of $15.09 and 21 minutes of provider time can be saved. Additionally, through robust infrastructure updates, the CAQH CORE Claim Status and ERA Infrastructure Rules promote increased automation and can respectively save upwards of $16.65 and 22 minutes of provider time and up to $4.06 and 7 minutes of provider time.

St. Joseph's Heath would also acknowledge the profound benefits adoption of these updated operating rules have on our revenue cycle. Increased system availability facilitated by updates to the infrastructure operating rules speeds submission, acknowledgment, and processing of submitted claims – leading to less of our revenue being tied up in accounts receivable. Relatedly, submission errors are detected more quickly in a reliable, automated environment, allowing our team to address resubmissions more promptly when compared to manual adjudication. Lastly, granular details about benefit structures and eligible services support the correct submission of claims and prior authorization requests, reducing the time our team spends resolving or appealing rejections and denials. Granular information about patient financial responsibility also allows us to optimize point-of-care collections.

7. Alternatives Considered for Operating Rules

St. Joseph's Health submits that no reasonable alternatives exist that fulfill the fundamental benefits and opportunities that CAQH CORE Operating Rules provide to all healthcare stakeholders. The rules accommodate a robust, durable framework for the uniform implementation of all standards thereby reducing industry variability and fragmentation. Additionally, we recognize the negative consequences for interoperability and security that would arise by maintaining outdated requirements. St. Joseph's Health strongly recommends adoption of the proposed operating rule package.

8. Assessment of New CAQH CORE Attachments Operating Rules for Prior Authorization and Health Care Claims

The exchange of supplementary health information to support prior authorization and claim submissions is burdened by the lack of an accepted, named standard. Health plans maintain proprietary requirements for the submission of attachments, leading to market fragmentation and implementation variability. According to the 2021 CAQH Index, in response to this difficult context, only about 21% of attachment transactions are carried out fully electronically, with the remaining workflows using outdated or insecure methods, such as web portals, fax, email, or snail mail. At St. Joseph's Health, we encounter these difficulties daily, spending as much as 2 - 4 hours per attachment exchange. Even when we fulfill a request with relative efficiency, given the lack of a standard, difficulties on the health plan side re-associating the information with the request can lead to costly or dangerous delays of care.

The proposed CAQH CORE Attachment Operating Rules provide necessary uniformity for the exchange of supplementary health information, aligning the industry around a key set of principles. First, in recognition of the different formats used to exchange additional documentation, the attachment operating rules are standard-agnostic and provide best practices for the exchange of information without interrupting existing workflows. Second, the operating rules carry forward key mandated infrastructure requirements establishing the same secure platform that is used for other HIPAA-mandated transactions while adding maximum file size requirements to eliminate unnecessary rejections of attachments by health plans. Finally, the operating rules specify key data content provisions that aid in the re-association of information with the request it is supporting – speeding time to adjudication and combating dangerous delays of care.

St. Joseph's Health further acknowledges the important role operating rules play in unifying implementation of the soon-to-be-released attachment standards which may include X12 275, HL7 CCDA, or HL7 FHIR. Authored specifically to be standard agnostic, the operating rules are designed to support industry-wide uniformity regardless of the standard or standards named. This is of utmost importance as the industry is already encountering extreme fragmentation and variability and, although a named standard is important to align stakeholders around the technical exchange of information, it

does little to promote uniformity of data content and infrastructure, as exhibited across the industry with past standards implementations.

We strongly recommend that NCVHS recommend that HHS adopt the CAQH CORE Attachment Operating Rules concurrently with named attachment standards within the same regulation. This step aligns implementation timelines that are already extending into 2026 and serves to unify the industry around a single set of best practice, implementation guidelines.

Considerations for Mandating CAQH CORE Attachments Operating Rules

The operating rules under consideration align infrastructure and data content requirements to support the electronic exchange of attachments. St. Joseph's Health and the industry-at-large can no longer withstand market variability that requires the inefficient allocation of resources and prolongs determinations, risking costly or dangerous delays in care.

In absence of a named standard the CAQH CORE Operating Rules provide necessary uniformity that supports the myriad workflows and formats that have penetrated the industry. In conjunction with a standard, if one or several should be named, the operating rules provide a structure that optimizes its effectiveness and stimulates industry conformance. As such, we strongly urge NCVHS to recommend concurrent adoption of the named attachment standards and the CAQH CORE Operating Rules, aligning timelines and resources and combating continued variability.

From: Danziger, Stephen
To: NCVHS Mail (CDC)
Subject: virtual credit card payments 12-17-22
Date: Saturday, December 17, 2022 2:44:05 PM

Yet another ploy by huge profit-making insurers instead of issuing paper checks, they send, by the same snail mail as it would a paper check and at the same expense, a virtual payment which many doctors cannot process since they may not have a electronic terminal to accept them.

This causes further delay and further money-making by way of the float, as payments are slowed by the doctor having to call the insurer (or a third party they use) to demand "real" payment.

This must stop

From: John C Lin NCVHS
To: Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals, Addendum
Date: Thursday, December 8, 2022 1:47:55 PM

Dear NCVHS members,

I am writing to comment on the X12 proposal that the current standard is updated from version 5010 to version 8020 for the adopted administrative standard for the health care claims (professional, institutional, and dental) and the remittance advice 835 transactions.

I see absolutely NO need for virtual credit card payment by 3rd parties such as insurers to our medical practice. It simply adds more burden, incurs more costs to the practice, and provides no benefit.

In particular, I am against the X12 proposed addition of the "card payments"; remittance information to 835 ERA.

I absolutely question and dispute the benefits of using card payment for payment of health care services.

I oppose any legislation to adopt such standards.

Sincerely,

John C. Lin, MD
Sunrise Urology, PC
Gilbert, AZ

From: Terrie Reed
Sent: Wednesday, December 7, 2022 11:37 AM
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals, by December 15, 2022
Attachments: 12.7.2022 Symmetric Public Comments to NCVHS.docx

Dear NCVHS team,
Please see attached public comment for your consideration. Thank you for the opportunity to share our support for the addition of UDI-DI to claims.

Terrie L. Reed, MSc

Chief Strategy Officer

Symmetric Health Solutions LLC

Visit us: symmetrichealthsolutions.com

NCVHS Request for Public Comment on:
Proposal for Updates to X-12 Transactions and New and Updated CORE Operating Rules

Symmetric Health Solutions (Symmetric) offers data management products for all medical supplies found in hospitals, including implants, instruments, biologics, in vitro diagnostics, biomedical equipment, durable medical equipment, medical equipment, and pharmaceuticals. Our products include a web application for medical device data cleansing and enrichment, integrated data feeds, APIs, and a mobile label imaging application. To power our software, we use the latest technology in Optical Character Recognition (OCR), Natural Language Processing (NLP), and machine learning (ML) trained on medical supply terminology. Every night, we refresh, cleanse, and build sophisticated insights sourced from 100+ open public sources, to present over 400+ attributes across 14+ million medical products. We use federal standards like the device identifier part of the Unique Device Identifier (UDI-DI) and associated data (e.g., Manufacturer, Brand, Model, Global Medical Device Nomenclature (GMDN)), functional equivalence item relations, item image URLs, premarket / post-market reports (e.g. FDA approvals, recalls, and adverse events and other operational data as data feeds that are currently being used in over 700 hospitals to cleanse and maintain supplies master data, implement point of use scanning in procedural areas, increase revenue charge capture, accurately classify spend, and identify supplies standardization opportunities.

We appreciate the opportunity to advocate on behalf of patients and our customers by providing the following comments to the request posed by NCVHS to address "**additional value, if any, that the UDI and UDI-DI provide as data elements in the updated version of the X12 claim transaction."**

We strongly support and echo the comments made by the Association of Healthcare Resources and Materials Management (AHRMM) and other healthcare system stakeholders on the value the inclusion of the UDI-DI in claims data makes to clinical care medical research, tracking of patient outcomes, and healthcare costs. We agree with AHRMM that "Limiting analysis of medical devices to what information is captured in an individual health care organization's Electronic Health Record (EHR) does not provide a sufficient data pool or the comprehensive information necessary to do comparative research. Patients often seek treatment from multiple health care providers and information about real world device performance can only be obtained by including the UDI-DI for implantable devices in claims data."

Including the UDI-DI on insurance claims is an important step forward toward linking a patient's use of a device to the additional information captured in claims data, especially for implants. The connection of patient use to claims data will advance the FDA vision for UDI as a catalyst for increasing transparency around the specific devices used in patient care. The result for patients will be more accurate and comparative data about device performance, a higher degree of confidence that population outcome data are being used to detect device safety issues in a timelier manner and that they, as patients, will receive direct communication if their device is recalled. Likewise, hospitals will have a new source of patient-device research and revenue data that can be used to better link device-patient outcomes, manage recalls, and monitor and improve charge capture. *For these reasons, we strongly advocate for the addition of the UDI to claims data.*

TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

December 14, 2022

Jacki Monson, JD
Chair
National Committee on Vital and Health Statistics
Centers for Disease Control and Prevention
National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: Request for Public Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules

Dear Ms. Monson,

On behalf of the Texas Medical Association (TMA) and our more than 56,000 physician and medical student members, we appreciate the opportunity to comment on the National Committee on Vital and Health Statistics' (NCVHS') request for comment on "Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules" as posted to the *Federal Register* on Nov. 1, 2022.

The request for comment seeks input on the cost impact to implement the updated X12 version 8020 electronic claims and electronic remittance advice (ERA) transaction. It also asks to what extent, relative to the potential implementation cost, the updated transaction implementation guides are beneficial. While TMA is not currently in possession or aware of any cost analysis or positive benefits in adoption overall, we urge NCVHS to carefully consider the costs and impositions placed on physician practices. Upgrading their electronic health record and practice management systems to adopt the new version of the electronic claim and ERA creates expenses in both staff time and further practice infrastructure investments. **TMA believes neither physicians nor patients should incur additional costs when electronic health records or health information technology systems are updated to reflect the latest of ever-changing regulatory requirements.** The cost of adoption will vary widely depending on the size, location, and current capabilities of the practice. Before mandating new transactions and operating rules, TMA asks NCVHS to provide additional time for the impacted industries to analyze and comment to NCVHS on the economic impact of adoption.

The request for comment also asks whether the new version supports value-based purchasing claims. Since current alternative payment models are based on fee-for-service claims processing, at this time TMA is not aware of benefits of the revised version for such payment models.

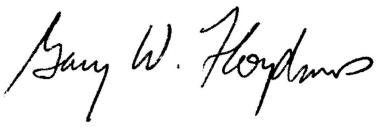
NCVHS seeks input on the time frame for the adoption and implementation of new versions of standards, and on whether HIPAA's required two-year implementation time frame is sufficient. TMA agrees a two-year implementation time frame, at minimum, is reasonable as it is consistent with previous HIPAA regulatory requirements.

Though not directly referenced in the request for comments, TMA has heard some concerns NCVHS' electronic funds transfer (EFT) transaction standards may be viewed as promoting the use of virtual credit cards. As such,

TMA notes it supports and appreciates the Centers for Medicare & Medicaid Services' (CMS') creation of guidance and related frequently asked questions on health plans' payment of health care claims using virtual credit cards, and adoption of HIPAA standards for health care EFT and ERA. **We call on NCVHS to explicitly recognize and embrace CMS policy, specifically that health plans must comply if a practice requests a health plan to pay the provider's claim using the adopted HIPAA health care EFT and ERA transaction standards. Physician practices must continue to have the ability to request automatic clearinghouse EFTs.**

TMA appreciates the opportunity to comment. Any questions may be directed to Robert Bennett, vice president of medical economics, by emailing robert.bennett@texmed.org or calling (512) 370-1409.

Sincerely,



Gary W. Floyd, MD
President
Texas Medical Association

United States Senate
WASHINGTON, DC 20510

December 15, 2022

Denise E. Love and Richard W. Landen
Co-Chairs of the Subcommittee on Standards
National Committee on Vital & Health Statistics
3311 Toledo Road
Hyattsville, M.D. 20782

RE: RFC on X12 and CAQH CORE Proposals

Dear Ms. Love and Mr. Landen,

We are writing to you in support of including the device identifier (DI) portion of a medical device's unique device identifier (UDI) on Medicare claims forms. We applaud the American National Standards Institute's Accredited Standards Committee (X12) for making a formal recommendation to the National Committee on Vital and Health Statistics (NCVHS) calling for this change following years of our engagement.[1] In our June 22, 2022, letter to NCVHS Chair Jacki Monson,[2] we urged NCVHS to promptly evaluate X12's recommendation, provide more information about its review and recommendation, and support the inclusion of DI information on Medicare claims forms in NCVHS's recommendations to the Department of Health and Human Services (HHS) for the next version of standard transactions.[3] We appreciate NCVHS's request for input as it deliberates in developing its recommendation to HHS.

In response to our July 2021 letter,[4] HHS Secretary Becerra noted that, before HHS can take steps to add the DI portion of UDI in Medicare claims, X12 "must first submit formal recommendations on the proposed health care claims transaction standards to the National Committee on Vital and Health Statistics (NCVHS)," and NCVHS must, in turn, "officially recommend to the Department that it should adopt the standards."[5] At this time, X12 has formally submitted their recommendation to NCVHS and stressed that "[i]ncluding device identifier information on claims transactions greatly improves the industry's ability to identify risks and reach patients who may be affected by device failures."[6] X12 further noted that this

[1] Letter from X12 to NCVHS, June 8, 2022, https://x12.org/news-and-events/letter-to-ncvhs.
[2] Letter from Senator Warren, Senator Grassley, Representative Pascrell, Representative Doggett, and Representative Fitzpatrick to Jacki Monson, National Committee on Vital and Health Statistics, Committee Chair, https://www.grassley.senate.gov/imo/media/doc/grassley_et_altonationalcommitteeonvitalandhealthstatisticsdiinfoonmedicareforms.pdf.
[3] NCVHS, "Recommendation Letters," https://ncvhs.hhs.gov/reports/recommendation-letters/.
[4] Letter from Senator Warren, Senator Grassley, Representative Pascrell, Representative Fitzpatrick, and Representative Doggett to HHS Secretary Becerra and CMS Administrator Brooks-LaSure, July 22, 2021, https://www.warren.senate.gov/imo/media/doc/2021.07.21%20Letter%20to%20HHS%20and%20CMS%20re%20UDI%20&%20Claims.pdf.
[5] Letter from HHS Secretary Becerra to Senator Warren, October 28, 2021, https://www.warren.senate.gov/imo/media/doc/2021.11.2%20Response%20to%20Letter%20to%20Becerra%20and%20Brooks-LaSure%20on%20UDIs.pdf.
[6] Letter from X12 to NCVHS, June 8, 2022, https://x12.org/news-and-events/letter-to-ncvhs.

policy "improves patient outcomes and reduces patient health risks and enhances tracking and reporting related to specific devices," while "also [saving] taxpayer funds."[7]

Medical device failures contribute to serious health problems and significant financial costs. In 2017, an HHS Office of Inspector General (OIG) investigation found that recalls or premature failures of just seven faulty cardiac devices resulted in an estimated $1.5 billion in Medicare payments and $140 million in out-of-pocket costs to beneficiaries.[8] Without DI information, OIG had to rely on a "complex and labor-intensive audit" to calculate these costs, which it acknowledged yielded a conservative estimate.[9] As a result, OIG recommended the addition of DIs to Medicare claims forms to better "identify and track the additional health care costs incurred by Medicare resulting from recalled or prematurely failed medical devices," reduce those costs, shield beneficiaries from unnecessary out-of-pocket costs, and improve beneficiary access to appropriate follow-up care.[10]

The inclusion of DIs on claims transactions would greatly improve the health system's ability to identify risks and reach patients who may be affected by device failures. Researchers can rely on claims data to track patients' interactions with the health system, even when the patient changes providers. The data can then be used to establish population-level correlations between a particular treatment and a long-term outcome or side effect.[11] For years, we have called for DI information to be collected in both electronic health records and on claims transactions[12] to help reduce health risks and costs to the Medicare system.

