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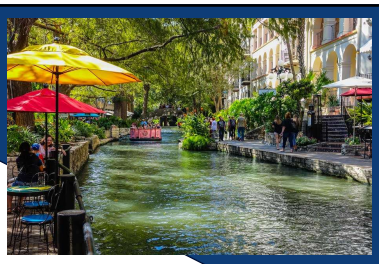
Clearinghouse Caucus Agenda
Tuesday, June 6, 2023



Rio Grande Center
5:00 – 6:00pm

I. **Welcome and Introduction of Cooperative Exchange -** Pam Grosze, Board Chair, Cooperative Exchange and VP, Senior Product Manager, PNC Bank

II. ***Update on X12 Proof of Concept for Transaction Updates –*** Tara Rose, Product Manager, OptumInsight

III. ***Harmonization Task Group Activity –*** Pat Wijtyk, Cognizant, TGH Chair

IV. ***Attachments NPRM – Overview of CE and Other Comments –*** Pam Grosze, Board Chair, Cooperative Exchange and VP, Senior Product Manager, PNC Bank

V. ***NCVHS Activity*** – Pam Grosze, Board Chair, Cooperative Exchange and VP, Senior Product Manager, PNC Bank

VI. **Meeting Wrap-Up -** Pam Grosze, Board Chair, Cooperative Exchange and VP, Senior Product Manager, PNC Bank

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Overview of Cooperative Exchange (CE)

- 18 Clearinghouse Member Companies
- Represent over 85% of the clearinghouse industry
- Over 750,000 submitting provider organizations
- Maintain over 8,000 Payer connections
- 1000 plus HIT vendor connections
- Process over 4 plus billion claims annually
- Value of transactions –over $1.1 Trillion
- Infrastructure framework supports BOTH administrative and clinical transactions

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Our Members

Availity · CHANGE HEALTHCARE · CLAIM MD · eTactics
experian health · FinThrive · InstaMed · JOPARI SOLUTIONS, INC.
mitchell · nextgen healthcare · Office Ally · OPTUM
PHIcure · PNC · SMARTDATA SOLUTIONS · SSI
TRIZETTO Provider Solutions · A Cognizant Company · veradigm · WAYSTAR REVENUE CYCLE TECHNOLOGY

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2023 Board of Directors

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PC Bank

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M3Solutions

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X12 PoC Update

Tara Rose, X12N Chair, Strategic Product Manager, OptumInsight

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Proof of Concept Update

- How we started:
  - In the summer of 2022, X12 solicited its licensing partners to participate in a Proof of Concept (PoC) Program for new versions of its transactions that are recommended for adoption under HIPAA, with strict anti-trust and NDA protection
  - The initial objectives were narrow in focus, in identifying the viability of such a program, the scope, resource constraints, and potential schedule
- Participants represent payers, providers, clearinghouses, and software vendors

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Proof of Concept Update

- The current objectives include:
  - Verifying the transactions work as expected and don't break something that worked in 005010
  - Validating that the business benefits are achievable
  - Estimating the implementation/transition costs
  - Identifying unforeseen obstacles related to cross-version transaction dependencies and adjust accordingly
- With these objectives in mind, the key milestones include the following through several iterations:
  - Analysis of X12-created artifacts
  - Remediation and integration into existing systems
  - Testing approach definition
  - Test scenario creation
  - Test execution
  - Provide evidence to industry stakeholders

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Proof of Concept Update

- Testing approach:
  - End-to-End focus with de-identified real scenarios and synthetically generated test data:
    - X12 Standard Validation
    - Implementation Guide Validation
    - Balancing and Inter-Segment Validation
    - Code Set Validation
    - Cross-version compatibility
- X12 artifacts, resources, and insight include:
  - Online Implementation Guides and Differences Summaries
  - X12 Table Data and XML Schema Definitions (XSDs)
  - Test Data and Files
  - Online collaboration tools

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Proof of Concept Update

- As of now, here's where we are:
  - Testing for X12 Standard and Implementation Guide validation has proven to be solid; there have been challenges which participants have worked through together without issue
  - Resource commitments, or in some cases, a lack thereof, have been challenging; without a proposed rule, at least, most large companies have not committed resources to proceed at the pace we had hoped; there have been indications that this might change for the better
  - The expected business benefits appear to be achievable by transitioning from 005010 to the new version
  - As recently as last week, participants are revisiting and updating test scenarios based on the collaborative efforts between participants representing different players in the industry

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Questions?

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X12 HARMONIZATION

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DISCLAIMER

- This presentation is for informational purposes only
- This presentation does not represent legal advice
- This presentation contains point-in-time content and is subject to revision

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TOPICS

- Task Group Background
- Harmonization Work
- Questions
- Wrap Up

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Background

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RELATED INFORMATION

- ASC and X12N subcommittee recognize the benefits of consistency within and between WEDI Standard.
- X12N established the Harmonization task group (TGH) to facilitate and oversee consistency and harmonization in X12N-maintained products
  - *Was TGCWG5 Harmonization*
- Consistency - Ensuring X12 products have the same instructions, wording, or options all the time or in identified situations.

