Subcommittee on Standards

Meeting Summary

August 25–26, 2020

National Committee on Vital and Health Statistics (NCVHS)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

This meeting summary report was written by NCVHS consultant Jill W. Roberts, MS, and colleagues at Rose Li and Associates, Inc., in collaboration with NCVHS members and staff.

NCVHS Members and Staff in Attendance

Alexandra (Alix) Goss, Subcommittee Co-chair*
Richard W. Landen, MPH, MBA, Subcommittee Co-chair*
Tammy Feenstra Banks, MBA*
Denise Chrysler, JD
James (Jim) Cimino, MD*
Nicholas L. Coussoule*
Jamie Ferguson*
Melissa M. Goldstein, JD
Denise E. Love, BSN, MBA*
Vickie M. Mays, PhD, MSPH
Frank Pasquale, JD
Margaret A. Skurka, MS, RHIA, CCS, FAHIMA*
Debra Strickland, MS*
Wu Xu, PhD

*Member of the Subcommittee on Standards

Lorraine Tunis Doo, MPH
Lead Staff to the Subcommittee on Standards
Centers for Medicare and Medicaid Services (CMS), HHS

Rebecca Hines, MHS
NCVHS Executive Secretary/Designated Federal Officer
Health Scientist
NCHS, CDC, HHS

Marietta Squire
Committee Management Specialist
NCHS, CDC, HHS

See Appendix B and C for complete lists of meeting participants.

NCVHS—The National Committee on Vital and Health Statistics

NCVHS serves as the advisory committee to the Secretary of Health and Human Services (HHS) on health data, statistics, privacy, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C. 242k[k]). The Committee also serves as a forum for interaction with interested private-sector groups on important health data issues. Its membership includes experts in health statistics, electronic interchange of health care information, privacy, confidentiality, and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. The HHS Secretary appoints 16 of the 18 committee members to 4-year terms. Two additional members are selected by Congress. The NCVHS website provides additional information at ncvhs.hhs.gov.

Issued October 2020

Table of Contents

Meeting Overview

The NCVHS Subcommittee on Standards monitors and makes recommendations to the Full Committee on health data standards and associated areas of focus, including operating rules and interoperability. In fulfillment of these charges, on August 25–26, 2020, the Subcommittee on Standards held a virtual meeting to hear testimony on three newly proposed operating rules. This report summarizes the meeting.

Over the 2-day period, invited patient representatives, health care providers, health plans, vendors, and clearinghouse representatives provided testimony for consideration by Subcommittee and Full Committee members to support consideration of recommendations to the HHS Secretary. The testimony is described below and will be considered alongside submitted public comments.

See Appendix A for agenda, Appendix B for the roster of invited speakers, Appendix C for audience attendees, and Appendix D for a list of acronyms used. All resources from the meeting are available on the NCVHS website at https://ncvhs.hhs.gov/meetings/standards-subcommittee-meeting-2/.

Background Information

As an introduction, the following subsections include an explanation of operating rules and electronic data interchange (EDI) transactions, an overview of the meeting, and a description of the role that the Council for Affordable Quality Healthcare, Inc. (CAQH) plays in developing and proposing operating rules to NCVHS for consideration.

Explanation of Operating Rules

Operating rules were federally mandated as a part of the Patient Protection and Affordable Care Act (ACA) of 2010. They are officially defined as "the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications." Each electronic exchange of information is called a transaction.

HIPAA-covered entities and business associates that engage in HIPAA standard transactions on behalf of covered entities must adhere to all operating rules which apply to both financial and administrative transactions if they are adopted by the Secretary. Ideally, operating rules improve the utility of existing HIPAA standard transactions, reduce administrative costs, specify the information that must be included in each transaction, and make it easier for providers to use electronic means to handle administrative transactions.

The ACA requires the Secretary of the Department of Health and Human Services (HHS) to adopt and regularly update standards, implementation specifications, and operating rules for the electronic exchange and use of health information.

278 Transactions

Standards development organizations are industry-based organizations that develop and publish industry specific standards. The standards development organization (SDO) known as X12, develops and maintains standard transactions for the exchange of administrative and financial information for several industries, including healthcare. These transactions are referred to as Electronic Data Interchange (EDI) transactions. X12's Insurance Subcommittee (X12N) develops and maintains standard transaction for health care, such as eligibility, enrollment and claims. One of these transactions is called "Health Care Services Review—Request for Review and Response Version 5010, X12 278. This transaction establishes the rules and requirements for requesting authorizations from a payer, such as an insurance company. Industry professionals refer to this transaction as a "prior authorization (PA) request," a "278 transaction," or more simply a "278." Another EDI transaction set that is referenced in this report is the "Patient Information Specifications," Version 5010 X12 275, also referred to as "additional patient information" or "attachments".

The Role of CAQH CORE

CAQH is a collaborative nonprofit alliance of health plans and related associations with a mission to accelerate the transformation of business processes for health care stakeholders through collaboration. In their presentation, they indicated that they seek to develop and lead initiatives that positively impact and streamline the business of health care.

CAQH's Committee on Operating Rules for Information Exchange (CORE) includes 110 organizations representing health care providers, health plans, vendors, government entities, associations, and standard-setting bodies. CAQH CORE seeks to engage the health care industry in developing, recommending, and adopting consistent business processes. CORE-participating health plans represent 75% of the privately insured population of the United States.

HHS has designated CAQH CORE as an Operating Rules Authoring Entity (ORAE) to develop operating rules to complement HHS-adopted standards and implementation guides for HIPAA-covered administrative transactions. CAQH CORE efforts are focused on developing operating rules that remove unnecessary cost and complexity from the health care industry.

Welcome and Call to Order

To open the meeting on Tuesday, August 25, NCVHS Executive Secretary Rebecca Hines welcomed new Subcommittee members and called roll. Subcommittee Co-Chair Alix Goss reviewed the agenda, reminded attendees that the patient was central to the discussion, and described the process for the hearing. The meeting's objective was to enable members of the Subcommittee on Standards to hear testimony to inform the decision whether to recommend that NCVHS advise the HHS Secretary to adopt the proposed CAQH CORE operating rules.

Subcommittee Co-chairs Alix Goss and Richard Landen presented information describing HHS's authority to adopt operating rules and the process for initiating and conducting the operating rules hearing.

HHS Authority to Adopt Operating Rules

When ACA became law in 2010, it amended the HIPAA statute and required the HHS Secretary to authorize adoption of operating rules for each standard transaction. Congress assigned the role of advising and recommending operating rules for adoption to NCVHS and asked NCVHS to perform the following tasks:

- Advise the Secretary as to whether a nonprofit entity meets the requirements to serve as an authoring entity for operating rules;
- Review the operating rules developed and recommended by the nonprofit entity;
- Determine whether operating rules represent a consensus view of the health care stakeholders and are consistent with and do not conflict with other existing standards;
- Evaluate whether such operating rules are consistent with electronic standards adopted for health information technology; and
- Submit to the Secretary a recommendation as to whether the Secretary should adopt such operating rules.

NCVHS has recommended (and HHS has adopted) operating rules for the following standard transactions: eligibility and claim status, electronic remittance advice (ERA), and electronic funds transfer (EFT). The regulations to adopt and mandate these operating rules were published in 2011 (*Federal Register* 76, p. 40458) and 2012 (*Federal Register* 77, p. 1556), respectively.

In February 2015 and 2016, NCVHS reviewed proposed operating rules for health plan enrollment/disenrollment, premium payment, prior authorization, and claims. NCVHS did not recommend adoption because the value was unclear for the level of effort needed. Instead, NCVHS strongly supported their voluntary use.

Request to Review New Operating Rules

In February 2020, NCVHS received a letter from CAQH CORE requesting review of three new operating rules. Two of the proposed operating rules would support the X12 278 implementation guide's prior authorization standard transaction, and one proposed operating rule would address connectivity and essentially impact all of the adopted HIPAA X12 standard transactions.

NCVHS requested industry input through a *Federal Register* Notice, outreach to covered entities asking for written testimony, and invitations to payers, providers, vendors, clearinghouses, and other stakeholders to participate virtually in this hearing.

Evaluation Strategy for the Proposed Operating Rules

Prior to the hearing, the Standards Subcommittee developed the general evaluation framework and evaluation criteria for reviewing the proposed operating rules. This framework included the following considerations:

- Element 1: Does the proposed operating rule conform to the requirements of the legislation?
- Element 2: Does the proposed operating rule reduce burden?
- Element 3: Will the U.S. health care system be better off with the proposed operating rule to an extent that exceeds the cost of development and/or implementation, i.e., does the rule provide value?

After hearing stakeholder testimony, Subcommittee members will consolidate and analyze all of the written and oral input from stakeholders. The Subcommittee will then deliberate, draft its recommendations, and present the recommendations to the Full Committee. The Full Committee will finalize the recommendations and send them to the HHS Secretary.

All background resources, including questions for commenters and written public comments are posted on the NCVHS website at https://ncvhs.hhs.gov/meetings/standards-subcommittee-meeting-2/.

Process for the Hearing

To prepare for the hearing, Subcommittee members reviewed all written testimony. The Subcommittee asked all oral presenters to follow a themed template that included the anticipated value of the proposed operating rules, the anticipated concerns about the proposed operating rules, and the top three to five points for NCVHS to consider when making its recommendations to HHS for adoption of the proposed operating rules. Presenters were asked to limit their comments to 7 minutes each. Subcommittee members asked questions at the end of each group of presentations.

Administrative Simplification, Education, and Enforcement

Daniel Kalwa, a Policy Advisor in the Centers for Medicare & Medicaid Services (CMS)'s National Standards Group, presented a brief overview of how CMS oversees the adoption of HIPAA standards under administrative simplification and provides education and enforcement activities for operating rules. He provided history for how operating rules came into existence to reduce burden and costs and described how ACA specified the role of the HHS Secretary and NCVHS in this area.

Daniel provided the criteria for establishing an operating rule entity (e.g., CAQH CORE), outlined the mandated NCVHS review and selection process for operating rules, and confirmed that the Subcommittee is following the requirements outlined by the Secretary. He noted that more than 20 operating recommended by NCVHS have been adopted by the Secretary and that some exceptions to the operating rule requirements do exist. Actions that require rulemaking include changing the version of operating rules specified, changing the phrase structure referenced in current regulations, and removing the existing exception.

The CMS National Standards Group can be reach via email at administrative.simplification@cms.hhs.gov.

A committee member asked whether an operating rule can be used on a voluntary basis by a covered entity if no regulation exists for that operating rule. Daniel Kalwa replied "yes," if no standard or operating rule is adopted in a regulation, then covered entities are free to use whatever they would like.

Description of Newly Proposed Operating Rules, Their Development Process, and Impact

Representatives from CAQH CORE, April Todd (Senior Vice President), Susan Turney (Immediate Past Chair), and Tim Kaja (Current Chair), presented slides to provide a brief background on CAQH CORE, a detailed description of the complex process involved in developing the newly proposed operating rules, and an overview of the significant impact that adopting the proposed operating rules would have on the health care industry.

Prior Authorization (278) Data Content Rule v5.0.0

The CAQH CORE Prior Authorization (278) Data Content Rule v5.0.0 was formally approved and adopted by CAQH CORE in May 2019 and applies to the conduct of the 5010 X12 278 Request and Response. This proposed operating rule addresses one of the most significant problem areas in the prior authorization process—requests for medical services that are pended due to missing or incomplete information—by giving health plans a more robust electronic means to communicate with providers about missing clinical information and documentation. Specifically, the rule:

- Enhances and standardizes the data shared between plans and providers, eliminating unnecessary back and forth and therefore enabling shorter adjudication time frames and fewer resources spent on manual follow-up.
- Specifies information needed for patient identification and communication of error/action codes.
- Enables a health plan to clearly communicate next steps in the prior authorization process, including what additional documentation is needed through Logical Observation Identifiers Names and Codes (LOINC) and/or paperwork (PWK) codes.
- Enables consistent and uniform use of Health Care Service Decision Reason Codes (HCSDRCs), to limit ambiguity and enhance electronic communication.
- Applies to procedures, laboratory testing, medical services, devices, supplies, and medications within the medical benefit.

The full text for this operating rule can be found at: https://www.caqh.org/sites/default/files/core/Prior-Authorization-Referrals-278-Data-Content-Rule.pdf.

Prior Authorization (278) and Referrals Infrastructure Rule v4.1.0

The Prior Authorization (278) Infrastructure Operating Rule v4.1.0 was updated in January 2020 and includes requirements for system availability, acknowledgements, companion guides, and response times for the 5010 X12 278 Request and Response. Specifically, the rule:

- Sets a minimal amount of time that systems must be available to receive and send data (86% per calendar week), and the ability to track and report system downtimes.
- Requires use of acknowledgements to ensure the transaction has been received, has not been lost between entities, and will be addressed.
- Lays out a common format that entities must use when providing information about their proprietary data exchange systems via "companion guides."
- Sets a maximum response time requirement of two business days for a health plan to request any information/clinical documentation from a provider.
- Sets a maximum response time requirement of 2 business days for a health plan to send a final determination, once all requested documentation has been received.
- Requires compliance with maximum response times for at least 90% of non-urgent/non- emergent prior authorizations within a calendar month.
- Provides for an optional response time requirement of 15 business days for a health plan to close out a prior authorization request if documentation requested from a provider has not been received.

The full text for this operating rule can be found at: https://www.caqh.org/sites/default/files/core/Prior-Authorization-Referrals-278-Infrastructure-Rule.pdf.

Connectivity Rule v4.0.0

As a result of HHS's federal mandate of the CAQH CORE Connectivity Rules v1.1.0 and v2.2.0 in 2013, a large industry-installed base of these connectivity rules exists among HIPAA-covered entities that exchange administrative transactions. The CAQH CORE Connectivity Rule v2.2.0 includes requirements for the message envelope, corresponding envelope metadata, vocabularies and semantics, real-time and batch processing modes, authentication, and transport security. The CAQH CORE Connectivity Rule v4.0.0 updates the CAQH CORE Connectivity Rule v2.2.0 to improve security and simplify interoperability across administrative transactions. Specifically, the proposed operating rule:

- Reduces complexity and simplifies interoperability by requiring a single Simple Object Access Protocol (SOAP) plus a Web Service Definition Language (WSDL) envelope standard versus two envelope standards.
- Establishes uniform support for handling transaction payload by requiring a Message Transmission Optimization Mechanism (MTOM) for SOAP for both real-time and batch processing modes.
- Improves security by requiring use of X.509 Client Certificate–based authentication and removing the ability to authenticate via only a username plus password.
- Provides support for Federal Information Processing Standard (FIPS) 140-2 compliance for entities requiring such compliance, in terms of transport security and message envelope security.
- Provides support for additional transactions relative to the previous rules, including prior authorization in addition to eligibility, claim status, and ERA.

To support the industry in applying a single connectivity safe harbor across all HIPAA transactions aligned with industry best practices, CAQH CORE proposes that the new/updated CAQH CORE connectivity rule v4.0.0 replace the current requirements for CAQH CORE Connectivity Rules v1.1.0 and v2.2.0 in the federally mandated CAQH CORE eligibility, claim status, and ERA infrastructure operating rules, as well as for the prior authorization (278) infrastructure operating rule.

CAQH indicated that implementation of the CAQH CORE Connectivity Rule v4.0.0 would be voluntary for health care claims, premium payment, and benefit enrollment and maintenance transactions. A single connectivity rule across all transactions that can be updated over time would eliminate industry confusion and barriers to adoption and would ensure industry alignment on best practices. Should the CAQH CORE Connectivity Rule v4.0.0 be federally mandated across these transactions, CAQH CORE would sunset the CAQH CORE Connectivity Rules v1.1.0 and v2.2.0.

The full text for this operating rule can be found at: https://www.caqh.org/sites/default/files/core/Connectivity-Rule-vC310.pdf.

