March 25, 2022

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
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Thank you for the opportunity to comment on the referenced Request for Information (RFI). The HL7® Da Vinci Project and its membership appreciate the recognition and consideration of the HL7 FHIR Da Vinci Burden Reduction Implementation Guides (IGs), specifically:

- Coverage Requirements Discovery (CRD),
- Documentation Templates and Rules (DTR), and
- Prior Authorization Support (PAS).

Prior Authorization (PA) is increasingly documented as a burden for providers and payers, and the impact on patients is noteworthy. According to research conducted by RTI on behalf of the AHIP1, any move toward electronic PA (ePA) can reduce the time between when a PA is submitted and a decision is made three-fold, or by an average of about 69%. This means more timely care for patients and less burden for all parties engaged in the PA process. The HL7 FHIR Da Vinci Burden Reduction IGs can meaningfully support the move to ePA.

As a result, the HL7 Da Vinci Project, and its members, support leveraging the HL7 FHIR Da Vinci Burden Reduction IGs to enable a Health IT Module to be certified through the ONC Health IT Certification Program. To address the true burden the current PA process places on patients, providers, and payers it is necessary to integrate PA into the workflow and automate the end-to-end process. FHIR, and specifically the HL7 FHIR Da Vinci Burden Reduction IGs, facilitate both workflow integration and automation.

We acknowledge that one of the challenges for the health care community in implementing these IGs and ePA will be payers declaring the data needed for PA decision-making. We therefore

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support phasing in the use of all or elements of the IGs and taking an incremental approach where ePA is first focused on those policies that leverage fully structured data and/or provider attestation. An incremental approach supports the needed business transformation that will be required to move from a document driven to a data driven approach and support automation. It is important to note that specialty medications covered under the medical benefit should also be included in this ePA discussion and included in any requirements around a certified Health IT Module as the NCPDP SCRIPT Standard is already captured under ONC certification.

It is critical that any requirements placed on any of the parties involved in the PA process – providers, payers, or vendors – are consistent and complimentary for all parties. We encourage ONC and their partners at CMS to work to actively align the requirements for providers, payers, and vendors so that the benefits of ePA can be shared and that the primary drivers of burden associated with the PA process can be most efficiently addressed. Only in this way will patients also see the maximum benefit of a PA process embedded in a provider’s workflow, fully automated – the ability to have a meaningful conversation with their provider at the point of care about their options, facilitating more timely care and adherence to their care plan.

The Da Vinci Project leadership with active participation from our membership, would like to make the following comments and suggestions regarding specific questions in the RFI:

**Benefits to Patients, Providers, Payers, and Vendors**

Improving the PA process through automation and incorporation into the provider workflow could have a **profoundly positive impact on patients**. If the provider can know at the point of care if PA is needed and what the implications of that are for a patient in terms of cost and alternative options while the patient is in the office with them, the provider can have a conversation with the patient. In this way, together, the provider and patient can make informed choices during the care visit. The HL7 FHIR Da Vinci Burden Reduction IGs facilitate the ability to have this conversation. These IGs could facilitate a PA being approved before a patient leaves the provider’s office. This can improve care by reducing delays in treatment and supporting adherence to care plans. It can reduce cost by supporting timely care delivery. It supports transparency by giving patients and their advocates access to PA information and a line of sight into the PA process. Any application, via an API, could access this information and help keep patients informed and engaged. Using these IGs, automating the PA process, and integrating the PA process into a provider’s workflow would therefore significantly benefit patients.

Providers would also significantly benefit from use of the HL7 FHIR Da Vinci Burden Reduction IGs. It would reduce burden by automating a now manual process. It would incorporate the process into the provider’s clinical and administrative workflow allowing them to make the best care decisions for their patients, with their patients, which could also improve the provider/patient relationship further supporting improved care outcomes. It would also increase transparency for providers by allowing them to better understand when a PA is needed and when it is not, what documentation is needed, and it would provide support in compiling that
documentation. This reduces the need to resubmit PAs or revisit a pending PA request multiple times.

**Payers** would see similar benefits around reduced burden with an automated process and lower effort resulting from fewer unnecessary PAs being submitted and PAs being initially submitted with insufficient documentation. It will be an initial effort for payers to declare the data needed for PA decision-making, but if an incremental approach is taken, and ePA starts with those items and services leveraging fully structured data and/or provider attestation, this initial effort could be minimized and payers could be afforded the time to make the needed business transformation to support a more streamlined, automated, and efficient PA process. Building the infrastructure needed to support this work could also provide the foundation to support efficiencies across other processes such as claims attachments, claims denials, and chart pulls as this foundation is potentially reusable and applicable across multiple use cases.

As critical partners, **vendors** would be able to support and facilitate providers and payers in this effort by supplying the technological tools needed to integrate the PA process into clinical workflows, providing a valuable additional service to their customers, and a benefit to patients.

