Hearing on Electronic Attachments Standards and Operating Rules

Testimony Provided to the Subcommittee on Standards National Committee on Vital and Health Statistics

Gwendolyn Lohse
CAQH CORE
glohse@caqh.org
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Testimony Overview Per Questions Posed by NCVHS

• Background.
• Relationship of Operating Rules to Standards.
• Process to Develop Operating Rules for Attachments.
• Research Findings to Date.
• Preliminary Options and Relevant Lessons Learned.
Background

- Council for Affordable Quality Healthcare (CAQH) is a non-profit catalyst for industry collaboration on initiatives that simplify healthcare administration.

- CAQH Committee on Operating Rules for Information Exchange (CORE).
  - Established in 2005.
  - HHS-designated operating rule authoring entity.
  - Over 130 participants representing all stakeholder health sectors.
  - Transparent voting process with multiple options for input by non-participants.
  - Recent updates:
    - For EFT/ERA operating rules, first CARC/RARC code maintenance completed.
    - In last few months, 10 new entities voluntarily CORE-certified or pledged, e.g., Kaiser, BCBSNE, GE.
    - New CORE governing board members.
    - At least four free education sessions per month with over 1,500 registrants on the last call; several held jointly with standards development organizations (SDOs), e.g., ASC X12 and NACHA, and CMS OESS.
Relationship of Operating Rules and Standards

• Operating rules support and build upon Federally recognized content and communication-focused standards, including:
  – Healthcare-specific standards, e.g., ASC X12, HL7, NCPDP, range of code sets.
  – Industry neutral standards, e.g., OASIS, W3C.
  – An iterative process is used in which operating rules are updated based on new mandated versions of the content standards, e.g., removed CORE requirements mandated by v5010; this iterative process has been a key CORE Guiding Principle since CORE’s inception.
  – There is also coordinated and active engagement among the authoring entities.

• CAQH CORE key criteria for development of operating rules include:
  – Work in unison with the HIPAA-mandated financial and administrative transactions to drive administrative simplification.
  – Fill gaps in standards or offer new approaches to expand use of transactions.
  – Build from existing momentum to encourage feasible and meaningful milestones.
  – Do not repeat or contradict standards.
  – Vendor neutral.
  – Do not build switch or database.
Process to Develop Operating Rules for Attachments: 

**Timeline**

- **Q3 2012:**
  - CAQH CORE recommended as operating rule author by HHS.

- **Q4 2012 / Q1 2013:**
  - Build industry awareness of upcoming option to participate in rule writing, ACA goals, CORE Guiding Principles and existing CORE operating rules; assisted by partners, e.g., AHA, Medicaid groups, WEDI, SDOs, CMS OESS, CORE Town Hall.
  - Conduct environmental assessment, e.g., research key opportunities, identify out of scope items; issue White Paper.

- **Q2 2013:**
  - Launch Subgroup to review, develop and agree on potential rule options and seek input from Work Group and public channels.

- **Q3 2013:**
  - Subgroup continues its work, Work Group/public channels continue to provide feedback; update NCVHS.

- **Q4 2013:**
  - Detailed draft rule requirements prepared for formal Work Group ballot in preparation for full CORE vote.

- **Q1 2014:**
  - Operating rules forwarded to CMS OESS.
Process to Develop Operating Rules for Attachments: Research

- CAQH CORE rule development begins with research to gather best practices, identify out of scope items, understand ways to support proposals for next version of a standard, and outline State mandates, such as:
  - Participate in other national initiatives, e.g., S&I Framework, Blue Button payer group.
  - Attend and dialogue with SDOs to understand status and goals.
  - Outline alignment with large scale adoption programs, e.g., Meaningful Use (MU) EHR incentive program, CMS Electronic Submission of Medical Documentation (esMD) initiative.
  - Conduct over forty multi-stakeholder interviews.
    - Medical, dental, long-term care, P&C plans/vendors, and medical health plans, HIEs, hospital, physician, and lab providers, SDOs and related entities, EHRs, practice management systems, and health plan vendors, and CMS and other government entities, e.g., Social Security Administration (SSA).
      - Business needs: purposes, other uses of additional information than primary purpose.
      - Functional requirements: formats, structured/unstructured, use of acknowledgments, code sets, vocabularies, workflow.
      - Technical needs: transport, enveloping, security and data integrity.
      - Top priorities/key requirements for operating rules.
  - Public, online survey of priorities for third set of mandated operating rules in progress.
    - Nearly 150 unique organizations registered, over 70 organizations completed priorities (33% providers, 37% health plans and others, e.g., vendors, HIEs, SDOs, Government).
  - Analyze code use for describing Attachment issues with claim.
Research Findings to Date:
Attachments Definition and Business Uses

• **Definition:** Strong support for defining “Attachment” broadly, especially in light of increasing audit requests for medical record, MU Stage 2, and health reform. Interviews suggested defining “Attachment”.
  - Additional information supplied by one party for the specific need(s) of another party.