Subcommittee members asked about the implications or consequences of the proposed operating rules in light of other standards, new technologies, or new security approaches becoming available for prior authorization. The CAQH CORE representatives said that although the field will certainly evolve, it is important to start in a stepwise fashion to create common expectations around certain aspects of transactions (e.g., data content for prior authorization, response times). Furthermore, waiting for implementation of these rules could place additional burden on patients to make them wait for the functionality.

Testimony on Proposed Prior Authorization Operating Rules

Testimony on the proposed prior authorization operating rules was provided by one standards organization, one patient organization, four health plans, six provider organizations, and four vendors/clearinghouses.

Standards Development Organizations Perspective

X12 provided testimony on the three proposed operating rules with specific comments on the prior authorization data content operating rule.

X12

The X12 organization develops standards for business-to-business electronic information exchange. Standardizing electronic transactions allows efficient and effective communication between business partners. X12 developed and currently maintains the non-pharmacy administrative transactions adopted under HIPAA, including the standard addressed by the current operating rule for requesting review and response [i.e., 005010 X12 278 Health Care Services Review—Request for Review and Response (278) implementation guide]. The proposed prior authorization data content rule was developed to support and enhance this operating rule. While presenting slides, Cathy Sheppard said that X12 has a cooperative, collaborative, and supportive working relationship with CAQH CORE and highly values its outputs.

With regard to data content operating rules, X12 supports rules for mandated transaction sets that:

- Align with the purpose of the underlying standard or implementation guide.
- Do not contradict or countermand the instructions defined in the mandated standard or implementation guide.
- Pilot potential data content or data use revisions so that corresponding revisions can be considered for inclusion in a future version of the underlying standard or implementation guide if the operating rule resulted in confirmed, measurable improvements in patient care, provider workflow, automation, efficiency, or consistency, an increase in the use of transactions, or a cost reduction.

With regard to infrastructure operating rules, X12 supports rules that:

- Consider and balance the diverse interests of the stakeholders represented in the health care industry.
- Increase consistency across the implementation base.
- Demonstrate a measurable positive impact based on proven tangible value and realistic implementation costs.
- Do not address data content or data use defined within a mandated transaction or implementation guide.

With regard to connectivity operating rules, X12 supports rules that:

- Consider and balance the diverse interests of the stakeholders represented in the health care industry.
- Increase consistency across the implementation base.
- Demonstrate a measurable positive impact based on proven tangible value and realistic implementation costs.
- Set a technology floor, not a technology ceiling.
- Do not address data content or data use defined within a mandated transaction or implementation guide.

With this background in mind, X12 made the following comments on the newly proposed operating rules:

Rule	Comment	Additional Notes
Prior Authorization Data Content Rule	X12 generally supports, but also submitted written testimony on specific aspects of this proposed operating rule.	Refer to public comments for details on elements of the proposed rule. See p 170-172 of public comments: https://ncvhs.hhs.gov/wp-content/uploads/2020/09/Public%20Comments-CAQH%20CORE%20Operating%20Rules%20for%20Federal%20Adoption-August%202020.pdf
Prior Authorization and Referrals Infrastructure Rule	X12 is neutral on this proposed operating rule.	None
Connectivity Rule	X12 is neutral on this proposed operating rule.	None

If the proposed prior authorization data content operating rule moves forward as a federal mandate, X12 will work closely with CAQH CORE to assess and evaluate any statistical improvements in patient care, provider workflow, automation, efficiency, or consistency; any increases in the use of the standard for electronic prior authorizations; or any cost reductions based on the implementation of this data content operating rule. X12 will also present simple cross-referenced instructions to ensure that implementers understand any modifications required to implement the mandated standard based on the proposed operating rule and will present education on the intersection of the mandated standards and mandated operating rules to assist health care industry stakeholders.

When asked about future projects that X12 has in development, Ms. Sheppard responded that the organization intends to propose updated implementation guides in the coming months to be considered for adoption in 2021. Revisions to existing standards will specify any affected or impacted operating rules, and NCVHS may have to address timing considerations.

Patient Perspective

One patient organization provided testimony on the proposed prior authorization operating rules.

Arthritis Foundation

To provide the patient perspective, the Vice President of Advocacy and Access at the Arthritis Foundation, Anna Hyde, presented slides to describe how the proposed operating rules might affect patients with a chronic degenerative disease that must be managed.

The Arthritis Foundation collects a large amount of patient experience data. Each year, benchmark surveys have shown prior authorization as the top health care challenge. For patients, managing prior authorization is a large part of their administrative burden, because 48% of those surveyed spend more than 5 hours per month and 17% spend more than 15 hours per month managing their health coverage. The Arthritis Foundation's focus groups have shown across-the-board frustration with the complexity of the health system, its constant policy changes, and unclear communication. The prior authorization process causes stress and anxiety, treatment delay, therapy abandonment, and administrative-driven decision making.

When asked about prior authorization, one focus group patient said, "My physician decided the biologic medication I was on was not working. It took over six weeks before a new biologic was approved. The pain level required I return to prednisone, which causes other issues, such as weight gain, thinning of bones, interrupted sleep, and higher blood glucose levels. I ended up needing a painful procedure to reduce the buildup of fluid in my knee. I can't help but think if I had gotten the new medication approved sooner, I would have been able to avoid this painful procedure."

The Arthritis Foundation worked with the American Medical Association and other provider groups to establish 21 prior authorization principles, including the following:

- Establish a single, standardized form for physicians to submit prior authorization requests.
- Establish electronic systems for the submission of prior authorization requests.
- Require completion of prior authorization requests by insurers within 48 hours of submission or receive automatic approval.
- Once approved, permit authorizations to remain in place for up to 12 months for people with chronic conditions, such as rheumatoid arthritis.
- If a prior authorization request is denied, the member must be given clear instructions on how to file an appeal, the information required, and deadlines.
- Provide a process for expedited appeals, especially for urgent care services.
- Health plans should offer providers/practices at least one physician-driven, clinically based alternative to prior authorization, including but not limited to "gold-card" or "preferred provider" programs or attestation of use of appropriate use criteria, clinical decision support systems, or clinical pathways.

Overall, patients want a streamlined process with online tracking capability through an online portal for filing and managing claims. This capability would reduce the administrative burden for both patients and providers. Patients

also want faster response times, especially for drugs that they are already taking, and transparency about the process from beginning to end. A response to a prior authorization request should be measured in hours, not days. Furthermore:

- 95% of survey respondents want to know which medications will require prior authorization *before* it is prescribed.
- 75% of survey respondents want transparency every step of the way, not just when a service is approved or denied.
- Patients want relevant contact information and a step-by-step process on how to file an appeal.
- Patients want clear, reasonable explanations for denials.

In response to a question about the 48-hour prior authorization decision time, Anna Hyde said that patients in urgent care settings who take complex biological medications can suffer major setbacks when their care is interrupted. The Arthritis Foundation would prefer either an immediate response or a response within 24 hours for an urgent prior authorization request.

In response to a question about how prior authorization operating rules can most help patients, Anna Hyde said that any operating rule that allows a patient to remain continuously stable on therapy is helpful. She also advocated for continuity and standardization across all health plans nationwide.

Several Subcommittee members noted the amount of time that patients spend managing their health care coverage. One member suggested that patient time, monitoring, and management should be considered when adopting standards, their underlying transactions, code sets, and implementation guides in the future.

In response to a question about whether patients are spending time obtaining prior authorization for medications, laboratory tests, or other procedures, Ann Hyde said that the Foundation has not collected data on the exact breakdown of services. However, time spent is for all types of management, not solely prior authorization. In addition, the time spent may be for reporting on behalf of multiple family members.

Health Plan Perspective

Four health plans provided testimony on the proposed prior authorization operating rules.

Anthem

Christol Green, Anthem's E-Solutions Portfolio Manager, showed slides to describe Anthem's efforts to improve its prior authorization process and shared concerns about the proposed prior authorization operating rules.

Anthem removes prior authorization requirements for certain services, when appropriate, to reduce administrative costs and burdens and to deliver on its mission to simplify health care. Anthem regularly updates its processes and criteria to recognize emerging evidence and new technologies. By promoting safe and effective care for patients, Anthem ensures that providers' choices of drugs, medical procedures, treatments, and services for patients are founded on the latest evidence-based, peer-reviewed literature and guidelines. Ensuring patients do not receive unnecessary tests and treatments (based on the latest medical evidence), particularly early in the diagnostic process for a condition, lowers patients' out-of-pocket costs and avoids potentially harmful over-treatment. Promoting information sharing between the provider and the health plan creates opportunities for the health plan to improve care management and coordination. Anthem has several examples of its efforts to improve the overall care provider experience with prior authorization.

Anthem's anticipated concerns about proposed operating rules relate to connectivity, data content, infrastructure, and appropriate implementation timelines and include the following points:

- Maintaining multiple platforms to accommodate entities in various stages of implementation is burdensome. All stakeholders, regardless of size, should have 24 months of implementation time to operate under new rules.

- Adding standards to an outdated process does not generate meaningful change to the prior authorization process. Anthem recommends that NCVHS adopt a standards adoption process that moves forward on a continuous basis, bringing all stakeholders along at the same time.
- Regarding the X12 278 transactions:
  - The ability to request and receive supporting documentation electronically is critical for an effective workflow. The lack of adoption of attachment regulations leaves the industry with an incomplete prior authorization process.
  - Some payers and providers will need to manually request and submit supporting documentation as needed follow-up. Health care systems and their applications are at varying levels of adoption and maturity required to support these critical business functions and technical workflow.
  - Operating rules do not address turnaround times for current business processes that are not conducted electronically end-to-end.
- Regarding data content:
  - The ownership of data content requirements and usage is the sole responsibility of the standard development organization and not the operating rule–authoring entity.
  - Rules regarding data content should be communicated via data specifications or implementation guides created from the industry-approved standards development organization (SDO) process. Data content rules created outside of an SDO create confusion and inconsistency in health care electronic data interchange standards deployment.
  - HIPAA security and the federal Health Information Technology for Economic and Clinical Health (HITECH) Act rules cite the National Institute of Standards and Technology as the authoritative industry source, not the operating rule–authoring entity.
  - Connectivity rules created outside of and divorced from the National Institute of Standards and Technology standard guides/specifications create confusion and disparity in health care electronic data interchange standards deployment.
- The proposed connectivity rule limits the inclusion of new and emerging technologies [e.g., Fast Healthcare Interoperability Resources (FHIR), extensible markup language (XML) via web portal, representational state transfer (RESTful) application programming interfaces (APIs), OAuth authorization framework, security assertion markup language (SAML) authorization, and identity services platforms].
- Web portal operating rules discourage adoption of HIPAA electronic transaction standards.
  - Web portals are utilized in the industry as a bridge strategy for low-tech providers and lack of industry adoption and maturity of electronic data interchange automation.
  - Operating rules regarding payer portals, such CAQH CORE's Prior Authorization and Referrals Web Portal Rule vPA.1.0, are not aligned with the goals/requirements of HIPAA administrative simplification provisions and are burdensome and costly to providers.

Anthem's top points for NCVHS to consider when making its recommendations to HHS for adoption of the proposed operating rule(s) are as follows:

- Anthem has long been an early adopter of CAQH rules and will continue to work and participate with CAQH CORE and other SDOs to improve the prior authorization process.
- Require all stakeholders, regardless of size, to move to new rules at the same time and allow at least 24 months for implementation.
- Adopt the connectivity rule only if it is adopted across all transactions for which operating rules are in place, eliminating the possibility of a requirement to implement and support regardless of usage or solutions currently in place.
- Address inconsistencies in the data content rule provisions.
- Afford stakeholders the flexibility to use newer business technologies that allow for a more efficient communication exchange between the clinical staff and the health plan.

Kaiser Permanente

Cathy Plattner, Kaiser Permanente's Business Consulting Specialist, showed slides to provide testimony on the proposed prior authorization operating rules. Kaiser Permanente is the largest private integrated health care delivery system in the United States. It serves 12.4 million members in eight states and the District of Columbia.

Overall, Kaiser Permanente supports the adoption of the proposed operating rules for prior authorization data content and infrastructure, as well as for the overarching connectivity rule (which would apply to all other operating rules before).

Cathy Platter described Kaiser Permanente's anticipated concerns. Regarding the prior authorization data content rules set, new operating rules may overlap or override X12's Technical Report 3 implementation guide requirements that are included in the X12 278 implementation guide. Previous experiences with implementing new operating rules have been both positive and negative. Some required multiple implementations. Testing tools have been helpful, especially when extensive testing was required. Operating rules on data content should be incorporated progressively until they become stable and widely used. For the infrastructure rules set, Kaiser Permanente sees no issues with the response time limits for the various submission and response requirements because its processes are fully automated, but others might. The connectivity rules set does a good job at increasing the security of transactions; however, Kaiser Permanente raises two main concerns:

- CAQH CORE proposes to replace older versions of the connectivity rule, but new operating rules have already been adopted with specific connectivity processes. Therefore, a clear roadmap and well-defined cost-benefit analysis are needed.
- Some of the technology standards noted as acceptable in the proposed connectivity operating rule are already outdated (e.g., SSL 3.0 transport standards), which may present a safe harbor issue.

Kaiser Permanente's top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed operating rule(s) are as follows:

- Kaiser Permanente recommends that NCVHS and regulatory bodies consider pursuing increased voluntary adoption of standards through the use of appropriate program incentives and policy levers.
- Kaiser Permanente is concerned about the degree to which the operating rules can be implemented in a scenario where HL7's FHIR standards are used.
- Kaiser Permanente supports a HIPAA exception to allow end-to-end implementation testing of a FHIR-based transaction model for HIPAA transactions, including prior authorization and other real time transactions.

Medicare Fee-for-Service

Connie Leonard, from CMS's Center for Program Integrity, discussed Medicare's fee-for-service perspective on the proposed prior authorization operating rules. Medicare has limited statutory authority in this area, and its services are packaged. CMS supports attempts to streamline the prior authorization process to make it easier for everyone: payors, providers, beneficiaries, and patients. However, the operating rules may have unintended consequences for the CMS fee-for-service program. When CMS receives a prior authorization request, it performs a full medical record review before returning a decision. It is similar to a prepayment or post-payment review before the service is provided. A limited number of cases are moved forward.

CMS uses prior authorization as a program integrity tool to ensure that the right services are being provided to beneficiaries at the right time. The CMS prior authorization requests are typically non-urgent and for services that require a lead time (e.g., for elective surgery, durable medical equipment, prosthetics). CMS allows its contractors to take 10 days to decide, and the usual response time is within 5 days, which raises concerns about the 2-day timeline specified in the proposed operating rule. Although most prior authorization requests are non-emergent, CMS does allow providers to make expedited requests when necessary. This system has worked well for fee-for-service. When establishing new prior authorization requirements, CMS works with industry partners to obtain feedback. This practice has led to removal of codes that might be considered emergent.

With appropriate training, the prior authorization process becomes smoother for providers after the first 2 months. Most Medicare-authorized providers use the online portal for this process, but some are still using facsimile machines and paper copies sent through the U.S. mail. Although the fee-for-service office has the capacity for 278 compliance using an electronic submission and medical documentation (ESMD) process, no providers have yet used that system.

CMS has been listening to providers' feedback on the prior authorization process. They do not see a "one size fits all" solution for obtaining prior authorization. Some exceptions may be necessary, and with variable parameters, especially concerning the proposed implementation timeline.

Blue Cross Blue Shield Association (BCBSA)

Gail Kocher, BCBSA's Director of National Standards, discussed the health plan perspective as a representative of 36 community-based, locally operated Blue Cross and Blue Shield companies. These companies provide health plans for one in three Americans. BCBSA has processed an average of 150 million transactions each month of this year. Two-tenths of 1% of the transactions are the 278 request and response transactions, and as many as 95% are for eligibility.

In general, BCBSA supports operating rules that support and supplement the implementation of standards developed by the standards organizations. Operating rules should not replace what is contained in implementation guides.

