



March 10, 2023

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services (CMS)  
Department of Health and Human Services  
Attention: CMS-0057-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

Submitted electronically to:  
<http://www.regulations.gov>

Re: CMS-0057-P -Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule

Dear Administrator Brooks-LaSure:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on CMS' proposed rule *Advancing Interoperability and Improving Prior Authorization Processes*. HL7 is the global authority on healthcare 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 healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors and consulting firms. HL7 standards, implementation guides (IGs) and related tools provide both a fundamental and innovative backbone to achieving our national goals of an interoperable health system.

Regarding this proposed rule, HL7 strongly supports CMS' move toward greater use of FHIR-based Application Programming Interfaces (APIs) to facilitate interoperable, standards-based data sharing between all patients, providers, and payers and believes in the transformative difference this will make for healthcare delivered in America.

HL7's detailed feedback on the *Advancing Interoperability and Improving Prior Authorization Processes* proposed rule is below. We offer overarching comments, recommendations and implementation perspectives, particularly related to adding prior authorization information to the patient access, provider access, and payer-to-payer APIs.

Overall, HL7 appreciates the recognition and consideration of the HL7 Fast Healthcare Interoperability Resources (FHIR)<sup>®</sup> and related Da Vinci, CARIN and SMART on FHIR Implementation Guides (IGs) noted in this proposed rule including:

### **HL7 FHIR (General)**

- HL7 FHIR US Core Implementation Guide
- HL7 FHIR Bulk Data Access (Flat FHIR)
- HL7 SMART Application Launch Framework Implementation Guide

### **Da Vinci Project**

- Payer Data Exchange (PDex)
- PDex U.S. Drug Formulary
- PDex Plan Net
- Coverage Requirements Discovery (CRD)
- Documentation Templates and Rules (DTR)
- Prior Authorization Support (PAS)
- Member Attribution (ATR) List

### **CARIN Alliance**

- CARIN Consumer Directed Payer Data Exchange Implementation Guide
- CARIN Consumer Directed Payer Data Access Implementation Guide (CARIN IG for Blue Button<sup>®</sup>)

### **Key issues highlighted in HL7's proposed rule comments are:**

- **Consistent and Complimentary Prior Authorization Requirements** - HL7 believes it is critical that requirements placed on any of the parties involved in the prior authorization process – providers, payers, or vendors – are consistent and complimentary for all parties. We encourage CMS and their partners at the Office of the National Coordinator for Health Information Technology (ONC) to work to actively align the requirements for providers, payers, and vendors so that the benefits of electronic prior authorization can be shared and that the primary drivers of burden associated with the prior authorization process can be most efficiently addressed.
- **IGs and Versioning** - HL7 recommends that CMS and ONC work closely together to establish a clear, predictable path to true interoperability that, in regards to required IGs includes: (1) the ability to advance IG versions outside the regulatory cycle; (2) adequate time for industry understanding and adoption of new IG versions; and (3) limits the options, so as not to disrupt interoperability. The HL7 community and its relevant Accelerators and Work Groups look forward to working with CMS and ONC to find the best approach to IG versioning requirements.
- **HL7 FHIR Da Vinci CDex IG As a Recommended IG to Support Use of PARDD API** - HL7 strongly urges CMS to name the HL7 FHIR Da Vinci CDex IG as one of the recommended IGs to use in support of the Prior Authorization Requirements, Documentation and Decisions (PARDD) API, as it is a critical part of the Burden Reduction IG constellation and plays a critically important role in support FHIR-based prior authorization transactions as proposed in this rule.

- **Sequencing, Phased Implementation and the PARDD API** - The proposed rule highlights that payers be required to implement the PARDD API for all prior authorization rules and requirements for items and services, excluding drugs, by January 1, 2026. HL7 supports phasing in the use of all or elements of the IGs and taking an incremental approach where electronic prior authorization is first, focused on those policies that leverage fully structured data and/or provider attestation.
- **Incentivizing Providers and the PARDD API** - HL7 agrees that it is important to incentivize providers to engage with the PARDD API. We support leveraging the HL7 FHIR Da Vinci Burden Reduction IGs to work toward future readiness for a certified Health IT Module or Modules to be included within the ONC Health IT Certification Program.

HL7 also recommends that financial and technical incentives -- such as for rural broadband -- should be put in place to ensure provider adoption of these standards. Many providers do not have the electronic capabilities to utilize such standards, particularly those in underserved communities.

