



December 15, 2022

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Submitted electronically to:  
[NCVHSmail@cdc.gov](mailto:NCVHSmail@cdc.gov)

RE: RFC on X12 and CAQH CORE Proposals

Dear NCVHS Subcommittee on Standards Co-Chairs Love and Landen:

Health Level Seven (HL7) International welcomes the opportunity to provide feedback on the November 28 Request for Comment (RFC) seeking input, as NCVHS develops recommendations to the U.S. Department of Health and Human Services (HHS) on adopting proposed updated standards from X12 and proposed updated and new operating rules from the Committee on Operating Rules (CAQH CORE). Our organization's views detailed here build on [HL7 testimony](#) and the written follow-up related to the June 9, 2022 NCVHS Subcommittee on Standards listening session. This testimony contained many important points, including that HL7 urges NCVHS to formally recognize HL7® FHIR® as an alternate standard to existing mandated HIPAA transaction standards, furthering the nation's journey of intersecting of clinical and administrative frameworks and related interoperability objectives. Our RFC feedback detailed here also provides a foundation for further sharing HL7 views at the planned January 18-19, 2023 NCVHS hearing.

As you know, HL7 is the global authority on health care interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing health care consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms. A critical part of the HL7 mission is to provide a comprehensive framework and related standards for electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 produces a family of standards, including FHIR, as well as Implementation Guides and Specifications, which enable both routine and cutting-edge health care functions. FHIR aids in removing barriers to many of the challenges to interoperable health care data exchange – as stand-alone specifications and as a bridging mechanism across standards. The HL7 product family is robust end-to-end and is well supported by the health care industry, as reflected by our Accelerator community, long-standing Work Group structure, and expanding technical capabilities to support the HL7 development and implementation divisions. HL7 also actively supports cross-community terminology and value set needs to further benefit data driven policy and operational needs.

Our [HL7 FHIR Accelerators](#) drive groundbreaking cross-sector innovation in interoperability and bridging historical investments through partnerships to provide capabilities needed in today's modern health care ecosystem. Examples are the Da Vinci Project, addressing value-based care data exchange efficiencies, the HL7 FHIR at Scale Taskforce (*FAST*) for infrastructure and connectivity, the Gravity Project for social determinants of health, Helios for public health and CodeX for improving data interoperability related to oncology, cardiovascular medicine and genomics. As the nation works toward converging administrative, financial, and clinical data we must keep in focus the broader interoperability needs such as public health and patient engagement. We are confident HL7's standard and implementation specifications are comprehensive enough to rise to this challenge and provide the necessary business rules and guidelines for the exchange of electronic exchange of information using HL7 work products. And if there are gaps, then we are well positioned to fill those gaps. For example, development cycles are responsive to industry needs through our collaboration and partnering efforts across the industry including interoperability federal policies and programs.

On the overall issue recommendations contained in the RFC, HL7 supports our sister ANSI accredited Standards Development Organization (SDO) X12's efforts but we are also concerned with the industry compliance strain related to a range of requirements related to multiple federal and state departments and programs. Further, determining the appropriate balance in this scenario may be challenging without robust cost information, which is typically an analysis not performed by industry until a formal mandate is released. We urge if any update is to be recommended, NCVHS also consider HIPAA policy shifts that could be included in proposed rulemaking, not just technical standards proposals at this critical juncture. Lastly, to continue being efficient, clean lines of responsibility should be ensured to minimize risk of confusion and expense to the Health IT industry that has come far in embracing standards development, adoption and support because of our nation's HIPAA journey.

Comments detailed in this RFC response reflect the combined perspectives of HL7's leadership, the Policy Advisory Committee, the Payer/Provider Information Exchange (PIE) Work Group and the HL7 FHIR at Scale Taskforce (*FAST*). Should you have any questions about the attached document, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at [cjaffe@hl7.org](mailto:cjaffe@hl7.org) or 734-677-7777. We look forward to continuing this discussion and as always, offer our assistance to NCVHS and its Subcommittee on Standards.