BCBSA believes that the proposed operating rules will likely increase the reliability and performance of data exchange without affecting the data content of the standards. However, the proposed operating rules will likely increase administrative costs for health plans and for health care providers. As currently published, these operating rules are unlikely to add value to the current workflows. Some BCBSA health plans have already automated prior authorization, and these may be negatively impacted by the timeline requirements of the proposed operating rules. The health plans would need to conduct significant systems analyses to determine whether the automated systems could be revamped to meet the 20-second real-time turnaround requirement.

BCBSA's top points for NCVHS to consider in its recommendations to HHS for adoption of proposed operating rule(s) are as follows:

- Health plans continue to seek solutions to improve the prior authorization process, including the flexibility to use new technologies for exchanging information (e.g., FHIR, XML, Web Portal). Newer technologies accommodate the need for the more iterative processes required by prior authorization.
- Real-world testing with all stakeholders is needed to document the possibility of implementing the proposed operating rules in the designated time frames.
- Adoption of the proposed operating rules is unlikely to increase adoption of the 278 prior authorization transaction. The low volume of providers using the 278 transaction creates a low value proposition for implementation. The barriers to adoption are the complexity of the transaction and the lack of an attachment standard. Adoption rates might increase when a health plan attachment standard is adopted.
- A reasonable cost-benefit analysis with detailed project planning, analysis, and review should be conducted. BCBSA would be happy to work with NCVHS and CMS to develop a set of data points on which to conduct such analysis.

Health Plan Q&A

A Subcommittee member asked whether the proposed prior authorization operating rules provide an intermediate step along the path toward a major improvement in reducing the complexity, improving timelines, and improving the experience of the patient, provider, and payor. Christol Green said that the proposed rules do not necessarily remove the administrative burden for patients because the interaction is primarily between the health plan and the provider. Anthem is developing patient portal capabilities to provide transparency, and considers parts of the proposed operating rules as outdated and requiring a large number of manual processes. Other types of workflows might be more efficient and modern. Anthem also has a prior authorization pilot program to internally streamline the process. Cathy Plattner said that Kaiser Permanente's integrated model already uses automated workflows, and the rule does not address interactions with outside trading partners (e.g., emergency rooms or immediate care clinics).

A Subcommittee member asked whether national adoption of the proposed operating rules is important enough to compete for resources in these challenging times. Cathy Plattner confirmed that resource use is a concern for Kaiser Permanente, especially because it has utilized all resources to support a recent rule on interoperability.

Christol Green agreed and added that Anthem is also implementing interoperability and other rules and moving forward to allow its providers to exchange information electronically.

A Subcommittee member asked Kaiser Permanente about a comment on end-to-end testing. Cathy Plattner said that Kaiser Permanente supports the use of FHIR-based transactions because they work seamlessly with the Epic electronic health record (EHR) system. Kaiser added that they strongly support the need for an external entity, such as Da Vinci, to submit a request for a HIPAA exception from current regulations that mandate the use of the 278 for prior authorization. In this way, industry could implement end-to-end testing for alternative standards (e.g., HL7 FHIR) for prior authorization.

A Subcommittee member asked to what degree the exchange of electronic clinical information is a prerequisite for a better or more successful 278 update. Connie Leonard (Medicare FFS) responded that the availability of more electronic clinical information might increase its use, but many stopping points remain and many providers still do not use EHRs. Gail Kocher (BCBSA) added that prior authorization tends to be a conversational process with give-and-take or a back-and-forth exchange of information from the medical record. Adoption of standard for health claim attachments and use of other new technologies could achieve this type of exchange, but stakeholders are not in the same place with respect to new technologies.

Because the X12 278 transaction is used only a small fraction of the time when prior authorization is needed, a Subcommittee member asked what proportion of that unmet potential could be achieved by adopting these proposed operating rules. Connie Leonard said that adoption would not move the needle from the fee-for-service perspective, because no providers choose to use the 278 transaction. She added that attachment standards might move the needle. Gail Kocher added that as currently drafted, the proposed operating rules would not move use of the X12 278 forward; instead, it would cause plans to pull back on their automation or use other methodologies to obtain faster responses. When asked for further clarification, Gail Kocher said that the proposed operating rules could increase the use of facsimile or web portals, especially web portals.

A Subcommittee member asked whether the 2-day turnaround requirement would increase adoption of the X12 278. Gail Kocher said that BCBSA health plans consider the 2-day turnaround to be too limiting because most prior authorizations require a manual intervention and complex back-end electronic interactions. BCBSA supports 3-day turnaround as a good balance. Connie Leonard said that a 2-day turnaround period would have the unintended consequence of an increased number of denials to meet the time frame, followed by multiple resubmissions (i.e., increase burden).

A Subcommittee member asked how the COVID-19 pandemic would impact implementation of the proposed operating rules, should they be adopted. Connie Leonard said that the pandemic may create increased interoperability and sharing of EHRs, because it has illuminated problems in the timely sharing of critical information. Conversely, the pandemic has paused progress because it has consumed so many available resources. Gail Kocher agreed with this assessment, adding that the pandemic has upended the traditional work environment, affected every industry across the country, and created a reprioritization of resources.

A Subcommittee member asked whether the CMS fee-for-service prior authorization experience was comparable to the experience of the rest of the marketplace payors. Connie Leonard said that her remarks pertained only to the Medicare fee-for-service market.

A Subcommittee member asked what type of incentive would motivate health plans to use the X12 278. Gail Kocher said that although all of the BCBSA health plans are 278-enabled, they have not seen an uptick in its use or a positive return of investment for the health provider community.

Provider Perspective

Three provider associations and three provider organizations provided testimony on the proposed prior authorization operating rules.

American Hospital Association (AHA)

Terrence Cunningham, the AHA's Director of Administrative Simplification Policy, showed slides to provide testimony from the AHA and its members.

Current problems with prior authorization processes include delays caused by inefficient implementation, differences in requirements and submission methods between health plans, questionable application of prior authorization, and inappropriate denials. Delays and burdens caused by inefficient implementation include documentation preparation and submission problems, slow processing times that delay patient care, and unavailability of prior authorization outside of business hours. Most methods of requesting prior authorization require significant manual work (including electronic portals), staff, and resources that could otherwise be devoted to patient care. Each insurer or health plan has different requirements, specifications, and submission methods.

Similar to the presentation from the Arthritis Foundation, Terrence Cunningham noted that providers and patients have the same opinions on many of these issues.

The anticipated value of the prior authorization infrastructure operating rule is that it would reduce delays by requiring health plans to respond to completed prior authorization requests and to request additional information within 2 business days of receipt, and to acknowledge real-time prior authorization within 20 seconds of receipt. Further it would streamline the prior authorization process by promoting an electronic method that can be used across various payers and therefore help to address the pended roadblock of some X12 278 implementations. Each of these improvements contribute to improved patient care.

The anticipated value of the prior authorization data content operating rule is that it would increase transparency and eliminate variability. It would require health plans to use standardized code sets (e.g., PWK01 or LOINC) to identify additional clinical information needed for prior authorization requests. It would also require health plans to return health care decision reason codes.

Two changes would improve the proposed prior authorization operating rules. First, the "business day" concept should be removed. Providers care for patients 24 hours per day/7 days per week, so health plans seeking to insert steps in this process (e.g., prior authorization) should abide by the same time frames. Second, the compliance requirements should be increased. When health plans are only required to meet the operating rule requirements 90% of the time over the course of a month, prior authorization become insufficient and providers' ability to establish reliable time frame expectations for their patients become limited.

Furthermore, the AHA asks NCVHS to continue to advocate for the adoption of an attachment standard. No standard method exists to send clinical information and other documentation that is required by health plans for completing prior authorization requests. Health plans vary in how they accept or prefer to receive this information, which often results in inefficient manual processes, such as mail, facsimile, or telephone.

In conclusion, the AHA supports adoption of the proposed prior authorization operating rules because they establish necessary process improvements that increase revenue cycle efficiencies and improve patient care. The prior authorization issue has been ongoing for many years.

American Medical Association (AMA)

Heather McComas, the AMA's Director of Administrative Simplification Initiatives, showed slides to provide testimony from the AMA on behalf of its membership.

Data from the 2019 AMA Prior Authorization Physician Survey suggest that prior authorization delays necessary care (91% of physician responses), can lead to treatment abandonment (74%), has a negative impact on patient clinical outcomes (90%), has led to a serious adverse event for a patient in their care (24%), and has led to a patient's hospitalization (16%).

Prior authorization is a practice burden for physicians. Each physician surveyed requested an average of 33 prior authorizations each week, which required an average of 14.4 hours (approximately 2 business days) each week by

the physician or staff to complete. Of the physicians surveyed, 86% reported that prior authorization burdens have increased over the past 5 years, and 30% of providers have staff that work exclusively on prior authorization. In January 2018, the AMA partnered with the AHA, BCBSA, and other organizations to release a consensus statement on improving the prior authorization process. The group concluded that although a reduction in the volume of prior authorizations is still the goal, prior authorization operating rules can improve transparency and automation.

The AMA participated in all discussions and straw polls involved in the development of the proposed operating rules under consideration. Prior authorization reform is an advocacy priority for the AMA's physician members. The AMA urged CAQH CORE to refine the original prior authorization infrastructure rule to address the response time for final determinations.

The AMA supports federal adoption of the CAQH CORE prior authorization infrastructure and data content rules. The infrastructure rule represents an important and necessary initial step in reducing patient care delays related to prior authorization. The data content rule improves prior authorization–related transparency and communication.

The AMA considers the requirement to provide final prior authorization within 2 business days of information receipt to offer value. This is a major improvement over existing industry accreditation requirements, i.e., 14 to 15 days. Further, health plans must respond to real-time X12 278 prior authorization requests within 20 seconds and must indicate whether any additional information is needed when documentation requirements are referenced in published policy. This increased transparency would minimize the time spent by physicians and their staff searching for the documentation requirements, which vary widely across health plans. Health plans must send a second, unsolicited X12 278 response with the final determination when an initial prior authorization request is pended—an advancement toward end-to-end prior authorization automation because most pended prior authorizations drop to manual workflows (i.e., telephone, fax, or web portal).

The AMA has two concerns about the proposed prior authorization infrastructure rule. First, the rule's 2 business day processing time requirement does not fully address patient care needs, because health care is a 24/7 business (i.e., Every day is a "business day."). The Prior Authorization and Utilization Management Reform Principles (supported by the AMA, 16 original partner organizations, and more than 100 other groups) state that health plans should provide a final determination for nonurgent prior authorizations within 48 hours of obtaining all necessary supporting documentation (48 hours does not equal 2 business days, especially during a long holiday weekend). Second, the proposed rule does not dictate a processing time for urgent prior authorizations. The lack of specifications for urgent prior authorizations is particularly problematic because nonurgent prior authorization processing time is defined in business days. The AMA urges NCVHS to recommend that any federal rulemaking on X12 278 infrastructure requirements includes a provision for urgent requests.

Heather McComas described the AMA's anticipated value of the proposed prior authorization data content rule. First, health plans must include a PWK01 code and/or a LOINC in an X12 278 pended response to indicate the necessary supporting clinical documentation for certain medical services. Improved transparency of prior authorization documentation requirements would decrease physician and staff time spent searching through insurer manuals, websites, or bulletins. Second, health plans must include one or more HCSDRCs in the X12 278 response, and the code should offer "the most comprehensive information back to the provider." Third, the proposed rule provides for consistent and uniform use of AAA error and action codes, therefore reducing confusion due to less variability in messaging between payers.

The AMA has several concerns about the proposed prior authorization data content rule. The lack of standards for electronic clinical attachments would limit this rule's ability to increase adoption of the X12 278. More than 20 years have passed since the original HIPAA legislation indicated the need for attachments standardization. The lack of HIPAA-mandated electronic attachment standards is a rate-limiting factor to automation of medical services prior authorization. The June 2014 NCVHS vendor testimony on attachments indicated that the "uncertainty in the area has had a paralyzing effect" and serves as a disincentive for vendors to allocate resources to attachment development. The spring 2020 Federal Regulatory Unified Agenda suggests a September 2020 release of attachments notice of proposed rulemaking (NPRM).

Because of the anticipated reduction in harmful patient care delays and practice administrative burdens, the AMA supports federal adoption of the prior authorization infrastructure and data content operating rules. The AMA's

top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed operating rules are as follows:

- To protect timely care delivery, NCVHS should recommend that the infrastructure rule's 2 business day requirement be viewed as the "floor" for the industry and should recommend shortened processing times in future operating rules.
- NCVHS should recommend that federal rulemaking on X12 278 infrastructure requirements includes a provision that requires 24-hour processing for urgent prior authorizations.
- NCVHS should reiterate its previous recommendations on the need to adopt of standards for electronic clinical data exchange (i.e., attachments).
- NCVHS should consider the operating rules in the larger context of other concurrent industry discussions regarding prior authorization automation.

Medical Group Management Association (MGMA)

Robert Tennant, MGMA's Director of Health Information Technology Policy, presented slides to provide testimony from medical practice managers.

MGMA surveyed its members in 2019 about regulatory burden. Prior authorization was deemed the most burdensome administrative requirement. Prior authorization requirements have increased for 90% of MGMA members. They disrupt continuity of care, interfere with the patient-physician relationship, and increase costs and burden.

Regarding anticipated value, the proposed prior authorization data content rule includes receipt and processing of diagnosis/procedure/revenue codes for specified categories of services and detection and display of all code descriptions. It includes consistent patient identification and verification, which should reduce common errors and denials to ensure a better patient/subscriber match. It returns specific AAA error and action codes, which should improve communication between practices and plans and reduce the need for manual follow up. The return of HCSDRCs should provide a clearer explanation of plan-required next steps. The use of PWK01 code should provide direction on status and what additional clinical information is needed for plan adjudication of the prior authorization request. Detection and display of all code descriptions should reduce the burden of interpretation on the provider. "Requesting Additional Documentation for a Pended Response" has potential to improve the current workflow. Knowing what documentation the plan requires allows the provider to determine the information that should be supplied. All measures that increase transparency appeal to MGMA.

MGMA would optimally support making a single entity responsible for data content (most likely the appropriate SDO). Yet, this presupposes that the SDO will actively solicit input from providers, incorporate modifications that increase the usefulness of the transaction, and act quickly to meet industry needs. When these conditions are not met, operating rules must be enacted to ensure that the transactions respond to the needs of practices and are approved in a timely manner.

Regarding anticipated value, the proposed prior authorization infrastructure rule sets provider expectations on standard system availability plus notifications of any down time; however, the permitted 24 hours per week down time is excessive. The rule would also allow providers to immediately learn whether the plan has received the prior authorization request rather than manually following up. The rule's standard companion guide format enables consistency across trading partners. The rule gives the health plan 2 business days to review a prior authorization request from a provider or respond that additional documentation is needed to complete the request. After all requested information has been received from a provider, the plan has 2 business days to respond with a final determination. The rule's time frame requirements could act as an incentive for practice adoption of the 278.

The proposed prior authorization infrastructure operating rule needs some enhancements. A prior authorization request that is deemed urgent should have a maximum response time of 24 hours after the health plan receives all of the required supporting documentation. Response times for initial plan response and final response of 2 "business" days should be changed to 48 hours for each response. Health care delivery is not a Monday through Friday event. Business days do not include weekends or federal holidays. In practical terms, 2 business days could translate to a full 5 calendar days between plan responses, leading to unacceptable delays in patient care. The

maximum of 15 business days to respond to a health plan request for additional supporting documentation before the request is closed by the plan should be extended to 30 business days.

All covered entities, regardless of their size or type, should be given 24 months to comply with this federal mandate. This is the same amount of time provided to implement the operating rules for the 270/271, 276, 835, and EFT transactions.

In conclusion, MGMA supports federally mandating the CAQH CORE prior authorization data content and infrastructure operating rules. Adoption of these rules would improve the current prior authorization process by standardizing data content and requiring a maximum time for health plans to respond to requests. Two business days was a necessary compromise between providers and plans during the rule development process, and MGMA would prefer less time. Although this time frame would be an improvement over currently lengthy and non-standardized plan response times, the maximum time frames should still be significantly shortened.