- **National Healthcare Directory (NDH)** - A critical issue impacting HL7 FHIR transactions generally -- and the proposed APIs in this rule specifically-- is the current lack of an authoritative central directory of digital endpoints. This deficiency creates a significant gap in our ability as a health care industry to move many critical interoperability initiatives forward. To support implementing the proposals in this rule, HL7 believes it is necessary to initiate the NDH with relevant digital endpoint information and to focus the initial version on providers, payers, and their organizational affiliations. And, to support the Provider Access and Payer-to-Payer APIs, as well as the Prior Authorization Requirements, Documentation, and Decision (PARDD) PARDD API, provider and payer endpoints must be included in an initial NDH minimum viable product (MVP). This MPV must also be available to support endpoint discovery in advance of the implementation of the proposed APIs.
- **Advancing Trusted Exchange Framework and Common Agreement (TEFCA)** - HL7 recommends a consistent set of standards between TEFCA and CMS mandated APIs, so that the industry does not have to implement multiple, different standards depending upon the exchange partner or mechanism for exchange. TEFCA must support FHIR and require Payment and Operations Purpose of Use before TEFCA could be a viable option for payers.

In addition to our leadership and Policy Advisory Committee, HL7 Accelerators including the Da Vinci Project and the Fast Healthcare Interoperability Resources at Scale (FAST) Taskforce, as well as the Orders and Observations and the Payer/Provider Information Exchange (PIE) Work Groups contributed to these comments. The HL7 Da Vinci Project gathered their members to provide in-depth feedback and their insights, recommendations and relevant, direct comment excerpts are foundational to this HL7 submitted response.

Should you have any questions about our attached comments, 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 working with CMS as this rule is finalized and implemented and as America transitions to a more automated, interoperable patient experience and prior authorization process.

Sincerely,



Charles Jaffe, MD, PhD  
Chief Executive Officer  
HL7 International



Andrew Truscott  
Board of Directors, Chair  
HL7 International

## HL7 Responses

HL7's comments on the *Advancing Interoperability and Improving Prior Authorization Processes* proposed rule are below.

### **Adding Prior Authorization Information to the Patient Access, Provider Access, and Payer-to-Payer APIs -**

HL7 strongly affirms adding prior authorization information to the Patient Access, Provider Access, and Payer-to-Payer APIs. Making these data more broadly available increases transparency and has the potential to reduce burden on patients, providers, and payers. The HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG can facilitate sharing the proposed data through each of these APIs. The Da Vinci PDex Workgroup is actively completing an initial set of updates to the PDex IG to facilitate sharing prior authorization information. The next version of PDex has gone through initial Connectathon testing and is targeted for publication in two to three months. In addition to the updates already incorporated, we also plan to support the proposal to include any related administrative and clinical documentation. Specifically, ensured will be that the necessary data elements are required in the appropriate profile and an example is provided to best support this proposed requirement. The Da Vinci PDex Workgroup will work to incorporate all needed updates to support the functional requirements as finalized for sharing prior authorization information in support of the January 1, 2026 implementation timeline.

The proposed rule states that in the case of a prior authorization decision, the payer must provide a specific reason code. HL7 agrees that this is important information, but requests that CMS define a standard list of prior authorization codes to ensure consistency throughout the industry. This could be based on an updated version of the X12 Service Decision Reason Codes, understanding that the needed updates will require industry effort, but will offer a shared foundation from which to work.

**Patient Access API** - In addition to adding prior authorization information to the Patient Access API, the proposed rule highlights that payers share metrics annually, starting with API use in calendar year 2025, to be reported to CMS by March 31, 2026. HL7 agrees these are valuable data to capture and sharing annually will help provide valuable information regarding API adoption and use. HL7 supports the proposed amendments to the Patient Access API, but request that CMS provide clear guidance --in alignment with the Office of the National Coordinator (ONC) -- regarding use of newer versions of the United States Core Data for Interoperability (USCDI) and the associated HL7 FHIR US Core IG, so that when multiple versions of the USCDI are available for use patients, payers, and third-party app vendors all have clear expectations and understanding regarding what data elements are available to share and receive when.

**Provider Access API** - HL7 strongly supports the addition of the proposed Provider Access API. Having the same payer data shared with patients via the Patient Access API, available to providers will support care coordination and

informed care that could lead to improved patient outcomes and help patients be an active partner at the center of their care journey.