Sincerely,



Charles Jaffe, MD, PhD  
Chief Executive Officer  
HL7 International



Andrew Truscott  
Board of Directors, Chair  
HL7 International

## NCVHS Request for Comment: X12 and CAQH CORE Proposals

### I. OVERARCHING COMMENTS

#### Comments

- HL7 emphasizes that HL7 FHIR-based implementation guides are developed in an open, public, consensus-based process and are systematically tested and reviewed by industry stakeholders in order to proceed with publication. This consensus-based process precludes the need for other organizations to define operating rules, where historically that role may have been needed.
- HL7 and its FHIR Accelerators such as the Da Vinci Project, HELIOS and *FAST* will continue to work with the community of relevant stakeholders to identify FHIR infrastructure and scalability barriers that need to be addressed to support national interoperability.
- Relevant to this RFC -- *FAST* --the HL7 FHIR Accelerator focused on FHIR infrastructure and scalability, is laying the groundwork for a national interoperability approach that enables consistent data exchange via application programming interface (API) using FHIR. *FAST* implementation guides do not include HIPAA transactions and will continue to follow the HL7 ANSI-accredited processes for developing, testing, and publishing standards.

### II. Updates: X12 Transaction Standards

Question	HL7 Comments
<b>Costs:</b> If your organization has conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional or dental claim) and remittance advice transactions, to what extent, relative to the potential cost of implementation, do the updated transaction implementation guides provide net positive value? Please explain.	<ul style="list-style-type: none"><li>• Operational assessments will be conducted when the Notice of Proposed Rulemaking (NPRM), is published in the Federal Register. We are aware that there are significant changes (with these changes come costs) within the X12 837 8020 version of the Claims that will impact providers, vendors and payers.</li></ul>

<p><b>Operational Impacts:</b> If your organization has conducted an operational assessment or workflow analysis of the impact of transitioning to the updated X12 8020 claims and remittance advice transactions, what process improvements has your organization identified would result from implementation of the updated versions of any of the updated transactions? Please provide information for the Committee to reference in its considerations and feedback to HHS.</p>	<ul style="list-style-type: none"> <li>Operational assessments will be conducted when the Notice of Proposed Rulemaking (NPRM) is published in the Federal Register.</li> </ul>
<p><b>XML Schema:</b> X12 has indicated that each of the X12 implementation guides included in their recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. In its letter to NCVHS, X12 noted that it mechanically produces these representations from the same metadata used to produce the implementation guide. X12 recommends that HHS permit both the 8020 EDI Standard representation (the implementation guide) and the XML representation, and that both be named in regulation as permissible syntaxes. Please comment on the proposal to adopt the 8020 EDI standard and the XML representation as permitted syntaxes.</p>	<ul style="list-style-type: none"> <li>Standards should not be limited to XML. X12 to FHIR crosswalks do assist with newer technology so that these tables may be included within HL7 FHIR IGs. (i.e. Prior Authorization Support, Clinical Data Exchange). Unless there is a substantial industry need of XML, any alternate format should consider FHIR. This allows representation in multiple formats natively. HL7 FHIR includes other syntax that entities would like to include (i.e., JSON). If there are multiple syntax allowed, they should be semantically interoperable.</li> <li>While additional syntax representations can be viewed as a positive aim of the X12 organization, it should be noted that other syntactical considerations exist that would provide the healthcare industry with a more homogeneous solution. The use of JSON (JavaScript Object Notation) would better align with industry standards developed for healthcare solutions.</li> <li>Adding additional standard formats to be supported does place more burden on the healthcare payer community as these organizations must support all standards formats and do not recover any of the development costs, especially related to formats their trading partners will not use. Whereas organizations that provide the services to convert to various formats can pass along the costs to providers that have contracted with their organization.</li> </ul>