Additional reforms are needed to substantially improve the prior authorization process. For example, prior authorization should be eliminated for services that are routinely approved and for providers that assume risk in contracts. Attachment regulation should be promulgated, and new standards to automate the authorization process should be developed. Finally, enforcement against noncompliant health plans should be stronger.

Provider Association Q&A

A Subcommittee member asked whether the proposed prior authorization operating rules go far enough as an intermediate step to reduce complexity, improve timeliness, improve the experience of providers and practice managers, increase the number of 278 transactions, and move the industry away from using telephone calls and web portals. Terrence Cunningham said that the proposed operating rules improve the response time and incentivize provider adoption of the rules. He added that the 2-day time frame for receiving a response to a prior authorization request is a "game changer" and makes health plans' expectations transparent. Not having an attachment standard should not prohibit these rules from making an impact. Heather McComas agreed, adding that the decrease from 14-15 business days to 2 business days is a significant improvement, a meaningful change, and an incentive to use a 278 transaction for both initial and pended authorization requests. Robert Tennant said that the proposed operating rules represent excellent compromise from all stakeholders. The rules are not perfect, but they are a phenomenal step forward for prior authorization.

A Subcommittee member asked whether adopting the proposed operating rules is advisable in an environment where other, related technical developments were currently under way. Terrence Cunningham advised against waiting for a development that *might* be better in the future. That type of reasoning has led to tabling of many advances, and patients are the ones who bear the burden. Robert Tennant agreed and added that launching new technology involves many steps, including those in development (e.g., FHIR). Heather McComas said that the work with FHIR fits into the 278 transaction model but may not be readily available to all health care providers because practice sizes, specialties, and service types vary.

A Subcommittee member asked whether the industry would be willing to comply with voluntary adoption of the proposed operating rules without a federal mandate. Terrence Cunningham expressed his belief that not everyone would volunteer to comply. He said that adopting standards ensures consistency across the board. Robert Tennant agreed and said that HHS has not developed an attachment standard in 20 years of work, even with successful pilot programs. He stated that a federal mandate is the only way to ensure adoption of standards and asked, "How are we going to convince physician practices—especially smaller ones—to invest in an untried technology when we can't even get health plans to support standards that have been around for decades?" Heather McComas also agreed and added that voluntary adoption of operating rules and standards does not work because the vendor community prioritizes what is mandated. A mandate is necessary before the industry will invest resources.

Montefiore Health System Medical Center

Noam Nahary, Montefiore Health System's Senior Director of Health Service Receivables, presented slides to provide testimony to the Subcommittee. At Montefiore, federally mandated operating rules for eligibility, claim status, and payment and remittance transactions have decreased claim denials and accounts receivable,

transaction fees, and registration and billing time and have increased patient collections at the time of service and auto-adjudication of payments and remittances.

Montefiore anticipates that adoption of the proposed prior authorization operating rules would produce faster, timelier patient care; improve automation of prior authorization workflows; and reduce costs/resources to support the prior authorization process. Current health plan response times to initial prior authorization requests range from 1 to 14 days, which delays care. The response time requirements would reduce procedure wait times, improve patient scheduling processes, create common expectations across health plans, and ensure timely delivery of essential patient care. Implementation of the proposed operating rules by all HIPAA-covered entities would enable Montefiore to transition away from web portals and manual prior authorizations and to implement greater automation via the X12 278. With a higher volume of electronic transactions that better clarify reasons for an authorization decision and additional documentation needs, Montefiore can create efficiencies in its workflows and simplify processes. Montefiore employs approximately 175 staff [$11 million in annual full-time equivalent (FTE) costs] to manage prior authorization requests via web portals, telephone, and facsimile. Staff spend significant time on data entry into web portals, telephone calls, and facsimile machines to support initiation, submission, and confirmation of each authorization. With a federal mandate of the proposed rules, Montefiore estimates a $6 million annual reduction in FTE costs plus additional savings due to fewer denials and appeal efforts.

Montefiore has several anticipated concerns about the proposed prior authorization operating rules. First, the organization expects limited adoption without a federal mandate. Given the current state of prior authorization, more than just goodwill is necessary to drive efficiencies and automation. A federal mandate would accelerate industry adoption beyond early implementers by making investment dollars and resources available to ensure compliance. CORE Certification data suggest that federal mandates drive adoption and certification, enabling prioritization and vendor development. Second, a federal attachments standard is needed. Industry has waited many years for a HIPAA-mandated attachment standard to automate the exchange of additional documentation for claims and prior authorization. Federal adoption of the proposed CAQH CORE operating rules would lead to greater industry-wide prior authorization automation, efficiencies, and cost savings, but the lack of a common standard for documentation exchange may prevent fully electronic business processes. Third, with previously mandated operating rules, HHS excluded requirements pertaining to acknowledgements. An electronic acknowledgement provides immediate assurance that a transaction has been received. Excluding these requirements for prior authorization would result in costly, manual telephone and facsimile follow-up with health plans to determine transaction status.

Montefiore's top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed operating rule(s) are as follows:

- Adoption of the proposed CAQH CORE prior authorization and connectivity operating rules would drive greater automation, increase efficiencies, improve access to timely patient care, enhance health plan and provider data exchange, and significantly reduce industry spend on prior authorization processes.
- Without a federal mandate, implementation of the operating rules will lag, resulting in continued inefficiencies and delays and, ultimately, poorer patient outcomes.
- Patient experience is a cornerstone of the care model employed at Montefiore. Delays and inefficiencies in the current prior authorization process have a direct, negative impact on patient care. The industry must address this challenge now. The proposed operating rules enable greater automation, reducing and eliminating unnecessary delays and inefficiencies.

Ohio Health

Margaret Schuler, Vice President of Revenue Cycle at Ohio Health System, presented slides to provide testimony. Ohio Health greatly values the direct impact of operating rules on its revenue cycle because the rules provide consistency in infrastructure and data content for administrative transactions. Operating rules close gaps in the standards and ensure that providers receive consistent data across health plans for key transactions. For example, patient financials in the eligibility transactions enable Ohio Health to collect fees from patients at the time of service, uniformity in adjustment/denial codes on the ERA enable greater automation, and reassociation of ERA and EFT transactions results in more efficient payment and remittance processes. Infrastructure rules ensure

common expectations, connectivity, and Service Level Agreements (SLAs) across health plans for consistent data exchange and automation.

Ohio Health is eager to see similar impacts from the proposed prior authorization and connectivity operating rules. More than 20,000 Ohio Health patients are affected by prior authorization denials annually, and even more patients experience care delays due to inherent process inefficiencies. If the proposed operating costs are federally mandated, Ohio Health estimates a savings of $5 million because of reduced staffing, initial denial appeal costs, and net write offs. Ohio Health employs approximately 70 staff to submit prior authorization information via web portals, telephones, and facsimiles, at an annual cost of $3 million. Ohio Health spends another $5 million on appeals and $2 million on net write-offs due to lost appeals. Altogether, Ohio Health spends approximately $10 million per year to manage an ineffective and inefficient prior authorization process. The proposed operating rules would streamline review of prior authorization requests, enable faster response times, and provide for an automated adjudication of a final determination.

Ohio Health anticipates the value of both proposed prior authorization operating rules to be high. Faster prior authorization would reduce delays in patient care and ultimately improve patient outcomes. Adoption would also increase provider adoption of the X12 278 due to shorter, reliable response times. State response time requirements vary from 2 to 15 days, and current health plan response times are up to 15 days for Ohio Health. The anticipated value for Ohio Health would be higher volumes of electronic prior authorizations, standardized workflows to meet the turnaround times, and standardized and more efficient two-way communication, error reporting, and request for additional documentation. The new operating rules would significantly enhance the X12 278 transaction and would lead to better auto-adjudication of prior authorizations. These enhancements would help the industry move away from web portals, which involve significant training and FTE costs. The rules would reduce the number of exchanges between providers and health plans to confirm medical necessity and would shorten adjudication timeframes. Ohio Health's EHR vendor has created functionality to send and receive an X12 278, and these rules would support that effort to move prior authorization out of web portals and into provider workflows. Finally, the operating rules would inform understanding of next steps, status, and the additional documentation needed for adjudication of the prior authorization request, reducing the burden on Ohio Health staff and processes.

Regarding the anticipated value of the proposed data content rule, the addition of a PWK segment with document-specific codes would help Ohio Health determine the requested supporting document without ambiguity. Further, it would minimize delays in returning the requested documentation and in the approval process. The use of HCSDRCs would help to clarify the authorization decision and to determine the appropriate response and next steps. With the use of AAA error and action codes, Ohio Health could segregate content errors from security errors and route the task to the correct support queue for quick resolution.

Regarding the anticipated value of the proposed infrastructure operating rule, reduced wait times for procedures requiring prior authorization would improve the patient experience and access to care. Standardized SLAs across health plans and states with predefined response times would improve scheduling. The connectivity requirements would further strengthen security as Ohio Health plans payer integrations.

Ohio Health's anticipated concerns about the proposed prior authorization operating rules are four part. First, HIPAA-covered entities typically have 2 years to comply with operating rule mandates. This timeline would extend unnecessary delays in patient care and increase cost of care. Ohio Health's and health plans' technical team need only 9 to 12 months to build, connect, and test electronic transactions. Ohio Health would only need 9 to 12 months of lead time. Therefore, enforcement of HIPAA administrative simplification provisions is needed. HHS never implemented the health plan certification program related to standards and operating rules outlined in the ACA; thus, industry relies on the complaint-driven process for non-compliance supported by CMS. Second, with a federal mandate, organizations could prioritize investments in prior authorization. If the rules are voluntary, plans and vendors will not invest in prior authorization automation. Third, the proposed operating rules represent a critical first step toward automating prior authorization. As new technology and approaches are considered, consistency across the data content and response times will be needed to ensure streamlined communications. Fourth, adoption of attachment and acknowledgment standards would enhance the operating rules' value.

Margaret Schuler discussed several top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed operating rules. During the past few years, the health care industry has lamented the current state of prior authorization without taking real action. The proposed operating rules are strongly supported by greater than 80% of CAQH CORE's participating organizations and offer a pathway to auto-adjudication. The industry is ready to move away from web portals, telephone, and facsimile and cannot wait 5 years or more for emerging standards or solutions. These operating rules are a first, positive step toward aligning clinical and administrative systems to support timely prior authorization. A federal mandate would ensure appropriate allocation of resources and commitment levels. A standard method for provider–health plan communication would provide benefits and savings to both groups and, in time, to patients. Prior authorization directly impacts patient care, and solutions to shorten the process are needed now.

Veterans Health Administration (VHA)

Katherine Knapp, a program analyst at the VHA, presented slides to provide testimony on behalf of the U.S. Department of Veterans Affairs as a health care provider. The VHA supports adoption of the proposed operating rules.

The VHA is the largest integrated health care system in the United States. In 2019, it sent and received more than 80 million health care transactions. It is committed to implementing HIPAA-mandated electronic transactions to ensure that the benefits of administrative simplification are met across the health care industry and passed on to U.S. veterans. The VHA is proactive in developing internal software solutions to meet electronic standards. Success is limited until a standard is mandated and enforced. VHA's internal prior authorization software was developed and ready to test in 2016. However, development of solutions before final operating rules are in place and before a wide range of payers are using the transaction is difficult. VHA first began to develop a template to streamline information provided to payers from utilization review nursing staff.

The VHA anticipates that the proposed operating rule would reduce administrative burden and provide better and faster care for patients. Limited use of the 278 transaction makes it difficult to gauge whether implementation of the proposed operating rules would positively impact workflow efficiency, but the VHA is optimistic that clear guidelines and increased adoption of the transaction and its associated processes would realize the intended benefits.

One anticipated concern about the proposed operating rules relates to the lack of health care payers with which to test their automated prior authorization software for the 278 transaction. Only 4 of the nearly 700 payers with which the VHA exchanges electronic transactions offer the X12 278 transaction through the clearinghouse. This small number of payers with which to exchange information limits efficiency. The lack of use of the 278 transaction places an administrative burden on utilization review staff, who must investigate which payers accept electronic transactions and which require manual processing. Furthermore, manual follow-up is often required with the payers that do accept electronic transactions.

Another concern is that, as written, the proposed data content operating rule does not mandate that all HIPAA-covered entities or their agents use the X12 278 transaction (i.e., those that do not currently do so). The qualifier precludes industry adoption and stunts the opportunity to realize benefits for patients. Several of the few payers that do offer the 278 transaction have delegated authorization for specialty services to utilization management organizations (UMOs). In these situations, the VHA must first submit a 278 request, which is rejected and then referred to the UMO for clarification. However, because the UMO does not utilize the 278 transaction, the VHA's utilization review staff must complete the process manually. The proposed rule does not mandate UMOs to use the X12 278 transaction, leaving the prior authorization process disjointed with a combination of electronic and manual processes. This is not the intent of HIPAA.

VHA remains committed to the benefits of using HIPAA-mandated electronic transactions and will continue to support the prior authorization transaction and its supporting operating rules. VHA recommends and supports further adoption of this transaction across the industry to end the need for multiple processes to secure prior authorization and payments for health care services provided to U.S. veterans.

Provider Organization Q&A

A Subcommittee member asked whether the proposed operating rules, as written, would apply broadly with a large variation in patient demographic and specialty services (e.g., laboratory tests). Margaret Schuler said that the proposed operating rules would be a good start toward changing the health care ecosystem. She encouraged the group to use the phrase, "Don't let perfect stand in the way of good." Although a proposed operating rule could still be improved, it would begin to reduce administrative burden and improve patient care. Katherine Knapp agreed, stressing the importance of moving forward. Noam Nahary also agreed and reminded the Subcommittee members that the proposed operating rules would continue to build the base of EDI; the same systems that were previously developed would also be used for the 278 transactions.

A Subcommittee member asked Margaret Schuler what, besides the federal mandate, would ensure adoption of the proposed operating rules. Margaret Schuler responded that the content and infrastructure rules would help. Further, providers will become more likely to use the transaction once they see the benefits of the 2-day turnaround requirement. Katherine Knapp added that making educational and implementation resources available to providers and health plans would also improve adoption.

A Subcommittee member asked the providers to comment on any enforcement or incentive options that would encourage adoption of or assure compliance with the proposed operating rules. Margaret Schuler said that penalties or fines are used to enforce mandates such as provider price transparency, which causes industry to weigh the cost of implementation against the fine. At a minimum, a federal mandate allows payers and providers to cite the applicable law as leverage for contract negotiations. Mandates often encourage large electronic medical record providers to implement specific transactions.

Vendor and Clearinghouse Perspective

Four vendors or clearinghouses provided testimony on the proposed prior authorization operating rules.

Availity

Paul Joiner, Availity's Chief Operating Officer, presented slides to provide testimony on the proposed prior authorization operating rules. Availity is the largest health information network in the United States. Availity is a CAQH-certified clearinghouse that works with providers and health plans. It facilitates more than 6 billion administrative, clinical, and financial transactions annually on a real-time platform that enables collaboration among health plans, providers, and their partners. Availity has a unique relationship with many payers and is positioned at the intersection of payer and provider connectivity.

For several years, Availity has worked with health care stakeholders to solve the challenges of prior authorization through a market-based approach. Its "Is Auth Required" solution allows providers to quickly check whether an authorization is required before beginning the process.

Availity fully supports the intent of the proposed rules, which is to reduce the burden of prior authorizations. Patient procedures are delayed when providers must wait for prior authorization confirmation. Driving greater automation through portal and EDI capabilities will benefit the industry, and there is value in applying operating rules to the 5010X12 278 transaction. Over time, operating rules will lead to better marketplace adoption of the transaction.