• **Business Uses:** Additional information is used in traditional financial/administrative transactions as well as other forms of information exchange.

  1. Claim adjudication.
  2. Prior authorization.
  3. Medical record reviews/audits.
  4. Coordination of benefits.
  5. Disability determinations.
  6. Medical management.
  7. Submission of data to registries.
  8. Credentialing.
  10. Other, e.g., enrollment, contracting needs.

  – Due to health reform and MU, less frequent uses today are anticipated to grow; the physical size of the Attachments will grow, which will impact processing capabilities and cost.

  – CORE’s most recent CARC/RARC code combination update reveals that over 300 new code combinations were requested for use in CAQH CORE Business Scenario #1 “Additional Information Required – Missing/Invalid/Incomplete Documentation”
    - CARC/RARC codes are used to communicate why a claim is rejected/denied.
    - Aggregated data on CARC/RARC usage initiated with CORE EFT/ERA operating rules.
Research Findings to Date:  
Attachments Business Uses

CARC: Claim Adjustment Reason Code  
RARC: Remittance Advice Remark Code

Examples of RARCs that are Used in CAQH CORE  
Business Scenario #1: Additional Information Required – Missing/Invalid/Incomplete Documentation

- Missing oxygen certification/re-certification.
- Missing/incomplete/invalid place of residence for this service/item provided in a home.
- Missing invoice.
- Missing operative note/report.
- Missing pathology report.
- Missing radiology report.
- The medical necessity form must be personally signed by the attending physician.
- Missing/incomplete/invalid internal or document control number.
- Missing/incomplete/invalid procedure code(s).
- Missing Certificate of Medical Necessity.
- Missing/incomplete/invalid other diagnosis.
- Missing patient medical record for this service.
- Missing physician financial relationship form.
- Missing pacemaker registration form.

...and hundreds more RARCs with different or related requests for additional information after Claim is Submitted.

These RARC examples are paired with CARC 251: “The attachment content received did not contain the content required to process this claim or service.” Many of same RARCs also are paired with CARC 16: “Claim/service lacks information which is needed for adjudication.”
Research Findings to Date:
Attachments Migration Path for Format and ROI

• **Formats** currently used to send Attachments reflect a *three-step* migration path that is based on market readiness and return on investment (ROI):

1. **Paper** delivered through U.S. Postal Service.
   - Recipients of paper almost always scan the paper immediately upon receipt.

2. **Electronic transmission of paper** (via e-fax, e-mail, CD, or portal) of Word, PDF, scanned image such as JPG, TIF, many others.
   - Vast majority of requests and responses for additional information are conducted via paper or electronic transmission of paper.
     - CMS’s esMD initiative recognized this reality in its design.
     - Providers have mostly anecdotal information on ROI; few organizations track volumes or key business needs driving majority of Attachments, e.g.,
       - Seven hospital integrated delivery network has 40 staff devoted to processing requests for additional information and related tasks.
       - AHIP reported in 2011 that the average cost of processing a claim is $1.36; $0.99 if adjudicated without manual intervention and $3.99 when “additional information” is required.
       - Transparent CARC/RARC usage is not yet industry best practice.
   - Health plans support auto-adjudication of claims where additional information is required, but lack of structured data and operating rules results in manual review of narrative information.
3. **Fully-automated structured data** that is delivered through a range of **data exchange** methods:

- Additional information collected for one purpose is infrequently used for another purpose; there is some interest in such, but proceeding cautiously due to privacy concerns.
- Growing but minimal use of: HL7 C-CDA primarily for exchange of clinical data among providers, e.g.,
  - SSA use of fully automated workflow has resulted in time to make disability determinations reduced by half.
- Use of Federally mandated CAQH CORE Connectivity Rule (well aligned with CONNECT) for HIPAA transactions is growing (transport/envelope/security).
  - In clinical arena, use of eHealth Exchange using Direct growing due to MU 2.
- Reportedly some growing interest for use of XML by health plans for workflow and physicians with new EHR products; less in hospitals with legacy systems.
Research Findings to Date:

**Current Usage of Attachments-Related Standards**

- As an operating rules authoring entity, CAQH CORE looks to SDOs for the status regarding the development of the standards for Attachments.
- Findings on current standards usage and needs demonstrate that the industry is in the very early stages of adoption and understanding:
  - **Structured content needs.**
    - At a basic level, there is use of imaging formats, e.g., JPG, TIF.
    - Widely held view that additional information is clinically-focused, therefore clinical standards more suitable and also provide alignment with MU requirements; HL7 C-CDA can provide linkage given MU has required use of HL7 C-CDA.
    - Logical Observation Identifiers Names and Codes (LOINC) is becoming a more heavily used vocabulary standard; yet, a lack of understanding and variations in use creates barriers to adoption.
  - **Other clinical content standards-related considerations.**
    - Recognize the need in some cases for trace number/identifiers to link request/response or clinical/administrative data.
    - Making changes to ASC X12 837 claim suggested as a means to reduce number of Attachments.
    - Use of all data elements on ASC X12 v5010 837 could reduce need for COB-related Attachments.
    - Use of ICD-10-CM and acceptance of all of these codes on ASC X12 v5010 was suggested as a means to reduce Attachments.
Research Findings to Date:
Current Usage of Attachments-Related Standards (cont’d)

• **Communications and Infrastructure:** *Messaging / Transport / Enveloping / Security* - *a single standard or specification cannot meet the needs of the current migration path.*
  - Majority of clinical data exchanges are HL7 2.x.
  - Little use of, but growing interest in, Digital Imaging and Communications in Medicine (DICOM); concerns expressed about size of payload and optionality.
  - Lack of significant industry experience with HL7 C-CDA Release 2 (R2) in its native standard format, but reportedly easy for Health Information Exchanges (HIEs) to create for transport purposes; LOINC Attachment Types in the HL7 C-CDA are successful when used and understood.
  - For clinical transactions, some very focused use of Direct, less experience with CONNECT; for HIPAA transactions, use of CAQH CORE Connectivity Rule has grown due to Federal mandate.
    • Recognition that CAQH CORE Connectivity Rule, Specifications for Direct and CONNECT will all need to evolve along with business needs.
    • Other proprietary approaches are being used, and there is interest in maintaining the existing CORE “Safe Harbor” approach in order to provide administrative data exchange.
  - Most attachments are sent via multiple point-to-point exchanges using various security protocols from Internet Protocol Security (IPSec) to Transport Layer Security (TLS) with various uses/levels of encryption.
  - Minimal experience with ASC X12 275; addition of metadata to support workflow and inclusion of standards such as digital signatures could change use; related transaction standard ASC X12 277 to request additional information does not appear to have significant user base.
  - Use of acknowledgement standards are important where applicable, but do not apply uniformly due to preferences for different connectivity standards for the exchange of additional information.
Preliminary Options From Research: Migration for Attachment Standards and Operating Rules

• Migration path should apply to standards as well as operating rules.
  – Focus on **both electronic submission of paper and initial move to ultimate electronic exchange of structured data**. Milestone-based migration path must be:
    • Driven by ROI and business needs.
    • Aligned with clinical arena including MU given incentives, and CMS esMD effort given Medicare’s ability to drive industry adoption.
    • Aligned with related and mandated implementations.
    • Addressing connectivity requirements given growing size/number of Attachments:
      – Which transport standards and metadata are needed, and what is the cost to HIPAA covered entities?
    • Enhancing the level of privacy and security protection needed and addressing risks:
      – Which envelope and security standards are both technically and economically viable, and how do they align with efforts such as esMD and regulations such as recent Omnibus HIPAA Privacy and Security Rule?

• Operating rules can help drive an adoption path for the selected standards.
  – Recommendations for content standard(s) must be sufficiently stable.
    • Use of Notice of Proposed Rulemaking (NPRM) could be useful tool.
    • HL7 C-CDA for content; options for use of ASC X12-related standards and HL7 C-CDA Supplement.
  – Operating rules must address migration needs for **content and communication** of Attachments.
    • CORE rule development has and will continue to consider a range of potential standard(s) to address communication needs.
    • Market need and usage have been, and will continue to be, key CORE criteria.
    • Going beyond the common denominator is also a key CORE criterion.
Preliminary Options from Research: Options for Attachments Operating Rules