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RELATED INFORMATION

→ **Wordbook:**

Consistency - Ensuring X12 products have the same instructions, wording, or options all the time or in identified situations.

Harmonization - Ensuring X12 products have corresponding instructions, wording, or options that support the smooth flow of data in specific workflows or lifecycles

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Harmonization Work

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RELATED INFORMATION

- Segment Models
  - *Create model gives direction for each element*
  - *PER, NM1, DTM, DTP*
    - Segment name, situational rules, code notes
- Harmonization Suggestions
  - *Is available, is known, duplicates/near duplicates, examples*
- Common Content
- MRs and HRs
- Rules Repository

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Questions

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Wrap Up

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STAY CONNECTED

- Learn more about X12 and become a member at X12.org
- Stay informed by following X12
  - *@x12standards on Twitter*
  - *#X12 on LinkedIn*

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Attachments NPRM

Cooperative Exchange Comments

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Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures NPRM

On December 21, 2022, the Office of the Secretary, Department of Health and Human Services, published a proposed rule to adopt standards for "health care attachments" transactions, which would support both health care claims and prior authorization transactions, and a standard for electronic signatures to be used in conjunction with health care attachments transactions.

The proposed rule would:

- Place new requirements on HIPAA covered entities and their business associates to support the proposed transaction standards 24 months after the effective date of the final rule.
- Modify the HIPAA referral certification and authorization transaction standard to move from the X12 278, Version 5010, to the X12 278, Version 6020.

Comment period ended March 21, 2023

Link to the federal register proposed rule publication: https://www.federalregister.gov/documents/2022/12/21/2022-27437/administrative-simplification-adoption-of-standards-for-health-care-attachments-transactions-and

Link to the CMS fact sheet: https://www.cms.gov/newsroom/fact-sheets/administrative-simplification-adoption-standards-health-care-attachments-transactions-and-electronic

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Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures NPRM

The following standards & implementation guides are listed in the Health Care Attachments proposed rule:

For requesting attachments, the following standards:

- For claim-related attachment requests, the ASC X12N 277 Health Care Claim Request for Additional Information.
- For non-claim-related attachment requests, the ASC X12N 278 Health Care Service Review—Request for Review and Response—Response.

For attachment message content and format in the transmission of attachment information, the following standards:

- The HL7 CDA R2—Consolidated CDA Templates for Clinical Notes R2.1.
- The HL7 Attachment Supplement Specification Request and Response Implementation Guide R1.
- The Attachment Type Value Set: Logical Observation Identifier Names and Codes (LOINC) developed and maintained by the RegenstriefInstitute, Inc."
- The HL7 Implementation Guide for CDA Release 2: Additional CDA R2 Templates—Clinical Documents for Payers—Set 1.

For the routing/envelope of attachment information, the following standards:

- The ASC X12N 275 Additional Information to Support a Health Care Claim or Encounter.
- The ASC X12N 275 Additional Information to Support a Health Care Services Review.

Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures NPRM

The following standards & implementation guides are listed in the Health Care Attachments proposed rule:

Attachments:

- X12N 275 - Additional Information to Support a Health Care Claim or Encounter (006020X314), September 2014; IBR approved for § 162.2002(d).
- X12N 275 - Additional Information to Support a Health Care Services Review (006020X316), August 2021; IBR approved for § 162.2002(c).
- X12N 277 - Health Care Claim Request for Additional Information (006020X313), September 2014; IBR approved for § 162.2002(e).
- HL7 CDA R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 – March 2017; IBR approved for§162.2002(a).
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1— Introductory Material, June 2019 with Errata; IBR approved for §162.2002(b).
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2 — Templates and Supporting Material, June 2019 with Errata; IBR approved for §162.2002(b).

Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures NPRM

The following standards & implementation guides are listed in the Health Care Attachments proposed rule:

Attachment Type Value Set:

- Logical Observation Identifier Names and Codes (LOINC) developed and maintained by the Regenstrief Institute, Inc.

Electronic Signatures:

- HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 (NOTE: updated version provided that includes this)

Prior Authorization:

- X12N 278 - Health Care Services Request for Review and Response (006020X315), September 2014; IBR approved for § 162.1302(e).