Availity has several anticipated concerns about the proposed operating rules. Data content should be handled by SDOs, and CAQH should focus primarily on developing operating rules. Unless health plans are given adequate time to adopt the rules, they will face a significant challenge to complying with the 48 hour/2 business day requirement for returning an authorization decision with supporting documentation. Most organizations want to ensure flexibility in connectivity with trading partners to deliver content rather than being forced into specific requirements under safe harbor rules, which may increase implementation burdens. Provider core systems may not be able to support a native prior authorization transaction, which means providers will continue to use payer portals or manual processes. The requirement to convert specific information into generic messages may increase administrative costs and provider abrasion. When a provider lacks sufficient information to act on a transaction, they will visit payer portals or call the health plan call center. There is no strategy for enforcing standards among

carve-out vendors (e.g., radiology benefit managers, oncology, others) that play a critical role in the authorization process.

Top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed operating rules are as follows:

- To comply with the rules as proposed, there is a risk that the authorization review will move from earlier in the process to later. Although upfront authorizations might be relaxed, the claims might pend at adjudication points, which creates a new pain point for providers.
- These rules seem to augment some of the recent rules from CMS and the Office of the National Coordinator for Health Information Technology (ONC). An industry shift to implement these rules could detract focus from innovation in other critical areas, such as interoperability and efficiencies of care.

In summary, Availity does not support adopting the operating rules as currently proposed at this time, but it supports doing so on the right timeline and with broad industry consensus. The new CAQH CORE Connectivity and Security work group is in progress, and Availity recommends waiting until that work group's connectivity rules are released. Availity also recommends that the CAQH data content work group reconsider timing and flexibility. Similar to HHS and CAQH, Availity is deeply invested in solving the prior authorization problem.

Availity later added that the system uptime[1] component of the proposed prior authorization operating rules should be withheld, and consideration should be given to smaller health plans with fewer resources. With many competing priorities, Availity suggested prioritizing the mandates so that companies can weigh their resources against various market pressures and threats of enforcement.

Cooperative Exchange

Sherry Wilson, a past Chair and Board Member for the Cooperative Exchange, presented slides to provide testimony on behalf of the National Clearinghouse Association. Cooperative Exchange membership includes 23 clearinghouse organizations that represent greater than 90% of the clearinghouse industry. Member organizations process more than 6 billion health care claims valued at $2 trillion annually. Clearinghouses enable nationwide connectivity for more than 800,000 provider organizations, more than 7,000 payer connections, and 1,000 Health Information Technology (HIT) vendors. Cooperative Exchange represents the U.S. health care EDI interstate highway system and enables connectivity across all lines of health care eCommerce.

Cooperative Exchange sees value in a standard infrastructure and EDI transaction response time frame. The rule provides uniform use of acknowledgments, a time requirement for initial response (including requests for additional clinical information), a standard time frame for identifying whether a request has been pended, standard system availability and downtimes, and optimal closeout so that stakeholders understand when a request will be closed if additional documentation is not received. The proposed operating rule enhances workflow automation and business processes and drives a partially automated process.

Cooperative Exchange has several anticipated concerns about the proposed operating rules. Despite numerous efforts, the same critical business processes and technical workflow are not addressed. Operating rules involving data content should be coordinated with SDOs. A cost-benefit analysis cannot be determined due to gaps in automation. The current level of implementation of prior authorization across the industry is extremely low (i.e., less than 13% of all prior authorizations). Cooperative Exchange is concerned about the implementation cost to the industry as a whole.

In conclusion, Cooperative Exchange does not support federal adoption of the proposed prior authorization infrastructure or data content operating rules as proposed. There is value in the existing infrastructure rules; however, the transaction is missing information necessary to automate the complete business process and achieve the business purpose. The same critical issues identified in the July 2016 NCVHS Letter to HHS on the Recommendations for the Proposed Phase IV rules remain unchanged. Without the adoption of attachment

[1] Uptime: the minimum number of days and hours that the electronic processing system must be up and running and available to trading partners.

regulations, the industry is left with an incomplete prior authorization workflow that does not meet stakeholder business needs.

Further, without full automation and decision support, and until the industry can redesign the prior authorization workflow and business process, much of the manual labor currently required to support health plan prior authorizations will not be eliminated. It has not been proven that adopting these operating rules without filling the necessary gaps in automation would increase industry adoption. Cooperative Exchange strongly recommends that implementation and maintenance costs from proven pilot studies are evaluated for return on investment before regulations are adopted.

Cooperative Exchange concurs with and supports the findings and recommendations in the February and December 2019 NCVHS letters to the HHS Secretary that outline actions to improve the adoption of standards under HIPAA. Despite numerous, concise NCVHS letters of recommendation to the HHS Secretary that were backed by industry and focused on prior authorization initiatives, minimal measurable action or change (e.g., attachments, prior authorization, acknowledgments) has occurred. The collective stakeholder investment costs incurred over the years with minimal or no realized progress or return of investment is of great industry concern. Cooperative Exchange is interested in learning how to support NCVHS efforts in this area.

Electronic Health Record Association (EHRA)

Hans Buitendijk, EHRA's Chair, presented slides to provide testimony on the proposed prior authorization operating rules. EHRA has 30 member companies that serve the vast majority of hospitals and post-acute, specialty-specific, and ambulatory health care providers across the United States, all of which use EHRs. EHRA conducts collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

Regarding the way that EHRs interact with 275/278 transactions, prior authorization processes create a burden for providers and their staff. Efforts to integrate prior authorization into EHR workflows has been challenging because of the variation in payer rules. Human intervention is needed to collect supporting information and evaluate the request. Because available technologies are inadequate, EHRs do not directly implement 275/278 transactions. Although administrative and revenue cycle management systems can do prior authorization transactions, most are done via facsimile, telephone, separate solutions, and payer portals.

The HL7's Da Vinci project is pursuing a promising approach for prior authorization using 275/278 transactions. This project addresses the entire prior authorization workflow, beginning within the EHR clinical workflow at the time when a referral, procedure, test, or piece of durable medical equipment is considered or ordered. Step 1 would be a query or indication of the need for an authorization for the referral, service, procedure, or item. Step 2 would be completion of the supporting documentation automatically or, when needed, through human intervention. Step 3 would be submission of the prior authorization and receipt of the response. For step 3, the translation in and out of 275/278, as required to process a prior authorization, would most likely be done by an HL7 FHIR-based smart application or intermediary rather than by the EHR. Several EHRA member companies are active in this initiative.

The purpose of any operating rule is to provide more specific implementation guidance to create consistent interoperability with minimum, if not zero, variations between parties. The underlying standard should allow for flexibility and variances. For the 278 data content rule, EHRA appreciates the clarification on patient identification fields. For the 278 infrastructure rule, EHRA appreciates the increased clarification and improvements on response times.

Hans Buitendijk discussed EHRA's anticipated concerns about the proposed data content operating rule. Patient matching or identification remains a challenge, and obtaining clean matches requires collaboration among all stakeholders. Alignment with emerging FHIR APIs that cover U.S. Core Data for Interoperability standards to automatically retrieve supporting information would enable increased consistency and efficiency. Alignment with e-Prescribing prior authorization flow is a concern. Although these concerns are not necessarily within current

scope, they should be key principles in advancing alignment to improve interoperability with EHRs and minimize, if not remove, human intervention to collect the relevant data.

Regarding anticipated concerns for the proposed infrastructure operating rule, 20-second response times and an up-time rate of 86% are insufficient to enable deeper integration into clinical workflow without creating a need for hands-off and human intervention. A holistic prior authorization perspective is essential to improve the total flow, from flagging the clinician, to automated data collection with minimum human involvement, automatic evaluation of rules, and sub-second response times that enable the clinician to enhance their decision making with the patient. Longer response times, or authorization requests requiring human intervention to gather additional data, would have to be managed through back-office processes, including awareness of payer downtimes.

Although the operating rules reflect a step toward further clarity and consistency, EHRA does not believe that the proposed rules will substantially increase electronic prior authorization flows. Further needs include harmonization of terminology, automatable authorization rules, supporting documentation requirements that are rooted in existing clinical documentation and increasingly accessible through HL7 FHIR-based APIs, and data transport/access technologies and standards that span clinical and administrative processes.

EHRA members look forward to working with all stakeholders to improve the overall flow of prior authorization.

Healthcare Business Management Association (HBMA)

Arthur Roosa, HBMA's representative, presented slides to provide testimony on the proposed prior authorization operating rules.

HBMA is a nonprofit professional trade association and a major voice in the U.S. revenue cycle management industry. Collectively, HBMA members submit a significant percentage of all initial medical claims to the country's government and commercial payers. HBMA members include the nation's largest billing companies (1,000+ employees submitting millions of claims) as well as small- to medium-sized businesses that employ 40 to 50 individuals. A typical HBMA member submits claims for providers in more than one state. HBMA provides education, advocacy, collaboration, and certification for health care billing professionals and providers engaged in the business and technology of health care revenue cycle management.

HBMA considers the proposed infrastructure rule to be an important first step in providing a reliable conduit for data transfer between provider and payer. The ability to submit a prior authorization request electronically and to receive a timely response—positive or negative—to that submission would significantly reduce the staff time spent and, hence, the cost to the provider. The data operating rules would advance the ability to both submit and approve authorizations electronically. Whether this goal of reduced burden is realized, however, depends on how hundreds of small insurance companies or self-insured health plans embrace not only the requirements of these proposed rules but also the spirit behind them. Many of the HIPAA-related administrative simplification requirements create administrative headaches and additional costs for smaller, regional health plans or employer-sponsored health plans that either do not understand their HIPAA obligations or simply refuse to comply with them.

HBMA's principal concerns with the proposed rules rest not with the rules themselves but with their adherence and, by extension, enforcement. The HBMA membership wonders whether health plans would comply to the new operating rules, and, if not, whether the CMS National Standards Group would impose penalties. If the past is prologue, HBMA expects that Medicare, large national commercial insurers, and large employer-sponsored health plans would make every effort to comply with the new operating rules, but state Medicaid programs and smaller health plans would not. Based on years of experience, HBMS is not confident that the CMS National Standards Group would penalize health plans for failure to comply.

Top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed prior authorization operating rules are as follows:

- HBMA strongly recommends that HHS ensures CMS National Standards Group oversight and enforcement of these operating rules.

- HBMA rejects the proposed "companion guide" standardization recommendation and instead recommends that HHS prohibit the use of companion guides within the next 3 years. Failure to discontinue use of companion guides would be viewed as prima facie evidence of failure to comply with HIPAA and subject the violating health plan to immediate penalties as authorized by the ACA.[2]
- HBMA suggests establishing a safe harbor floor where trading partners can expect their transaction to be read and processed through to response. This capability is not guaranteed in the proposed prior authorization operating rules (although it is guaranteed in the proposed connectivity rule).

Vendor and Clearinghouse Q&A

A Subcommittee member asked whether adoption of these operating rules would increase usage of the 278 transaction, especially in an environment with many initiatives competing for resources. Arthur Roosa replied that the answer depends on the time allowed to implement the rule. A 1-year time frame would interfere with higher priority initiatives, whereas a time frame of 24 to 30 months could shift focus to the 278 transaction. Paul Joiner added that the 278 transaction often requires a conversation and should therefore be accompanied by a 275 transaction. Sherry Wilson agreed, stating that a 278 is incomplete without a 275 and that the industry continues to use manual processes because the underlying issues have not been resolved. Hans Buitendijk said that the adoption of 278 does not align with the direction in which EHRs are headed; EHRs are unlikely to pursue adding this transaction over the next 24 months because of competing priorities and the fact that integration and flow capabilities are not in place.

A Subcommittee member asked how the proposed operating rules would be received if HHS excluded the prior authorization acknowledgement requirement (HHS excluded acknowledgement for previous operating rules because no underlying standard existed). Sherry Wilson said that acknowledgement would be a critical component of the prior authorization process and the transaction set would be ineffective without it. Paul Joiner agreed, adding that the lack of a clear request acknowledgement would create "black holes" of confusion. Arthur Roosa concurred with the vendor and clearinghouse representatives. Hans Buitendijk said that interoperability becomes challenging without acknowledgment.

A Subcommittee member asked Arthur Roosa whether the proposed prior authorization rule is a sufficient intermediate step to provide value to the HBMA membership. Arthur Roosa replied that the proposed operating rule requires robust data content capability to be useful. If the 275 transaction and the acknowledgment and response time components were included, then the proposed operating rule would be sufficient.

A Subcommittee member asked whether any additional vendor perspectives were missing or unrepresented. Hans Buitendijk said that because transactions usually originate in the administrative business office, a representative from that function may offer an interesting perspective. Paul Joiner suggested that the Subcommittee consult with the other SDOs, intermediaries between health plans and providers for authorization processes (e.g., radiology benefit managers), and representatives from the quality assurance community. Sherry Wilson added additional patient voices to this list.

Public Comment

Public comments submitted prior to the meeting can be found at:
https://ncvhs.hhs.gov/wpcontent/uploads/2020/09/Public%20Comments-CAQH%20CORE%20Operating%20Rules%20for%20Federal%20Adoption-August%202020.pdf

[2] The Companion Guides are to clarify, supplement and further define specific data content requirements to be used in conjunction with, and not in place of, the X12 Technical Review Type 3 (TR3s) and National Council for Prescription Drug Programs (NCPDP) Implementation Guides for all transactions mandated by HIPAA and/or adopted by Medicare FFS for Electronic Data Interchange (EDI)." Companion Guides clarify detail around data and transmission requirements but can be problematic in that they can be different for each health plan, creating a burden on submitters to customize transactions for each health plan.

During the hearing, Laura Caldwell from GDIT/New York State Medicaid asked the Subcommittee to solicit testimony from state Medicaid representatives. Rebecca Hines and Alix Goss responded that the Subcommittee had indeed requested testimony from state Medicaid representatives and the national Medicaid EDI group.

Closing Remarks and Adjournment

To close Day 1 of the meeting, Rich Landen thanked attendees for providing tremendous feedback on the proposed prior authorization operating rules. The testimony described possible avenues for, but no guarantees of, adoption of the proposed operating rules. It included both complementary and conflicting views on what might incentivize stakeholders to implement the rules should they be adopted, especially within the current ecosystem of competing priorities and a national pandemic. Automation, efficiency, value, and the need for conversations to secure prior authorization were themes of the day. On Day 2 of the meeting, the Subcommittee will hear testimony from the same organizations on the proposed connectivity rules. Alix Goss agreed with this accurate synopsis of the day and thanked attendees and Subcommittee members for their contributions. Rebecca Hines asked the group to reconvene at 10:00 a.m. on August 26, thanked the Subcommittee co-chairs and technical team, and adjourned the meeting.

* ~ * ~ *

Welcome Back, Call to Order, Review Agenda

To open the meeting on Wednesday, August 26, 2020, Rebecca Hines welcomed attendees and called roll. Subcommittee Co-chair Alix Goss reviewed the agenda for the day, which focused on hearing testimony on the proposed connectivity operating rules. She explained that the Subcommittee has received extensive written comments, which are available on the meeting website.

Testimony on Proposed Connectivity Operating Rule

Four vendors or clearinghouses, five provider organizations, and three health plans provided testimony on the proposed connectivity operating rule.

Vendor or Clearinghouse Perspective

Four vendors or clearinghouses provided testimony on the proposed connectivity operating rule.

Availity

Paul Joiner, Availity's Chief Operating Officer, reviewed his final slide to provide testimony on the proposed connectivity operating rule. Availity does not support adopting the operating rule as currently proposed, but would support doing so on the right timeline with broad industry consensus. Availity recommends waiting for the new CAQH CORE Connectivity and Security work group to release of its new version (i.e., version 4.x) of connectivity rules.

Cooperative Exchange

Sherry Wilson, a past Chair and Board Member for the Cooperative Exchange, presented slides to provide testimony on behalf of the Cooperative Exchange and its parent organization, the National Clearinghouse Association.

The proposed connectivity operating rule offers value in that it would solve the current challenge of multiple (former Phase I-III vs. Phase IV) safe harbor connectivity rules by proposing a single and uniform safe harbor connectivity rule. Such a rule would standardize EDI connectivity for application vendors, clearinghouses, providers, and health plans that choose to use the safe harbor connectivity method.