HL7 also affirms the proposed requirement to leverage the HL7 FHIR Bulk Data Access IG for the Provider Access API, so that if a provider has a panel of patients associated with a single payer, that payer can share those data asynchronously in one transaction. Use of the Bulk standard also supports sharing data for a single patient asynchronously, which may also be valuable to support this proposed data sharing. The Da Vinci PDex Workgroup is actively discussing incorporating support for Bulk patient member matching and the ability to share data for multiple patients in a single Bulk transaction, contributing to more efficient, effective healthcare.

**Payer-to-Payer API** - HL7 strongly supports the withdrawal of the original Payer-to-Payer policy in favor of a FHIR-based API approach. Leveraging the same standards and IGs already being utilized for the Patient Access API, and also proposed for the Provider Access API, will greatly support efficient implementation.

**Additional Considerations for the Provider Access and Payer-to-Payer APIs** - The HL7 FHIR Da Vinci PDex IG is well positioned to support both of these proposed APIs, but we note that many of the proposed requirements are covered in Standard for Trial Use (STU) 2, which is targeted for publication within the next two to three months. And, as indicated, based on final functional requirements, additional updates can be made to the IG to ensure the IG fully supports the proposals once finalized. The Da Vinci PDex Workgroup will ensure these updates are made timely to support the January 1, 2026 implementation date with ample testing. This is a good example of why it is necessary to ensure that the regulation supports use of subsequent versions of a given IG. As noted in the proposed rule, IGs and underlying standards are evolving more quickly than the established regulatory cycle. It is equally important to ultimately require specific IGs to ensure industry has clear direction and a common set of interoperable standards to definitively work from as it is to find the regulatory flexibility in the new world of rapid standards development to allow a new version of an IG to be used as soon as it is available. As noted in our introduction, HL7 recommends that CMS and ONC work closely together to establish a clear, predictable path to true interoperability that includes required IGs, the ability to advance IG versions outside the regulatory cycle, provides adequate time for industry adoption of new IG versions, and limits the options as not to disrupt interoperability. We look forward to working with CMS and ONC to find the best approach to IG versioning requirements.

**National Healthcare Directory (NDH)** - Another critical issue that impacts HL7 FHIR transactions generally -- and the proposed APIs in this rule specifically-- is the current lack of an authoritative central directory of digital endpoints. This deficiency creates a significant gap in our ability as a health care industry to move many critical interoperability initiatives forward. To support implementing the proposals in this rule, HL7 asserts it is necessary to initiate the NDH with relevant digital endpoint information and to focus the initial version on providers, payers, and their organizational affiliations. And, to support the Provider Access and Payer-to-Payer APIs, as well as the Prior Authorization Requirements, Documentation, and Decision (PARDD) PARDD API, provider and payer endpoints must be included in an initial NDH minimum viable product (MVP). This MVP must be available to support endpoint discovery in advance of the implementation of the proposed APIs.

Regarding the Provider Access API, a bi-directional exchange mandate could be considered by CMS (as opposed to one-sided provider access to payer data) to cover payment and operations, in addition to treatment.

**Improving Electronic Prior Authorization Process (ePA): Overarching** - Regarding overarching issues, first HL7 supports the use of common industry standard electronic prior authorization (ePA) decision codes. We do not believe there are any additional standards that need to be developed in order to support the ePA APIs.

Second, one of the significant issues identified by the HL7 balloting and review process for the Burden Reduction Implementation Guides is the need to make information regarding prior authorization (PA) and documentation

supporting medical necessity assembled by the ordering provider available to the performing provider. This may either be documentation to enable the performing provider or supplier to submit a prior authorization if they are required to do so, or to inform the performing provider supplier that an authorization has been provided. CMS may wish to note that HL7 has approved extending an implementation guide focused on exchange of this information for Durable Medical Equipment (DME) and Home Health services --supported by CMS-- to all exchanges of FHIR-based orders and the supporting documentation between an ordering and performing provider. The updated IG is currently entitled FHIR Orders Exchange (FOE). This is intended to address a common approach across orders and referrals to external providers and suppliers. The primary sponsor is the HL7 Orders and Observations WG. Updates should be balloted in the HL7 September 2023 ballot cycle. While this IG is not yet ready to be cited as recommended or required in the expected final rule, it may be appropriate to note its development in the preamble to encourage implementers to support a common method of exchanging PA information between an ordering and performing provider.

HL7 also notes that for enabling the performing provider or supplier to obtain additional information that may have been missing or not yet available on the initial order transaction, the Da Vinci CDex implementation would similarly be targeted to support request for further information from the ordering provider.

