The Office of the National Coordinator for Health Information Technology

Intersection of Clinical and Administrative Data Standards Discussion and Next Steps

HITAC Meeting
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Challenge: Separate Clinical and Administrative Data Standards

- 21st Century Cures Clinician Burden Reduction work in partnership with CMS
  - Listening sessions and public feedback
- Some HIPAA transaction standards have low utilization rates despite 2003 mandate
- Electronic Health Record (EHR) capabilities notably advanced over the past decade in parallel to care delivery and payment reimbursement models
- The lack of harmonized clinical and administrative data standards and policy leads to ecosystem burden such as:
  - Inefficient workflows impacting patient outcomes
  - Time consuming discovery of payer specific requirements
  - Technical barriers related to vendor support and integrated platforms
- All this impacts patient safety and the quality of health care delivery

Evolving Policy Landscape and Current Work

- The evolving policy landscape encourages integration of data and exchange to reduce clinician burden and improve patient safety and care quality.
  - » HIPAA, MMA, HITECH, 21st Century Cures…
- The 21st Century Cures Act encourages ONC/HITAC and NCVHS to engage:
  - » "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."
- March 2019 Health Information Technology Advisory Committee (HITAC) joint meeting with NCVHS Subcommittee on Standards
- Joint ONC-NCVHS discussions during NCVHS's June and November 2019 meetings
- Ongoing discussion of opportunities to identify and support potential approaches as administrative and clinical data converge

A New Task Force: Assessing a Manageable Topic of Convergence

- Vision: Support the convergence of clinical and administrative data to improve data interoperability to support clinical care, reduce burden and improve efficiency—furthering implementation of "record once and reuse."
- Overarching Charge: Produce information and considerations related to the merging of clinical and administrative data, its transport structures, rules and protections, for electronic prior authorizations to support work underway, or yet to be initiated, to achieve the vision.

Target: Prior Authorization

Background: Standards Rulemaking Authorities Separated Across Programs

1. HIPAA standards are adopted by the Secretary of HHS who has delegated the authority to the Division of National Standards at CMS.
    - HIPAA rules apply to all covered entities – health care providers, clearinghouses and health plans, including Medicare and Medicaid as health plans.
    - HIPAA stipulates NCVHS's role to provide input into standards adoption and implementation through recommendations to the HHS Secretary.
2. EHR standards & EHR certification are under the authority of the Office of the National Coordinator (ONC).
3. New standards such as HL7 Fast Healthcare Information Resources (FHIR) are being proposed for adoption under various authorities.
    - The CMS proposed Interoperability Rule will affect Medicare Part C, D, Medicaid, the Exchanges, and Medicare health care providers.
    - ONC is also proposing to adopt the FHIR standards under the Health IT Certification program.

Background: Standards Rulemaking Authorities (2)

4. Some pharmacy standards for electronic prescribing for prescribers are adopted under the authority of CMS Part D program under Medicare. The Medicare program writes these regulations which impact Medicare prescribers.

    - The Drug Enforcement Agency (DEA) also has a regulatory role with electronic prescribing of controlled substances

5. Other pharmacy standards are adopted under HIPAA (i.e. NCPDP D.0), and impact all covered entities. These are written by the Division of National Standards at CMS.

What is Prior Authorization?

- An administrative process which requires a health care provider (physicians, pharmacists, medical groups and hospitals) to request approval from a health plan to provide a medical service, prescription medication or supply to a patient.
- The authorization must be obtained in advance of the service or prescription being delivered to the patient.
- The health plans' purpose for authorizations is to ensure the use of evidence-based guidelines, prevent potential misuse or overuse of services, control costs and monitor care coordination.
  - » Authorizations are often required under a payer's medical policy or coverage rules to support downstream payment processes.

Prior Authorization Transactions Under HIPAA

The Referral Certification and Authorization transaction is described in 45 CFR §162.1301 as any of the following transmissions:

a) a request from a health care provider to a health plan for the review of health care to obtain an authorization for the care

b) a request from a health care provider to a health plan to obtain authorization for referring an individual to another care provider

c) a response from a health plan to a health care provider to a request as described above

Note: This is from the regulation implementing the Health Insurance Portability and Affordability Act of 1996 (HIPAA)

Standard Transactions for Prior Authorization *(Current)*

HIPAA

- For medical services, including hospitalization and dentistry:
  - » ASC X12N/005010X217 (the 278)
- For retail pharmacy drugs:
  - » NCPDP D.0 Telecommunication standard

Medicare Part D

- CMS has released a proposed rule to adopt a standard for electronic Prior Authorization (ePA) between prescribers and pharmacies:
  - NCPDP version 2017071 Script Standard between prescribers and pharmacies, known as ePA
  - The adoption of this standard is required under the SUPPORT Act of 2010

Methods of Electronic Prior Authorization Exchange *(Current)*

- HIPAA leverages Electronic Data Interchanges (EDI) through mandated transaction standards
  - HIPAA permits portals as an exception (Direct Data Entry)
- Promoting Interoperability program leverages Application Programming Interface (API) standards and Fast Healthcare Interoperability Resources (FHIR)
- Providers largely use portals, phone, fax and mail
- Pharmacy industry is using SCRIPT standard on voluntary basis

Discussions to Date – the Big Questions

- The most common PA services are drugs, high end imaging, and DME.
  - » Is there a specific target or set of initial targets for which solutions would be generalizable to the wider field?
- How can tools to aid prior authorization also help patients shop for value based care?
- How can the diversity of payer rules/requirements and lack of transparency/discoverability be managed?
- Can USCDI handle prior authorization decisions?
  - » Are there possible pilots with X12 and WEDI?
- How does FHIR fit in threading this all together?
  - » What is the role of CMS DLRS pilots and HL7 Da Vinci Project?
- Where do attachments fit in as technology and standards evolve?
- How to address privacy concerns while balancing information needs?
- How can we define a path forward to converge clinical and administrative data needs and exchange “paradigms”?

Task Force: Prior Authorization

- Vision: Support the convergence of clinical and administrative data to improve data interoperability to support clinical care, reduce burden and improve efficiency—furthering implementation of "record once and reuse."
- Overarching Charge: Produce information and considerations related to the merging of clinical and administrative data, its transport structures, rules and protections, for electronic prior authorizations to support work underway, or yet to be initiated, to achieve the vision.
  - » Leverage existing information from HITAC and NCVHS prior authorization hearings, and other sources, to inform the Task Force's information acquisition and analysis efforts.

Task Force: Specific Charges

- Design and conduct research on emerging industry innovations to:
  - validate and extend landscape analysis and opportunities
  - invite industry to present both established and emerging end-to-end solutions for accomplishing medical and pharmacy prior authorizations that support effective care delivery reduce burden and promote efficiencies.
- Identify patient and process-focused solutions that remove roadblocks to efficient medical and pharmacy electronic prior authorization and promotes clinical and administrative data and standards convergence.
- Produce Task Force recommendations and related convergence roadmap considerations for submission to HITAC for their consideration and action. The Task Force will share deliverables with NCVHS to inform its convergence and PA activities.
- Make public a summary of its findings once task force activities are complete, no later than September 2020.

Immediate Next Steps

- NCVHS will be working in parallel on prior authorization related recommendations. We anticipate that the Task Force work products will further efforts to align and coordinate the two committees' respective work.
- HITAC Members consider interest and availability to join Task Force, and what outside SMEs would be needed
- Task Force co-chairs refine the scope and charge with ONC leadership as needed
- Establish when work begins