The Cooperative Exchange has four concerns about the proposed connectivity operating rule. First, CAQH CORE's Connectivity and Security work group is actively working on a rewrite of the connectivity rule. The industry should wait for the rewrite process to conclude before considering this proposed operating rule, to mitigate unnecessary implementation costs and utilization of resources.

Second, NIST already has an industry connectivity framework. HIPAA security rules and HITECH Act rules cite NIST as the authoritative industry source, not the entity that authored the operating rule. Connectivity rules developed outside of and divorced from NIST standard guides and specifications would lead to confusion and disparity in health care EDI standards deployment.

Third, the proposed operating rule provides only one option for authentication (i.e., X.509 digital certificates), which limits stakeholders' ability to meet differing business needs and may impede EDI adoption. Per prior testimony by multiple organizations, the cost of using X.509 digital certificates would be passed on to providers and would be a mere shift in the transaction cost, while increasing administrative burden for stakeholders that must comply with the operating rule. Further, the proposed operating rule would limit the inclusion of new and emerging technologies such as RESTful APIs, OAuth, SAML authorization, and identity services.

Four, the costs and resources needed to implement the proposed operating rule would be high, with no perceived offsetting benefits. Organizations would be required to implement and support the rule regardless of usage or current solutions. A federal connectivity mandate could supersede other business development initiatives that are based on an organization's defined product roadmap and client needs. Development would be required for all organizations that did not implement X.509 digital certificate-based authentication over SSL/transport layer security (TLS) and SOAP 1.2 plus WSDL 1.1 and MTOM (for both real time and batch). Cost and resources would vary by product and architecture, and some organizations would need to implement the operating rule for multiple products based on product delivery and past acquisitions. Testing would be required for all organizations, and the costs to allocate resources and stage a complete testing environment could not be recouped.

In conclusion, the Cooperative Exchange and the National Clearinghouse Association do not support federal adoption of the proposed connectivity operating rule. The Cooperative Exchange recommends that the industry wait for the 2020 CAQH CORE connectivity operating rules version C4.x rewrite process to conclude (which is expected by the end of 2020) before considering the proposed operating rule. Finally, any proposed connectivity operating rules should align with existing HIPAA and HITECH Act security regulations that reference federal NIST guidelines.

EHRA

Hans Buitendijk, EHRA's Chair, presented additional slides from his deck to provide testimony on the proposed connectivity operating rule. He reiterated that EHR systems are not typically used for the proposed transactions.

The purpose of any operating rule is to provide more specific implementation guidance to create consistent interoperability with minimum, if not zero, variations between parties. The underlying standard should allow for flexibility and variances. EHRA appreciates the proposed operating rule's increased focus on secure transactions. EHRA supports comments made by other organizations that other proposed operating rules may be more closely aligned with what industry needs.

EHRA deferred to other stakeholders to provide input on anticipated concerns with the proposed connectivity operating rule.

As with the proposed prior authorization operating rules, EHRA recommends that NCVHS consider the needs for harmonization of terminology, automatable authorization rules, supporting documentation requirements rooted in existing clinical documentation that are increasingly accessible through HL7 FHIR-based APIs, and data transport/access technologies and standards that span clinical and administrative processes.

HBMA

Arthur Roosa, HBMA's representative, presented slides to provide testimony on the proposed connectivity operating rule.

HMBA believes that significant value can be found in the proposed operating rule. It would provide consistent, reliable transaction formatting and data interchange and response expectations and would move the industry in a unifying direction—that is, streamlined and standardized claim submittal, authorization, and enrollment processes. The potential benefits derived from a standardized real-time file submission and retrieval system for all ASC X12N files would be substantial, and this rule would represent a valuable step, albeit a first step, toward achieving that goal. HBMA appreciates the payload agnostic design and hope that it leads to a standard method of submission and retrieval for all the X12N formats. As noted during Day 1, realization of this goal depends on whether hundreds of small insurance companies or self-insured health plans embrace not only the requirements of this proposed operating rule but also the spirit behind it.

HBMA has several concerns about the proposed connectivity operating rule. First, the security protocols outlined in the proposed operating rule are inadequate for the modern era. For example, SSL 3.0, TLS 1.0, and TLS 1.1 all have well-documented security vulnerabilities. Second, HBMA members wonder whether health plans would comply with the new operating rules, and, if not, whether the CMS National Standards Group would impose penalties. If past is prologue, HBMA would expect Medicare, large national commercial insurers, and large employer-sponsored health plans to make every effort to comply with the new operating rules, while state Medicaid programs or smaller health plans would not. Based on years of experience, HBMA is not confident that the CMS National Standards Group would penalize health plans for failure to comply.

Top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed connectivity operating rule are as follows:

- NCVHS should require the use of TLS 1.2, which is a more secure and well-understood and widely implemented protocol.
- NCVHS should ensure that HHS provides oversight and the CMS National Standards Group enforces this operating rule.
- HHS should require that all operating rules be written in clear language to reach a wider audience. The way in which CAQH CORE publishes its operating rules is almost unintelligible. Confusing language causes individuals to focus on the technical specifications, rather than purpose, of a proposed operating rule.

Vendor and Clearinghouse Q&A

A Subcommittee member asked whether version 4.x of CAQH CORE's connectivity operating rules would solve the security issues raised during testimony. Sherry Wilson replied that she cannot make that conclusion until the final version is released but is hopeful that the rules will align, rather than be redundant, with current standards. Paul Joiner agreed, saying that he is optimistic.

A Subcommittee member asked about the expected value-added by version 4.x of CAQH CORE's connectivity operating rules. Paul Joiner said that any value-added would depend on whether the rules were enforced. Sherry Wilson expressed concerns about redundancy and additional administrative burden for stakeholders, especially clearinghouses, because the revised rules could impede their EDI adoption. Paul Joiner stated that many health plans lack the resources to implement many different modes at one time. Sherry Wilson said that companies should not be mandated to implement systems that will have low or no use.

A Subcommittee member asked whether the proposed connectivity rule fills a gap in the NIST security standards and whether its enforcement language sets it apart from other operating rules. Sherry Wilson said the NIST standards do not have a gap and are more flexible.

A Subcommittee member asked Arthur Roosa whether the enforcement component would be important to ensure compliance. He replied "yes," the operating rule would only work if the entire industry adopts it. Paul Joiner described one nuance of enforcement, that is, the framework that prevails (and therefore carries the budget) must

consider all of the other frameworks, avenues, and messaging that were developed before enforcement. This process might not lead to the best outcome (i.e., most innovation) if flexibility is limited.

A Subcommittee member asked whether safe harbor laws conflict with the need for a robust level of security. Jamie Ferguson responded that the proposed operating rule would mandate a higher level of security, while providing a safe harbor for systems that do not meet that level of security. He opined about the potential for the safe harbor clause to undo the enforcement clause of the proposed operating rule by protecting the use of older security technologies. Arthur Roosa said that HBMA suggested removing older technologies from the rule and allowing the safe harbor to define the lowest acceptable level of security for data exchange. Sherry Wilson agreed and said that the best practices to adopt are those remain current with technology, especially in the environment where organizations with varied readiness levels are adhering to multiple standards and guidelines.

Alix Goss highlighted the need for a roadmap that sequences efforts and prioritizes resources in a way that allows all stakeholders to reach the same goal at the same time. Sherry Wilson said that the Cooperative Exchange would look to CAQH CORE to provide coordination and alignment with all national standards.

A Subcommittee member asked whether the safe harbor clause would protect trading partners from being required to implement lower levels of security for any type of exchange. Arthur Roosa shared his understanding that connectivity with a trading partner that connects at a lower security level would not be guaranteed unless the trading partners strike an agreement. The safe harbor clause means that any trading partner that has developed code that connects at the minimum security level is guaranteed a connection.

A Subcommittee member asked EHRA to describe touch points between practice management systems and EHR systems and how the proposed operating rule might affect interaction between these systems. Hans Buitendijk said a health care organization's clinical EHR system and its financial and administrative systems are usually separate and therefore must exchange data. Clinical data is transferred from the EHR system into the administrative system for coding, charging, and filing claims. The administrative system is the one that interacts with payer systems or their intermediaries and clearinghouses, and therefore the proposed connectivity rules do not impact EHR systems. There is value in consistency and alignment with processes and security for all administrative systems. No organization wants to invest in one system one year and then be forced to switch to another system the following year. Alix Goss said that these comments may also apply to NCVHS's upcoming convergence project. The vendor and clearinghouse representatives commented that integrated frameworks are needed to bring clarity to the industry. Arthur Roosa said that lack of integration is a fundamental issue for the entire health care system.

Provider Perspective

Five provider organizations provided testimony on the proposed connectivity operating rule.

AHA

Terrence Cunningham, the AHA's Director of Administrative Simplification Policy, presented slides to provide testimony on the proposed connectivity operating rule.

The current landscape includes a safe harbor clause. This concept provides vendors, providers, and health plans with the security of knowing that other parties will support the connectivity method described in the operating rule. Safe harbors are currently permitted for different transactions. Current connectivity rules also permit outdated, less secure authentication methods (e.g., username plus password).

The proposed operating rule would improve security by requiring an X.509 digital certificate-based authentication process. It would streamline safe harbor methodology across transactions and would eliminate the potential for variance, which is problematic.

Current system availability requirements are antiquated and fail to support the industry need. The proposed operating rule specifies that systems need to be available only 86% of the time to be compliant, but health care is a 24 hours per day, 7 days per week industry. Permissible systematic downtime should be much less than 14%.

In conclusion, the AHA recommends that NCVHS approve the proposed connectivity operating rule in order to improve security and streamline safe harbor across the HIPAA transactions.

AMA

Heather McComas, the AMA's Director of Administrative Simplification Initiatives, presented slides to provide testimony on behalf of the AMA and its membership. She reminded the group that a physician's main focus is patient care rather than the business of health care. Physicians want technology that is effortless, seamless, secure, and behind the scenes.

To this end, AMA has a policy that informs its position on the proposed connectivity operating rule. "Information Technology Standards and Costs D-478.996". This policy states that AMA will (a) encourage the setting of standards for health care information technology whereby the different products will be interoperable and able to retrieve and share data for the identified important functions while allowing the software companies to develop competitive systems. AMA will…(c) review the following issues when participating in or commenting on initiatives: (i) cost to physicians at the office-based level; (ii) security of electronic records; and (iii) the standardization of electronic systems; (d) continue to advocate for and support initiatives that minimize the financial burden to physician practices of adopting and maintaining EHRs; and (e) continue its active involvement in efforts to define and promote standards that will facilitate the interoperability of health information technology systems. Accordingly, the AMA participated in all discussions and straw polls involved in the development of CAQH CORE's connectivity rule v3.1.0. The AMA supports federal adoption of the proposed connectivity rule and believes it will enhance the interoperability, efficiency, and security of electronic health care transactions.

The AMA believes the proposed operating rule would add value in several ways. First, the operating rule would create a single set of connectivity specifications across transactions, and it would improve efficiency and interoperability by aligning these connectivity requirements. A single safe harbor across transactions would reduce burden and complexity. The proposed operating rule reflects a logical change for connectivity methods that underlie and facilitate the transmission of all transactions, regardless of content (i.e., connectivity is "payload agnostic"). Second, the operating rule would replace the vulnerable username plus password authentication with the more secure X.509 client certificate-based authentication, which promotes best practices in information technology security and protects industry systems from exposure associated with outdated authorization methods. Third, the proposed operating rule would serve as an important steppingstone between current industry status quo and anticipated future connectivity enhancements, ensure that vendors update their technologies, avoid much larger and costly future implementations, and establish the structure for efficient and less complicated updates and maintenance if more sophisticated rule requirements arise in the future.

To ensure value, the proposed operating rule should replace all currently existing connectivity requirements. To have the desired impact, any federal rulemaking must—as outlined in CAQH CORE's recommendation—replace the current connectivity requirements in the federally mandated Eligibility, Claim Status, and ERA Infrastructure operating rules and create one uniform connectivity rule that applies across all transactions. Federal adoption of this connectivity rule without adjustments to existing mandated rules would cause mass confusion. For example, the safe harbor established by the proposed connectivity rule is incompatible with the safe harbor provisions in currently mandated rules. Moreover, it is illogical (and burdensome) to ask industry to comply with different safe harbors for different transactions.

The health care industry needs robust and consistent system availability requirements. Like the other connectivity concepts outlined in the proposed operating rule, system availability is "payload agnostic" and should be consistent across electronic transactions. Currently, system availability is addressed in CAQH CORE infrastructure rules for individual transactions, which is a barrier to uniform improvement of system availability. The inadequacy of the current system availability requirement elevates these concerns. The current requirement allows for nearly 24 hours of downtime per week, yet industries such as banking and finance deem anything less than 99.9% system availability as incompatible with vital business functions. For an industry whose "business" is human health, such low system availability is wholly unacceptable. During the update of the prior authorization infrastructure rule, CORE participants generally supported the improvements to system availability requirements but acknowledged the impracticality of implementing them for a single transaction—highlighting the need for uniform specifications across transactions.

Because of the anticipated improvements in efficiency, interoperability, and security, the AMA recommends federal adoption of CAQH CORE's Connectivity Rule 3.1.0. To prevent confusion and increased industry burden, NCVHS should clearly recommend that HHS fully replace the current connectivity requirements in the federally mandated infrastructure operating rules with Connectivity Rule 3.1.0. Any future connectivity operating rules should (1) include system availability requirements that apply across all electronic transactions and (2) require at least 95% system availability. The AMA recommends collaboration, coordination, and mutual surveillance between CAQH CORE, SDOs, and related groups to ensure alignment.

MGMA

Robert Tennant, MGMA's Director of Health Information Technology Policy, presented slides to provide testimony on behalf of medical practice managers.

The value proposition for the proposed connectivity operating rule is that it covers and aligns HIPAA-mandated 270/271, 276, 835, and 278 transactions. CORE connectivity rules that were federally mandated in 2013 have been largely and successfully implemented. Building on the existing infrastructure for real-time and batch processing in place for the 270/271, 276, and 835 transactions will allow streamlined implementation of the 278 rule. Updating the federally mandated connectivity requirements from vC1.1.0 and vC2.2.0 would provide enhanced interoperability and efficiency. Defining technical requirements for the exchange of the transactions between trading partners would assure entities of a common connectivity method, thereby creating a safe harbor. The proposed operating rule would ensure enhanced security because it requires the use of updated security protocols. It would also improve messaging and error reporting and commonality.

Medical practices would likely not be required to implement the technical portions of the proposed operating rule. These practices would depend on their EHR and practice management vendors to implement new system functionalities that support system changes and optimize organization data or information integration. Smaller EHR vendors and other trading partners related to implementing the proposed operating rules would face greater challenges.

CAQH CORE is currently working on an updated set of connectivity operating rules with potential completion by the end of 2020. If feasible, and if it does not delay federal mandates for other operating rules, MGMA recommends that NCVHS wait until CAQH CORE finalizes and approves its new version before including it in a set of federal mandates.

Regarding implementation of the connectivity rule, all covered entities, regardless of their size or type, should be given 24 months to comply with this federal mandate. This is the same amount of time that was provided for implementing the operating rules for the 270/271, 276, 835, and EFT transactions.

In conclusion, MGMA supports federal mandating an updated connectivity operating rule to improve the security and functionality of current electronic transactions environment. CORE is developing another new connectivity operating rule, and its future work should improve security and simplify interoperability across administrative transactions.

Montefiore Health System Medical Center

Noam Nahary, Montefiore Health System's Senior Director of Health Service Receivables, presented slides to provide testimony to the Subcommittee. Montefiore supports adoption of the proposed connectivity operating rule.

