



National Committee on Vital and Health Statistics  
Advising the HHS Secretary on National Health Information Policy

## Recommendations Regarding 3 Operating Rules from CAQH CORE Proposed for Adoption under HIPAA:

- **Prior Authorization Data Content Rule**
- **Prior Authorization Infrastructure Rule**
- **Connectivity Rule**

**Subcommittee on Standards**  
**November 2020**

# Agenda



## **1. Background and NCVHS' Role in Making Recommendations on Operating Rules**

- NCVHS' charge for operating rules
- Previous NCVHS recommendations

## **2. Overview of Subcommittee's Evaluation Strategy and Criteria**

## **3. Recommendations**

## **4. Discussion**

# Role of NCVHS for Operating Rules



- 1. The Affordable Care Act amended the HIPAA statute to require the Secretary of HHS to adopt operating rules for each adopted standard transaction**
- 2. NCVHS role in making recommendations for operating rules:**
  - Advise the Secretary as to whether a nonprofit entity meets certain requirements to serve as an authoring entity for operating rules;
  - Review the operating rules developed and recommended by a nonprofit entity;
  - Determine whether operating rules represent a consensus view of 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 a recommendation to the Secretary whether an operating rule should be adopted.

# NCVHS Previous Recommendations on Operating Rules



- 1. Two previous NCVHS recommendations to adopt operating rules accepted by HHS:**
  - Operating rules for Eligibility, Claim Status, Electronic Remittance Advice/Electronic Funds Transfer adopted in Interim Final Rules in 2011 and 2012 ([76 FR 40458](#) and [77 FR 1556](#), respectively)
- 2. In February 2016, NCVHS evaluated proposed operating rules for Health Plan Enrollment/Disenrollment, Premium Payment, Prior Authorization and Claims.**
  - Advised HHS to support and encourage voluntary use rather than require adoption through regulation.
  - See recommendation letter [here](#).

# Background for Currently Proposed Operating Rules



- 1. February 2020 - CAQH CORE submitted request for review of three new operating rules for consideration:**
  - Two proposed operating rules (Data Content rule and Infrastructure rule) to support the X12 prior authorization standard transaction (X12 278):
  - One proposed operating rule (Connectivity) to address connectivity for certain X12 standard transactions – e.g. claims, enrollment/disenrollment, premium payment.
- 2. NCVHS solicited industry input through Federal Register Notice**, outreach to covered entities, and invitations to selected cross-section of payers, providers, vendors, and patients for the hearing.
- 3. Virtual hearing held in August 2020.**

# Evaluation Strategy for Reviewing the Proposed Operating Rules

# General Evaluation Framework and Criteria



- Part 1** - Does the proposed operating rule conform to the requirements in the law? *(Section 1173 (A)(4) of the law; see slide #3)*
- Part 2** - Does the proposed operating rule reduce burden?
- Part 3** - Will the US health care system be better off with the proposed operating rule to an extent that exceeds the cost of development and/or implementation?

# Post Hearing Activities



- Additional Subcommittee assessment of each proposed operating rule
- Review of written submissions and transcript of the hearing
- Weekly Subcommittee analysis, discussion and development of consensus
- Preparation of draft recommendations



# Draft Recommendations for HHS



- 1. Adopt an attachments standard.**
- 2. Support and encourage voluntary use of the two proposed operating rules for prior authorization prior to an action for adoption.**
- 3. Do not adopt the proposed operating rule for connectivity and encourage CAQH CORE to complete its new version.**
- 4. Increase visibility of enforcement information related to operating rules.**

# Draft Recommendation #1



## **Adopt an attachments standard.**

- Industry testimony was strong that without an attachment standard, providers and payers are unlikely to increase their implementation or use of an electronic prior authorization standard (278)
  - The X12 278 transaction is designed to carry only minimal data internally
  - The clinical data payload is designed to flow in a separate “attachment” transaction that is robust enough to carry codified, non-codified, structured and non-structured data (e.g., physician notes, lab results, reports) as well as images, wave forms, genomics and other types of information
- Without an electronic payload capability, providers fall back to phone, fax or portal
- If providers must use manual processes in their workflow, there is little incentive to purchase a systems upgrade to enable use of the 278.

# Draft Recommendation #2



## **Support and encourage voluntary use of the two proposed operating rules for prior authorization prior to an action for adoption.**

- Rules represent a critical step forward but not a complete PA solution
- Many parts of the proposed operating rules are promising, however
  - Unproven: needs piloting and testing to provide objective evaluation
  - Industry and subcommittee concern with unintended consequences (e.g. timeframes)
- Voluntary use and testing period aligns with NCVHS Predictability Roadmap
  - Robust testing to prove or disprove value
  - Testing will provide data needed by HHS for rulemaking Impact and Fiscal analyses
  - Identify and feed back implementation experience to CAQH CORE
- Competing industry implementation priorities, e.g., interoperability, information blocking, pandemic response
- Significant innovation occurring around prior authorization among multiple industry sectors and groups
  - HITAC/ICAD, HL7 FHIR, Clinical Decision Support and EHRs



# Draft Recommendation #3

**Do not adopt the proposed operating rule for connectivity and encourage CAQH CORE to complete its new version.**

- Proposes a security standard that has known vulnerabilities
- Allows continued use of obsolete security practices
- Could require re-promulgation and adoption of earlier HIPAA-adopted operating rules
- Articulation of rule was complex, difficult to understand
- CAQH CORE already working on revisions to this connectivity operating rule

# Draft Recommendation #4



## **Increase visibility of enforcement information related to operating rules.**

- Low industry awareness of HHS enforcement activities for operating rules
- Stakeholders requested that HHS act upon and publicize its efforts on compliance and enforcement for operating rules

# NCVHS References on Proposed Operating Rules



## Hearing Resources:

- August 2020 hearing [agenda](#) and [meeting summary](#)
- [Original](#) *and* [updated](#) CAQH CORE request letter to NCVHS to consider the operating rules for adoption
- Written [testimony and public comments](#) received



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# Discussion