We urge NCVHS to expeditiously assess X12's recommendations to include DI information on Medicare claim forms and to issue an official recommendation to HHS to adopt these standards.

Sincerely,

Elizabeth Warren
United State Senator

Charles E. Grassley
United State Senator

Bill Pascrell, Jr.
Member of Congress

[7] *Id.*
[8] Department of Health and Human Services Office of Inspector General, "Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices," September 2017, p. 7, https://oig.hhs.gov/oas/reports/region1/11500504.pdf.
[9] *Id.*, p. 9.
[10] *Id.*, p. 10.
[11] Pew Charitable Trusts, "Unique Device Identifiers Improve Safety and Quality," July 5, 2016, https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/07/unique-device-identifiers-improve-safety-and-quality.
[12] Letter from Senator Warren, Senator Grassley, Representative Doggett, Representative Fitzpatrick, and Representative Pascrell to Gary Beatty, Steering Committee Chair, Accredited Standards Committee X12, https://www.warren.senate.gov/oversight/letters/in-bipartisan-letter-warren-grassley-doggett-fitzpatrick-and-pascrell-advocate-for-unique-device-identifiers-udi-information-to-be-added-to-electronic-health-insurance-claims-forms; Letter from Senators Warren and Grassley to Gary Beatty, Chair of Accredited Standards Committee X12, http://ct.symplicity.com/t/wrn/5879b49d5129bd5a44c94261b3cac11e/2057710565/realurl=http://www.warren.senate.gov/files/documents/2016-8-29_UDI_letter_to_ASC_X12.pdf.

UNITEDHEALTH GROUP

9900 Bren Road East, MN000-T000, Minnetonka, MN 55343

Submitted via E-mail: NCVHSmail@cdc.gov

December 15, 2022

Richard Landen MPH, MBA
Denise Love BSN, MBA
Co-Chairs
Subcommittee on Standards
National Committee on Vital and Health Statistics
National Center for Health Statistics
HHS/Centers for Disease Control and Prevention
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: Request for Comments on X12 and CAQH CORE Proposals

Dear Mr. Landen and Ms. Love:

UnitedHealth Group (UHG) is pleased to submit the following comments in response to a Request for Comments from your Subcommittee regarding recommendations from X12 for updated electronic transaction standards and proposed updated and new operating rules from the Committee on Operating Rules for Information Exchange (CAQH CORE). UHG is generally supportive of these changes but we offer a number of recommendations and questions for your consideration.

UHG is a mission-driven organization dedicated to helping people live healthier lives and helping our health care system work better for everyone through two distinct business platforms – UnitedHealthcare (UHC), our health benefits business, and Optum, our health services business. Our workforce of 380,000 people serves the health care needs of 149 million people worldwide, funding and arranging health care on behalf of individuals, employers, and the government. We not only serve as one of the nation's most progressive health care delivery organizations, we also serve people within many of the country's most respected employers, in Medicare serving nearly one in five seniors nationwide, and in Medicaid supporting underserved communities in 32 states and the District of Columbia.

X12 Transaction Standards

1. Costs. If your organization has conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional or dental claim) and remittance advice transactions, to what extent, relative to the potential cost of implementation, do the updated transaction implementation guides provide net positive value? Please explain.

Response: Currently, there are many unknown factors that inhibit our ability to conduct a true cost impact analysis. The recommended approach is different than the approach used in the migration to v4010 and the update to v5010 of the transaction standards. Optum is participating in X12's Proof of Concept (PoC) pilot which will give us true cost analysis once completed. As discussed below, we believe it is important to have a 14-month transition period for covered entities to transition from v5010 to implementation of v8020 (80next).

2. Operational impacts. If your organization has conducted an operational assessment or workflow analysis of the impact of transitioning to the updated X12 8020 claims and remittance advice transactions, what process improvements has your organization identified would result from implementation of the updated versions of any of the updated transactions? Please provide information for the Committee to reference in its considerations and feedback to HHS.

Response: As noted in our response to Question 1 above, there are many unknowns that prevent us from determining the operational impact. However, we do know that covered entities will need to dedicate resources for team education, collaboration, and extensive end to end testing. The effort will be very similar to that required for the transition from v4010 to v5010. UHG supports a requirement to adopt v8020 (80next) and Optum is prepared to implement v8020 (80next) early as part of the X12 PoC and will be able to provide the industry with important feedback around cost and operational impacts at a later date.

3. XML Schema. X12 has indicated that each of the X12 implementation guides included in their recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. In its letter to NCVHS, X12 noted that it mechanically produces these representations from the same metadata used to produce the implementation guide. X12 recommends that HHS permit both the 8020 EDI Standard representation (the implementation guide) and the XML representation, and that both be named in regulation as permissible syntaxes. Please comment on the proposal to adopt the 8020 EDI standard and the XML representation as permitted syntaxes.

Response: X12 has offered the XML Schema for several years. UHG supports the proposal to adopt both the XML and the v8020 (80next) EDI standard as long as they are both semantically equivalent.

4. FHIR Crosswalks. X12 indicated that it intends to provide FHIR crosswalks for the proposed X12 version 8020 transactions (claims and electronic remittance advice) submitted for consideration in time for inclusion in the Federal rulemaking process. Please comment on how FHIR crosswalks would apply to the implementation of the HIPAA claims and remittance advice transaction standards.

Response: As an enterprise, UHG has business use cases and solutions whereby having access to FHIR crosswalks would be helpful. We would ask that X12 provide additional clarification regarding the content (e.g., all transactions or a limited set), availability (e.g., without cost), and timing of any crosswalks. For example, how will crosswalk information be maintained between standards organizations and will X12 and FHIR implementation guides be semantically interoperable when supporting the same business use case?

5. Unique Device Identifier (UDI). The device identifier (DI) portion of a medical device's unique device identifier (UDI) is now included as a data element on the updated claim transaction in the institutional and professional version of the 8020. The UDI is also an element in the US Core Data for Interoperability (USCDI) for Certified Health Technology required by the Office of the National Coordinator, and can be found in certified Electronic Health Records, and in standardized hospital discharge reports. Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction.

Response: UHG supports the inclusion of the Device Identifier (DI) in the 837 transaction for patient safety purposes.

6. Alternative Payment Models (APM) and Value Based purchasing (VBP). Does X12 version 8020 support VBP claims? In what ways does the version 8020 of the claims transactions accommodate APMs such as medical homes or accountable care organizations (ACOs)? Please discuss the implications of this topic to HIPAA administrative simplification policies and continued innovation of non-fee-for-service business models.

Response: The X12 version v8020 (80next) does support APM and VBP claims because the DRGs, CPT codes, and ICD-10 codes are included in the 837 Institutional transaction. These exist today in the current version and there should not be a concern around the HIPAA administrative simplification policies.

7. Implementation time frame. HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, what would be the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e. g. does the window need to be longer than two years from the publication date of a final rule? Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?

Response: UHG recommends a 2 years plus a 14-month transition period between v5010 and v8020 (80next). This was the timeline adopted for the move from v4010 to v5010. We feel this glidepath allows for sufficient time for education, development, testing, and implementation. We do not support an implementation date on or around January 1st of any year given other operational and information technology projects that covered entities may be implementing at the same time. We ask that you consider implementation dates at the end of second or third quarter of the calendar year.

8. Implementation. NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?

Response: UHG supports a grace period that allows for the submission of both v5010 and v8020 (80next) for a definitive period of time. As mentioned in the response above, please consider a 14-month transition period. This approach gives more time for clearinghouses and other vendors to assist with implementation and prevents providers from having to drop to paper transactions if they are not prepared to implement the new standard.

9. Simultaneity. What, if any, are the data impacts, limitations or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g., claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?

Response: Optum and UHC are prepared to support both v8020 (80next) and v5010 during a specified transition period, should it be required. The barriers to adoption would be minimal as providers and vendors could continue to submit v5010 transactions and then migrate to v8020 (80next) during the transition period until the time frames for submitting v5010 transactions has expired.

However, there is some concern about returning or accepting transactions in v5010 where the corresponding transaction is in v8020 (80next). More specifically returning a v5010 277CA transaction when responding to an 8020 (80next) 837 transaction. The response transaction would not contain all of the new data loops, segments, and element changes that exist in the v8010 (80next) 277CA transaction. The expectation of allowing mixed versions poses a challenge and covered entities could decide that only v5010 transactions should be submitted until the remaining v8010 (80next) transactions are mandated and implemented.

We do not support an approach where covered entities would be required to adopt updates to certain HIPAA transactions by a certain date and updates to the remaining transactions by a second date. In other words, the implementation date should apply to all HIPAA transactions at the same time (with a transition period to migrate from one version to the next). Traversing and maintaining a "phased or sequenced" regulatory approach for logically grouped transactions for a given version would be very costly, complex, and confusing across the entire industry.

10. Alternatives Considered. X12 indicated that there were over 2,000 changes identified in the change logs for the four updated transactions in version 8020, categorized by operational, technical and editorial. If your organization has conducted assessments of the technical changes, what is your determination of these with respect to reducing burden on payers or providers once the updates have been implemented? What is the opportunity cost of remaining on Version 5010 and not implementing the updated version 8020 of the claims and remittance advice transaction standard? What will the healthcare industry risk by not adopting version 8020?

Response: The 5010 version of the standards do not contain the most recent regulatory and legislative requirements applicable to health care transactions. The over 2000 changes mentioned in the X12 submission include updates that will meet the current healthcare industry requirements. UHG has not conducted a complete and in-depth analysis of v8020 (80next). This analysis will be part of Optum's workflow during the X12 PoC pilot.

As mentioned in our other responses, we cannot address the cost of implementing v8020 (80next) at this time. We do believe that remaining to utilize the v5010 standard will have adverse downstream impacts as regulatory requirements will not be met. UHG agrees that v8020 (80next) should be adopted and mandated.

11. General. Does your organization support HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards? Please provide a brief rationale.

Response: UHG fully supports the adoption by covered entities of the v8020 (80next) transactions. These transactions will provide the ability to meet the latest regulatory and legislative requirements. The X12 transactions are already implemented in other versions, well understood, and a proven method of exchanging administrative data.

CORE Operating Rules

1. Efficiency Improvements. Infrastructure updates to the adopted Eligibility and Benefits and Claim Status Operating Rules. CAQH CORE has proposed updates to the adopted versions of the eligibility and benefits and claim status operating rules currently required for use. Updates include an increase in overall system availability from 86% per calendar week to 90%, and an optional 24 additional hours of system downtime per quarter to accommodate large system migrations, mitigation and more integrated system needs, when applicable. Please comment on the potential for improvements in efficiency for your organization these updates would contribute when using the adopted X12 HIPAA transaction standards.

Response: UHG supports the infrastructure updates. Healthcare is a fluid industry that often requires frequent system updates to support customers' benefit plan designs. Full integration of systems that have complex code may require extended downtime for installation, validation, and regression testing beyond 24 hours per quarter. The improvements in efficiencies resulting from adoption may continue to contribute to compliant and successful transactions that meet regulatory requirements and address provider abrasion.

2. Data Content updates for Eligibility and Benefits Operating Rule. The updated version of the Eligibility and Benefits operating rule includes the requirement to indicate coverage of telemedicine, remaining coverage and tiered benefits, and to indicate if prior authorization or certification is required. The rule has been updated to include a list of CORE-required service type codes (section 5) and CORE-required categories of service for procedure codes. If your organization has conducted an analysis of these updates and the potential impact to increasing use of the adopted standard, please comment on your assessment of these enhancements for your organization and/or your trading partners.

Response: Adoption will be a challenging and resource intensive endeavor however health care providers and other trading partners will greatly benefit from these proposed data content updates. The Eligibility and Benefits operating rule proposals will eliminate the current need for message segments to identify specific benefits such as telemedicine or tiered benefits. Supporting additional service type code (STC) and procedure codes will allow for detailed requests and benefit response without additional manual inquires.

3. New: Patient Attribution. Content rule within the new Eligibility and Benefits Operating Rule (vEB.1.0). CAQH CORE has proposed a new operating rule to apply to the selection of value-based payment models by providers. If your organization has conducted an analysis of this operating rule, please provide information on your organization's evaluation of the extent to which the proposed operating rule requirements support the adopted HIPAA transactions or improve administrative simplification.

Response: UHG has not conducted analysis of this operating rule and requires further details to understand this operating rule and determine future implementation impacts.

4. Companion Guide Template. CAQH CORE has updated the requirements for the companion guides in the adopted operating rules to promote flexibility. Please comment on your organization's experience with the companion guide template in the first set of operating rules, how it has impacted workflows and whether your assessment of the proposed new template indicates value for implementations of the standard transactions.

Response: We find there is value in having a template as it provides consistency across transactions and a standard guide across the industry. In particular, Sections 6 (Control Segments/Envelopes), 7 (Payer Specific Business Rules and Limitations), and the Appendices beneficial in identifying issues and questions for the Trading Partner.

5. Updated Connectivity Rule.

A) As part of the re-structuring of the CAQH CORE operating rules for each administrative transaction, CAQH CORE updated the connectivity requirements and published a stand-alone Connectivity Rule (vC4.0.0), for which it is seeking a recommendation for adoption. In addition to the requirements for the use of HTTPS over the public internet and minimum-security conditions, the Connectivity Rule addresses Safe Harbor, Transport, Message Envelope, Security, and Authentication. What changes would be necessary to your organizational infrastructure, policies and contracts to implement the CAQH CORE c4.0.0 Connectivity rule?

Response: Based on the preliminary description and our review of the Connectivity Rule vC4.0.0, the coding required to support the new rule is certainly feasible. In a future enhancement it would be helpful for the endpoint naming conventions to distinguish between development, staging, and production environments.

B) The updated Connectivity rule adds support for the exchange of attachments transactions, adds OAuth as an authorization standard, provides support for X12 (HIPAA) and non-X12 (non-HIPAA) exchanges, and sets API endpoint naming conventions. The CAQH CORE letter states that the impact of mandating these requirements for HIPAA covered entities includes: "setting a standards-agnostic approach to exchanging healthcare information in a uniform manner using SOAP, REST and other API technologies; facilitates the use of existing standards like X12 in harmony with new exchange methods like HL7 FHIR, and enhancing security requirements to align with industry best practices." Please comment on the scope of the CAQH CORE Connectivity operating rule vC4.0.0 under consideration for adoption under HIPAA.

Response: In 2002, with the implementation of the X12 4010A1 standard in concert with the intent of Administrative Simplification, there was significant work from health plan and health care clearinghouse teams to migrate to a single standard format from hundreds, if not thousands, of proprietary formats used to trade administrative data. This migration reduced costs associated with developing and maintaining many formats supporting the same data.

It is difficult to evaluate Connectivity Rules for FHIR as much work needs to be done to socialize, understand, and consider the complexities associated to this concept based on the several guides that exist for clinical use and the assumption that there would be multiple guides associated to the administrative data. Our teams feel confident that if non-X12 formats are mandated, there would be large impacts to development and maintenance costs (including, but not limited to operations and information technology) in order to consistently apply validations, process, and store each standard. In addition, there will be impacts to Service Level Agreements between trading partners.