**Functional Capabilities for Electronic Prior Authorization in Certified Health IT**

We agree that the first six functional capabilities outlined in the RFI are important to support a complete end-to-end ePA process and should be considered for inclusion in ePA certified Health IT Modules. As we discuss in more detail below, we do not believe the seventh functional capability noted in the RFI is needed. Regardless, each of the seven functional capabilities noted in the RFI are facilitated by one or more of the HL7 FHIR Da Vinci Burden Reduction IGs. Table 1 maps the seven functional capabilities to the relevant IG(s).

Table 1: Functional Capabilities and the Relevant HL7 FHIR Da Vinci Burden Reduction IG(s)

<table>
<thead>
<tr>
<th>#</th>
<th>Functional Capability</th>
<th>Relevant Da Vinci IG(s)</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Identify when prior authorization is applicable for an item or service, using clinical decision support (CDS) and/or user input, and for receiving notifications of changes in such applicability</td>
<td>CRD</td>
</tr>
<tr>
<td>2</td>
<td>Query a payer API for prior authorization requirements for each item and service and identify in real time specific rules and documentation requirements</td>
<td>CRD &amp; DTR</td>
</tr>
<tr>
<td>3</td>
<td>Collect clinical and administrative documentation needed to complete prior authorization documentation (electronic forms or templates) from a health IT system</td>
<td>DTR</td>
</tr>
<tr>
<td>4</td>
<td>Electronically submit completed documentation for prior authorization to a payer’s API, along with supporting information</td>
<td>PAS</td>
</tr>
<tr>
<td>5</td>
<td>Receive a response from a payer regarding approval, denial (including a reason for denial), or need for additional information</td>
<td>PAS</td>
</tr>
</tbody>
</table>
6. Query a payer’s system for updates on a pending prior authorization request and have a reason returned as to why a request is still pending

7. Effectively capture and persist digital signatures (or other indications of provider review and assent), enable data integrity of documentation over time, and support other features necessary to meet payer administrative requirements associated with prior authorization transactions

The HL7 FHIR Da Vinci CRD IG defines a standard for Health IT initiating the PA workflow to use CDS Hooks in the clinical workflow to query a payer CDS endpoint to determine:

- If an item or service is covered and/or requires PA,
- Alternative items or services with improved coverage and/or lower cost,
- Documentation requirements to demonstrate medical necessity and appropriateness, and
- Requirements for appropriate use.

The HL7 FHIR Da Vinci CRD IG also supports the ability to determine changes in payer coverage compared to a prior coverage request. In this way, the IG facilitates the first two functional capabilities. The HL7 FHIR Da Vinci DTR IG, as a companion IG to CRD, also supports the second capability by ensuring documentation requirements are met.

We understand that previously, specifically in response to the CMS Interoperability and Prior Authorization (CMS-9123-P) and ONC Healthcare Operations Standards proposed rules available for public comment in December 2020, stakeholders raised concerns about the fact that these IGs use CDS Hooks and CQL, as well as SMART on FHIR. We appreciate the concerns raised, and the Da Vinci community has been working to address these concerns. Additional refinement to the currently published HL7 FHIR Da Vinci Burden Reduction IGs is part of the early May 2022 ballot cycle. This is an indication of the continued work to evolve these IGs in the year since rule comments were reviewed. Though there is still work to be done, given the advancements made and the continued opportunity to refine in the current ballot cycle, the Da Vinci community feels stakeholder concerns are being actively addressed and these IGs are valuable and actionable in their current state.

That said, we acknowledge that one of the challenging aspects of implementing the HL7 FHIR Da Vinci Burden Reduction IGs will involve payers doing the work to express the data needed for PA decision-making in CQL so the documentation collection and evaluation process can be automated. In the end, this is less a technology issue and more a business transformation issue. Payers will need to declare the data needed for PA decision-making. And, providers will need to adjust to interacting with and incorporating the new ePA capabilities. It is for this reason we advocate phasing in the use of all or elements of these IGs and using an incremental approach, starting with PA rules for items and services that leverage fully structured data and/or provider attestation. From here, additional items and services can be added to the requirement over time providing the opportunity for payers to work through the needed business transformation to support PA automation.
The fourth, fifth, and sixth functional capabilities are facilitated by the HL7 FHIR Da Vinci PAS IG, which is discussed in more detail below.