<p><b>FHIR Crosswalks:</b> X12 indicated that it intends to provide FHIR crosswalks for the proposed X12 version 8020 transactions (claims and electronic remittance advice) submitted for consideration in time for inclusion in the Federal rulemaking process. Please comment on how FHIR crosswalks would apply to the implementation of the HIPAA claims and remittance advice transaction standards.</p>	<ul style="list-style-type: none"> <li>• Overall, X12 to FHIR crosswalks assist with newer technology so that these tables may be included within HL7 FHIR IGs (e.g., Da Vinci Prior Authorization Support, Clinical Data Exchange). Mapping development and maintenance would need to be a joint effort with HL7, given HL7's FHIR responsibility and leadership and so that all FHIR elements are crosswalked in the best manner possible.</li> <li>• There is a need for crosswalks such as these. HL7 appreciates current crosswalk limited license access but optimally; they should be more broadly available.</li> <li>• Unless NCVHS were to allow FHIR claims to be submitted in a HIPAA context, there would be no impact. However, for non-HIPAA covered use cases, this could help.</li> <li>• It is unclear until fully built and tested, the utility of FHIR crosswalks to HL7 FHIR claims and remittances.</li> <li>• Advance Explanation of Benefits- dependable crosswalks between elements are useful.</li> <li>• The community developing FHIR-based specifications and solutions is progressing rapidly. HL7 recommends, and is willing to support, a mapping process that is open, transparent, and responsive to the evolving needs of the industry.</li> <li>• FHIR Crosswalks are helpful for implementers but only part of the entire solution. Industry writ large must be educated on the various components --e.g., cyber security and trading partners management -- along with server configuration and best practices.</li> <li>• Notable is that dependable mapping should decrease costs involved to providers with more rapid, efficient development.</li> </ul>
<p><b>Unique Device Identifier (UDI):</b> The device identifier (DI) portion of a medical device's unique device identifier (UDI) is now included as a data element on the updated claim Posted online at:</p>	<ul style="list-style-type: none"> <li>• This allows health plans and industry players to uniquely identify a device and tie it to specific members to track patient outcomes, device defects and recalls, thus improving member experience. Inclusion</li> </ul>

<p><a href="https://ncvhs.hhs.gov/January-2023-Standards-Subcommittee-Hearing-Public-CommentGuidelines">https://ncvhs.hhs.gov/January-2023-Standards-Subcommittee-Hearing-Public-CommentGuidelines</a> Page 3 of 6 transaction in the institutional and professional version of the 8020. The UDI is also an element in the US Core Data for Interoperability (USCDI) for Certified Health Technology required by the Office of the National Coordinator, and can be found in certified Electronic Health Records, and in standardized hospital discharge reports. Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction</p>	<p>of specific device information on claims provides opportunities for additional data analysis.</p> <ul style="list-style-type: none"> <li>We are concerned however that if UDI is implemented, this might make payers responsible for all recall information, scheduling and other elements that may occur around the devices. Responsibility should remain with the device company.</li> </ul>
<p><b>Alternative Payment Models (APM) and Value Based purchasing (VBP):</b> Does X12 version 8020 support VBP claims? In what ways does the version 8020 of the claims transactions accommodate APMs such as medical homes or accountable care organizations (ACOs)? Please discuss the implications of this topic to HIPAA administrative simplification policies and continued innovation of non-fee-for-service business models.</p>	<ul style="list-style-type: none"> <li>X12 version 8020 supports the use of individual diagnoses and procedure codes that are used in value-based purchasing. Additional information can be accommodated in a claim attachment as necessary.</li> </ul>
<p><b>Implementation Time Frame:</b> HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, what would be the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e.g. does the window need to be longer than two years from the publication date of a final rule? Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?</p>	<ul style="list-style-type: none"> <li>The utility and appropriateness of a two-year implementation timeframe depends on the scope and impact of the update. Industry will comment on implementation timeframe issues once the regulation is published. CMS should provide incentives and/or enforcement actions if timeframe is not met.</li> <li>The months of June or July would be optimal implementation dates.</li> <li>Any implementation timing should acknowledge and provide appropriate weight to other existing mandates for industry and relevant health care stakeholders. In addition, thoughtful consideration should be given to exactly what to upgrade in order to advance the interoperability journey. While upgrade requires concerted effort, the longer the waiting period to amend existing mandated standards, the harder the lift.</li> <li>Implications of vendor readiness to support covered entities should also be thoughtfully considered, since vendors are not Covered Entities.</li> </ul>