6. Costs. If your organization has conducted a cost analysis to determine the impact of implementing the updated eligibility and benefits and or claim status operating rule updates for your entity type, what are the estimated costs or types of costs for system and operational changes? In what programmatic ways do the updates to the operating rule for infrastructure (system availability and response time), data content, additional data elements for telemedicine, prior authorization coverage benefits, tiered benefits and procedure-level information add value for your organization? Please provide examples pertinent to your organization.

UHG has not conducted a cost analysis to determine the true impact of implementing the updated eligibility and benefits operating rules. Based on the size and complexity of the operating systems the costs may be significant. The proposed changes have potential to reduce call volumes into provider/customer service centers, increase stakeholder satisfaction, and reduce manual processing pain-points with automation.

7. Alternatives considered for operating rules. What are the consequences to your organization if NCVHS recommends adoption of the updated versions of the eligibility or claim status operating rules? Please provide specific examples to describe the impacts (benefits, opportunities) of the changes included in the update for each operating rule.

Response: If NCVHS recommends adoption of the updated versions of the eligibility operating rules as there is risk to the current average response times due to the complexity of the operating systems and additional calls to obtain required benefit data. The proposed changes have potential to reduce call volumes into provider/customer service center; increase stakeholder satisfaction; and reduce manual pain-points with automation. The additional STC and procedure codes will increase the number of segments and size of the transaction and greatly impact the necessary processing time. The solution development will need to limit the impact to the processing time.

8. Attachments Prior Authorization Infrastructure and Data Content Rules (vPA.1.0) and Attachments Health Care Claims Infrastructure and Data Content Rules (vHC.1.0). CAQH CORE has proposed infrastructure and data content operating rules for Prior Authorization and health care claims. The proposed infrastructure rules for attachments for prior authorization and health care claims include requirements for the use of the public internet for connectivity, Batch and Real Time exchange of the X12 v6020 275 transaction, minimum system availability uptime, consistent use of an acknowledgement transaction, use of uniform data error messages, minimum supported file size, a template for Companion Guides for entities that use them, a policy for submitting attachment specific data needed to support a claim adjudication request (standard electronic policy), and support for multiple electronic attachments to support a single claim submission.

The operating rules include the requirement for a health plan or its agent to offer a “readily accessible electronic method to be determined…. For identifying the attachment-specific data needed to support a claim adjudication request by any trading partner, and electronic policy access requirements so services requiring additional documentation to adjudicate the claim are easily identifiable (health care claims only).” The CAQH CORE letter indicates that the proposed attachments data content rules for prior authorization and health care claims apply to attachments sent via an X12 (HIPAA) transaction and those sent without using the X12 transaction (nonHIPAA). Please provide your assessment of this proposed operating rule.

Response: We are in agreement with this list of infrastructure and data content rules included in the submission. We do not believe however, that operating rules should be adopted until the standard is finalized.

9. Attachments operating rules – general question. HHS has not proposed adoption of a standard for attachments under HIPAA. Please comment on the proposed operating rules for attachments. What should NCVHS consider prior to making any recommendations to HHS regarding operating rules for attachments?

Response: UHG will be ready to implement the claims attachment transaction standards when finalized by HHS. We do not believe, however, that operating rules should be adopted until the standard is finalized.

There will be a learning curve for the industry which must be taken into consideration – in particular those trading partners that are currently not using attachments or using non-HL7 unstructured attachments. Combining two standards (X12 and HL7) into the 275 transaction will add additional time to implementation. UHG recommends that a 14-month transition period be provided to fully migrate from v6010 to v8020 (80next) for this transaction adoption.

UHG appreciates the opportunity to provide these comments and looks forward to working with NCVHS on this initiative.

Sincerely,

Christopher Carlson
Senior Vice President – Provider Digital Transformation
UnitedHealthcare

From: Jean-Pierre Geagea
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Friday, December 9, 2022 9:26:20 AM

We are against the X12 proposed addition of "card payments" remittance information to 835 ERA.

It is about time to put the doctors interests first, otherwise, American healthcare will be depleted of care before long.

Thank you.

Jean-Pierre Geagea

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December 15, 2022

Jacki Monson, JD
Chair
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted electronically via NCVHSmail@cdc.gov

Dear Ms. Monson:

The Workgroup for Electronic Data Interchange (WEDI) writes today in response to the publication of a Request for Comment (RFC) entitled “Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules” published on the National Committee for Vital and Health Statistics (NCVHS) website. In this letter, we will provide specific responses to questions included in the RFC as well as offer our viewpoints on critical implementation issues impacting standards and operating rules. We appreciate the opportunity to offer our perspectives on these important topics.

WEDI, formed in 1991, is the leading authority on the use of health IT to improve health care information exchange to enhance the quality of care, improve efficiency, and reduce costs of our nation’s healthcare system. WEDI’s membership includes a broad coalition of organizations, including health plans, hospitals, other providers, vendors, government agencies, consumers, not-for-profit organizations, and standards development organizations. WEDI was designated in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) legislation as an advisor to the HHS Secretary.

X12 has submitted a letter to the NCVHS proposing that the current standard be updated from version 5010 to version 8020 for the adopted administrative standard for the health care claims (professional, institutional, and dental) and the remittance advice transactions. CAQH CORE submitted a letter to NCVHS requesting review of updates to the adopted eligibility and claim status operating rules for the adopted HIPAA transactions (version 5010), as well as a proposal for consideration of operating rules for connectivity and operating rules to support the adopted standard transaction for prior authorization. The letter included a request to review an operating rule for attachments related to prior authorization, for which a standard has not yet been adopted under HIPAA.

WEDI Member Input

To address the proposals submitted to the NCVHS and subsequent NCVHS RFC, WEDI leveraged our Member Position Advisory (MPA) process. Our MPA process engaged the WEDI membership through virtual events and surveys asking questions specific to the proposals and questions focused on implementation issues.

Virtual Event

As part of this MPA process, WEDI hosted a 4-hour virtual member event where 75 participants shared their perspectives on the RFC questions and how best to implement new standards and operating rules. Throughout the MPA virtual event, WEDI conducted polls to capture additional viewpoints from the participants. We will include the results from that polling in our comments.

Survey

Another component of our MPA process was the collection of industry perspectives on the X12 and CAQH CORE proposals through a survey conducted September 28 through October 27, 2022. We received a total of 77 responses on the X12 proposals and 58 responses to CAQH CORE proposals. The following table outlines the number of respondents who completed the surveys and the stakeholder groups they represent:

X12 Survey Participants

Answer Choices	Responses (%)	Responses (Number)
Provider	15.6%	12
Payer	46.6%	36
Clearinghouse	14.3%	11
Vendor	23.4%	18
Total		77

WEDI asked survey respondents “Identify your level of familiarity with the X12 initiative to update the electronic transactions from version 005010 to version 008020 of the Health Care Claim and Health Care Claim Payment/Advice electronic transactions.” The following table suggests many of the MPA participants had a good understanding of the X12 proposal.

Response

Answer Choices	Responses (%)	Responses (Number)
We are X12 members and participated in the development of the claim and remittance advice standards.	**45.6%**	31
We are X12 members but did not participate in the development of these standards.	8.8%	6
We have reviewed these Implementation Guides	19.1%	13
We are aware that things are changing but do not know the details	22.1%	15
We have no familiarity with these changes.	4.4%	3

Total		68

CAQH CORE Survey Participants

Answer Choices	Responses (%)	Responses (Number)
Provider	15.5%	9
Payer	43.1%	25
Clearinghouse	19%	11
Vendor	22.4%	13
Total		58

WEDI asked respondents "Identify your level of familiarity with the CAQH CORE initiative to create updated and new operating rules in support of electronic transactions." The following table suggests many of the MPA participants had a good understanding of the CAQH CORE proposal.

Response

Answer Choices	Responses (%)	Responses (Number)
We are CAQH CORE members and participated in the development of the updated and new operating rules.	**39.19%**	39
We are CAQH CORE members but did not participate in the development of these operating rules.	5.56%	3
We have reviewed these operating Rule proposals.	22.20%	12
We are aware that CAQH CORE have developed updated and new operating rules but do not know the details.	29.63%	16
We have no familiarity with these proposals.	7.41%	4
TOTAL		54

In addition to receiving input through our MPA process, WEDI also collected member perspectives on the X12 and CAQH CORE proposals through our Claims Subworkgroup, chaired by Beth Davis, Stanley Nachimson, and Chuck Veverka, and our Remittance Advice and Payment Subworkgroup, chaired by Pamela Grosze and Patricia Wijtyk. WEDI thanks the co-chairs of these Subworkgroups for leading the workgroup discussions and at our MPA event and thanks all the members of the Subworkgroups and MPA attendees for their input.

X12 Proposal: 008020 Electronic Claim (837I, 837P, and 837D)

WEDI asked the following survey question: "For the following issues, please rate the impact each potential benefit (i.e., cost, utility, improvement in quality of care delivered) of the 008020 version of the **Institutional Electronic Health Care Claim (837I)** will have on your organization."

Response Highlights:

- **51%** responded that “Added the ability to transmit the Device Identifier (DI) of the Unique Device Identifier (UDI) for supplies, implants, and explants” would have Positive or Strong Positive Impact, 20% stated “Unsure” and 20% indicated “No Impact.”
- **59%** responded that “Increased the number of prior authorizations and referrals that can be reported at the line level.” would have Positive or Strong Positive Impact, 25% stated “Unsure” and 12% indicated “No Impact.”
- **71%** responded that “Replaced the Claims Adjustment (CAS) segment with the Reason Adjustment (RAS) segment to support the association of Adjustment Reason Codes and Remark Codes and better synchronization with the Healthcare Claim Payment/Advice (835)” would have Positive or Strong Positive Impact, 19% stated “Unsure” and 4% indicated “Negative Impact.”
- **72%** responded that “Added support for transmitting Coordination of Benefits (COB) allowed amounts.” would have Positive or Strong Positive Impact, 17% stated “Unsure” and 4% indicated “No Impact.”
- Full results are included in the appendix

WEDI asked MPA participants the following question: “*Does your organization utilize the Professional Electronic Health Care Claim (837P) transaction or its data content*?” **93% said yes** with 7% indicating no.

WEDI asked the following survey question: “For the following issues, please rate the impact each potential benefit (i.e., cost, utility, improvement in quality of care delivered) of the 008020 version of the **Professional Electronic Health Care Claim (837P)** will have on your organization.”

Response Highlights:

- **63%** responded that “Increase the maximum number of diagnosis codes from 12 to 24 to provide a more complete picture of the patient's condition” would have Positive or Strong Positive Impact, 15% stated “Unsure” and 12% indicated “No Impact.”
- **65%** responded that “Increased the number of diagnosis code pointers from 8 to 12 per service line for Professional Claims” would have Positive or Strong Positive Impact, 16% stated “Unsure” and 10% indicated “No Impact.”
- **72%** responded that “Added support for transmitting Coordination of Benefits (COB) allowed amounts.” would have Positive or Strong Positive Impact, 16% stated “Unsure” and 4% indicated “Negative Impact.”
- **74%** responded that “Greater focus on reducing ambiguity throughout the implementation guide” would have Positive or Strong Positive Impact, 12% stated “Unsure” and 12% indicated “No Impact.”
- Full results are included in the appendix

WEDI asked the survey question: “For the following issues, please rate the impact each potential benefit (i.e., cost, utility, improvement in quality of care delivered) of the 008020 version of the **Dental Electronic Health Care Claim (837D)** will have on your organization.”

Response Highlights:

- **66%** responded that “Added a data element used for Coordination of Benefits when a claim is adjusted.” would have Positive or Strong Positive Impact, 21% stated “Unsure” and 3% indicated “Negative Impact.”
- **69%** responded that “Revised to support reporting of claim level Remark Codes not associated with an Adjustment Reason Code” would have Positive or Strong Positive Impact, 25% stated “Unsure” and 12% indicated “No Impact.”
- **72%** responded that “Revised to support line-level prior authorizations when no authorization is sent at the claim level. This reduces the need to split claims” would have Positive or Strong Positive Impact, 18% stated “Unsure” and 4% indicated “Negative Impact.”
- **72%** responded that “Revised to support the transmission of the allowed amount received on the primary claim.” would have Positive or Strong Positive Impact, 12% stated “Unsure” and 6% indicated “Negative Impact.”
- Full results are included in the appendix

X12 Proposal: 008020 Electronic Remittance Advice (835)

WEDI asked the survey question: “For the following issues, please rate the impact each potential benefit (i.e., cost, utility, improvement in quality of care delivered) of the 008020 version of the Electronic Health Care Claim Payment/Advice (835) will have on your organization.”

Response Highlights:

- **71%** responded that “Added information that will aid in automating the posting of remittance advice information” would have Positive or Strong Positive Impact,15% stated “Unsure” and 8% indicated “No Impact.”
- **72%** responded that “Standardized and added clarity for reporting COB adjudication information” would have Positive or Strong Positive Impact, 21% stated “Unsure” and 4% indicated “No Impact.”
- **73%** responded that “Standardized the forward balance and overpayment recovery processes” would have Positive or Strong Positive Impact, 21% stated “Unsure” and 4% indicated “Negative Impact.”
- **73%** responded that “Added the ability to re-associate a recovery amount to a specific claim to reduce manual processes to track when the funds have been recouped” would have Positive or Strong Positive Impact, 23% stated “Unsure” and 2% indicated “Negative Impact.”
- Full results are included in the appendix

Additional Discussion

- WEDI members discussed the issue of the value of adding the ability to transmit the Device Identifier (DI) of the Unique Device Identifier (UDI) for supplies, implants, and explants. The consensus was that this is necessary because the NDC was replaced by the UDI for supplies. Other types are dependent on trading partner.

- In terms of the added instructions for real-time adjudication, WEDI members suggested that this was dependent on trading partners desire to implement. There are also potential additional use cases, such as supporting the No Surprises Act Advanced Explanation of Benefits (AEOB) provision and ability to report real-time pre-determination. Members also noted a heightened awareness of the instructions being in the TR3 and noted that the current state in the industry is that this process has not been widely adopted.

- WEDI members noted that adding the ability to report remittance information related to card payments (purchasing card, debit card, and credit card) would facilitate autoposting. Further, it would allow for compliant reporting in the 835 when payment type is a virtual card.

- Replacing the Claims Adjustment (CAS) segment with the Reason Adjustment (RAS) segment to support the ability to report all associated messages about an adjustment including all reasons associated with the adjustment amount would be a positive addition for providers by allowing for better and more educated follow-up with the health plan and a more complete understanding of reasons when receiving all information, the first time. WEDI members believe this would result in fewer phone calls between providers and health plans but note it would be a major technical and business change for the industry. Our members concur that this enhancement has been needed for a long time.

- Adding the ability to report Remark Codes, not associated with an adjustment code, will also be a positive change for providers. It would give them additional information that should result in fewer calls to health plans. WEDI members note that adding LQ segment to the claim loop and moved reporting of alerts and other remark codes from existing segments will allow for consistent use of segments in the transaction.

- Standardized and added clarity for reporting COB adjudication is seen as a positive, with WEDI members believing that this modification will add clarity to reporting coordination of benefits (COB), which is arguably one of the more confusing aspects of the 835.

- Standardizing the forward balance and overpayment recovery processes will have a significant impact. WEDI members note that currently a lot of time is

spent tracking this. This proposed change will add clarification to the process and provide for structured instructions. Added Provider Level adjustment codes is expected to make the process easier for providers and will have a great impact.

- WEDI members noted that adding the ability to re-associate a recovery amount to a specific claim will have a significant impact on the industry. This change, while potentially challenging to implement, is expected to reduce manual processes to track when the funds have been recouped. Provider Level Adjustment Codes moved to an external list will allow for greater flexibility as changes are needed.

- Also viewed as a positive change by WEDI members is the reporting of the specific DRG type used in adjudication and the ability to report multiple DRG types.

