NCVHS Standards Subcommittee Project Scope
Development of Recommendations to Support Convergence of Clinical And Administrative Data:
with initial focus on the prior authorization transactions and workflow
March 2020

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Background and History:

Standardized, interoperable data exchange for U.S. healthcare has long been a policy goal of the federal government. The administrative transactions between provider and payer were ripe for standardization in the early 1990s as the industry began to modernize and automate the flow of health information. Efforts toward standardization culminated in the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Standardization of clinical data flows were not as ready for standardization in that era, but the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) set the stage for clinical data standardization by means of incentives for provider adoption of ONC-certified[1] electronic health records under the CMS[2] Meaningful Use program, now renamed Promoting Interoperability.

When HIPAA was enacted, providers used one system for their clinical data and a completely separate system for their financial or practice management data – and these systems did not communicate with each other. Health plans typically had no clinical systems since the only clinical data processed by health plans were those directly in support of claims or eligibility processing. Clinical data were often processed in a separate division of the health plan company or by contracted utilization management organizations.

Times have changed. Provider clinical and administrative systems, while often still separate, do now have some degree of interoperability. Health plans have both clinical and non-clinical component systems. Technology has changed from mainframe processing to Application-Programming Interfaces (APIs) and neither bandwidth nor cost of electronic storage is a significant barrier as it had been.

Another shift in the health care industry is the move to value-based payment models, which align provider compensation with improvements in care and cost controls. The shift from fee-for-service to value-based payment requires greater access to clinical information for both payers and providers to effectively execute this transformation, making the industry primed for innovation.

[1] Office of the National Coordinator (ONC): https://www.healthit.gov/topic/about-onc
[2] Centers for Medicare & Medicaid Services (CMS) https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms

NCVHS and ONC recognize both the desirability and the inevitability of merging administrative and clinical data streams. However, the "installed base" throughout the vast health care industry is such that merging those streams is a complex challenge implicating policy, processes, and technology.

One good example that demonstrates the issue associated with merging clinical and administrative data is the process and exchange of prior authorization – the request and response related to approving care for medical or pharmacy services between a provider and a health plan. This is one of the most burdensome and complex issues currently hampering the health care industry's efficiency opportunities, contributing to provider burnout and patient care problems. NCVHS identified the provider, payer and patient burden associated with prior authorization several years ago and documented the challenges with industry use of the HIPAA-adopted standard in its October 13, 2016 Review Committee report.[3] There are numerous business and technical issues with the current HIPAA-mandated transaction standards, which are based on electronic data interchange (EDI) technologies.

For the past three years, several industry workgroups have been working to identify and address the prior authorization workflow and business process issues for payers and providers. In one effort, the American Medical Association (AMA) formed a workgroup of 17 state and specialty medical societies, national provider associations, health plans, and patient representatives to develop best practices for prior authorization and other utilization management requirements by identifying the most common provider and patient concerns. The outcome in 2016 was a consensus on 21 reform principles[4], widely shared with legislators and policy makers. This set of principles remains viable today, and the provider associations presented it to congressional leaders this year during discussions of prior authorization legislation. CMS has identified the prior authorization process as one of its key initiatives in its Patients over Paperwork initiative – a key project looking at ways to remove barriers and unleash innovation across the agency and industry.

Over the past few years, in another effort to both improve efficiencies and increase access to clinical data, HL7, one of the standards development organizations, has been successfully testing the FHIR (Fast Healthcare Interoperability Resources) standard and a variety of implementation specifications for specific business cases. FHIR is promoted for its ability to support interoperability between systems. The FHIR standard leverages web tools for APIs and is easy to use in developing API-based exchanges between electronic health record and payer systems. The benefit of FHIR is that it uses electronic and codified data available in many electronic health records (EHRs), which house the clinical data. The ability of APIs to access EHR data helps address workflow issues and reduce burden for both providers and payers, who may now be able to use these APIs for certain transactions to pull needed clinical data they could not access before. Specific to prior authorization, developers have created and are testing a FHIR implementation specification along with Electronic Data Interchange (EDI) crosswalks. The set of HL7 FHIR implementation guides supporting prior authorization are addressing transactional, policy and workflow barriers.

[3] October 13, 2016 Review Committee Findings and Recommendations on Adopted Standards and Operating Rules: https://ncvhs.hhs.gov/wp-content/uploads/2018/03/RC_Report_TD-Final-as-of-Oct-12-2016rh.pdf

[4] Reform principles for prior authorization: https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf

In the project described in this scoping document, NCVHS, in collaboration with ONC, is attempting to identify and recommend a path toward convergence of administrative and clinical data. It proposes to use the prior authorization processes of industry as an exemplar, and to better understand and guide convergence paths for health care policy and standards.

Ongoing issues related to prior authorization

As noted above, the Subcommittee has been monitoring industry's progress in addressing burden, barriers, and opportunities for prior authorization and has determined that, in spite of many efforts, the prior authorization transaction remains one of the top administrative inefficiencies for both payers and providers. Importantly, delays and burdens of prior authorization contribute to the erosion of patient care and safety objectives.