The seventh functional capability identified in the RFI was noted as an area the HL7 FHIR Da Vinci Burden Reduction IGs did not fully support. We do not believe this seventh functional capability—the ability to effectively capture and persist digital signatures—should be included in a certified Health IT Module(s). If these IGs are implemented, even incrementally, the ePA process will be moving toward automation, DTR can be leveraged for a thorough understanding of requirements, and additional documentation should not be needed. In addition, we believe there are sufficient system controls in place (e.g. user names, passwords, audit trails, etc.) making digital signatures unnecessary. We believe it is important to move forward with ePA in a way that does not just digitize the current paper process, but transforms it into an optimized digital solution. Including this final functional capability in a certified Health IT Module(s) could impede this transformation and inhibit a move to an automated process.

Though we do not believe this seventh functional capability is needed, if it were to be included in a certified Health IT Module(s), we have identified an opportunity to support it in the HL7 FHIR Da Vinci Burden Reduction IGs. The HL7 FHIR Da Vinci Clinical Data Exchange (CDex) IG defines support for digital signatures in the draft Attachments section of the IG. This will be taken to ballot in the May 2022 cycle. This same solution will be leveraged for DTR and PAS. In this way, to the extent signatures (physical, electronic, or digital) are created as part of the PA documentation, they could be exchanged as part of that documentation within the digital workflow. We do caution this could encourage increased documentation burden and potential delays in the ePA process, and from a digital signature perspective, may be redundant given the system controls noted.

The first six functional capabilities identified in the RFI are foundational for the effective implementation of ePA and thus are the appropriate minimum capabilities needed to support ePA. The HL7 FHIR Da Vinci Burden Reduction IGs facilitate implementation of these functional capabilities. There are opportunities to continue to improve and iterate on these IGs, but that is the value of IGs born out of an Agile methodology. Through the ballot process, we can continue to build on the strong, tested foundation that already exists and continue to improve based on real world experience. Da Vinci community members are seeing the value of these IGs in action. For instance, members that have CRD functionality in place are seeing reduced PAs because providers now know when a PA is needed and when it is not, meaning unnecessary PAs are not submitted. This is actively reducing burden for providers and payers and improving the patient experience.

Implementation Specifications to Support Electronic Prior Authorization Capabilities
Collectively, the HL7 FHIR Da Vinci Burden Reduction IGs support existing federal and state PA requirements and processes, while simultaneously providing a path forward to a more effective and efficient ePA process. The PA process as it exists today requires improvement. Phasing in these IGs is one way to begin to improve the process. And, because HL7 and the Da Vinci Project have a proven model for rapid standards improvement, this improvement can be iterative,
supporting an incremental adoption of ePA that supports the health care community in their transition to an automated PA process that is integrated into their clinical and administrative workflow. ONC, through a certified Health IT Module(s), could leverage all or elements of these IGs as a floor indicating the minimum capabilities necessary to allow those in the community new to ePA and FHIR the opportunity to initiate this new process and provide the space for those on the leading edge to continue to pioneer the next level of implementation.

It is important to recognize that, though not widely adopted, there are existing regulations in place for ePA, and that some in the health care community have invested in the standards included in these regulations. At this time, use of the X12 278 Request and Response standard is required by law and regulation per the Health Insurance Portability and Accountability Act (HIPAA). To ensure that these requirements can be met, the HL7 FHIR Da Vinci PAS IG does include the ability to “translate” a FHIR transaction to the required X12 278 transaction and back to FHIR. In this way, the required standard is appropriately used, but the efficiencies of FHIR can also be leveraged. This “translation” step also recognizes the investment that has been made by members of the health care community in this standard and maintains the ability to use it accordingly.

The RFI asks about the value of this “translation” and asks if ePA were to be included in a certified Health IT Module(s) if such a “translation” should be included. It is necessary to have this “translation” option available given the current HIPAA regulations. For this reason, this “translation” is currently supported by both HL7 and X12 in the relevant PAS and 278 specifications, respectively. It is important to note that the HL7 FHIR Da Vinci PAS IG is written in such a way that if the requirement to use the X12 278 was removed, the structure is there for a FHIR-only transaction – the “translation” step could be removed without degrading the integrity of the IG and the ability to complete the needed ePA transaction. This is being illustrated by the fact that payers and their trading partners have the opportunity to use the PAS IG without the X12 278 “translation” under the Da Vinci HIPAA Exception that was approved by CMS through July 14, 2024. This is further support for leveraging this IG now to begin to move toward a more efficient and effective current state understanding it can also support a more streamlined future state FHIR-only option.

This “translation” has been extensively tested in numerous connectathons, indicating this IG is ready for production implementation. As discussed with the CRD and DTR IGs, the HL7 Agile process supports continuous improvement. Leveraging this opportunity for such improvement is one of the many benefits of the FHIR standards. Accordingly, the Da Vinci community is looking to introduce additional capabilities to the HL7 FHIR Da Vinci PAS IG through the May 2022 ballot. These enhancements include defining consistent error handling, and leveraging CDex as noted above, if needed. Both of these enhancements further support the ability of PAS to address immediate attachment needs. In total, these enhancements continue to build on the strong, tested foundation of the current published version of the IG.