- Added more granular source of payment codes giving providers more transparency into the process used to adjudicate the claim was viewed by WEDI members as a positive. Also viewed as a positive is making available the information needed for state and federal reporting.

- Including information that will aid in automating the posting of remittance advice information was seen as a positive by WEDI members, as was the ability to exchange more detailed patient responsibility information. Providers will know the exact amount to collect and having this information should result in a decrease in days in accounts receivable.

RFC Questions

NCVHS Questions
Costs. If your organization has conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional or dental claim) and remittance advice transactions, to what extent, relative to the potential cost of implementation, do the updated transaction implementation guides provide net positive value? Please explain.

Operational impacts. If your organization has conducted an operational assessment or workflow analysis of the impact of transitioning to the updated X12 8020 claims and remittance advice transactions, what process improvements has your organization identified would result from implementation of the updated versions of any of the updated transactions? Please provide information for the Committee to reference in its considerations and feedback to HHS.

WEDI Response
WEDI conducted a poll during the MPA event, asking the question: “When will you conduct an analysis of the impact on your organization of the new X12 transactions?”

4% answered We have already conducted an analysis, 29% stated "We will conduct an analysis within the next year," **38% "We will conduct an analysis only when CMS issues a Proposed Rule**," 8% stated "We will conduct an analysis only when CMS issues a Final Rule," and 21% said they had "No plans to conduct an analysis."

We note that without a proposed rule many entities will not conduct an ROI analysis in part because it is difficult to allocate resources when a target implementation date has not yet been identified. MPA participants could not identify any cost impact analyses completed by providers. One MPA participant representing a large health plan indicated that while they had done a very high-level assessment, based on the number and types of changes, they would not get into the detail needed to budget personnel time and money until a proposed rule was issued by CMS.

NCVHS Question
XML Schema. X12 has indicated that each of the X12 implementation guides included in their recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. In its letter to NCVHS, X12 noted that it mechanically produces these representations from the same metadata used to produce the implementation guide. X12 recommends that HHS permit both the 8020 EDI Standard representation (the implementation guide) and the XML representation, and that both be named in regulation as permissible syntaxes. Please comment on the proposal to adopt the 8020 EDI standard and the XML representation as permitted syntaxes.

WEDI Response
WEDI asked MPA participants the following question: "Do you support the proposal to adopt the 8020 EDI standard and the XML representation as permitted syntaxes? **58% of respondents replied Yes**, 8% answered No, and 33% replied Don't Know.

NCVHS Question
Unique Device Identifier (UDI). The device identifier (DI) portion of a medical device's unique device identifier (UDI) is now included as a data element on the updated claim transaction in the institutional and professional version of the 8020. The UDI is also an element in the US Core Data for Interoperability (USCDI) for Certified Health Technology required by the Office of the National Coordinator, and can be found in certified Electronic Health Records, and in standardized hospital discharge reports. Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction.

WEDI Response
WEDI asked MPA participants the following question: "Rate the level of potential additional value that the DI and UDI provide as data elements in the updated version of the X12 claim transaction." 20% responded that there was Significantly Improved Value, 16% stated Somewhat Improved Value, 12% replied No Change in Value, 0% stated Somewhat Decreased Value 0%, 8% replied Significant Decrease in Value, with **44% stating Don't Know**.

NCVHS Question
Alternatives Considered. X12 indicated that there were over 2,000 changes identified in the change logs for the four updated transactions in version 8020, categorized by operational, technical and editorial. If your organization has conducted assessments of the technical changes, what is your determination of these with respect to reducing burden on payers or providers once the updates have been implemented? What is the opportunity cost of remaining on Version 5010 and not implementing the updated version 8020 of the claims and remittance advice transaction standard? What will the healthcare industry risk by not adopting version 8020?

WEDI Response
WEDI asked MPA participants the following question: "Rate the likelihood that implementation of these four Administrative Transactions will reduce burden for health plans and providers." 11% answered Significantly Reduce Burden, 21% replied Somewhat Reduce Burden, 11% stated No Change in Burden, 5% replied Somewhat Increased Burden, 5% stated Significantly Increase Burden, with **47% saying Don't Know**.

NCVHS Question
General. Does your organization support HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards? Please provide a brief rationale.

WEDI Response
WEDI asked MPA participants the following question: "Overall, should WEDI recommend adoption of the proposed 008020 837 (Dental, Institutional, Professional)?" **62% answered Yes**, 17% replied No, with 21% stated Don't Know.

WEDI also asked MPA participants the following question: "Overall, should WEDI recommend adoption of the proposed 008020 835?" **46% answered Yes**, 21% replied No, and 33% stated Don't Know.

CAQH CORE Operating Rules

In May 2022, CAQH CORE submitted a letter to NCVHS requesting review of updates to the adopted eligibility and claim status operating rules for the adopted HIPAA transactions (version 5010), as well as a proposal for consideration of operating rules for connectivity and operating rules to support the adopted standard transaction for prior authorization. The letter also included a request to review an operating rule for attachments related to prior authorization, for which a standard has not yet been adopted under HIPAA.

NCVHS Question
Costs. If your organization has conducted a cost analysis to determine the impact of implementing the updated eligibility and benefits and or claim status operating rule updates for your entity type, what are the estimated costs or types of costs for system

and operational changes? In what programmatic ways do the updates to the operating rule for infrastructure (system availability and response time), data content, additional data elements for telemedicine, prior authorization coverage benefits, tiered benefits and procedure-level information add value for your organization? Please provide examples pertinent to your organization.

WEDI Response
The discussion at our MPA indicated that stakeholders have yet to conduct a cost analysis to determine the impact of implementing the updated eligibility and benefits and or claim status operating rule updates. We note that MPA respondents suggested moving to the new and updated rules would be less resource-intensive than when first adopting operating rules.

CAQH CORE Connectivity Rule vC4.0

NCVHS Question
Updated Connectivity Rule. A) As part of the re-structuring of the CAQH CORE operating rules for each administrative transaction, CAQH CORE updated the connectivity requirements and published a stand-alone Connectivity Rule (vC4.0.0), for which it is seeking a recommendation for adoption. In addition to the requirements for the use of HTTPS over the public internet and minimum-security conditions, the Connectivity Rule addresses Safe Harbor, Transport, Message Envelope, Security, and Authentication. What changes would be necessary to your organizational infrastructure, policies and contracts to implement the CAQH CORE c4.0.0 Connectivity rule? B) The updated Connectivity rule adds support for the exchange of attachments transactions, adds OAuth as an authorization standard, provides support for X12 (HIPAA) and non-X12 (non-HIPAA) exchanges, and sets API endpoint naming conventions. The CAQH CORE letter states that the impact of mandating these requirements for HIPAA covered entities includes: "setting a standards-agnostic approach to exchanging healthcare information in a uniform manner using SOAP, REST and other API technologies; facilitates the use of existing standards like X12 in harmony with new exchange methods like HL7 FHIR, and enhancing security requirements to align with industry best practices." Please comment on the scope of the CAQH CORE Connectivity operating rule vC4.0.0 under consideration for adoption under HIPAA.

WEDI Response
WEDI asked the survey question: "Please rate your level of agreement or disagreement with the following statements regarding the impact the updated CAQH CORE Connectivity Rule vC4.0.0 will have on your organization and/or the industry."

Response Highlights:

- **35%** responded "Agree or Strongly Agree" that "These operating rules will reduce cost, enhance utility, and improve quality of care delivered" would have Positive or Strong Positive Impact, 22% stated "Unsure at this Time" and 38% "Neither Disagree nor Agree."
- **46%** responded "Agree or Strongly Agree" that "These operating rules take an

important step to standardize operational challenges within value-based payment Models," 15% stated "Unsure at this Time," and 23% "Neither Disagree nor Agree."

- **53%** responded "Agree or Strongly Agree" that "These operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption," 18% stated "Unsure at this Time," and 20% "Neither Disagree nor Agree."
- **58%** responded "Agree or Strongly Agree" that "This update to existing federally mandated rules will respond to immediate industry need to align requirements with current and emerging business, operational, security, and connectivity best practices, while promoting technological advances within the industry," 15% stated "Unsure at this Time," and 18% "Neither Disagree nor Agree."
- **58%** responded "Agree or Strongly Agree" that "These operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption," 15% stated "Unsure at this Time," and 18% "Neither Disagree nor Agree."
- Full results are included in the appendix

Additional Polling. WEDI asked MPA participants the following question: "Rate the level of potential benefits associated with the New Connectivity operating rule." **31% answered Significantly Improved Benefits, 31% replied Somewhat Improved Benefits**, 15% replied No Change in Benefits, 4% stated Somewhat Decreased Benefits, 4% replied Significant Decrease in Benefits, and 15% stated Don't Know.

CAQH CORE Infrastructure Rules

NCVHS Question

Attachments Prior Authorization Infrastructure and Data Content Rules (vPA.1.0) and Attachments Health Care Claims Infrastructure and Data Content Rules (vHC.1.0). CAQH CORE has proposed infrastructure and data content operating rules for Prior Authorization and health care claims. The proposed infrastructure rules for attachments for prior authorization and health care claims include requirements for the use of the public internet for connectivity, Batch and Real Time exchange of the X12 v6020 275 transaction, minimum system availability uptime, consistent use of an acknowledgement transaction, use of uniform data error messages, minimum supported file size, a template for Companion Guides for entities that use them, a policy for submitting attachment specific data needed to support a claim adjudication request (standard electronic policy), and support for multiple electronic attachments to support a single claim submission. The operating rules include the requirement for a health plan or its agent to offer a "readily accessible electronic method to be determined…. For identifying the attachment-specific data needed to support a claim adjudication request by any trading partner, and electronic policy access requirements so services requiring additional documentation to adjudicate the claim are easily identifiable (health care claims only)." The CAQH CORE letter indicates that the proposed attachments data content rules for prior authorization and health care claims apply to attachments sent via

an X12 (HIPAA) transaction and those sent without using the X12 transaction (nonHIPAA). Please provide your assessment of this proposed operating rule.

WEDI Response
WEDI asked the following question: "Please rate your level of agreement or disagreement with the following statements regarding the impact the updated CAQH CORE Infrastructure operating rules will have on your organization and/or the industry*."*

Response Highlights:

- **36%** responded "Agree or Strongly Agree" that "These operating rules will reduce cost, enhance utility, and improve quality of care delivered" would have Positive or Strong Positive Impact, 24% stated "Unsure at this Time" and 24% "Neither Disagree nor Agree."
- **39%** responded "Agree or Strongly Agree" that "These operating rules take an important step to standardize operational challenges within value-based payment Models," 21% stated "Unsure at this Time," and 21% "Neither Disagree nor Agree."
- **54%** responded "Agree or Strongly Agree" that "This update to existing federally mandated rules will respond to immediate industry need to align requirements with current and emerging business, operational, security, and connectivity best practices, while promoting technological advances within the industry," 12% stated "Unsure at this Time," and 21% "Neither Disagree nor Agree."
- **56%** responded "Agree or Strongly Agree" that "These operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption," 15% stated "Unsure at this Time," and 15% "Neither Disagree nor Agree."
- Full results are included in the appendix

Additional Polling. WEDI asked MPA participants the following question: "Rate the level of potential benefits associated with the updated Infrastructure operating rules." 22% answered Significantly Improved Benefits, **43% replied Somewhat Improved Benefits**, 13% indicated No Change in Benefits, 0% replied Somewhat Decreased Benefits, 0% said Significant Decrease in Benefits, with 22% stating Don't Know.

CAQH CORE Eligibility & Benefits (270/271) Data Content Rule vEB.2.0

NCVHS Questions
Data Content updates for Eligibility and Benefits Operating Rule. The updated version of the Eligibility and Benefits operating rule includes the requirement to indicate coverage of telemedicine, remaining coverage and tiered benefits, and to indicate if prior authorization or certification is required. The rule has been updated to include a list of CORE-required service type codes (section 5) and CORE-required categories of service for procedure codes. If your organization has conducted an analysis of these updates and the potential impact to increasing use of the adopted standard, please comment on

your assessment of these enhancements for your organization and/or your trading partners.

Efficiency Improvements. Infrastructure updates to the adopted Eligibility and Benefits and Claim Status Operating rules. CAQH CORE has proposed updates to the adopted versions of the eligibility and benefits and claim status operating rules currently required for use. Updates include an increase in overall system availability from 86% per calendar week to 90%, and for the response time for a claim status request from 20 seconds 86% of the time to 20 seconds or fewer 90% of the time and an optional 24 additional hours of system downtime per quarter to accommodate large system migrations, mitigation and more integrated system needs, when applicable. Please comment on the potential for improvements in efficiency for your organization these updates would contribute when using the adopted X12 HIPAA transaction standards. Alternatives considered for operating rules.

What are the consequences to your organization if NCVHS recommends adoption of the updated versions of the eligibility or claim status operating rules? Please provide specific examples to describe the impacts (benefits, opportunities) of the changes included in the update for each operating rule.

WEDI Response
WEDI asked the following survey question: "Please rate your level of agreement or disagreement with the following statements regarding the impact the updated CAQH CORE Eligibility & Benefits (270/271) Data Content operating rule vEB.2.0 will have on your organization and/or the industry*."*

Response Highlights:

- **39%** responded "Agree or Strongly Agree" that "These operating rules take an important step to standardize operational challenges within value-based payment Models," 18% stated "Unsure at this Time," and 21% "Neither Disagree nor Agree."
- **39%** responded "Agree or Strongly Agree" that "These operating rules will reduce cost, enhance utility, and improve quality of care, 24% stated "Unsure at this Time" and 15% "Neither Disagree nor Agree."
- **54%** responded "Agree or Strongly Agree" that "This update to existing federally mandated rules will respond to immediate industry need to align requirements with current and emerging business, operational, security, and connectivity best practices, while promoting technological advances within the industry," 12% stated "Unsure at this Time," and 21% "Neither Disagree nor Agree."
- **54%** responded "Agree or Strongly Agree" that "These operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption," 12% stated "Unsure at this Time," and 21% "Neither Disagree nor Agree."
- Full results are included in the appendix

Additional polling. WEDI asked participants at our MPA event the following question: "Rate the level of potential improvement in efficiency that these Eligibility and Benefits operating rules would contribute to your organization." 10% answered Significant Improvement in Efficiency, **37% replied Improvement in Efficiency**, 30% indicated No Change in Efficiency, 7% replied Decreased Efficiency, 0% replied Significant Decrease in Efficiency, with 17% stating Don't Know.

WEDI also asked participants at our MPA event the following question: "Rate the level of potential benefits to Value-Based Care that would be associated with the new Eligibility and Benefits Data Content operating rules." 4% answered Significantly Improved Benefits, **35% replied Somewhat Improved Benefits**, 12% indicated No Change in Benefits, 0% replied Somewhat Decreased Benefits, 8% said Significant Decrease in Benefits, with 42% stating No Opinion.

CAQH CORE Attachments Operating Rules

WEDI asked the following survey question: "Please rate your level of agreement or disagreement with the following statements regarding the impact the new CAQH CORE Attachments operating rules for health care claims will have on your organization and/or the industry.*"*

Response Highlights:

- **30%** responded "Agree or Strongly Agree" that "These operating rules take an important step to standardize operational challenges within value-based payment Models," 21% stated "Unsure at this Time," and 27% "Neither Disagree nor Agree."
- **39%** responded "Agree or Strongly Agree" that "These operating rules will reduce cost, enhance utility, and improve quality of care delivered," 24% stated "Unsure at this Time" and 15% "Neither Disagree nor Agree."
- **42%** responded "Agree or Strongly Agree" that "This update to existing federally mandated rules will respond to immediate industry need to align requirements with current and emerging business, operational, security, and connectivity best practices, while promoting technological advances within the industry," 18% stated "Unsure at this Time," and 24% "Neither Disagree nor Agree."
- **45%** responded "Agree or Strongly Agree" that "These operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption," 15% stated "Unsure at this Time," and 27% "Neither Disagree nor Agree."
- Full results are included in the appendix

WEDI asked the survey question: "Rate your level of agreement for the following statement: "New Attachment operating rules should be nationally mandated and implemented at the same time as the Electronic Health Care Attachment (275) transaction standard to decrease industry burden and cost and increase the value of the transaction."