**Prior Authorization Requirements, Documentation, and Decision (PARDD) API** - HL7 strongly supports the PARDD API, bringing together the Da Vinci Burden Reduction IGs, specifically the CRD, DTR, and PAS IGs. HL7 also agrees that it is important to incentivize providers to engage with the PARDD API. We recommend leveraging the HL7 FHIR Da Vinci Burden Reduction IGs to work toward future readiness for a certified Health IT Module or Modules to be included within the ONC Health IT Certification Program. We look forward to supporting the start of a dialogue between industry and both CMS and ONC on an appropriate timeline and path to such certification, consistent with our response to the ONC RFI and to exploring how best to engage not only providers leveraging their EHR systems. Other provider and payer IT systems must be considered to ensure that the complex workflows across IT systems engaged in prior authorization are accounted for.

HL7 supports the addition of a new measure under the Health Information Exchange (HIE) objective in the MIPS Promoting Interoperability Program for MIPS eligible clinicians, eligible hospitals, and critical access hospitals (CAHs) for those clinicians already leveraging Certified EHR Technology (CEHRT). We do suggest, that CMS consider not limiting this measure to only data relevant to a prior authorization that is obtained from an EHR, however. Relevant prior authorization data may not be limited to the provider's EHR alone.

In addition, HL7 believes that the prior authorization timeframes proposed in this rule could be leveraged to promote adoption of the PARDD API. For instance, to start, the proposed enhanced turnaround times for prior authorization decisions could only apply to those prior authorization requests facilitated by a PARDD API transaction. Understanding the value to providers to get decisions as quickly as possible to facilitate care and reduce burden, this could be a valuable incentive for providers to use the PARDD API.

The proposed rule highlights that payers be required to implement the PARDD API for all prior authorization rules and requirements for items and services, excluding drugs, by January 1, 2026. HL7 supports phasing in the use of all or elements of the IGs and taking an incremental approach where electronic prior authorization is first focused on those policies that leverage fully structured data and/or provider attestation. We note that an incremental approach supported the needed business transformation required to move from a document driven to an automated and data driven approach.

It is important to recognize that the HL7 FHIR Da Vinci Burden Reduction IGs recommended in support of the PARDD API support existing federal and state prior authorization requirements and processes, while simultaneously providing a path forward to a more effective and efficient electronic prior authorization process.

HL7 strongly recommends that CMS name the HL7 FHIR Da Vinci CDex IG as one of the recommended IGs to use to support the PARDD API as it is a critical part of the Burden Reduction IG constellation and plays a particularly important role in support FHIR-based prior authorization transactions as proposed in this rule.

Regarding the PARDD API and the HL7 FHIR Da Vinci Prior Authorization Support (PAS) IG specifically, HL7 puts forth a floor versus ceiling approach for consideration --in which the X12N 278 Request and Response standard currently required by the Health Insurance Portability and Accountability Act (HIPAA) requirements -- is the floor and a standard FHIR approach using the HL7 FHIR Da Vinci Prior Authorization Support (PAS) IG could be allowable as the ceiling.

**Reporting of Prior Authorization Metrics** - CMS is proposing to require impacted payers to publicly report a set of aggregated metrics about prior authorization. HL7 encourages CMS to consider delineating this reporting by those prior authorization transactions supported by a FHIR API transaction and those otherwise conducted. We think it is important to evaluate the impacts of leveraging the FHIR API approach on timeframes, denials, appeals, etc. And, to reduce burden on payers, HL7 encourages CMS to evaluate how the recommended IGs for the PARDD API can be leveraged to automate the collection of the needed data to support calculation of prior authorization metrics.

**Request for Information (RFI) Topic: Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)** – The RFI portion of the proposed rule inquires about what concerns commenters have about potential requirements related to enabling exchange under TEFCA, if such an approach could present burdens or barriers and what CMS could do to reduce these barriers.

HL7 makes the following observations and recommendations:

- TEFCA must support FHIR and require Payment and Operations Purpose of Use before TEFCA could be a viable option for payers. Payers have not equally invested in document-based exchange technology being used today to exchange treatment information and the industry is moving toward more modern API technology to exchange discrete data using FHIR. Additionally, current exchange policies require responses to treatment-related requests, but not payment and operations requests for data.
- There should be a consistent set of standards between TEFCA and CMS mandated APIs so that the industry does not have to implement multiple, different standards depending upon the exchange partner or mechanism for exchange.