• For 2016 mandate, drive migration from paper to electronic submission of paper.
  – Address the need for a basic standard for electronic exchange of paper due to business use and ROI.
    • Recognize a limited number of basic platforms for unstructured content, e.g., PDF, TIF.
  – Similar to what has been done with other CAQH CORE operating rules, require that additional information requests and responses be transmitted electronically.
    • Definition of electronic under HIPAA is broad and can support multiple approaches.
  – Build on the interdependencies with the first two sets of Federally mandated operating rules given the implementation base.
    • CAQH CORE Connectivity Rule will be key to this; supports range of industry-neutral standards, e.g., HTTP/S, SOAP, digital certificates, for transport, enveloping and security.
    • Use infrastructure-focused operating rules to help standardize, or provide transparency of, logic for when/what/how much additional information will be accepted or is required, e.g.,
      – Unsolicited Attachments from providers to health plans significantly impact payment processing time and storage needs. Start with a limited set of business scenarios regarding when, and how much, unsolicited information can be sent with the claim to support faster payment process; evolve based on impact.
  – Align clinical and financial/administrative data by using identifiers and trace numbers as a means to link requests and responses.
Preliminary Options from Research: Options for Attachments Operating Rules (cont’d)

- For 2016 mandate, also address initial migration from electronic submission of paper to electronic exchange of structured data.
  - Support HL7 C-CDA; start by supporting a very limited number of business scenarios, e.g., medical audits, or selected components of its structured data for claim adjudication issues, e.g., post-operative report.
    - Allow for additional business scenarios when ROI is demonstrated along with alignment with other Federal efforts; address market changes (e.g., bundled payments, ACOs).
    - Address option to use ASC X12-related standards.
    - As with EFT/ERA operating rules, operating rules can provide ability to add scenarios.
  - Support standardization of code sets and adherence to standards that already exist, such as eliminating out-of-date CPT code usage.
  - Encourage a common data model, including data definition standards, as industry develops and uses more structured data, e.g., support beginning stages of standardizing content using LOINC Attachment Type codes.
  - Support targeted set of information exchanges/communications approaches.
    - Enhance CAQH CORE Connectivity Rule to continue to drive administratively-focused attachments; maintain that method is a “safe harbor”, meaning other methods can be used.
    - Consider role of Direct and CONNECT, and maintain existing CAQH CORE criteria that operating rules align with Federal HIT requirements and focus on industry-neutral standards.
    - Consider role of esMD Specifications within CAQH CORE Operating Rules.
Preliminary Options from Research: Applying Implementation Lessons Learned

• Lessons learned from operating rules implementation to-date will be key to developing operating rules for Attachments.
  – Recognize any key market dependencies in reaching goal, e.g., routing directories, and determine market availability.
  – Integrate outcomes findings with first two sets of operating rules, e.g., RARCs/CARCs.
  – Address inclusion/exclusion of large volume specialty areas, e.g., P&C, LTC
  – Continue to create operating rules that allow end-users of vendor products to easily check if they have the expected outcomes/ROI for new operating rules.
  – Maintain a focus on reliable handling of administrative transactions given the multiple point-to-point exchanges that exist from request to response.
    • Operating rules should support streamlining, not increasing, the flow of information among the points involved in an Attachment exchange, e.g., what is the impact of HIEs?
• Maintaining CAQH CORE integrated model is critical.
  – To drive a migration path for Attachment operating rules, CAQH CORE will maintain an equal focus on development as well as adoption activities such as building awareness, providing free implementation tools, certifying progress and tracking ROI.
    • Conduct more free joint education sessions with SDOs.
    • Highlight case studies of HL7 C-CDA adoption by health plans.
    • Work with the ONC-authorized certifying bodies for EHRs to harmonize processes.
Appendix
Federally Mandated CAQH CORE Connectivity Rules: *Message Structure*

The CAQH CORE Connectivity Rules with metadata is prescriptive to facilitate interoperability of administrative transactions

- **Network**
  - **Communications (Transport) Protocol**
    - **Message Envelope + Message Metadata**
      - **Message Payload (Content)**

**Message Structure**

- = Public Internet (TCP/IP).
- = HTTP over SSL (HTTP/S); includes security of payload during transmission (X.509 certificate over SSL or TLS; username/password).
- = **Message Envelope & Message Metadata:** Independent of payload; two options for envelope, HTTP MIME Multipart and SOAP + WSDL based on technical criteria and market use.
- = HIPAA Administrative Transactions (X12).
  - HL7 Clinical Messages.
  - Zipped Files.
  - Personal Health Record.
  - Other Content.

**NOTE:** Developed to align with NwHIN/eHealth Exchange efforts and esMD, which includes a CORE specification; ongoing goal to include similar specifications where possible.