Response

STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
3.13%	3.13%	12.50%	**37.50%**	25.00%	32	3.96

Additional polling. WEDI asked participants at our MPA event the following question**:** **"**Rate the level of potential benefits associated with the new Attachments operating rules." 32% answered Significantly Improved Benefits, 23% replied Somewhat Improved Benefits, 3% said No Change in Benefits, 3% indicated Somewhat Decreased Benefits, 0% replied Significant Decrease in Benefits, and **39% stated Don't Know**.

NCVHS Question
Attachments operating rules – general question. HHS has not proposed adoption of a standard for attachments under HIPAA. Please comment on the proposed operating rules for attachments. What should NCVHS consider prior to making any recommendations to HHS regarding operating rules for attachments?

WEDI Response
WEDI asked participants at our MPA event the following question: "Should NCVHS recommend adoption of the new Attachments operating rules prior to publication of a Proposed Rule establishing an Attachment standard?" 12% answered Yes, **64% replied No**, 20% answered Unsure, and 4% stated No Opinion.

Additional Discussion. We understand the advantage of convening industry stakeholders to develop supporting Operating rules for attachments, even prior to a standard being named by CMS. However, we do not recommend mandating operating rules for attachments prior to the adoption of an attachment standard. With the proposed rule "Administrative Simplification: Adoption of Standards for Health Care Attachment Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Standard (CMS-0053)" currently under review at the Office of Management and Budget, we continue to be hopeful that CMS will issue this regulation. Should the attachments regulation be released, we anticipate that WEDI members would advocate for operating rules to support the standard.

Toward this, we note that many of the MPA participants see value in moving forward with an attachment standard and supporting operating rules at the same time. This could potentially shorten the overall implementation process (perhaps by a year or more) and assist organizations more effectively target the necessary resources.

We also recognize that attachment operating rules cannot be federally mandated without a regulated/named attachment standard. However, they could potentially be recommended for voluntary industry adoption.

CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Content Rule vEB.1.0

NCVHS Question

New: Patient Attribution. Content rule within the new Eligibility and Benefits Operating Rule (vEB.1.0). CAQH CORE has proposed a new operating rule to apply to the selection of value-based payment models by providers. If your organization has conducted an analysis of this operating rule, please provide information on your organization's evaluation of the extent to which the proposed operating rule requirements support the adopted HIPAA transactions or improve administrative simplification.

WEDI Response

WEDI asked the following survey question: "Please rate your level of agreement or disagreement with the following statements regarding the impact the new CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Content operating rule vEB.1.0 will have on your organization and/or the industry*."*

Response Highlights:

- **27%** responded "Agree or Strongly Agree" that "These operating rules will reduce cost, enhance utility, and improve quality of care delivered," 27% stated "Unsure at this Time" and 30% "Neither Disagree nor Agree."
- **33%** responded "Agree or Strongly Agree" that "This update to existing federally mandated rules will respond to immediate industry need to align requirements with current and emerging business, operational, security, and connectivity best practices, while promoting technological advances within the industry," 24% stated "Unsure at this Time," and 30% "Neither Disagree nor Agree."
- **33%** responded "Agree or Strongly Agree" that "These operating rules take an important step to standardize operational challenges within value-based payment Models," 27% stated "Unsure at this Time," and 27% "Neither Disagree nor Agree."
- **36%** responded "Agree or Strongly Agree" that "These operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption," 27% stated "Unsure at this Time," and 21% "Neither Disagree nor Agree."
- Full results are included in the appendix

Additional Discussion: The survey results suggest only modest support for the patient attribution Operating Rule. The weighted average for the questions tended to be lower for this proposal than for the other CAQH CORE proposals. It appears from the MPA discussion that few stakeholders have completed an analysis to determine the impact and potential value of implementing an operating rule for patient attribution.

Some health plan members indicated that only a small percentage of their members are currently in value-based care arrangements, thus limiting the potential impact of a patient attribution operating rule. MPA participants noted that the value-based care

model is so small at this point that many processes are not yet automated. These entities indicated that this operating rule would be lower on the list of the health plan's priorities.

Health plan representatives commented that the new business case for single patient attribution has the potential of adding a significant challenge to the system because it requires pulling in data not currently included and interrogating it for every 270/271. Given the high volume of transactions, this could add a lot of processing for a small population (although it was noted by MPA respondents that is expected to grow).

There was discussion that the patient attribution rule is directionally correct but may be ahead of overall industry adoption of value-based care. The current attribution process is often manual and needs to be automated. As more and more value-based care contracts are being conducted between health plans and providers, opportunities to improve the data flow and thus improve the process of delivering care should be explored.

WEDI asked participants at our MPA event the following question: "Overall, should WEDI recommend adoption of the updated and new Operating rules?" **32% indicated Yes-All of the Operating rules**, 20% indicated Yes-All Operating rules except for the Attachments Operating Rule, 20% indicated no, WEDI should not recommend adoption of the Operating rules, and 28% responded "Don't Know."

Implementation Recommendations

NCVHS Question
Implementation time frame. HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, what would be the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e. g. does the window need to be longer than two years from the publication date of a final rule? Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?

WEDI Response
We asked participants at our MPA event the following question: "Should the implementation window for standards be longer than two years from the publication date of a final rule?" 6% indicated Yes, 44% stated No, and **50% responding Don't Know**.

As NCVHS notes, past government practice has generally stipulated a January 1 implementation date for new standards. WEDI members noted that the January 1 date overlaps with many compliance and contractual obligations and recommend exploring an alternative date for implementation of new standards.

WEDI conducted a poll during the MPA event, asking the question: “How important is it that new/updated administrative transactions be implemented on a regular schedule (i.e., every two years)?” **26% answered Very Important**, 16% replied Important, 21% stated Somewhat Important, 11% replied Somewhat Unimportant, 16% answered Very unimportant, and 11% said Don't Know.

NCVHS Question
Implementation. NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?

WEDI Response
In addressing this issue, we asked members to first respond to the question of should the government permit multiple standards to be used. We followed that question by asking what there organization would do if the government did permit multiple versions of one standard.

WEDI asked the survey question: “Should the government permit industry use of multiple versions of one standard (i.e., both the 005010 and 008020 versions of the electronic claim)?”

Response

YES	20%	10
NO	**70%**	35
Unsure	10%	5
TOTAL		50

WEDI also asked the question: “If multiple versions of one standard (i.e., both the 005010 and 008020 versions of the electronic claim) are permitted by the government, what do you expect your organization to do?”

Response

Answer Options	**Percentage**	**Number**
Continue supporting the 005010 version	6.00%	3
Switch to the 008020 version	26.00%	13
Support both	**48.00%**	24
Unsure	18.00%	9
N/A	2.00%	1
TOTAL		50

At our MPA event, we asked participants to rate the importance of allowing multiple standards in use for only a limited time (i.e., a maximum of two years). **45% answered**

Very important, 20% answered Important, 5% responded Neither important nor unimportant, 0% answered Unimportant, 10% responded Very Unimportant, and 20% answered Don't Know. At the MPA event we also asked participants "Should multiple versions of administrative standards (i.e., 005010 and 008020) be permitted to be in use at the same time? 43% answered Yes, 35% No, 13% Unsure and 9% Don't Know.

WEDI MPA participants also noted that if multiple standards for the same business/use case are allowed, we recommend that they should be semantically equivalent and interoperable.

Overall, WEDI members tend to support moving forward with the full suite of transaction standards, but at a minimum, transactions that interact with each other should move forward as a bundle. WEDI members do not support moving forward transaction by transaction.

NCVHS Question
Simultaneity. What, if any, are the data impacts, limitations or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g. claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?

WEDI Response
We note that if standards are adopted as bundles and not as a full suite of transactions, effective dates most likely will be different. WEDI members are concerned these out of sync compliance states could be confusing to the industry. We note that there are interactions between the various transactions and operating rules and there may be unknown and unanticipated impacts based on these interactions.

At the same time, WEDI members also suggest that each standard be evaluated on its own merits. They note that some transactions go naturally together like the claim and the claim payment, but to say that, for example, the industry needs to update the claim because a change in the enrollment transaction is needed is not a relevant argument.

WEDI asked the MPA participants "Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?" 25% answered Yes, **54% replied No**, 17% stated Unsure, and 4% said Don't Know.

WEDI also asked the MPA participants "How should the government mandate the next iteration of administrative standards?" 36% answered All at once (full suite of 008020 transactions), **50% stated Several related transactions at once**, 0% replied One transaction at a time, and 14% stated Don't Know.

Standards Release Cadence. WEDI asked the survey question: "Rate your level of support for the following statement: "The federal government should issue new or

updated electronic transaction standards on a consistent schedule (such as yearly or every two years)."

Response

STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
10.20%	8.16%	12.24%	**46.94%**	22.45%	49	3.63

WEDI asked the survey question: "How should the federal government adopt new or updated X12 008020 electronic transaction standards*?"*

Response

Answer Options	Percentage	Number
All at once (full suite of transactions)	23.40%	11
Several at once (groupings of transactions dependent on each other)	**61.70%**	29
One transaction at a time	10.64%	5
Unsure at this time	4.26%	2
TOTAL		47

WEDI asked the survey question: "Rate your level of support for the federal government permitting the use of the new standards prior to the required implementation date and phasing out the old standard over time*."*

Response

Strongly Oppose	Oppose	Neither Support nor Oppose	Support	Strongly Support	Total	Weighted Average
10.20%	16.33%	12.24%	**48.98%**	12.24%	49	3.37

WEDI asked the survey question: "Rate your level of support for the following statement: "If multiple versions of one standard is permitted, they should only be permitted for a designated time (i.e., a maximum of two years)."

Response

Strongly Oppose	Oppose	Neither Support nor Oppose	Support	Strongly Support	Total	Weighted Average
2.13%	2.13%	4.26%	**55.32%**	36.17%	47	4.21

WEDI asked the survey question: “How should the government establish the compliance date for implementation of new or updated X12 008020 electronic transaction standards?”

Response

Answer Choices	Percentage	Number
All impacted stakeholders (health plans, providers, clearinghouses) would be required to be in compliance on the same date	**64%**	32
Health plans would be required to be in compliance on one date, with providers and clearinghouses at a later date	6%	3
Health plans and clearinghouses would be required to be in compliance on one date, with providers at a later date	16%	8
Unsure at this time	8%	4
N/A	6%	3
TOTAL		50

Additional Comments

Known and predictable standards schedule. We note that it is taken 15 years to move from 5010 to the latest version of the HIPAA administrative transactions. This is far too long. The changes generated through both X12 and CAQH CORE were developed by broad array of industry participants and went through a thorough vetting process. We recommend moving forward to create a new baseline for the industry. Once the industry has transitioned to that baseline set of standards, the industry can then more efficiently move to a more incremental approach to standards updates. We note that this known and predictable transition cycle should apply to not only X12 standards and CAQH CORE operating rules, but other standards implemented by the health care industry.

After the transition to this baseline set of standards has taken place, we urge the development of a known and predictable standards upgrade cycle. When the industry has moved to an incremental yearly or bi-yearly upgrade schedule, changes to transactions should be based on their value to the industry. Finally, we recommend working with appropriate industry stakeholders like WEDI to develop the most appropriate glidepath for standards implementation.

Pilot Testing and Establishing ROI. WEDI asked the following question in our survey: “Rate your level of support for the following statement: No administrative transaction standard should be nationally mandated until a pilot test is conducted and the results indicate a clear return on investment for the industry.” There was general agreement from the 59 respondents that pilot testing of new standards should be conducted, with 59.2% supporting or strongly supporting the statement. 20.4% neither supported nor opposed the statement and 20.4% opposed the statement. No respondents strongly opposed the statement.

Similarly, WEDI asked MPA participants the following question: “How important is it that there be an industry ROI established prior to an administrative standard being

mandated?" 44% answered Very Important, 12% responded Important, 16% stated Somewhat Important, 25% replied Somewhat Unimportant, and 0% answered Very unimportant.

Prioritize the Attachment Regulation. Many WEDI members expressed the sentiment that the attachment regulation should be prioritized above moving to updated versions of the existing HIPAA transactions or new or updated operating rules. Adoption of the X12 275 standard would result in immediate value for the industry.

Establish a Comprehensive Health IT Roadmap. The current health IT landscape is complex, challenging, and rapidly changing. The federal government has an extremely ambitious vision of how health care stakeholders must deploy technology for both administrative and clinical purposes. Requirements for new and updated HIPAA administrative standards and operating rules must compete with 21st Century Cures Act, interoperability requirements, No Surprises Act data exchange provisions, and other federal mandates for scarce human and financial resources. Exacerbating this, the nation's health infrastructure continues to face COVID-19 related difficulties. We urge the development of a comprehensive and achievable roadmap that prioritizes these health IT requirements and recognizes the many implementation challenges faced by the industry.

Conclusion

WEDI applauds the efforts of NCVHS to solicit industry opinions on whether to move to the 008020 version of the X12 administrative transactions and whether to adopt updated and new CAQH CORE Operating rules. WEDI shares the Committee's commitment to improving data exchange efficiency within the health care industry and reducing administrative burden for all stakeholders. As the collective voice of the health care industry on health IT issues, we are pleased to continue our important partnership with the NCVHS and look forward to participating at the January 18-19, 2023, hearing conducted by the Standards Subcommittee.

Please contact Charles Stellar, WEDI President and CEO, at 202.329.9700 or cstellar@wedi.org with any questions you may have on the issues we have raised in this comment letter.

Sincerely,
/s/
Nancy Spector
Chair, Board of Directors

cc: WEDI Board of Directors

APPENDIX-Survey Questions and Responses

WEDI asked the following survey question: "For the following issues, please rate the impact each potential benefit (i.e., cost, utility, improvement in quality of care delivered) of the 008020 version of the Professional Electronic Health Care Claim (837P) will have on your organization."