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The Cooperative Exchange Comments

- The Cooperative Exchange continues to strongly advocate for the adoption of standards for health care claims attachments for both unsolicited and solicited workflows.
- The lack of attachment standards has and continues to directly impact 278/275 prior authorization adoption as well as hindering the advancement of fully electronic adoption and systematic automation of 837/277RFAI/275 claims attachments adding decades of unnecessary cost and burden for both workflows.
  - a lack of regulatory rulemaking mandating attachment standards results in the health care industry "waiting for regulatory rulemaking"
- In the CMS Medicare and Medicaid Programs Interoperability NPRM, the proposed standards and implementation guides for prior authorization workflows are based on HL7 FHIR and Da Vinci Burden Reduction (PARDD) implementation guides creating further industry confusion.

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The Cooperative Exchange Specific Recommendations

- Regarding the requirement to utilize C-CDA for the attachment payload: We strongly recommend that all available attachment payload types as designated by the following 275 Attachment Information Format Code qualifiers; "IA" Electronic Image, "MB" Binary Image, and "TX" Text, in addition to "HL" Health Industry Level 7 Interface Standards (HL/7) Format, continue to be supported as specified and allowed in the 275 v6020 TR3s.
  - A significant percentage of production attachments being exchanged via X12 275 today are not C-CDA structured documents/payloads and it is important to continue to allow and maintain the systematic exchange of unstructured attachment information electronically.
  - C-CDA structured information should be allowed and encouraged where appropriate, but not required.
  - Unstructured documents can, but should not be required to, utilize the Unstructured Document CDA template as there is no added business value, only added cost.
- Regarding requirements to utilize electronic signatures, we recommend the following:
  - An electronic signature should only be required if requested by or indicated required by the payer.
  - Evaluate the X12.58 Security Structures control standard as an X12 native authentication, verification, integrity, and electronic signature method.

The Cooperative Exchange Specific Recommendations

- The Cooperative Exchange recommends that the current HIPAA 278 Health Care Services Review - Request for Review and Response (005010X217) implementation guide be maintained pending the expected and imminent recommendation from X12 to replace v5010 with v80next. The Cooperative Exchange strongly supports adopting the most current version of the X12 278 Health Care Services Review - Request for Review and Response when it is recommended.
  - The joint WEDI-X12-HL7 November 2017 whitepaper “Guidance on Implementation of Standard Electronic Attachments for Healthcare Transactions” provides instructional guidance as to how additional information can be sent or requested using the 278 v5010X217 and 275 v6020X316 implementation guides.
  - the current HL7 Da Vinci Prior Authorization Support (PAS) implementation guide build is specific to the 278 v5010X217 & 275 v6020X316 IGs. FHIR mapping information needed to effectively crosswalk between the HL7 and X12 implementation guides is currently only available in the 278 v5010X217.
- We encourage CMS NSG to identify potential options to assure that standards and implementation guides being recommended for federal adoption are current, tested, and ready for use in production healthcare e-commerce workflows and that the federal rulemaking process be completed in a timely manner.

The Cooperative Exchange Specific Recommendations

- The Cooperative Exchange supports NCVHS recommendation #4 in its July 2022 letter to the HHS secretary which calls for the creation of a guidance framework for Standards Development Organizations and other industry stakeholders that outlines how to develop and report measures for new and revised standards readiness, costs, and overall adoption value to support HIPAA standards development, testing, evaluation and adoption.
  - A known and predictable version update cycle would allow affected stakeholders to plan, budget, and resource effectively and introduce changes in a flexible cadence as their business needs warrant, while also, by nature of the process, advance the industry forward to continuously improve and modernize applicable standards.

Other Comments to the NPRM

- The EHR Association is generally supportive of remaining current with newer versions of the X12 standard. we recommend that the proposed rule is not finalized to include prior authorization at this time.
- C-CDA structured information should be allowed and encouraged where appropriate, but not required.
- The Da Vinci Project is not in favor of finalizing the proposed Attachments regulations as written as the rule is at odds with the health care industry's efforts to leverage technology in achieving the quadruple aim: enhancing patient experience, improving population health, reducing costs, improving the work life of health care providers. Da Vinci strongly recommends withdrawal of the proposed Attachments NPRM
- PHIT supports the adoption of the X12N standards proposed for health care attachments transactions, particularly X12N 278 Version 6020 to replace X12N 278 Version 5010, as Version 6020 expands the drug authorization segment, which includes fields necessary to identify a drug, specify quantity of drug requested, specify drug dosage requested, and accommodate related codes. Version 5010 does not enable entities to supply this additional information.

  PHIT supports the adoption of the three proposed HL7 implementation guides, as HIPAA standards for the attachment information included in health care attachments transactions and for a transmission from a health care provider to a health plan, and for digital signatures

Other Comments to the NPRM

- our primary concern is on the differing standards proposed in this NPRM as compared to the CMS Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule (file code CMS0057-P). Specifically, providers submitting a relevant measure as they participate in the promoting interoperability program would be required to use a PARDD API, but for payers, the implementation guides are simply recommended but not required. We strongly feel that this misalignment (and approach of allowing optionality) will contribute to confusion and difficulties on both sides as the industry is stuck trying to comply with two different sets of standards
- we encourage alignment with the Advancing Interoperability and Improving Prior Authorization Processes rule with an emphasis on the Fast Healthcare Interoperability Resources (FHIR) standards.
- We recommend that implementation be established at 36 months after issuance of the final Rule and scheduled on a date other than the end of a calendar year.