<p><b>Implementation:</b> NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?</p>	<ul style="list-style-type: none"> <li>• Yes, HL7 sees a benefit in supporting a dual use period for multiple versions of a standard related to a like business function that is semantically interoperable. We would recommend a definitive sunset date within 2-3 years.</li> <li>• Having concurrent versions aligns to thinking that underlies both the Standards Version Advancement Process (SVAP) and United States Core Data for Interoperability (USCDI). Having a floor in this process is good, while supporting newer versions being vetted to address to technical aspects.</li> </ul>
<p><b>Simultaneity:</b> What, if any, are the data impacts, limitations or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g. claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?</p>	<ul style="list-style-type: none"> <li>• Following X12's paired transactions at the same version would be required. The impact with other transactions is unknown. As an example, Claims, Remittance and Coordination of Benefits (COB) would need to be in the same version.</li> <li>• Specifically, if the provider and the first payer are operating at the elevated version level and the processed claim information needs to be sent to a third organization that is operating on the previous (non-backwards compatible) version, the ramifications to the ecosystem are unknown.</li> </ul>
<p><b>Alternatives Considered:</b> X12 indicated that there were over 2,000 changes identified in the change logs for the four updated transactions in version 8020, categorized by operational, technical and editorial. If your organization has conducted assessments of the technical changes, what is your determination of these with respect to reducing burden on payers or providers once the updates have been implemented? What is the opportunity cost of remaining on Version 5010 and not implementing the updated version 8020 of the claims and remittance advice transaction standard? What will the healthcare industry risk by not adopting version 8020?</p>	<ul style="list-style-type: none"> <li>• There have been significant revisions and changes in the X12 Technical Report Type 3 (TR3) to help promote clarity. The changes in the 837 will help support accuracy of payment as well. The 837 8020 version supports new claim data as well as supporting pre-determination transactions that will be leveraged to support Advance EOB and Good Faith Estimate efforts.</li> <li>• Version 5010 was published around 2008-2010. The 8020 has improvements that will support new business capabilities that have evolved within the industry since then, 8020 adoption of the four updated transactions would be necessary to implement new business capabilities that are not easily available in 5010.</li> <li>• The risk of not adopting is the inability to implement new capabilities.</li> </ul>