Response

Answer Options	STRONG NEGATIVE IMPACT	NEGATIVE IMPACT	NO IMPACT	POSITIVE IMPACT	STRONG POSITIVE IMPACT	UNSURE AT THIS TIME	N/A	TOTAL	WEIGHTED AVERAGE
Added the ability to transmit the Device Identifier (DI) of the Unique Device Identifier (UDI) for supplies, implants, and explants.	4.08%	0.00%	**24.49%**	20.41%	22.45%	20.41%	8.16%	49	2.96
Replaced the Claims Adjustment (CAS) segment with the Reason Adjustment (RAS) segment to support the association of Adjustment Reason Codes and Remark Codes and better synchronization with the Healthcare Claim Payment/Advice (835).	4.08%	8.16%	0.00%	28.57%	**38.78%**	20.41%	0.00%	49	3.29
Greater focus on reducing ambiguity throughout the implementation guide.	2.04%	2.04%	10.20%	30.61%	**42.86%**	12.24%	0.00%	49	3.73
Revised the situational rules for Provider Accepts Assignment Code (CLM07) and Provider Agreement Code (CLM16) to provide specific data elements for both Medicare and non-Medicare payers.	2.04%	0.00%	12.24%	**28.57%**	**28.57%**	**28.57%**	0.00%	49	2.96
Revisions to add clarity for instructions for real-time use of the Health Care Claim (837) transactions.	4.08%	0.00%	12.24%	22.45%	**36.73%**	20.41%	4.08%	49	3.28
Increased the number of diagnosis code pointers from 8 to 12 per service line	4.08%	4.08%	10.20%	24.49%	**40.82%**	16.33%	0.00%	49	3.45

for Professional Claims.									
Added support for transmitting Coordination of Benefits (COB) allowed amounts.	2.04%	4.08%	6.12%	26.53 %	**44.90 %**	16.33%	0.00 %	49	3.59
Revised to support subrogation for payers other than Medicaid.	2.04%	0.00%	24.49%	20.41%	20.41%	**26.53%**	6.12%	49	2.76
Increase the maximum number of diagnosis codes from 12 to 24 to provide a more complete picture of the patient's condition.	0.00%	0.00%	12.24%	**34.69%**	24.49%	24.49%	4.08%	49	3.49
Increased the number of prior authorizations and referrals that can be reported at the line level.	2.04%	2.04%	10.20%	**32.65%**	20.41%	26.53%	6.12%	49	2.87
Added Drug Service (SV4) and Drug Adjudication (SV7) segments to support the reporting of drug rebate information	4.08%	2.04%	12.24**%**	22.45%	**28.57%**	26.53%	4.08%	49	2.89

For the following issues, please rate the impact each potential benefit (i.e., cost, utility, improvement in quality of care delivered) of the 008020 version of the Institutional Electronic Health Care Claim (837I) will have on your organization.

Responses

Answer Options	STRONG NEGATIVE IMPACT	NEGATIVE IMPACT	NO IMPACT	POSITIVE IMPACT	STRONG POSITIVE IMPACT	UNSURE AT THIS TIME	N/A	TOTAL	WEIGHTED AVERAGE
Added the ability to transmit the Device Identifier (DI) of the Unique Device Identifier (UDI) for supplies, implants, and explants.	4.26%	0.00%	19.15%	**27.66%**	23.40**%**	21.28%	4.26%	47	3.02
Replaced the Claims Adjustment (CAS) segment with the Reason Adjustment (RAS) segment to support the	6.38%	4.26%	0.00%	25.53**%**	**44.68**%	19.15%	0.00%	47	3.40

association of Adjustment Reason Codes and Remark Codes and better synchronization with the Healthcare Claim Payment/Advice (835).									
Greater focus on reducing ambiguity throughout the implementation guide.	2.13%	0.00%	10.64%	29.79**%**	**46.81**%	10.64**%**	0.00%	47	3.87
Revised the situational rules for Provider Accepts Assignment Code (CLM07) and Provider Agreement Code (CLM16) to provide specific data elements for both Medicare and non-Medicare payers.	2.13%	0.00%	14.89%	23.40**%**	25.53%	**31.91%**	2.13%	47	2.74
Revisions to the implementation guides to align with the National Uniform Billing Committee (NUBC).	2.13%	0.00%	8.51%	27.66%	**48.94%**	10.64%	2.13%	47	3.91
Added clear instructions for real-time use of the Health Care Claim (837) transactions.	2.13%	0.00%	17.02%	19.15**%**	**36.17%**	19.15%	6.38%	47	3.32
Added support for transmitting Coordination of Benefits (COB) allowed amounts.	2.13%	2,13%	4.26%	31.91%	**40.43%**	17.02%	2.13%	47	3.57
Revised to support subrogation for payers other than Medicaid.	2.13%	0.00%	23.40%	21.28%	23.40%	**25.53%**	4.26%	47	2.87
Increased the number of prior authorizations and referrals that can be reported at the line level.	0.00%	0.00%	13.04%	32.61%	26.09%	23.91%	4.35%	46	3.41

WEDI asked the survey question: "For the following issues, please rate the impact each potential benefit (i.e., cost, utility, improvement in quality of care delivered) of the 008020 version of the Dental Electronic Health Care Claim (837D) will have on your organization."

Responses

Answer Options	STRONG NEGATIVE IMPACT	NEGATIVE IMPACT	NO IMPACT	POSITIVE IMPACT	STRONG POSITIVE IMPACT	UNSURE AT THIS TIME	N/A	TOTAL	WEIGHTED AVERAGE
Replaced the Claims Adjustment (CAS) segment with the Reason Adjustment (RAS) segment to support the association of Adjustment Reason Codes and Remark Codes and better synchronization with the Healthcare Claim Payment/Advice (835).	6.06%	3.03%	0.00%	24.24%	**42.42%**	21.21%	3.03%	33	4.63
Revised to reflect the NPI mandate and clarify the relationship to other name information.	3.03%	0.00%	12.12%	**36.36%**	30.30%	15.15%	3.03%	33	4.41
Added a data element used for Coordination of Benefits when a claim is adjusted.	3.03%	3.03%	3.03%	**33.33%**	33.33%	21.21%	3.03%	33	4.59
Revised to support reporting of claim level Remark Codes not associated with an Adjustment Reason Code.	3.03%	6.06%	0.00%	27.27%	**42.42%**	18.18%	3.03%	33	4.59
Revised to support up to 12 diagnosis pointers per claim line.	3.03%	3.03%	15.15%	24.24%	**39.39%**	12.12%	3.03%	33	4.34
Revised to support line-level prior authorizations when no authorization is sent at the claim level. This reduces the need to split claims.	3.03%	6.06%	6.06%	**36.36%**	**36.36%**	9.09%	3.03%	33	4.28
Revised to support the transmission of the allowed amount received on the primary claim.	3.03%	6.06%	3.03%	33.33%	**39.39%**	12.12%	3.03%	33	4.41

WEDI asked the survey question: "For the following issues, please rate the impact each potential benefit (i.e., cost, utility, improvement in quality of care delivered) of the 008020 version of the Electronic Health Care Claim Payment/Advice (835) will have on your organization."

Response

Answer Options	STRONG NEGATIVE IMPACT	NEGATIVE IMPACT	NO IMPACT	POSITIVE IMPACT	STRONG POSITIVE IMPACT	UNSURE AT THIS TIME	N/A	TOTAL	WEIGHTED AVERAGE
Added the ability to transmit the Device Identifier (DI) of the Unique Device Identifier (UDI) for supplies, implants, and explants.	5.66%	0.00%	22.64%	24.53%	16.98%	**26.42%**	3.77%	53	2.67
Added instructions for real-time adjudication.	1.89%	0.00%	13.21%	18.87%	**39.62%**	22.64%	3.77%	53	3.27
Added the ability to report remittance information related to card payments (p-card, debit card, and credit card) to facilitate auto-posting.	7.55%	5.66%	1.89%	**28.30%**	26.42%	24.53%	5.66%	53	2.86
Replaced the Claims Adjustment (CAS) segment with the Reason Adjustment (RAS) segment to support the ability to report all associated messages about an adjustment including all reasons associated with the adjustment amount.	7.55%	1.89%	0.00%	18.87%	**45.28%**	26.42%	0.00%	53	3.13
Added the ability to report Remark Codes, not associated with an adjustment code.	5.77%	1.92%	3.85%	19.23%	**44.23%**	23.08%	1.92%	53	3.25
Standardized and added clarity for reporting COB adjudication information.	1.89%	0.00%	3.77%	22.64%	**49.06%**	20.75%	1.89%	53	3.56
Standardized the forward balance and overpayment recovery processes.	1.92%	0.00%	3.85%	21.15%	**51.92%**	21.15%	0.00%	52	3.58
Added the ability to re-associate a recovery amount to a specific claim to reduce manual	1.92%	1.92%	0.00%	25.00%	**48.08%**	23.08%	0.00%	52	3.46

processes to track when the funds have been recouped.									
Support reporting of the specific DRG type used in adjudication and the ability to report multiple DRG types.	1.92%	0.00%	7.69%	23.08%	**44.23%**	19.23%	3.85%	52	3.52
Added more granular source of payment codes giving providers more transparency into the process used to adjudicate the claim. In addition, the information is needed for state and federal reporting.	1.92%	1.92%	1.92%	30.77%	**36.54%**	25.00%	1.92%	52	3.24
Added information that will aid in automating the posting of remittance advice information.	1.92%	1.92%	7.69%	23.08%	**48.08%**	15.38%	1.92%	52	3.69

WEDI asked the survey question: "Please rate your level of agreement or disagreement with the following statements regarding the impact the updated CAQH CORE Connectivity Rule vC4.0.0 will have on your organization and/or the industry."

Response

Answer Options	STRONG NEGATIVE IMPACT	NEGATIVE IMPACT	NO IMPACT	POSITIVE IMPACT	STRONG POSITIVE IMPACT	UNSURE AT THIS TIME	N/A	TOTAL	WEIGHTED AVERAGE
This update to existing federally mandated Rules will respond to immediate industry need to align requirements with current and emerging business, operational, security, and connectivity best practices, while promoting	5.00%	5.00%	17.50%	**47.50%**	10.00%	15.00%	0.00%	40	3.0

technological advances within the industry.									
Consistent with the NCVHS recommendation in 2020, the updated Connectivity Operating Rule will support uniform interoperability requirements across clinical and administrative transactions and builds on industry interest to establish predictable, consistent connectivity mechanisms.	5.00%	5.00%	17.50%	**47.50%**	10.00%	15.00%	0.00%	40	3.0
This operating rule lays the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption.	5.00%	5.00%	20.00%	**40.00%**	12.50%	17.50%	0.00%	40	2.9
This operating rule takes an important step to standardize operational challenges within value-based payment models.	7.50%	5.00%	22.50%	**37.50%**	7.50%	15.00%	5.00%	40	2.8

This operating rule will reduce cost, enhance utility, and improve quality of care delivered.	7.50%	7.50%	**27.50%**	25.00%	10.00%	22.50%	0.00%	40	2.5

WEDI asked the following question: "Please rate your level of agreement or disagreement with the following statements regarding the impact the updated CAQH CORE Infrastructure operating rules will have on your organization and/or the industry.*"*

Response

Answer Options	STRONGLY DISAGREE	DISAGREE	NEITHER DISAGREE NOR AGREE	AGREE	STRONGLY AGREE	UNSURE AT THIS TIME	N/A DON'T PLAN TO USE	TOTAL	WEIGHTED AVERAGE
This update to existing federally mandated rules will respond to immediate industry need to align requirements with current and emerging business, operational, security, and connectivity best practices, while promoting technological advances within the industry.	6.06%	3.03%	15.15%	**51.52%**	9.09%	15.15%	0.00%	33	3.09
These operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption.	6.06	6.25%	15.63%	**46.88%**	9.38%	15.63%	0.00%	32	3.00
These operating	9.09%	3.03%	21.21%	**33.33%**	6.06%	21.21%	6.06%	32	2.58

rules take an important step to standardize operational challenges within value-based payment models.									
These operating rules will reduce cost, enhance utility, and improve quality of care delivered.	9.09%	6.06%	24.24%	**27.27%**	9.09%	24.24%	0.00%	33	2.48

WEDI asked the following survey question: "Please rate your level of agreement or disagreement with the following statements regarding the impact the updated CAQH CORE Eligibility & Benefits (270/271) Data Content operating rule vEB.2.0 will have on your organization and/or the industry."

Response

Answer Options	STRONGLY DISAGREE	DISAGREE	NEITHER DISAGREE NOR AGREE	AGREE	STRONGLY AGREE	UNSURE AT THIS TIME	N/A DON'T PLAN TO USE	TOTAL	WEIGHTED AVERAGE
This update to existing federally mandated Rules will respond to immediate industry need to align requirements with current and emerging business, operational, security, and connectivity best practices, while promoting technological advances within the industry.	6.06%	6.06%	21.21%	**45.45%**	9.09%	12.12%	0.00%	33	3.09
These operating rules lay the foundation for creating common	6.06%	6.06%	21.21%	**45.45%**	9.09%	12.12%	0.00%	32	2.75

expectations to enhance the exchange of attachments to drive electronic adoption.									
These operating rules take an important step to standardize operational challenges within value-based payment models.	9.09%	6.06%	21.21%	**33.33%**	6.06%	18.18%	6.06%	32	2.65
These operating rules will reduce cost, enhance utility, and improve quality of care delivered.	9.09%	12.12%	15.15%	**24.24%**	15.15%	**24.24%**	0.00%	33	2.52

WEDI asked the following survey question: "Please rate your level of agreement or disagreement with the following statements regarding the impact the new CAQH CORE Attachments operating rules for health care claims will have on your organization and/or the industry."

Response

Answer Options	STRONGLY DISAGREE	DISAGREE	NEITHER DISAGREE NOR AGREE	AGREE	STRONGLY AGREE	UNSURE AT THIS TIME	N/A DON'T PLAN TO USE	TOTAL	WEIGHTED AVERAGE
This update to existing federally mandated Rules will respond to immediate industry need to align requirements with current and emerging business, operational, security, and connectivity best	12.12%	3.03%	24.24%	**33.33%**	9.09%	18.18%	0.00%	33	2.70

practices, while promoting technological advances within the industry.									
These operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption.	9.09%	3.03%	27.27%	**33.33%**	12.12%	15.15%	0.00%	32	2.91
These operating rules take an important step to standardize operational challenges within value-based payment models.	15.15%	6.06%	**27.27%**	18.18%	12.12%	21.21%	0.00%	32	2.42
These operating rules will reduce cost, enhance utility, and improve quality of care delivered.	9.09%	12.12%	15.15%	**24.24%**	15.15%	**24.24%**	0.00%	33	2.52

WEDI asked the following survey question: "Please rate your level of agreement or disagreement with the following statements regarding the impact the new CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Content operating rule vEB.1.0 will have on your organization and/or the industry."

Response

Answer Options	STRONGLY DISAGREE	DISAGREE	NEITHER DISAGREE NOR AGREE	AGREE	STRONGLY AGREE	UNSURE AT THIS TIME	N/A DON'T PLAN TO USE	TOTAL	WEIGHTED AVERAGE
This update to existing federally mandated rules will respond to immediate industry	12.12%	0.00%	**30.30%**	21.21%	12.12%	24.24%	0.00%	33	2.48

need to align requirements with current and emerging business, operational, security, and connectivity best practices, while promoting technological advances within the industry.									
These operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption.	9.09%	6.06%	21.21%	21.21%	15.15%	**27.27%**	0.00%	32	2.45
These operating rules take an important step to standardize operational challenges within value-based payment models.	6.06%	3.03%	**27.27%**	21.21%	12.12%	**27.27%**	3.03%	32	2.47
These operating rules will reduce cost, enhance utility, and improve quality of care delivered.	15.15%	9.09%	21.21%	18.18%	9.09%	**27.27%**	0.00%	33	2.15

From: Yuehuei H. An
To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals
Date: Tuesday, December 13, 2022 9:11:38 AM

We are against the X12 proposed addition of the "card payments" remittance information to 835 ERA. This is clearly a "money sharing" mechanism. Please stop it!

Sincerely,
Yuehuei An, MD
Orthopaedic Surgeon (Board Certified) and Hand Surgeon
Yuehuei An Orthopaedics PC
Associate Professor of Orthopaedic Surgery
Zucker School of Medicine, Hofstra University
Clinic 1: 136-36 39th Avenue, 7th Floor, Flushing, NY 11354
Clinic 2: 245 West Main Street, Bay Shore, NY 11706
Website: www.anortho.com

To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals

Dear NCVHS Subcommittee Members,

Thank you for the opportunity to comment on the X12 proposal that the current standard be updated from version 5010 to version 8020 for the adopted administrative standard for the health care claims (professional, institutional, and dental) and the remittance advice 835 transactions.

I urge you to reject the X12 proposed addition of the "card payments" remittance information to 008020X322 835 ERA for the following reasons.