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2 [https://confluence.hl7.org/display/DVP/Da+Vinci+HIPAA+Exception](https://confluence.hl7.org/display/DVP/Da+Vinci+HIPAA+Exception)
The RFI also notes two other concerns about the HL7 FHIR Da Vinci PAS IG that were previously noted by stakeholders that are important to clarify. The first concern is that the number of transactions will be exponentially increased as a result of the “translation” from FHIR to the X12 278 and back to FHIR when both sending and receiving the ePA transaction. In actuality, the number of ePA transactions experienced by the provider and payer Health IT is the same whether using PAS or the X12 278 – there is simply one transaction during which the data transform as needed to meet the existing requirements. This “translation” step does not increase the number of needed end-to-end transactions.

The other concern raised was around the role of intermediaries. The RFI notes that stakeholders questioned if it was necessary to use a clearinghouse, for instance, to leverage the PAS IG. The term “intermediary” in the PAS IG can refer to a clearinghouse if that is an entity a provider and/or payer is engaging with. But an intermediary could also be a business associate, a software service, or a payer front-end. Essentially, the “intermediary” is simply a step in the process that accepts the FHIR bundle, translates it to and from the X12 278 as needed, and returns a FHIR bundle.

In this way, the HL7 FHIR Da Vinci PAS IG supports existing federal and state requirements, supports sharing attachments, and supports further transparency in the PA process. Consistent with the foundational functional capabilities noted in the RFI, the PAS IG facilitates receiving a response from a payer regarding whether a PA was approved, denied (and if denied, a reason for denial), or the need for additional information. The PAS IG also allows a payer’s system to be queried for updates on pending PA requests, including a reason the PA is pending. This transparency can assist providers and reduce burden by supplying valuable information to help them submit increasingly successful PAs over time with the right information the first time, and it can facilitate patients getting the information they need to be informed and active partners in their care. Burden is also reduced on payers who do not have to manage unnecessary or incomplete PA requests from providers or frequent inquiries from patients.

**Alternative Options and HL7 FHIR Da Vinci Burden Reduction IG Readiness**

The RFI asks if alternative IGs should be considered, if only base FHIR standards, or if no FHIR standards should be considered. The RFI also asks if only attachment standards should be considered for a certified Health IT Module(s) at this time. We feel strongly that this is not a question of “either/or”. Leveraging the HL7 FHIR Da Vinci Burden Reduction IGs is an opportunity to move forward with FHIR standards in order to work to address the primary drivers of PA burden, while taking advantage of the experience with and investment in existing standards like the X12 278. And, it is an opportunity to address the health care community’s need for standards to support attachments. Given the ability of the HL7 FHIR Da Vinci Burden Reduction IGs to bring these many important pieces of the PA puzzle together, we believe it is time to move forward and use any and all existing policy levers to support all providers, payers, and vendors moving to ePA using actively aligned requirements.
Addressing any one component of the PA process alone will not help address the primary drivers of PA burden – this is only possible if the process is automated and incorporated into the provider’s workflow, while recognizing that both on the payer and provider side capabilities are likely to be supported by multiple health IT systems, and thus Health IT Modules. FHIR, and specifically the Da Vinci Burden Reduction IGs, support this, but we acknowledge there is more work to do together to detail how to best leverage these IGs for a certification program. As previously noted, the Agile methodology these IGs are born out of, the ability to efficiently iterate and improve the IGs through an open, consensus-based ballot process, both support the ability to learn from real world experience and move forward accordingly. The HL7 FHIR Da Vinci Burden Reduction IGs have been vetted and tested and are good enough start to support this move forward, particularly when incrementally phased in and through further collaboration with ONC to do the work to fully articulated the interaction sets that could be distributed across multiple Health IT Modules that in combination support the full ePA workflow to the level of specificity needed for a certification program. We look forward to doing this work as a community to learn how best to continue to iterate through this process for the benefit of all patients, providers, payers, and vendors.

The Da Vinci Project is committed to continue to work with the health care community to incrementally advance these standards in an effort to benefit all patients, providers, payers, and vendors, and we look forward to the continued opportunity to advance this work with ONC. Specifically, we look forward to the opportunity to discuss in greater detail with ONC how to best phase in all or elements of these IGs as part of a certified Health IT Module(s) to be included within the ONC Health IT Certification Program. Da Vinci Project leadership and the teams that developed these IGs are eager to share their expertise and support ONC as the agency considers how certification criteria and certified Health IT Modules leveraging these IGs could be defined.

Sincerely,

The HL7 Da Vinci Project Steering Committee

cc: The HL7 Da Vinci Project Operating Committee

For more information about the HL7 Da Vinci Project, click here