For example, NCVHS is aware of other work conducted by stakeholders and associations such as the Workgroup for Electronic Data Interchange (WEDI), America's Health Insurance Plans (AHIP), the Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare & Medicaid Services (CMS), to understand the burden placed on payers and providers when conducting prior authorization related activities and tasks. Based on the findings from these organizations, ongoing challenges include:

1) federal and state policies including minimum necessary and other privacy considerations;
2) the requirement for (medication) supply authorization requests to be made using the HIPAA mandated transaction standard (the X12 278 Version 5010) rather than the more relevant NCPDP SCRIPT standard;
3) limited adoption of, or support for the mandated HIPAA transaction standard X12 278 for medical services;
4) outdated and ineffective payer and provider workflows;
5) unique and opaque payer policies and absence of patient or illness-specific authorization requirements; and
6) use of portals by payers affecting provider workflows.

Justification and Scope of Work:

Addressing the challenges of prior authorization could help garner workflow efficiencies and mitigate patient care risks. This is an exemplar opportunity to evaluate and plan for the convergence of administrative and clinical data policy and standards, because this task requires output and input from the EHR and practice management systems.

In parallel to the Standards Subcommittee interest in convergence and improving prior authorization processes, ONC has also been exploring the topic through its work related to the 21st Century Cures Act. The Act encourages collaborative engagement between ONC and NCVHS:

> "The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies."

NCVHS and ONC have been discussing the convergence of data standards and policy. There is strong agreement that harmonization of administrative and clinical standards is essential to improve data interoperability to support clinical care, reduce burden and improve overall efficiency of the health care

system. Using prior authorization as the prototype, specific recommendations can be developed and advanced by both NCVHS and ONC. To that end, while NCVHS is developing its initiative, ONC is forming a task force within its federal advisory committee, HITAC, to analyze the issue and to do so in a manner that can benefit the efforts of both committees.

Description of the NCVHS project: The NCVHS Standards Subcommittee will produce recommendations related to the convergence of administrative and clinical standards and improvement opportunities related to prior authorization. Specifically, this Standards Subcommittee project will use information from prior NCVHS hearings, reports, and recommendations and combine it with findings from the 2020 HITAC *Intersection of Clinical and Administrative Data Task Force* to produce new actionable recommendations for HHS and industry within the scope of this project.

Expected Outcome: The intent is to produce recommendations oriented towards improving delivery system performance through the convergence of clinical and administrative data exchange standards. Such standards may be existing standards, emerging standards, or a combination of both.

Timing: The NCVHS project is anticipated to run for 6-12 months and will result in the proposal of one or more concrete approaches for consideration by HHS and/or industry.

Timeframe and phases for the 2020 NCVHS project:

- Phase I: Discovery. Gather information from prior hearings and input received through participation in the HITAC task force.
- Phase II: Analysis. Evaluate the gathered information and HITAC task force findings (2nd or 3rd Quarter).
- Phase III: Develop and submit recommendations to HHS (3rd or 4th Quarter).

In this scoping document, the Subcommittee does not specify the types of recommendations that might result from the discovery and analysis work because the output is currently unknown. The Subcommittee will evaluate the information produced by HITAC and elsewhere regarding standards, technology, testing, processes, workflows, and patient impact.

Components of work

a) Continue collaboration with ONC leadership
b) Actively support and participate in the HITAC Intersection of Clinical and Administrative Data Task Force
c) Evaluate the existing body of evidence to identify relevant information and content
d) Coordinate with NCVHS's Privacy, Confidentiality, and Security Subcommittee (PCS) to address privacy implications of prior authorization and convergence of data standards
    - Invite PCS review and comment on privacy implications at appropriate milestones of drafting.
e) Determine scope of recommendations that would be useful and timely for the Secretary and to industry
f) Develop actionable recommendations and present to the full NCVHS for review and approval

Key inputs

a) Prior NCVHS artifacts informed by industry testimony and committee deliberations.
b) HITAC Intersection of Clinical and Administrative Data (ICAD) Task Force Report(s).
c) New industry efforts and work products relevant to this project.
d) Federal input: CMS and ONC Interoperability rules and information from other Federal agencies: SAMHSA, VA, DoD, IHS, Public Health Service, CDC and others.