Montefiore anticipates value in three key areas. First, CAQH CORE Connectivity Rule vC1.1.0 is federally mandated for the eligibility transaction. CAQH CORE Connectivity Rule vC2.2.0, which builds on vC1.1.0, is mandated for eligibility, claim status, and ERA transactions. When initially developed more than 10 years ago, these connectivity rules represented cutting-edge security and connectivity protocols. However, the industry has advanced since then. Compared to the current state (vC2.2.0), CAQH CORE Connectivity Rule vC3.1.0 would reduce complexity by moving to a single SOAP standard, enhance security using certificate-based authentication instead of username and password, and improve communication of errors. Second, the proposed operating rule would provide

consistent connectivity safe harbor across transactions. Updates to the connectivity requirements for eligibility, claim status, and ERA transactions, in addition to mandated support for the prior authorization transaction, would ensure consistent, best practice security and connectivity methods across administrative transactions. CAQH CORE Connectivity Rule vC3.1.0 would enable Montefiore to use a single, common connectivity method across EDI transactions and trading partners, which will reduce onboarding costs. Third, the proposed operating rule would lower ongoing costs related to support for multiple connectivity rules and security and network authentication.

Among the anticipated concerns about the proposed connectivity operating rule is the potential for limited adoption without a federal mandate. A federal mandate would accelerate industry adoption beyond early implementers by making investment dollars and resources available to ensure compliance. CORE certification data suggest that federal mandates drive adoption and certification, enabling prioritization and vendor development. Another concern is that enforcement is lagging. HHS never adopted a health plan certification program (as specified in the ACA); therefore, enforcement of federally mandated operating rules relies on the compliant-driven process used by CMS. Montefiore is concerned that even if this rule is federally mandated, limited enforcement may reduce adoption.

Top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed connectivity operating rule are as follows:

- A single connectivity rule across all transactions would be easier to update, reduce confusion, and promote industry alignment on best practices. The proposed rule would eliminate wasted industry resources that are spent supporting multiple connectivity models across trading partners.
- The connectivity safe harbor clause assures providers of a common method to connect across administrative transactions that is innovative and secure. The proposed rule would reduce the time to onboard new trading partners from weeks to just days because the specifications are normative and use the latest authentication standards.

Montefiore supports adoption of the proposed connectivity operating rule.

Ohio Health

Margaret Schuler, Vice President of Revenue Cycle at Ohio Health System, presented slides to provide testimony. Ohio Health supports adoption of the proposed connectivity rule. Krishna Tummalapalli, an Enterprise Architect at Ohio Health also joined the panel.

As a health system, Ohio Health greatly values the impact of operating rules on its revenue cycle. Operating rules provide consistency in infrastructure and data content for a given transaction. Operating rules close gaps in the standards, ensuring providers receive consistent data across health plans for key transactions. For example, patient financials in the eligibility transactions enable Ohio Health to collect fees from patients at the time of service. Uniformity in adjustment/denial codes on the ERA enable greater automation, and reassociation of ERA and EFT transactions results in more efficient remittance and payment processes. Connectivity and infrastructure rules ensure common expectations and SLAs across health plans for consistent/secure data exchange and automation. Connectivity safe harbor specifies connectivity methods that application vendors, providers, and health plans know will be supported by any conformant entity, meaning that the entity is capable and ready at the time of the request by a trading partner to exchange data using the CAQH CORE connectivity rule. The safe harbor simplifies onboarding and transaction exchange for providers across health plans.

Ohio Health anticipates that the proposed connectivity operating rule would offer value to both industry and Ohio Health. For industry, CAQH CORE Connectivity Rule vC3.1.0 supports best practice interoperability protocols from a single standard and enhanced security perspective. The proposed operating rule would reduce complexity and simplify interoperability by requiring a single SOAP plus WSDL envelope standard instead of two envelope standards, and would establish more robust and uniform support for handling transaction payload by requiring MTOM for SOAP for both real-time and batch processing modes. The proposed operating rule would require the use of an X.509 client certificate-based authentication system and would remove the security vulnerable username plus password system, resulting in more robust security that is aligned with industry standards. Further, the proposed operating rule would improve the communication of errors with updated error codes. Having a

consistent CAQH CORE connectivity rule version across administrative transactions simplifies connections. Mandating CAQH CORE connectivity vC3.1.0 for eligibility, claim status, ERA, and prior authorization enables HIPAA-covered entities to sunset support for CAQH CORE connectivity vC1.1.0 and vC2.2.0 (which are currently mandated for eligibility, claim status, and ERA). For Ohio Health, updating the federally mandated connectivity requirements to vC3.1.0 would strengthen security as Ohio Health integrates with health plans and would extend industry security standards that are used with other integrations to EDI transactions (e.g., eligibility, claim, ERA, prior authorization). A consistent CAQH CORE connectivity safe harbor across the EDI transactions would drive efficiencies and reduce onboarding costs (e.g., vendor onboarding, labor, IT, and customer support).

Ohio Health's anticipated concerns about the proposed prior authorization operating rules are three part. First, HIPAA-covered entities typically have 2 years to comply with operating rule mandates. In contrast, Ohio Health depends on vendor systems (e.g., EHR, health plan systems) that only need 9 to 12 months of lead time for implementations of this size. In addition, enforcement of the HIPAA administrative simplification provisions is needed. HHS never implemented the health plan certification program related to standards and operating rules outlined in the ACA; thus, industry relies on the complaint-driven process for non-compliance supported by CMS. Second, a federal mandate would encourage organizations to prioritize investments in connectivity. If the rules are voluntary, health plans and vendors may not invest. Some effort and minimal cost would be required to ensure that all components of the integration workflow meet the mandated security protocols. Given that the requirements align with standard security protocols, Ohio Health foresees significant alignment with its current initiatives. As new technology and approaches are considered, consistency across connectivity methods will be critical to ensure streamlined communications. CAQH CORE will continue to update its connectivity requirements to meet evolving business needs, so aligning first on vC3.1.0 would create a common baseline across transactions for future updates.

Top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed connectivity operating rule are as follows:

- Updating the currently mandated CAQH CORE connectivity requirements for eligibility, claim status, and ERA transactions will ensure that a modern and secure connectivity method is available for industry and would reduce the need for continued industry support for multiple authentication standards.
- A single connectivity rule across all transactions is easier to update, reduces confusion, and promotes industry alignment on best practices.
- CAQH CORE's Connectivity Rule vC3.1.0 requirements align with best practice security protocols and reduce vulnerabilities in prior rule versions (e.g., username plus password).
- A federal mandate will enable resource allocation and a level of commitment that are not possible on a voluntary basis.
- The benefits and savings derived from standard communications between providers and health plans will provide savings to both groups in time, resources, and patient/consumer satisfaction.

Provider Q&A

A Subcommittee member asked whether implementing the proposed connectivity operating rule would create a material burden if the new CAQH CORE connectivity rules soon followed (i.e., before the end of the 2-year implementation period. Terrence Cunningham expressed a reluctance to wait for new rules, because their development and release often take longer than anticipated. Alix Goss said that the Subcommittee invited representatives from CAQH CORE to provide additional testimony on the release of its their new connectivity rules later Day 2 of this meeting.

A Subcommittee member asked whether achieving one connectivity standard and adopting the proposed operating rule would facilitate future upgrades. Terrence Cunningham suggested that the Subcommittee contact CAQH CORE to ascertain the ease of upgrading from the proposed version to the new version under development. Robert Tennant stressed the importance of considering the entire implementation timeline, because it takes months for NCVHS to make a recommendation, months for CMS to propose a rule, and additional time for public comment and lawmaking. He suggested making a decision based on the timing of the overall process. Alix Goss confirmed that the approval process would take approximately 2 years. Robert Tennant added that the November presidential election may add more time to the adoption process. Heather McComas said that achieving one

connectivity standard would facilitate future upgrades. Noam Nahary said that previous transactions should be brought to a more secure level now. Margaret Shuler agreed that the implementation timeline should start as soon as possible.

A Subcommittee member asked whether the proposed operating rule's safe harbor security requirements would force some trading partners to use lower security standards. Robert Tennant said that the increasing number of threats in recent years have elevated MGMA members' concerns about security. He suggested asking CAQH CORE about its plans to address the safe harbor clause. Heather McComas said that the proposed rule addresses this concern. Terrence Cunningham agreed and said that higher levels of security are permitted.

A Subcommittee member asked whether gaps in the definition of a HIPAA-covered entity (e.g., vendors) apply to the proposed connectivity operating rule. Robert Tennant explained that providers' heavy reliance on vendors is the reason why clearinghouses exist. He added that if vendors are not required to adhere to the mandates, then small-sized providers that use vendors will experience problems. Providers are not focused on studying the requirements and therefore rely on vendors to keep them current and in compliance. Margaret Schuler said that exceptions to standards increase costs. Terrence Cunningham agreed that any entity that uses the transactions should be required to follow the rules, which may necessitate inclusion of other stakeholders under the umbrella. Robert Tennant said that certifications are another way to ensure compliance, but ONC's intense focus on the clinical side of health care (i.e., EHRs) neglects the administrative transactions that run through practice management software systems. Krishna Tummalapalli said that he is tasked with determining whether a project presents a clinical use case or a nonclinical use case. He appreciates the fact that the proposed connectivity operating rule is an industry-neutral standard that will enable common evaluation of metrics and security standards. In response to a question, Krishna Tummalapalli said that systems that exchange health care information usually have higher security functionality than systems that do not.

Health Plan Perspective

Three health plans provided testimony on the proposed connectivity operating rule.

BCBSA

Gail Kocher, BCBSA's Director of National Standards, described the health plan's perspective as a representative of 36 community-based, locally operated Blue Cross and Blue Shield companies.

BCBSA acknowledges the value in adopting connectivity rules that apply to all stakeholders if the connectivity requirements are sufficient, secure, and aligned with other industry standards and federal security protocols.

Regarding anticipated concerns about the proposed connectivity operating rule, the connectivity provisions limit submitter authentication to a single method of digital certificates, which would be costly to implement with little return on investment. Implementation costs will vary based on submitter authentication plans or methods already implemented and will be separate from costs incurred by the trading partner. Despite available technologies, providers still prefer web portal login methods. The safe harbor provision requires plans to implement the digital certificates even if no provider elects to use it—wasting resources and money. A health plan can only require trading partners to use such a system through contractual obligation. BCBSA prefers to use other means to encourage providers to use more secure and better-connected technologies. Although the proposed operating rule implies that all prior transactions will be replaced, it states that C.2.2.0 may not be discontinued. If true, multiple methodologies would need to be supported.

Top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed connectivity operating rule are as follows:

- The security protocols included in the proposed connectivity rule are outdated and considered insecure at the industry level.
- Implementing the proposed operating rule while maintaining prior connectivity methods related to safe harbor adds to overhead costs with little promise for return. This concern becomes magnified when protected health information is exchanged between trading partners.

- The cost to implement the connectivity requirements are significant with little promise for return, especially when multiple methods must be simultaneously maintained.

Kaiser Permanente

Cathy Plattner, Kaiser Permanente's Business Consulting Specialist, showed slides to provide testimony on the proposed connectivity operating rule.

Overall, Kaiser Permanente supports adoption of the proposed connectivity operating rule (which would apply to all previous operating rules). The proposed operating rule would make transactions more secure. Kaiser Permanente raises two main concerns:

- CAQH CORE proposes to replace older versions of the connectivity rule, but new operating rules have already been adopted with specific connectivity processes. Therefore, a clear roadmap and well-defined cost-benefit and return on investment analysis is needed.
- Some of the technology standards noted as acceptable in the proposed operating rule are already outdated (e.g., SSL 3.0 transport standards), which may be a safe harbor issue.

Top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed connectivity operating rule are as follows:

- NCVHS and regulatory bodies should consider encouraging voluntary adoption of standards through appropriate program incentives and policy levers.
- The degree to which the operating rule can be implemented if HL7 FHIR standards are in use is unclear. Kaiser Permanente supports a HIPAA exception to allow end-to-end implementation testing of a FHIR-based transaction model for HIPAA transactions (including prior authorization and other real-time transactions).

Anthem

Christol Green, Anthem's E-Solutions Portfolio Manager, presented slides to provide testimony on the proposed connectivity operating rule.

Regarding anticipated concerns, the proposed connectivity operating rule limits the inclusion of new and emerging technologies, such as FHIR, XML via web portal, RESTful APIs, OAuth, SAML authorization, and identity services. Limiting connectivity would prevent Anthem from meeting the needs of its trading partners. The safe harbor provision would allow providers to use outdated connectivity methods that would, in turn, need to be maintained by health plans.

Top points for NCVHS to consider in its recommendations to HHS for adoption of the proposed connectivity operating rule are as follows:

- All stakeholders, regardless of size, should be required to implement new rules within the same time frame, which should be at least 2 years.
- The proposed operating rule should be adopted only if it covers all transactions subject to current operating rules, to eliminate the possibility of a requirement to implement and support regardless of usage or solutions currently in place.
- Stakeholders should have the flexibility to use newer business technologies that allow for more efficient communication exchange between the clinical staff and the health plan.

Anthem has long been an early adopter of CAQH rules, and it will continue to work and participate with CAQH CORE and SDOs to improve the process.

Health Plan Q&A

A Subcommittee member asked about the cost if the proposed connectivity operating rule is not promulgated. Gail Kocher replied that industry would remain status quo, because each stakeholder is using the best possible security

protocols while adhering to previously mandated connectivity rules. Concerns exist about the requirement to implement an outdated system just to be compliant. Mandating a rule just to "do something" is not the right approach.

When a Subcommittee member asked whether the industry would voluntarily improve connectivity while waiting for regulations to catch up, Christol Green said "yes." For example, Anthem is moving forward with electronic attachments using the X12 standard because providers have asked for this functionality for a long time. Anthem is also working with the Da Vinci project to build use cases for FHIR and end-to-end processing. The industry seeks new technologies that save time and resources.

Subcommittee members asked Anthem to elaborate on both barriers to technology and innovative technologies on the horizon. Christol Green said that Anthem is concerned about its ability to use emerging technologies such as FHIR. Anthem wants to enhance its end-to-end work and to accept transactions from providers beyond the X12 278 transaction. Anthem wants flexibility so that it can explore the best options to improve patient care as its ultimate goal.

A Subcommittee member asked the panelist to comment on actions that would place the patient at the center of the proposed operating rule. Christol Green said that Anthem providers still use its web portal for many operations, including requesting prior authorizations 24 hours per day and checking their status. Anthem wants to extend this functionality to patients in the patient portal. Further, Anthem wants to develop complete and fully automated processes. Gail Kocher stated that, to achieve its goal to improve patient care, BCBSA goal wants to send information to the provider, at the point of care and as quickly as possible. Expending time, money, and resources to implement functions that will not be used contravenes this ultimate goal.

A Subcommittee member asked about the true need for enforcement to bring the entire industry into compliance with the standard. Gail Kocher replied that outliers will always exist and therefore the standards must apply to all stakeholders.

A Subcommittee member asked whether the proposed operating rule would allow willing partners to choose more advanced connectivity technologies. Gail Kocher replied that, while the interpretation does not limit stakeholders, it does specify that stakeholders must also provide the minimum requirements. The proposed operating rule would be stronger if does not require stakeholders to implement a technology that would not be used.

Public Comment

David Wilderman asked the Subcommittee about how the predictability roadmap informs NCVHS considerations of the proposed operating rules. Alix Goss responded that the roadmap provides perspective for evaluating the proposed operating rules within the committee's overall administrative simplification efforts.

Mike Denison, Senior Director of Regulatory and Standards Compliance at Change Healthcare, commented that because the proposed connectivity operating rule was initially balloted and approved nearly 5 years ago, its security vulnerabilities are now well known and published. Change Healthcare cannot support adoption of a safe harbor rule that is simply not safe. Although the proposed operating rule does not require trading partners to discontinue use of existing connections, Section 5 of the rule states that a HIPAA-covered entity or its agent must use the CAQH CORE connectivity rule if requested by a trading partner. It further states that a HIPAA-covered entity or its agent must accommodate a request by a trading partner to use the CAQH CORE safe harbor. As stated earlier by Nick [Coussoule], many security-conscious organizations have expended significant effort and investments to aggressively sunset SSL connectivity within their IT environment. Health care organizations should not be forced by federal mandate to re-implement legacy connectivity protocols with known security vulnerabilities simply because a trading partner insists, yet the proposed operating rule requires that they must.