Other Comments to the NPRM

- Availity supports the co-existence and adoption of ANSI X12 and HL7 FHIR and CDA standards for healthcare attachments to support healthcare claims and prior authorization transactions. Availity believes that allowing provider organizations to utilize the X12 275 transaction, if they have already adopted it, while also encouraging adoption of FHIR APIs, would meet both current- and future-state needs. Availity recommends that the requirements in CMS-0057-P and CMS-0053-P be brought into alignment prior to finalization of either proposed rule.
- We support the approach of splitting the consideration and requirements for claims attachments and prior authorization attachments. Although the content of those attachments sometimes may be similar, workflows and staff supporting the submission of attachments related to claims and authorizations vary widely for most hospitals and health systems.
- My suggestion is that the final rule adopt a current existing standard with a pathway to a future FHIR standard. The rule should be rewritten to adopt the most current version of the X12N 275, 277, and 278 standards for claims and prior authorization attachments, with an option (similar to the DDE option for claims) to support specific FHIR API IGs based on HL7/DaVinci implementation guides. This will enable adopting of attachment standards upon publication, as well as enable plans and providers to build and use the FHIR APIs if they wish, show costs and benefits, and build the case for adopting them as a national standard. Should the FHIR APIs prove superior to the X12 transactions, a rule can be issued in the future adopting them as a standard, with a phase out of the X12 transactions.

  This gives the industry a current national standard as well as a pathway to transition from X12 to FHIR if the ROI is established.

Other Comments to the NPRM

- Mandating the adoption of HL7 standards for HIPAA transactions is an important step forward towards facilitating EDI for dental practices, but the ADA is concerned that the standards proposed for adoption by CMS have yet to be assessed for suitability to the dental industry.

  We would encourage CMS to move forward to the USCDI version 2 or above which would move the industry toward ensuring that data elements and classes made available through the C-CDA based transactions are the most appropriate for information exchange.

  We would encourage CMS to provide technical support and incentives for the dental industry in piloting and validating the standards named in the final rule as well as consider adoption of industry specific standards.

  The ADA supports CMS' proposed adoption of (278) Version 6020.
- Having a standard version of this transaction will make the attachments process much easier for our members. We urge CMS to strongly enforce this new standard if it is finalized.
- Electronic Signatures:
  - Recommendation for TEFCA standards for electronic signatures
  - An electronic signature should only be required if requested by or indicated required by the payer. • Evaluate the X12.58 Security Structures control standard as an X12 native authentication, verification, integrity, and electronic signature method.

Next Steps

- Comment period has closed
- CMS reviewing comments, determining next steps
  - Update NPRM and publish as updated NPRM to get additional comments?
  - Retract NPRM, replace with new?
  - Publish Final Rule (updated per comments)?

NCVHS Standards Committee

Upcoming Meeting

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NCVHS Standards Committee

- Meeting June 14, 2023
- Agenda:
  - Review of Three Letters for Discussion and Action:
    - Recommendations on Updated and New CAQH CORE Operating Rules to Support Adopted HIPAA Standards
    - Recommendations on Updated Version of the X12 Standard for Claims and Electronic Remittance Advice Transactions (Version 8020)
    - Comments on NPRM "HIPAA Privacy Rule to Support Reproductive Health Care Privacy"
  - Recommendations from Standards Subcommittee for first two, creation of final recommendations for HHS
  - Final NCVHS Comment Letter on third item

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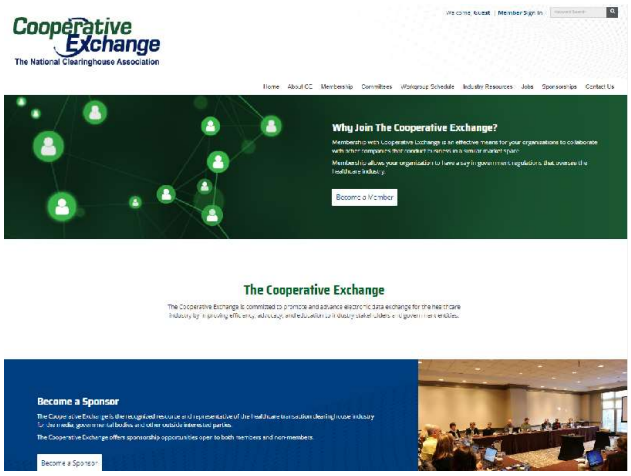

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Thank You for Attending!

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