Appendices

Appendix 1: NCVHS Recommendations related to prior authorization (2014-2019)

Highlights of NCVHS Recommendation Letters with Prior Authorization references by Date (most recent first)	Summary of NCVHS recommendations	Selected outcomes
October 2016. Review Committee Findings and Recommendations on Adopted Standards and Operating Rules https://ncvhs.hhs.gov/wp-content/uploads/2018/03/RC_Report_TD-Final-as-of-Oct-12-2016rh.pdf	Recommendation 10. Comprehensive list of recommendations pertaining to prior authorization processes, standard transactions, operating rules and collaboration for HHS, Standards Organizations and industry	*AMA convened work group with 17 state & specialty medical societies, and developed Prior Authorization Reform Principles[5].*
July 2016. Recommendation re: Proposed Phase IV Operating Rules https://ncvhs.hhs.gov/wp-content/uploads/2018/03/NCVHS-REV-Phase-IV-Ltr-July-1-2016-Final-Chair-CLEAN-for-Submission-Publication-REV-Jul-6.pdf	CAQH CORE proposed Phase IV operating rules for prior authorization	*NCVHS did not propose adoption by HHS; suggested voluntary testing by industry to assess usability.*
February 2016. Findings from Administrative Simplification Hearing https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2016-Ltr-to-Burwell-Findings-of-RC-Adm-Simp-June-2015-Hearing-Word.pdf	Recommendation 8. Evaluate the value of the current prior authorization standard. Identify why web portals are considered more effective than the adopted transaction standard. Consider changes to future versions of the standard. Leverage attachments transaction standards and operating rules to enhance	*a) CAQH addressing optional use of web portals in Phase V Operating rules. Not yet proposed to NCVHS for review.* *b) HHS regulation for attachments standard on unified agenda*

[5] https://www.ama-assn.org/practice-management/sustainability/prior-authorization-reform-initiatives

Highlights of NCVHS Recommendation Letters with Prior Authorization references by Date (most recent first)	Summary of NCVHS recommendations	Selected outcomes
	use of adopted transaction standard.	
February 2014 https://ncvhs.hhs.gov/wp-content/uploads/2014/05/140515lt2.pdf Also see the recommendation from the May 15, 2016 Report of the Review Committee re: pharmacy prior authorization	Name the NCPDP SCRIPT Standard Version 2016071 Prior Authorization transactions as the adopted standard for the exchange of prior authorization information between prescribers and processors for the pharmacy benefit	*CMS has adopted the NCPDP Script standard in a Part D rule for Part D prescribers and Part D plans (2019). HHS has not adopted this standard as a HIPAA standard transaction.*
May 2014 Letter to HHS re: findings on Prior Auth for Pharmacy benefit, HPID, EFT/ERA and operating rules https://ncvhs.hhs.gov/wp-content/uploads/2014/05/140515lt2.pdf	Adopt the NCPDP SCRIPT Standard Version 2013101 Prior Authorization transactions as the adopted standard for the exchange of prior authorization information between prescribers and processors for the pharmacy benefit	*HHS did not take any action on this recommendation. NCPDP released an updated version of the Script standard in 2016.*

Appendix 2: Collaboration between HITAC and NCVHS Federal Advisory Committees [6]

Vision

Coordination and collaboration between NCVHS and HITAC could provide opportunities to harmonize recommendations, reduce redundant work, and achieve both FACAs' objectives. NCVHS provides advice and assistance on key health data issues related to community and population health, standards, privacy and confidentiality, quality, and data access and use. HITAC makes recommendations on policies, standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, that advances the electronic access, exchange, and use of health information. Coordination and collaboration can mutually benefit the respective work of both—enabling identification of opportunities for convergence or coordination of committee deliverables, especially in the development of recommendations. At a minimum, the interaction can reduce the likelihood of non-harmonized recommendations to the Department of Health and Human Services that could inadvertently result in conflicting requirements on providers, payers, patients and other stakeholders. The driver in all such deliberations should be a strong focus on what will result in the best benefit and value to the U.S. population and to individual patients for both health and health care.

Statutory Requirements

Both FACAs broadly focus on aspects of health data but with different charges. What are the distinct statutory requirements for NCVHS and HITAC?

NCVHS is a longstanding committee charged with advising the HHS Secretary on health data, statistics, privacy, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42U.S.C.242k[k]). The Committee takes a broad view of health data policy including data usability, analytic capabilities, appropriate access, and use of data while ensuring relevant safeguards. Specific responsibilities include issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information. This includes the Treatment, Payment and Operations (TPO) standard transactions, code sets and operating rules section of HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), which is part of the American Recovery and Reinvestment Act of 2009 (ARRA) and by the 2010 Patient Protection and Affordable Care Act (ACA).

HITAC is a FACA created by the 21st Century Cures Act (Cures). Cures sunsets the previous Office of the National Coordinator (ONC) FACAs – the HIT Policy Committee and the HIT Standards Committee.

HITAC is charged by Cures to:

> "…recommend to the National Coordinator, consistent with the implementation of the strategic plan described in section 3001(c)(3), policies, and, for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information."

[6] NCVHS refers to the National Committee on Vital and Health Statistics: https://ncvhs.hhs.gov/ HITAC refers to the Health Information Technology Advisory Committee: www.healthit/hitac

Cures states that:

> ‘‘SEC. 3002. HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE.
> . . .
> “(d) MEMBERSHIP AND OPERATIONS.—
> . . .
> “(7) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.”

thus catalyzing discussions between ONC and NCVHS regarding the most useful approach to accomplish the convergence of clinical and administrative data exchange standards.