<p><b>General:</b> Does your organization support HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards? Please provide a brief rationale.</p>	<ul style="list-style-type: none"> <li>• Yes, HL7 supports HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards. It makes sense to promote the update of a widely adopted, currently in use standard.</li> <li>• We do caution in this scenario about the limitations in adopting and implementing the 11th edition of the International Classification of Diseases (ICD-11) and lifecycle reliability as upgrades are being brought forward. In other words, ICD11 is not supported in the version being proposed.</li> <li>• HL7 also emphasizes its support above for concurrent use of multiple versions of a standard and multiple standards over an extended period of time for flexibility and to advance innovation.</li> <li>• The X12 835(Electronic Remittance Advice) was updated to support different payment models including virtual card. The 835 has had many front matter revisions to support COB and Recoupments. These two developments alone are a significant pain point for industry and the suggested updates will help with streamlining the use of the 835 in reporting.</li> <li>• Several other data elements have been added to support Diagnosis-Related Group (DRG) and taxonomy, as well as the new structure for Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC). This will help promote provider autoposting and reduce calls.</li> <li>• The X12 837 (Healthcare Claim/Encounter) supports new claim data and pre-determination transactions that will be leveraged to support Advance Explanation of Benefits (AEOB) and Good Faith Estimate efforts.</li> </ul> <p>Other 835 8020 comments:</p> <ul style="list-style-type: none"> <li>• Regarding new types of DRGs the guides need to support, HL7 observes that right now they cannot but with new versions, they will be able.</li> </ul>
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<b>Other:</b> Are there other topics NCVHS should consider when making recommendations to HHS regarding adoption of proposed updates of the X12 standard?	<ul style="list-style-type: none"> <li>New and more collaborative models for testing could also be considered. HL7 is available to provide more perspective and details if desirable.</li> </ul>
II. CORE Operating Rules	
<b>Efficiency Improvements - Infrastructure updates to the adopted Eligibility and Benefits and Claim Status Operating Rules:</b> CAQH CORE has proposed updates to the adopted versions of the eligibility and benefits and claim status operating rules currently required for use. Updates include an increase in system availability from 86% per calendar week to 90%, and for the response time for a claim status request from 20 seconds 86% of the time to 20 seconds or fewer 90% of the time. Please comment on the potential for improvements in efficiency for your organization these updates would contribute when using the adopted X12 HIPAA transaction standards.	<ul style="list-style-type: none"> <li>The new response time proposals may require a notable effort and cost to participants and could impact system update and release schedules.</li> </ul>
<b>Data Content updates for Eligibility and Benefits Operating Rule:</b> The updated version of the Eligibility and Benefits operating rule includes the requirement to indicate coverage of telemedicine, remaining coverage and tiered benefits, and to indicate if prior authorization or certification is required. The rule has been updated to include a list of CORE-required service type codes (section 5) and CORE-required categories of service for procedure codes. If your organization has conducted an analysis of these updates and the potential impact to increasing use of the adopted standard, please comment on your assessment of these enhancements for your organization and/or your trading partners.	<ul style="list-style-type: none"> <li>Significant updates to internal payer systems -- along with clearinghouses and provider systems -- will be required if this schema is approved for final rule.</li> <li>A Service Type Codes addition of new discretionary and mandatory service types is a significant change to multiple systems.</li> </ul>
<b>New - Patient Attribution Content Rule within the New Eligibility and Benefits Operating Rule (vEB.1.0):</b> CAQH CORE has proposed a new operating rule to apply to the selection of value-	<ul style="list-style-type: none"> <li>A key challenge is that some of the cited data may not be contained in existing eligibility systems. This could perhaps be contained in a future roadmap.</li> </ul>

<p>based payment models by providers. If your organization has conducted an analysis of this operating rule, please provide information on your organization's evaluation of the extent to which the proposed operating rule requirements support the adopted HIPAA transactions or improve administrative simplification.</p>	
<p><b>Companion Guide Template:</b> CAQH CORE has updated the requirements for the companion guides in the adopted operating rules to promote flexibility. Please comment on your organization's experience with the companion guide template in the first set of operating rules, how it has impacted workflows and whether your assessment of the proposed new template indicates value for implementations of the standard transactions. What specific strategies, technical solutions, or policies could CMS implement to facilitate timely and accurate directory data updates?</p>	<ul style="list-style-type: none"> <li>• HL7 has no issue with the CAQH CORE requirement updates for the companion guides.</li> </ul>
<p><b>New Connectivity Rule:</b>  A) As part of the re-structuring of the CAQH CORE operating rules for each administrative transaction, CAQH CORE updated the connectivity requirements and published a stand-alone Connectivity Rule (vC4.0.0), for which it is seeking a recommendation for adoption. In addition to the requirements for the use of HTTPS over the public internet and minimum-security conditions, the Connectivity Rule addresses Safe Harbor, Transport, Message Envelope, Security, and Authentication. What changes would be necessary to your organizational infrastructure, policies and contracts to implement the CAQH CORE c4.0.0 Connectivity rule?   B) The new Connectivity rule adds support for the exchange of attachments transactions, adds OAuth as an authorization standard, provides support for X12 (HIPAA) and non-X12 (non-HIPAA) exchanges, and</p>	<ul style="list-style-type: none"> <li>• Overall, HL7 does not believe that the CAQH CORE Connectivity operating rule vC4.0.0 under consideration for adoption under HIPAA aligns with industry best practice.</li> <li>• HL7 agrees with the Safe Harbor, as some healthcare entities may not be implementing HTTPS and APIs like FHIR for some time. A complete analysis would need to be conducted with HL7 technical resources, in regard to this modification with X12 standards.</li> <li>• HL7 notes that there is a combination of HL7 FHIR <i>FAST</i> Implementation Guides<sup>1</sup> that are comparable guidelines to the Connectivity Rules.</li> </ul>