Rupinder Singh from CMS asked whether MIME would be part of the upcoming rule or whether it would be discontinued. Rebecca Hines replied this question signifies a request for clarification rather than a public comment.

Clarifying Questions with CAQH CORE

Subcommittee members asked April Todd and Bob Bowman from CAQH CORE the following clarifying questions:

Question: What is the current status, and what is CORE's current estimate of the timing for release of the updated C4 connectivity rules?

> **Answer:** CAQH is in alignment with NCVHS on the predictability roadmap's plans to deliver incremental rules to the industry. CAQH CORE understands the speed with which the process works. CAQH CORE's February 2020 letter to NCVHS noted efforts to update the operating rules, with the intent to build on existing rules to support clinical data, in particular, and the intersection between clinical and administrative data. In addition to the connectivity rules, CAQH is considering rules for attachments for prior authorization and for claims and rules for value-based purchasing (VBP) processes. The new connectivity rules include version 1.2 for TLS, OAuth 2.0, REST, and APIs. The intent is to join the connectivity, attachment, and VBP rules. Regarding timing, the workgroups have only recently started work on the attachment rules, so release of a rule package will occur sometime in 2021 or 2022.

Question: Does CAQH CORE intend to move the three proposed rules together as a packet?

> **Answer:** Yes.

Question: So, the connectivity rule in development will not stand on its own, that is, it will be packaged with attachment rules and VBP rules?

> **Answer:** Yes. CAQH Core is trying to create a predictable and achievable path. CAQH CORE needs to consider these rules together and to find ways for existing technologies to work together and to build on them.

Question: Does the C4 safe harbor connectivity operating rule eliminate optional support for obsolete transport security mechanisms? Will C4 align with the ONC trusted framework and the NIST TLS version 1.3 for 2024 for federal systems? Does CORE safe harbor obligate an entity that has discontinued a security mechanism to use that discontinued method with a trading partner that wants to use it?

> **Answer:** This rule aligns with NIST where applicable, but it also creates more standardization between trading partners to reduce the cost of onboarding and support. NIST covers security at a broad level. The connectivity rule applies to health care trading partners to facilitate a standardized, direct connection versus broader flexibility. The intention of the safe harbor is to create one method that is easy to support by all trading partners, and the expectation is that all trading partners will support at least that method to help promote connections and reduce cost. If trading partners mutually agree to use something outside of the operating rule, either a higher standard or a lower standard, they are allowed to do so. The safe harbor is intended to create one base that every trading partner is required to support, giving everyone that wants to connect a means to do so. CAQH also recommended that the predictability roadmap include provisions that ensure currency with technology. An active cross-reference to the most recent CORE connectivity rule might be a solution to the problem created by gaps in time.

Question: The system uptime is currently set at 86%. How did your membership reach that number?

> **Answer:** The development group compromised on this part of the rule. Some members advocated for as high as 95% uptime. Others advocated for uptime requirements that were consistent across all operating rules. CAQH is currently polling its members on this item.

Question: One criticism is that previous recommendations on the proposed connectivity operating rule were not addressed in version C3. For example, only one option is offered for authentication. Will these issues be addressed in version C4?

Answer: The purpose of the connectivity rules is to create one common standard that everyone will support as opposed to providing flexibility to use various options. Variability increases the need for support and maintenance. But once again, trading partners that mutually agree to use something different are welcome to do so. NCVHS previously recommended voluntary support for this operating rule. Since that time, many entities have completed CORE certification for this level of connectivity, including national health plans, many software vendors, and many nationwide clearinghouses. So, although it was not federally mandated, the industry adopted these transactions with this security and with these connectivity requirements. CAQH is bringing it forward for adoption because it has reached a tipping point in the industry where many stakeholders have already adopted it on a voluntary basis.

Question: Will the issues raised by Sherry Wilson in her slide deck be addressed in version C4?

Answer: C4 connectivity rules include a minimum number of ways to connect to reduce costs and maintenance. CAQH's desire is to remove the flexibility to reduce costs.

Question: Is X509 the only authentication method allowable? It's not a safe harbor approach, it's X509 or nothing?

Answer: No, the entirety of the rule is a safe harbor. If there is mutual agreement between trading partners to use something else, they are permitted to do that. The rule as written encourages participation in at least one method.

Question: So, if you pick one method that is in the rule you are protected?

Answer: The operating rules allow for predictability. Any trading partner or provider that is building their own system or using a vendor, clearing house, or health plan, will know the parameters for that connection. They do not have to build a VPN and set up separate lines. The rule provides for a web service that uses SOAP, a specific connectivity requirement, a specific authentication requirement, and a specific security requirement. Everything can be prebuilt in a "plug and play" fashion to allow trading partners to connect within a week.

Question: So, if you either follow the rule or have a trading partner agreement, you have a safe harbor?

Answer: Yes.

Question: So, it establishes a floor with a limited menu? Even if you do not like the menu?

Answer: Yes. It has longevity until the next version is released.

Question: Why is there a need to mandate the connectivity rule when most organizations are now voluntarily complying with the recommendation?

Answer: The rule creates a floor or minimum that everyone must comply with. It creates as much consistency as possible. Consistency reduces costs and maintenance. It is also important to note the historical component. Phase 2 adoption produced an immediate impact. The use of the ERA jumped exponentially. Mandating rules leads to a higher level of adoption.

Question: Do you anticipate that all organizations will implement the minimum requirements of the operating rule, or will some type of enforcement be needed?

Answer: Many entities will see the cost-benefit value of adoption. Those who have become certified see the value, and the national landscape will see the value as well. Adoption does significantly increase when there is a mandate. Organizations want to be compliant, and the mandate often frees up funds to become compliant.

Closing Remarks and Adjournment

Alix Goss and Rich Landen thanked attendees for their valuable participation and testimony. The Subcommittee adjourned to begin the process of analyzing the testimony and summarizing its recommendations for the Full Committee.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

/s/	October 15, 2020
Chair, NCVHS	Date

Appendix A: Agenda

National Committee on Vital and Health Statistics (NCVHS)

Subcommittee on Standards Hearing on
Request for NCVHS Review of CAQH CORE Operating Rules for Federal Adoption

August 25-26, 2020

Tuesday, August 25 – Prior Authorization Rules

Time	Panel	Participants
10:00 a.m.	**Welcome, Call to Order**	Rebecca Hines Executive Secretary/Designated Federal Officer
10:05 a.m.	**Opening Remarks/Agenda Review**	Alix Goss and Rich Landen, Co-Chairs Subcommittee on Standards
10:10 a.m.	**New proposed operating rules submitted to NCVHS from CAQH CORE**	Alix Goss and Rich Landen, Co-chairs
10:30 a.m.	**Overview of HHS authority to adopt operating rules**	National Standards Group, HHS/CMS Dan Kalwa, *CMS*
10:45 a.m.	**Overview of proposed operating rules for prior authorization and connectivity**	April Todd, *CAQH CORE* Susan Turney, *Marshfield Clinic Health System* Timothy Kaja, *UnitedHealthcare*
11:25 a.m.	**Intersection of standards and operating rules**	Cathy Sheppard, *X12*
11:50 a.m.	**Break**	
12:00 p.m.	**Patient Perspective**	Anna Hyde, *Arthritis Foundation*
12:20 p.m.	**Health Plan perspective on proposed prior authorization operating rules (Panel 1A)**	Christol Green, *Anthem* Cathy Plattner, *Kaiser Permanente*
12:50 p.m.	**Lunch**	
1:50 p.m.	**Health Plan perspective on proposed prior authorization operating rules (Panel 1B)**	Connie Leonard, *CMS Medicare Fee-For-Service* Gail Kocher, *BCBSA*
2:20 p.m.	**Provider perspective on proposed prior authorization operating rules (Panel 2A)**	Terry Cunningham, *AHA* Heather McComas, *AMA* Robert Tennant, *MGMA*
3:00 p.m.	**Break**	

Time	Panel	Participants
3:15 p.m.	**Provider perspective on proposed prior authorization operating rules (Panel 2B)**	Noam Nahary and Stephen Rosenthal, *Montefiore Medical* Margaret Schuler, *Ohio Health* Katie Knapp, *Veterans Health Administration*
3:55 p.m.	**Vendor & Clearinghouse perspective on proposed prior authorization operating rules**	Paul Joiner, *Availity* Sherry Wilson, *Cooperative Exchange* Hans Buitendijk, *EHRA* Arthur Roosa, *HBMA*
4:45 p.m.	**Public Comment on proposed prior authorization operating rules**	Rebecca Hines Executive Secretary/DFO
5:00 p.m.	**Closing and Adjourn**	Alix Goss and Rich Landen Co-chairs, Subcommittee on Standards

Wednesday, August 26 – Connectivity Rule

Time	Panel	Participants
10:00 a.m.	**Welcome, Call to Order**	Rebecca Hines Executive Secretary/Designated Federal Officer
10:05 a.m.	**Welcome and Review Agenda**	Alix Goss and Rich Landen, Co-Chairs Subcommittee on Standards
10:15 a.m.	**Vendor Perspective on proposed connectivity operating rule**	Paul Joiner, *Availity* Sherry Wilson, *Cooperative Exchange* Hans Buitendijk, *EHRA* Arthur Roosa, *HBMA*
11:00 a.m.	**Provider Perspective on proposed connectivity operating rule** *(with a break)*	Terry Cunningham, *AHA* Heather McComas, *AMA* Robert Tennant, *MGMA* Noam Nahary and Stephen Rosenthal, *Montefiore* Margaret Schuler, *Ohio Health*
12:00 p.m.	**Lunch**	
1:00 p.m.	**Health Plan perspective on proposed connectivity operating rule**	Gail Kocher, *BCBSA* Cathy Plattner, *Kaiser Permanente* Christol Green, *Anthem*
1:25 p.m.	**Public Comment**	Rebecca Hines Executive Secretary/DFO

Time	Panel	Participants
1:45 p.m.	**Closing Remarks**	Alix Goss and Rich Landen Co-chairs, Subcommittee on Standards
3:00 p.m.	**Adjourn**	Alix Goss and Rich Landen Co-chairs, Subcommittee on Standards

Upcoming NCVHS Meetings

- September 14, 2020, Hearing of the Subcommittee on Privacy, Confidentiality and Security
- November 18-19, 2020, Full Committee

Appendix B: Invited Speakers

Hans Buitendijk, Chair, Electronic Health Record Association

Terry Cunningham, Director of Administrative Simplification Policy, American Hospital Association

Christol Green, E-Solutions Portfolio Manager, Anthem

Anna Hyde, Vice President of Advocacy and Access, Arthritis Foundation

Paul Joiner, Chief Operating Office, Availity

Timothy Kaja, Chair, CAQH CORE

Daniel Kalwa, Policy Advisor, Centers for Medicare & Medicaid Services

Katherine Knapp, Program Analyst, Veterans Health Administration

Gail Kocher, Director of National Standards, Blue Cross and Blue Shield Association

Connie Leonard, Center for Program Integrity, Centers for Medicare & Medicaid Services

Heather McComas, Director of Administrative Simplification Policy, American Medical Association

Noam Nahary, Senior Director of Health Service Receivables, Montefiore Health System

Cathy Plattner, Business Consulting Specialist, Kaiser Permanent

Arthur Roosa, Healthcare Business Management Association

Margaret Schuler, Vice President of Revenue Cycle, Ohio Health System

Cathy Sheppard, X12

Rob Tennant, Director of Health Information Technology Policy, Medical Group Management Association

April Todd, Senior Vice President, CAQH CORE

Susan Turney, Immediate Past Chair, CAQH CORE

Sherry Wilson, Past Chair, Cooperative Exchange

Appendix C: Virtual Attendees

Hong Huang, Cambia Health
Michael Mabry, Radnet
Bob Bowman, CAQH
Paul Tyler, Deloitte
Diana Fuller, Michigan State Government
Pamela Grosze, PNC
Kasey Nicholoff, EHRA
Briana Pastrano, Deloitte
Laurie Woodrome, Labcorp
Michael Peters, ACR
April Todd, CAQH
Rupinder Singh, CMS
Dominic Saroni, Saroni Consulting
Matt Reiter, Capitol Associates
Celine Lefebvre, AMA
Matthew Downey, WEDI
Kristin Stewart, AHIP
Meryl Bloomrosen, Premier, Inc.
Gladys Wheeler, CMS
Eric Grindstaff
Margaret Weiker, NCPDP
Michelle Barry, Availity
Leslie Flaherty, CMS
Teresa Autery, Tibco
Merri-Lee Stine, Aetna
Mary Lynn Bushman, Anthem
David Haugen, Minnesota State Government
Leslie Welsh Flaherty, UMN
Sheryl Turney, Anthem
Thomas Kessler, CMS
Mary Lynam
Durwin Day, BCBSIL
Molly Malavey, AMA
Betty Lengyel-Gomez
Daniel Vreeman. RTI
Katie Campanale, Accel Solutions, LLC
Erin Weber, CAQH
Bill Finerfrock, Capitol Associates
Susan Langford, BCBST
Dan Medve, Cleveland Clinic
Geanelle Herring, CMS
Jill Roberts
C. Veverka, Kunz, Leigh and Associates
Susan Dardine, Genesis Healthcare
Tina Greene, Mitchell
Deborah McCachern, Change Healthcare
Rachel Foerster, Rachel Foerster & Associates, LTD
Laurie Burckhardt, WPS Health Solutions
Stanley Nachimson, Nachimson Advisors
Mike Denison, Change Healthcare
Laura Caldwell
Mostafa Nawabi, Deloitte
Ada Sanchez, CMS
Pat Waller, Cambia Health
Kathy Sites, Availity
Charles Stellar, WEDI
Adam Nichols
Mary Winter, Prime West
Walter Suarez, Kaiser Permanente
Nancy Spector, AMA
Melissa Myers, Cleveland Clinic
Sandra Jamison, Humana
Todd Omundson, AHA
David Wilderman, Deloitte
Valerie J.M. Watzlaf, (incoming NCVHS member)

Appendix D: List of Acronyms

AAA	Authentication, Authorization, and Accounting error and action codes
ACA	Patient Protection and Affordable Care Act of 2010
AHA	American Hospital Association
AMA	American Medical Association
ANSI	American National Standards Institute
API	Application Programming Interface
ASC	Accredited Standards Committee
BCBSA	Blue Cross and Blue Shield Association
CAQH	Council for Affordable Quality Healthcare, Inc.
CDC	U.S. Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
EFT	Electronic Funds Transfer
EHR	Electronic Health Record
EHRA	Electronic Health Record Association
ERA	Electronic Remittance Advice
ESMD	Electronic Submission and Medical Documentation
FDA	U.S. Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FIPS	Federal Information Processing Standard
FTE	Full-time Equivalent
HBMA	Healthcare Business Management Association
HCSDRC	Health Care Service Decision Reason Code
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIT	Health Information Technology
HITECH Act	Health Information Technology for Economic and Clinical Health Act
LOINC	Logical Observation Identifiers Names and Codes
MGMA	Medical Group Management Association
MTOM	Message Transmission Optimization Mechanism
NCHS	National Center for Health Statistics
NCVHS	National Committee on Vital and Health Statistics
NIST	National Institute of Standards and Technology
NLM	National Library of Medicine
NPRM	Notice of Proposed Rulemaking
PWK	Paperwork codes
RESTful API	Representational State Transfer Application Programming Interface
SAML	Security Assertion Markup Language
SDO	Standards Development Organization
SLA	Service Level Agreement
SOAP	Simple Object Access Protocol
SSL	Secure Sockets Layer
TLS	Transport Layer Security
UMO	Utilization Management Organization
U.S.	United States
VBP	Value-Based Purchasing
VHA	Veterans Health Administration
WSDL	Web Service Definition Language
X12N or X12	An accredited standards committee chartered by the American National Standards Institute
XML	Extensible Markup Language