- Credit cards cost our practice more than 3% of revenue to process and offer us no benefits.
- Card payments raise consumer and practice costs and offer no meaningful 'value-added' to our practice or consumers.
- There are no 'willing buyers' for "card payments" when it comes to standard electronic healthcare payments.

What we want is for health plans to honor our request for standard healthcare ACH EFT from the very first payment. When we do get unsolicited “opt-out” card payments, we do not want to auto-post them. Instead, our practice spends an inordinate amount of time and money to “opt-out” from card payments and to get a replacement check. I see no basis or justification to add the ability to 'report remittance information related to card payments.'

I want to make it very clear that I question and dispute the benefits of using VCC and credit cards for payment of health care services. Card payments, including VCC and credit cards, do not offer any benefits to medical practices. Card payments incur higher costs than checks or legally compliant standard healthcare. ACH EFT payments that must be delivered to the physician practice bank at no cost to the physician, just as paper checks arrive at a USPS mailbox at no cost to the physician practice. In short, card payments involve additional administrative work, and offer no value to physician practices.

I request that X12/NCVHS/CMS remove the section allowing card payments on remittance advice from 008020X322 immediately, as this has a significant detrimental effect on healthcare providers. I do NOT foresee a situation where card payments offer any benefits, and there is no situation where our medical practice would voluntarily "opt-in" to receive card payments. Thus there are no foreseeable benefits from adding 'card payments' to 835 transactions, and implementation costs are estimated to be significant.

I request that X12 / NCVHS / CMS provide published, peer-reviewed, real-world, non-simulated studies that sample a sufficiently broad spectrum of healthcare providers, including independent healthcare providers, small healthcare providers, healthcare providers offering services in rural areas, and healthcare providers not owned by or that own a health plan and that demonstrate how the addition of remittance information related to "card payments" reduce healthcare costs, and make healthcare administration more efficient when no provider wants to accept 'card payments.

Thank you for your attention to my comments.

TEMPLATE SUBMISSION #2

CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002
By email: NCVHSmail@cdc.gov
RE: RFC on X12 and CAQH CORE Proposals

Dear NCVHS Members,

We are writing to inform NCVHS that we are **AGAINST** the adoption of this standard in its current form. In particiluar, we are **against** the X12 proposed addition of the "card payments" remittance information to 835 ERA. In summary, there are a number of reasons that the ability to report remittance information related to “card payments" should **NOT** be added to the 835 ERA transaction, which we will explain in great detail below:

1. There is near **universal provider rejection of card payments** as an option for standard healthcare payment. If no provider wants 'card payments, there is **no basis or justification to add the ability to 'report remittance information related to card payments.'**
2. There is no industry consensus that "card payment" information on ERA serves a 'useful' purpose.
3. There are no studies and no industry consensus that adding "card payments" to the 835 ERA transaction fills a "missing" need.
4. Since there is no need or provider demand for 'card payments' to start with, there is no need or demand to autopost 'card payment' remittance advice, a product of unwanted transaction.
5. Card payments are not an adopted healthcare payment EFT standard. Remittance information related to card payments is a product of a non-adopted payment method, illegal to be used as a standard healthcare EFT transaction. A product of ‘illegal’ transaction cannot be “legal” and cannot be incorporated into a legal standard.
6. The X12 standards for 835 transactions are adopted under the HIPAA Act of 1996, Section 1172 (b) REDUCTION OF COSTS. Legally, this act does **not** give CMS

authority to add "card payments" to ERA as this proposal **does not satisfy the basic requirement** that it serves to "lower costs."

7. Adding card payment information to 835 ERA cannot occur without an act of Congress. An illegal or 'extra-legal' payment option cannot be adopted into and be reported in a legal, standard transaction.

We **disagree** with the September 23, 2014 statement from NCVHS and wish to **provide clarity** that we "**question and dispute the benefits of using VCC and credit cards** for payment of health care services."

- Card payments, including VCC and credit cards, do **not** offer any benefits to medical practices
- Card payments incur **higher costs** than checks or legally compliant standard healthcare ACH EFT payments that must be delivered to the physician practice bank at no cost to the physician, just as paper checks arrive to a USPS mailbox at no cost to the physician practice.
- Card payments involve additional administrative work
- Card payments are sent as **'opt-out**' payments precisely because they offer **no value** to physician practices, and no practice would ever choose it as a payment method without duress.

As you are well aware, card payments are universally **opt-out**; **independent healthcare providers do not willingly accept card payments**. There is absolutely no "demand" in the healthcare industry among healthcare providers for "card payments." In fact, as you are well aware, through prior testimony from the AMA, WEDI, and other organizations to NCVHS, healthcare providers have complained about the **unfair business practices** of sending virtual credit cards by health plans and charging fees for healthcare ACH EFT transactions. It is unclear what the reason is that X12 recommended the addition of 'card payment' information to 835 transactions, given near universal opposition to card payments by healthcare providers to start with.

There is **unanimous opposition** to card payments by independent healthcare providers. Card payments **raise consumer costs** and offer **no meaningful 'value-added' to providers** or consumers. That is why the only way it can exist is through 'opt-out' forced imposition on healthcare providers. In other words, there are **no 'willing buyers' for "card payments" when it comes to standard electronic healthcare payments**.

Healthcare providers do not want the ability to 'autopost' card payments, as most healthcare providers do not want to receive card payments to start with. **When they do get unsolicited card payments, they do not want to autopost them.** Instead physician practices spend an inordinate amount of time and money to "opt-out" from card payments. At most, the inability to autopost is a minor negative characteristic of 'card payments'. **Adding the ability to auto-post does not change the nature of card payments – they are costly and unwanted.** What healthcare providers wanted from CMS was to ban credit card payments, not making them 'less evil.' CMS's **unfortunate** position is that it is not illegal to send the first payment as a credit card, even while they raise the cost of healthcare relative to paper checks and certainly relative to standard ACH EFT.

X12 has not explained what is the nature of 'consensus' and detailed the vote that led to the recommendation to add 'card payment' remittance information to a standard 835 transaction. X12 has not detailed any studies it performed among independent providers to gauge a need for adding 'card pyment' reporting to 835 transaction.

Healthcare providers are very satisfied with the current healthcare ACH EFT standard. The provider complaints related to ACH EFT originate from (1) the fees that some plans and their affiliates impose

on ACH EFT; (2) barriers to enrollment; (3) failure by many banks to provide re-association data in electronic format at an affordable cost; in fact many banks use re-association data as a bargaining or extorsion item and require additional payment beyond what the account holder pays for ACH EFT delivery, to 'see re-association numbers' even as banks hide it in their database.

If there are no willing provider users of card payments, there is **no legitimate need to add card payment remittance information to the 835 transaction**. You do not need information about something that you do not want to have. It's as simple as that.

Card payments involve more administrative work, including the implementation of additional processes and policies, than check payments or healthcare ACH EFT payments. The processing costs are many times more than either check payments or ACH EFT. Card payments do **not** offer greater efficiency, nor do they offer lower costs. In other words, they **cannot be adopted under 'delegated" authority under HIPAA**. There is no legitimate need to report in a standard 835 ERA an unwanted payment method that is costly, inefficient, and unwanted.

While paper checks are not an adopted standard, they were clearly mentioned in all legislative history as the **default predicated healthcare payment method** from which a move to electronic ACH EFT was legislatively encouraged. Thus it is reasonable to report check payment information on a standard 835 ERA transaction as the **predicated** payment method. There is **no legal basis for equating the legal status of paper checks to card payments**, which were never considered as a legitimate payment option for standard transactions; card payments were never in wide use for healthcare payments by health plans to providers prior to the adoption of the HIPAA Administrative Simplification requirements. The option of using card payments was never considered to be legitimate enough to seek public comments on the issue during the adoption of HIPAA Administrative Simplification standards. There is no legitimate historical justification for adding card payment reporting to 835 ERA transaction.

Insofar as X12 rules are incorporated into federal law, the net result of remittance card reporting is to 'legitimize' card payments, which are currently not adopted as a 'standard EFT" transaction.

CMS does **not** have the **authority** under HIPAA to adopt standards that do not lower healthcare costs (42 US Code § 1320d–1 (b)). Neither card payments themselves nor reporting of card payment information on 835 transaction lower healthcare costs. Certainly, to report a card transaction information on 835 ERA, there has to be an associated card transaction; CMS has to look at them as a 'package' that raises the cost of healthcare and is not eligible to be added to any standard adopted under HIPAA.

It is critical to remember the intended goal of the legislation, HIPAA Act of 1996, Section 1172 (b) REDUCTION OF COSTS:

> To amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to **simplify the administration of health insurance**, and for other purposes.

42 US Code § 1320d–1 **(b) REDUCTION OF COSTS.**—Any standard adopted under this part shall be consistent with the objective of **reducing the administrative costs** of providing and paying for health care. (previously classified as Section 1172)

- Congressional intent was made clear again in section (2)(i)the different standard will **substantially reduce administrative costs** to health care providers and health plans compared to the alternatives;

The proposed allowance to include card payments information on 835 ERA transactions is **not consistent with the plain text of the law** , as card payments universally raise transaction costs, increase administrative costs and raise the cost of healthcare, even compared to the baseline historical option that the HIPAA standards sought to eliminate, which are paper checks. The mere addition of card payment information to 835 also raises costs without any quantifiable benefit to healthcare providers.

There is no mention of card payments in the HIPAA Act of 1996, Section 1172 (b) REDUCTION OF COSTS. HHS/CMS has **no authority to adopt regulations** that raise the cost of healthcare and make the administration of healthcare more complex. As you are aware, the X12 rule adoption by CMS/HHS relies on the delegation of congressional authority under 42 US Code § 1320d.

In the final interim rules adopting the ACH EFT as a standard transaction, section 5. EFT Conducted Outside the ACH Network states:

> The **health care EFT standards adopted in this interim final rule** with comment period do **not** apply to health care claim payments made via EFT outside of the ACH Network. Health plans are not required to send health care EFT through the ACH Network. They may decide, for instance, to transmit a health care EFT via Fedwire or via a payment card network . This interim final rule with comment period neither prohibits nor adopts any standards for health care EFT (as defined in § 162.1601(a)) transmitted outside of the ACH Network. When health plans do, however, send health care EFT through the ACH Network, they must do so using the health care EFT standards adopted herein.

Clearly, card payments are not 'legally' adopted as a healthcare EFT standard; thus, including them in a legally adopted standard transaction designed to report information about adopted standards "ACH EFT" and 835 ERA contents is not appropriate, **arbitrary, without precedent, a major change in policy**, and not legal.

There is a tremendous disagreement with this section of X12 rulemaking.

We request that X12/NCVHS/CMS **remove** the section allowing card payments on remittance advice from 008020X322 immediately, as this has a significant **detrimental effect** on healthcare providers.

There is **no legitimate industry demand or need** for this, and it is **universally opposed by independent healthcare providers that are not owned by or own health plans**. Legally, it cannot be adopted as this addition is **not authorized** under the governing law, and HHS/CMS has no delegated authority to add it to a federal standard.

As the NCVHS is well aware, **no standard can be adopted under HIPAA unless it has the effect to lower the costs of healthcare**. There are NO situations where a card payment is less expensive than

the standard ACH EFT transaction, the current standard. Thus, card payments cannot legally be adopted as ‘a legal” EFT payment method under HIPAA as they cannot be demonstrated to lower costs, the fundamental **litmus test** to qualify a transaction for adoption under HIPAA.

The proposal to add card payment information to 835 ERA does **not** meet the **requirements** that they are based on '**consensus-based review and evaluation process**." The correct standard to use is that the transaction has 2 users: senders and receivers. Healthcare providers is 50% of each transaction as a user – thus **any "consensus" must allow at least 50% representation of healthcare providers**. When >95% of healthcare providers are angrily **opposed to card payments** and have no need or desire for having card payments added to 835 ERA transactions, it is **mathematically impossible to claim that there is a "consensus"** or even a legitimate "majority" vote on this issue. See below for BBB complaints against providers of card payments (Zelis and ECHO Health).

> "Standards-setting organizations or the Designated Standards Maintenance Organization (DSMO) bring forward new versions of the adopted standards to NCVHS after completion of a consensus-based review and evaluation process. Under Section 1173(3)(B), the organizations with whom a DSMO should consult for input include the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (ADA)." CMS.

1. **Costs**. Medical practices do ***NOT*** foresee a situation where card payments offer any benefits, and there is no situation where any medical practice would voluntarily "opt-in" to receive card payments. Thus there are **no foreseeable benefits** from adding 'card payments' to 835 transactions. **Implementation costs** are estimated to be significant.

2. **Operational impacts. After a thorough analysis, we could not identify a positive operational impact on medical practices from the addition of 'card payment' information to 835 ERA transactions. The impact is strongly negative.**
    a. Adoption of the proposal to add card payments as a payment option to 835 ERA would require a significant expenditure of resources to retrain billing staff to recognize this situation. It would require vendors to update programming to add this option, and the costs are passed directly to physicians through subscription fees; in addition, given limited resources, implementation of this standard distracts vendor focus from more productive uses of programming resources to make medical practices more efficient and more profitable. There is a **significant material 'opportunity' cost to implementing an un-wanted and un-needed 'standard' update**.
    b. Practices would need to implement additional reconciliation steps between ERA and typical management of unwanted card payments – from which medical practices opt out whenever possible.

We cannot support the X12 835 8020, in its current form, with the inclusion of the ability to report remittance information related to "Card transaction."

1. We request that X12 / NCVHS / CMS provide published, peer-reviewed, real-world, non-simulated **studies** that sample a sufficiently broad spectrum of healthcare providers, including independent healthcare providers, small healthcare providers, healthcare providers offering services in rural areas, and healthcare providers not owned by or that own a health plan and that **demonstrate how the addition of remittance information related to "card payments"**

reduce healthcare costs, and make healthcare administration more efficient when no provider wants to accept 'card payments.

2. We request that X12 / NCVHS / CMS provide published, peer-reviewed, real-world, non-simulated **studies** that sample a sufficiently broad spectrum of healthcare providers, including independent healthcare providers, small healthcare providers, healthcare providers offering services in rural areas, and healthcare providers not owned by or that own a health plan, and that **demonstrate an 'unmet' demand or need for reporting remittance information related to "card payment" information on 835 ERA transaction.**

3. We request that X12 / NCVHS / CMS provide published, peer-reviewed, real-world, non-simulated **studies** that sample a sufficiently broad spectrum of healthcare providers, including independent healthcare providers, small healthcare providers, healthcare providers offering services in rural areas, and healthcare providers not owned by or that own a health plan, and that **demonstrate an 'unmet' demand or need for autoposting "card payment" information from 835 ERA transaction when nearly universally in our industry survey providers reject card payments, sometimes unsuccessfully; in no situations are providers' willing' and uncoerced recipients of card payments.**

Problem with the proposal to include “Card Payment” in Remittance Advice to Facilitate Autoposting Card Payments:

The rule as proposed is arbitrary and capricious, and is without legal support.

Card payments are not received ‘whole’. Card processors deduct merchant fees from deposits. The actual reconciliation can only occur once the merchant processing fees are deducted from the card payment, as merchant fee varies by the type of the transaction (card present, card not present, regulated debit, exempt debit, credit, corporate credit card, gift card, ec).

Even if physicians were to choose to accept a card payment as a result of being exhausted of trying to opt-out and being re-enrolled in card payments against our will, card information that is proposed to be included by X12 in 835 standards **would not be helpful or useful** as it will NOT help physician practices with autoposting payments. In fact, it will create additional problems and would require additional expenditures to either manually review every 835 ERA to mark those that contain ‘card payments’ for separate manual processing or would require us to add additional programming to put 835 ERA with ‘card payments’ into a separate process that disallows autoposting.