<sup>1</sup> HL7 FHIR at Scale Taskforce (*FAST*) , *FAST* Implementation Guide Dashboard, <https://confluence.hl7.org/display/FAST/FAST+Implementation+Guide+Dashboard>

<p>sets API endpoint naming conventions. The CAQH CORE letter states that the impact of mandating these requirements for HIPAA covered entities includes: “setting a standards-agnostic approach to exchanging healthcare information in a uniform manner using SOAP, REST and other API technologies; facilitates the use of existing standards like X12 in harmony with new exchange methods like HL7 FHIR, and enhancing security requirements to align with industry best practices.” Please comment on the scope of the CAQH CORE Connectivity operating rule vC4.0.0 under consideration for adoption under HIPAA.</p>	
<p><b>Costs:</b> If your organization has conducted a cost analysis to determine the impact of implementing the updated eligibility and benefits and or claim status operating rule updates for your entity type, what are the estimated costs or types of costs for system and operational changes? In what programmatic ways do the updates to the operating rule for infrastructure (system availability and response time), data content, additional Posted online at: <a href="https://ncvhs.hhs.gov/January-2023-Standards-Subcommittee-Hearing-Public-CommentGuidelines">https://ncvhs.hhs.gov/January-2023-Standards-Subcommittee-Hearing-Public-CommentGuidelines</a> Page 6 of 6 data elements for telemedicine, prior authorization coverage benefits, tiered benefits and procedure-level information add value for your organization? Please provide examples pertinent to your organization.</p>	<ul style="list-style-type: none"> <li>Operational assessments will be conducted when the Notice of Proposed Rulemaking (NPRM) is released. We are aware that there are significant changes.</li> </ul>
<p><b>Alternatives Considered for Operating Rules:</b> What are the consequences to your organization if NCVHS recommends adoption of the updated versions of the eligibility or claim status operating rules? Please provide specific examples to describe the impacts (benefits, opportunities) of the changes included in the update for each operating rule. What use cases would benefit from data being verified and what sort of assurances would be necessary for trust and reliance on those data?</p>	<ul style="list-style-type: none"> <li>Operational assessments will be conducted when the Notice of Proposed Rulemaking (NPRM) is released. We are aware that there are significant changes.</li> </ul>
<p><b>Attachments Prior Authorization Infrastructure and Data Content Rules (vPA.1.0) and</b></p>	<ul style="list-style-type: none"> <li>HL7 does not agree with this proposed rule, as an Attachment Rule has yet to be released. Until that time</li> </ul>