Most physician practices would **not** choose to autopost card payments

Most physician practices would rather decline card payments and request a paper check. Autoposting would create a wrong entry. It would require extra effort for us to track the card payment itself; decline and request a paper check. At the same time would need to track what potentially could be an **inadvertent** autoposting of card payment that was **rejected** by the practice.

1. Many providers choose to treat merchant fees associated with unwanted card payments and EFT fees separately and bill them to the patient. The proposed X12 standard does

not allow autoposting the card processing costs separately as it does not separate the gross amount into (1) net receipt by the practice after card processing fee and (2) the card processing fee / merchant processing fee itself. Typically, practices would only post the 'net' amount they receive from health plan via card payment and the balance attributable to the 'card processing' fees would remain as a patient liability. Alternatively, some practices charge fixed fees to account for card processing. It is not possible to autopost such fees as the X12 proposal does not account for them.

There are additional barriers to autoposting 'card payments' based on the current X12 prooposal:

- Would 'card payment" information in remittance advice 835 transaction include the actual merchant processing fee accounting to allow practices that choose to pass the fee to the patient to properly assign patient responsibility?

- In order to reconcile payments and to correctly attribute the merchant processing fee in accounting systems, additional information is necessary to auto-post payments, which the X12 proposal does not include.

- Does the card payment information on 835 provides information on the type of card payment that was sent: was it a regulated covered debit card transaction or an exempt debit card transaction? Corporate credit card, rewards credit card transaction? These carry vastly different interchange and merchant processing fees. This information would be necessary to reconcile payments and to comply with generally accepted accounting principles (GAAP). GAAP is the basis of 835 ERA, as X12 acknowledges. In fact, X12 rules require that each service line is 'balanced'. It would be arbitrary and capricious for X12 to propose an addition to the 835 ERA transaction that cannot be reconciled during auto-posting because adequate information is not included.

- Does the card payment information on 835 provide information on the type of card transaction triggered by the use of 'card payment': in-person card transaction or 'card-not-present' transaction? These carry vastly different interchange and merchant processing fees.

- Without this information, a healthcare provider would not be able to appropriately calculate the merchant fee and attribute it properly in the patient account to 'card fees' as opposed to 'patient care revenue' during auto-posting. Thus the transaction would have to be marked as 'exception' and would not be auto-posted, which eliminates the major purported benefit of including card payment remittance information in the 835 transaction.

- For a practice that generates $1 million in revenue per provider, a difference of 1% is $10,000 extra in merchant processing fees. If a covered debit card transaction costs $0.23 (0.23% for $100) vs 2% for in-person card vs 2.8% for 'card not present", these are meaningful differences. Even a 0.5% difference would result in a $5,000 difference in merchant processing fees – substantial amounts for any medical practice.

The proposed rule has missing calculations on cost-benefit analysis.

To accurately determine the costs and the benefits of the proposal, CMS must clarify:

1. What percent of independent medical practices **willingly** accept card payments?

2. What benefits do medical practices derive from card payments? If there are no net benefits from card payments to medical practices, it is questionable how can the inclusion of information about such payments be "net" beneficial to providers.
3. If only a small percentage of providers willingly accept card payments, the financial burden of implementing the proposal to include card payment information on 835 transactions may not be justified.
4. What percent of card payments are issued as 'opt-in" payments vs "opt-out" payments?
5. What percent of independent medical practices decline "opt-out" card payments when they receive them against their will? Providers that decline opt-out card payments would not benefit from having card payment information included in 835 transactions.
6. How many provider contacts occur yearly to health plans and their business associates to opt-out from card payments and request that a paper check replaces an unwanted card payment? What is the net cost of these contacts to providers? Health plans?
7. What percent of all "providers" decline out-out card payments?
8. What is the cost of each opt-out, including the cost of contacting the health plan on multiple occasions, waiting for 45 min on hold; not receiving the check, and needing to contact the payer again (as demonstrated in the attached BBB complaints against ECHO Health and Zelis).
9. What is the cost of processing a check payment vs processing a card payment?
10. What is the cost of autoposting a check payment or EFT payment on an 835 ERA vs **manual processing associated** with 835 ERA information of card payment that the practice does not want to autopost as the provider declined to accept card payment and requested that a check is sent instead?
11. What are the net financial benefit of including information in an 835 ERA transaction about unwanted card payments to an average small medical practice? This calculation would require the facts mentioned above: percent of providers willingly accept card payments from health plans vs the cost to those that decline and request paper checks. What percent of providers would autopost card payments vs the percent that would choose to manually process 835 transactions as an 'exception' in order to post the payment according to GAAP, as the full payment was not received and the merchant fees need to stay on the patient's account as a patient liability.

Without providing this information, **CMS cannot accurately compute the costs as required in its regulatory impact analysis**, making its determination that the benefits outweigh the costs "arbitrary" and "capricious".

We appreciate the opportunity to provide our comments to NCVHS. If you have any questions, please do not hesitate to contact us.

Sincerely,

X_____

To: NCVHS Mail (CDC)
Subject: RFC on X12 and CAQH CORE Proposals

We are against the X12 proposed addition of the "card payments" remittance information to 835 ERA."

HL7 International

December 6, 2022

Jacki Monson, JD
Chair, National Committee on Vital and Health Statistics (NCVHS)
c/o Rebecca Hines, MHS
Executive Secretary, NCVHS
3311 Toledo Road
Hyattsville, MD 20782

Re: HL7 FHIR Standards for Electronic Attachments

Dear Ms. Monson,

Health Level Seven International (HL7®) and the HL7 Da Vinci Project, Fast Healthcare Interoperability Resources (FHIR®) Accelerator, wish to update the Committee regarding our recent advances in maturing FHIR Implementation Guides capable of supporting HIPAA mandated transactions including Prior Authorization and Electronic Attachments.

Over the past several years, NCVHS has hosted a number of presentations by HL7 and others describing the value of FHIR in advancing and modernizing capabilities underpinning interoperability objectives. Regulatory requirements such as the *21st Century Cures Act* (Public Law 114–255) and CMS Patient Access API Rules have accelerated adoption of FHIR APIs by Certified Health IT vendors and the payer community. Other federal entities including the Department of Veterans Affairs, the National Institutes of Health and the Centers for Disease Control have embraced FHIR in their interoperability and technology planning. This broad adoption will enable the healthcare community to bridge to the future. Collaborations between HL7 and other Standards Development Organizations (SDOs), including X12 and NCPDP, demonstrate the ability of FHIR to support current exchange standards during this evolutionary period.

During the August 25, 2021 NCVHS Subcommittee on Standards' Listening Session, HL7 and representatives from the Da Vinci Project highlighted efforts to develop and publish FHIR implementations guides to reduce the burdens of prior authorization processes and payer to payer data exchange. Over the past year, these Implementation Guides have undergone additional updates and balloting, with publication anticipated within the next 90 days. Notably, Da Vinci members' Regence and MultiCare Connected Care announced in October 2022 their production implementation of an EHR-embedded prior authorization process based on the Da Vinci Burden Reduction Implementation Guides (IGs). This collection utilizes FHIR application programming interface standards (APIs) and includes the following Implementation Guides:

- Coverage Requirements Discovery
- Documentation Templates and Rules
- Prior Authorization Support

In June 2016, NCVHS recommended the use of the HL7 CCDA standard which was, at that point in time, the most mature HL7 standard at play for clinical data exchange. Since then, FHIR maturation and adoption has increased

dramatically. In March 2022, the NCVHS recommended the publishing of the CMS Interoperability and Prior Authorization proposed rule, which includes the HL7 FHIR standard to support APIs to automate payer and provider prior authorization workflows. Additionally, NCVHS recommended that HHS adopt a standard for Electronic Attachments, without specifying a specific standard. NCVHS recommended regulatory flexibility to allow the use of FHIR standards along with X12 HIPAA adopted standards.

In July of 2022 after deliberation of input from public hearings, NCVHS submitted to the Secretary Recommendation 1:

> *"In the Committee's assessment, HHS needs to ensure that regulations allow multiple standards (i.e., one, two or three implementation guides or implementation specifications) to co-exist as they are tested and used by stakeholders to meet specific business needs and addressing gaps, while preserving ongoing use of widely used existing standards."*

The HL7 and Da Vinci community have supported this action in our previous verbal and written testimony. The industry will benefit from the use of FHIR based APIs for clinical data exchange, and believes there is ample progress to warrant the consideration of enabling FHIR alongside existing industry investments to move forward with the goal of enabling adoption of newer technologies.

We believe that these recommendations can be achieved using the Da Vinci Clinical Data Exchange FHIR Standard for Trial Use Version 2 Implementation Guide (CDex), which was balloted earlier this year. Publication of this guide is planned for Q1 2023. This guide defines a FHIR-based approach to support Electronic Attachments. The CDex guide leverages EHR based FHIR capabilities to automate the exchange of both solicited and unsolicited Claims Attachments as well as supporting requests for additional information not identified and exchanged during the initial prior authorization and quality measure exchange processes defined by other Da Vinci FHIR Implementation Guides.

HL7 is presently preparing responses to NCVHS' Request for Comment (RFC) on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules due on December 15. Additionally, HL7 has accepted the invitation to provide oral testimony at the January NCVHS hearing. However, the Unified Agenda indicates that HHS/CMS has submitted an Attachments Notice of Proposed Rulemaking (NPRM) for review by the Office of Management and Budget (OMB). While we have no knowledge of the specifics of the NPRM, we are deeply concerned that CMS may not identify the CDex Implementation Guide as a standard for Electronic Attachments, consistent with NCVHS' recommendations noted above.

If FHIR and the CDex IG are not named in the NPRM and request for feedback on CDex is not solicited by HHS/CMS proposed rulemaking**, we as an industry will miss a significant opportunity to build upon the FHIR foundations and existing investments noted above. This missed opportunity will have long lasting and costly repercussions on the patients, providers, government and commercial funders payers and the broader healthcare community.**

In addition to this letter, HL7 will consult with the other members of the Designated Standards Maintenance Organizations (DSMOs) in preparing a formal recommendation to NCVHS, which would identify the CDex standard. The present DSMO processes are in need of revamping, as recognized by NCVHS's 2018 predictability roadmap and industry engagement efforts. As part of our outreach to the DSMOs regarding this matter, we will also include a request for discussion of the ongoing consultation approaches and related memorandum of understanding.

The advancements in FHIR adoption over the past 11 years have established a foundation for a dramatic transformation of healthcare using open APIs, as has been achieved by other industries including travel, commerce and finance. As we enter a renewed period of regulatory activity and the long awaited integration of clinical and

administrative standards, it is imperative that we prioritize maturing these processes and ensuring all healthcare stakeholder understand the impact and how to engage across these activities. HL7's collaboration with other SDOs demonstrates the ability for the FHIR standard to work coherently with other established standards, which offers a strategy for healthcare to transition to a FHIR-based, API infrastructure. Improved patient care, reductions in clinician burden and increased administrative efficiencies can be achieved if HHS/CMS and the healthcare industry continue to move forward with FHIR adoption.

Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

Andrew Truscott
Board of Directors, Chair
Health Level Seven International

Cc:
The Honorable Xavier Becerra, J.D.
Secretary of Health and Human Services
200 Independence Avenue, S.W.
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The Honorable Chiquita Brooks-LaSure
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Aetna Inc.
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800-872-3862

December 16, 2022

Jacki Monson, JD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: RFC on CAQH CORE Proposal to NCVHS - 2022

Submitted electronically to NCVHSmail@cdc.gov

Dear Ms. Monson:

Aetna, a CVS Health business, is grateful for the opportunity to provide feedback to the National Committee on Vital and Health Statistics (NCVHS) on the proposed new and updated operating rules from the CAQH Committee on Operating Rules for Information Exchange (CORE). Aetna encourages NCVHS to recommend both the new and updated rules to the Secretary of the Department of Health and Human Services (HHS) for federal adoption.

Aetna is committed to providing individuals, employers, health care professionals and producers with innovative benefits, products, and services. As both the needs of healthcare consumers and the care support offered across the industry evolves, Aetna's business products and solutions advance to improve health and build healthy communities. The CAQH CORE Operating Rules set a new minimum standard for correspondence that is necessary to ensure progress not only for Aetna but also its trading partners to meet our vision of providing improved access to quality healthcare for all Americans.

Aetna was part of more than 100 organizations that participated in CAQH CORE's multi-stakeholder, consensus-based rule development process. The new and updated operating rules bring workflow improvement and enable further automation of processes to reduce overhead costs in alignment with current and emerging business needs. Aetna is dedicated to providing a high-quality experience to its over 24 million medical members and appreciates the benefits industry-wide adoption of the proposed rules will bring to its members and the broader healthcare ecosystem.

On Attachments specifically, Aetna is piloting the CAQH CORE Attachment Operating Rules to increase automation, conserve financial resources, and provide timely coverage decisions for our members. Aetna implemented unsolicited X12 275 attachment capabilities in late 2021 and implemented the requirements outlined in the CAQH CORE Prior Authorization Attachments Rules in 2022. The operating rules provide common infrastructure, data content, and connectivity requirements that establish consistent expectations for exchanging attachments. Thus far, we have exchanged over 76,000 X12 275 fully electronic attachments with select trading partners using the operating rules. Aetna is planning to work with CAQH CORE into 2023 to continue piloting the Attachments Operating Rules to collect and analyze the associated benefits.

To simplify and accelerate implementation across the industry, Aetna recommends that NCVHS recommend concurrent federal adoption of attachments standards and operating rules by HHS. Given our experience piloting the Attachments Operating Rules, we understand firsthand how complementary implementation of standards and operating rules drives automation across the Attachments workflow.

Thank you for the opportunity to share feedback. Aetna reiterates its support that NCVHS recommend federal adoption of the proposed new and updated CAQH CORE Operating Rules to HHS. Please do not hesitate to reach out with questions.

Sincerely,

Scott Waller
Vice President, Information Technology
Aetna, Inc.

From: Terrie Reed
To: NCVHS Mail (CDC)
Subject: Public Comment on X12 updates
Date: Wednesday, January 18, 2023 2:59:08 PM

Symmetric Health Solutions (Symmetric) offers data management products for all medical supplies found in hospitals, including implants, instruments, biologics, in vitro diagnostics, biomedical equipment, durable medical equipment, and pharmaceuticals. Symmetric submitted public comments to the NCVHS Request for Comment dated October 26, 2022. After listening today to requests to identify the value of adopting the recommended updates from X12, I would like to highlight that after over 20 years of including the National Drug Codes (NDCs) on medical claims we all have empirical evidence that identifying the specific drug used on a patient not only increases the ability to obtain more accurate payment and better management of drug costs based on what was administered and billed but that this data is being extensively used by the research community - clinical trials, government research, to monitor and respond to safety concerns, Since the UDI-DI is an ID for devices similar to the NDC for drugs, we believe that not including UDI-DI in claims data has opportunity costs that can be directly correlated to the benefits obtained for drugs. These costs include decreases in the ability to obtain more accurate device payment information, worse management of device costs and a lack of device data that could be used to monitor and respond to safety concerns We believe that the same patient safety and administrative benefits for drugs should be afforded to devices use in the care of the millions of patients that receive implanted medical devices. The addition of UDI to claims is, in fact, long overdue, given that UDI now appears on the label of implantable devices, hospital inventory systems are routinely capturing UDI, and EHR vendors are now certified to capture the UDI for implantable devices,

Thank you for allowing us to provide this additional comment.

Terrie L. Reed

Chief Strategy Officer

Symmetric Health Solutions LLC

240-476-4076

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Visit us: symmetrichealthsolutions.com