<p><b>Attachments Health Care Claims Infrastructure and Data Content Rules (vHC.1.0):</b> CAQH CORE has proposed infrastructure and data content operating rules for Prior Authorization and health care claims. The proposed infrastructure rules for attachments for prior authorization and health care claims include requirements for the use of the public internet for connectivity, Batch and Real Time exchange of the X12 v6020 275 transaction, minimum system availability uptime, consistent use of an acknowledgement transaction, use of uniform data error messages, minimum supported file size, a template for Companion Guides for entities that use them, a policy for submitting attachment specific data needed to support a claim adjudication request (standard electronic policy), and support for multiple electronic attachments to support a single claim submission. The operating rules include the requirement for a health plan or its agent to offer a “readily accessible electronic method to be determined.... For identifying the attachment-specific data needed to support a claim adjudication request by any trading partner, and electronic policy access requirements so services requiring additional documentation to adjudicate the claim are easily identifiable (health care claims only).” The CAQH CORE letter indicates that the proposed attachments data content rules for prior authorization and health care claims apply to attachments sent via an X12 (HIPAA) transaction and those sent without using the X12 transaction (non-HIPAA). Please provide</p>	<p>there should not be a CAQH CORE proposed data content rule. Noted is that the following is currently at the OMB in review for an attachments rule: HHS/CMS RIN: 0938-AT38Publication ID: Spring 2022 Title: Administrative Simplification: Adoption of Standards for Health Care Attachment Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Standard (CMS-0053)</p> <ul style="list-style-type: none"> <li>• HL7 notes that the Da Vinci Project Accelerator has received a HIPAA exception to support projects validating the efficiency of a FHIR only solution for prior authorization support. This includes three implementation guides: Coverage Requirements Discovery (CRD)<sup>2</sup>, Documentation Templates and Payer Rules (DTR)<sup>3</sup> and Prior Authorization Support (PAS)<sup>4</sup>. The three guides support end-to-end FHIR based exchanges between provider and payer systems to reduce burden in prior authorization workflows. Recognizing the most current versions of these initial three IGs, supports other federal policy<sup>5</sup> to reduce burden through technology and policy-related enhancements.</li> <li>• HL7 observes that Prior Authorization done right doesn’t require a supplemental data request because transparency in coverage is created, as well as their specific requirements. HL7 is developing this in their FHIR pattern and methodology. This and other guides enable a level of specificity needed by payers.</li> </ul>
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<sup>2</sup> HL7 Da Vinci Project, Coverage Requirements Discovery Implementation Guide, December 2020, <https://confluence.hl7.org/pages/viewpage.action?pageId=21857602>

<sup>3</sup> HL7 Da Vinci Project, Documentation Templates and Payer Rules Implementation Guide, December 2020, <https://confluence.hl7.org/pages/viewpage.action?pageId=21857604>

<sup>4</sup> HL7 Da Vinci Project, Prior Authorization Support Implementation Guide, December 2021, <http://hl7.org/fhir/us/davinci-pas/>

<sup>5</sup> U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria, RIN 0955-AA04; FR 2022-01309, January 24, 2022, <https://www.federalregister.gov/documents/2022/01/24/2022-01309/request-for-information-electronic-prior-authorization-standards-implementation-specifications-and>

your assessment of this proposed operating rule.	
<p><b>Attachments Operating Rules – General Question:</b> HHS has not proposed adoption of a standard for attachments under HIPAA. Please comment on the proposed operating rules for attachments. What should NCVHS consider prior to making any recommendations to HHS regarding operating rules for attachments?</p>	<ul style="list-style-type: none"> <li>HL7 does not agree with this proposed rule, as an Attachment Rule has yet to be released. Further, it is anticipated that the long-anticipated proposed rule will be based on the related 2016 NCVHS recommendations. When that recommendation was prepared it was best of breed thinking. We believe that in today’s landscape any proposed regulation for Attachments should consider the Da Vinci Clinical Data Exchange FHIR Standard for Trial Use Version 2 Implementation Guide (CDex). This guide, balloted earlier this year and to be published soon, defines a more current approach to support Electronic Attachments. The CDex guide leverages EHR based FHIR capabilities to automate the exchange of both solicited and unsolicited Claims Attachments as well as supporting requests for additional information not identified and exchanged during the initial prior authorization and quality measure exchange processes defined by other Da Vinci FHIR Implementation Guides. Finally, the CDex guide aligns with NCVHS March 2022 letter recommending regulatory flexibility to allow the use of FHIR standards along with X12 HIPAA adopted standards.</li> </ul>
<p><b>Other:</b> Are there other topics NCVHS should consider when making recommendations to HHS regarding the current proposals from CAQH CORE?</p>	<ul style="list-style-type: none"> <li>Please see comments above supporting the release of an attachments rule, which includes new standards such as HL7 Clinical Data Exchange (CDex) and FHIR APIs.</li> <li>An additional topic to be considered is how should the current proposals from CAQH CORE be ranked in terms of priority against other relevant mandate and requirements.</li> </ul>