

March 10, 2022

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Dear Dr. Tripathi:

The Health Information Technology Advisory Committee (HITAC) asked the Electronic Prior Authorization Request for Information Task Force to provide recommendations in response to [ONC's Request for Information Regarding Electronic Prior Authorization in the ONC Health IT Certification Program](#). This request for information seeks input regarding electronic prior authorization processes, and how the ONC Health IT Certification Program could incorporate standards and certification criteria related to prior authorization. This transmittal letter offers these recommendations, which are informed by deliberations among the Electronic Prior Authorization Task Force and HITAC subject matter experts.

This transmittal letter offers the final report from the HITAC with recommendations therein which are hereby submitted to you for your consideration.

Respectfully submitted,

<i>Aaron Miri</i>	<i>Denise Webb</i>
/s/	/s/
Aaron Miri Co-chair, Health Information Technology Advisory Committee	Denise Webb Co-chair, Health Information Technology Advisory Committee



Final Report of the Health Information Technology Advisory Committee in Response to ONC's Electronic Prior Authorization Request for Information

March 10, 2022



Table of Contents

Table of Contents.....	2
Background.....	3
Charge	3
Additional Background Information	3
Overview of the Health IT ePA Landscape	4
Recommendations	6
Executive Summary: List of Recommendation Topics	6
Detailed Recommendations and Discussion.....	7
Recommendation 1: Suite of Certified Health IT Capabilities to Support the Prior Authorization Workflow.....	7
Recommendation 2: Readiness of Implementation Guides to Support Functional Capabilities	8
Recommendation 3: Patient-Centered Inclusion in ePA.....	10
Recommendation 4: Prior Authorization Roadmap to FHIR	12
Recommendation 5: Adoption at Scale.....	13
Recommendation 6: Regulatory Coordination	14
Recommendation 7: Attachments	14
Recommendation 8: Prior Authorization Proving Ground for FHIR	17
Recommendation 9: Establishment of an Advisory Process	17
Recommendation 10: Accessibility of Health IT for ePA at Scale	18
Recommendation 11: Innovation around ePA Integration	19
Recommendation 12: Innovation around ePA Bundles	19
Recommendation 13: Multi-Stakeholder Engagement	20
Attachments.....	21
Attachment A: Electronic Prior Authorization RFI Task Force Roster	22
Attachment B: Health IT ePA Functional Criteria Spreadsheet	23
Attachment C: Additional Resources Reviewed by the Task Force	28



Background

CHARGE

In January 2022, ONC issued “Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria”¹ to seek input from the public regarding how the ONC Health IT Certification Program could incorporate standards, implementation specifications, and certification criteria related to electronic prior authorization.

The RFI included questions on a variety of topics including:

- How should electronic prior authorization capabilities be addressed in the ONC Health IT Certification Program?
- What implementation specifications should ONC consider for adoption in the Certification Program to support electronic prior authorization?
- How should the Certification Program support the use of health care attachments for prior authorization transactions?
- What impact would support for electronic prior authorization within the Certification Program have on patients, providers, health IT developers, and payers?

ONC charged the HITAC to establish a new Electronic Prior Authorization (ePA) Request for Information (RFI) Task Force for 2022. The ePA RFI Task Force was charged with providing input and recommendations in response to the RFI on Electronic Prior Authorization to inform future rulemaking and other actions in this area.

ADDITIONAL BACKGROUND INFORMATION

The members of the ePA RFI Task Force 2022² sought to gather input and develop recommendations to respond to the RFI. Below is a summary of the Task Force’s approach and process:

- Reviewed the charge, the RFI, and the scope. Initiated a discussion on the capabilities that need to be in place to enable electronic prior authorization and asked members to share comments. Additional subject matter expertise was identified and secured to support the Task Force’s deliberations.
- Summarized comments and continued discussion on capabilities. Assigned Task Force members to update wording and provide input on each section of the RFI.
- Reviewed the questions in each section of the RFI and solicited draft input from the Task Force members.
- Invited the following speakers to present information to the Task Force to help frame discussion on specific topics:

¹ See <https://www.federalregister.gov/documents/2022/01/24/2022-01309/request-for-information-electronic-prior-authorization-standards-implementation-specifications-and>

² See roster of members in Attachment A.



- Viet Nguyen, HL7 Da Vinci Project – presented overviews of the three Implementation Guides (IGs) mentioned in the RFI:
 - CRD – Coverage Requirements Discovery
 - DTR – Documentation Templates & Rules
 - PAS – Prior Authorization Support
- John Kelly, WEDI – presented an overview of X12 and attachment standards for prior authorization.
- Hans Buitendijk, Cerner – presented an overview of the health IT ePA landscape and an overview mapping the Da Vinci IG functional capabilities to a bundled process view of the ePA process.
- Compiled and reviewed regulatory resources and citations related to the Da Vinci IGs, FHIR, the C-CDA, and related ONC and CMS resources,³ including the report of the Intersection of Clinical and Administrative Data Task Force report.⁴
- Mapped maturity and adoption readiness to the bundled view of the Da Vinci IGs to help support Task Force comments on certification and readiness for adoption.
- Reviewed the Task Force's early progress with HITAC during the February 17, 2022, meeting.
- Developed overarching recommendations, input on capabilities and responses to the RFI questions for submission to HITAC.
- Prepared our final report and presentation to HITAC.

Overview of the Health IT ePA Landscape

ePA functional capabilities may occur in different systems (i.e., RCM/PMS, EMR, SMART App or other vendor solutions). At this time, provider and payer systems may not be fully automated and may involve manual processing as well as automation. Supporting a prior authorization workflow would involve multiple health IT systems on the provider side:

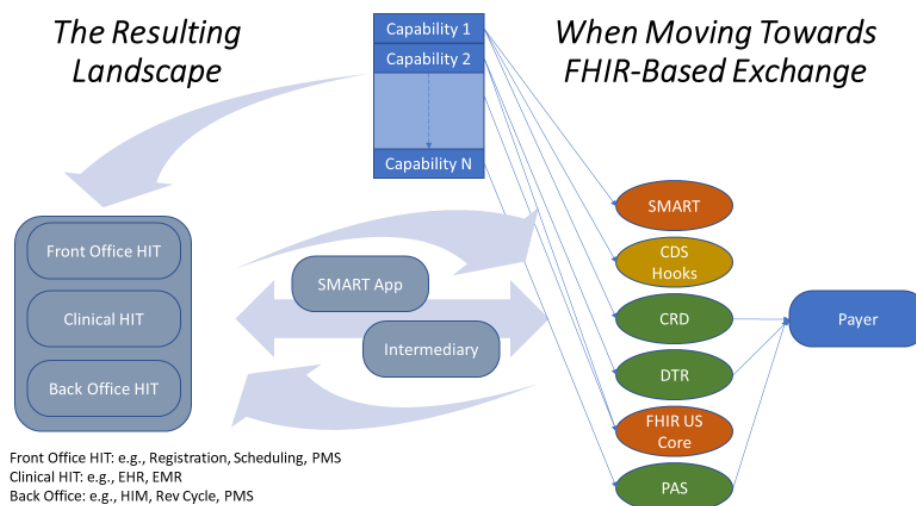
- Prior authorization may be initiated in a Scheduling, Registration, Practice Management, or EHR system.
- Supporting data may reside in an EHR, Health Information Management, or other source system.
- Data relevant to claims and billing are maintained in Revenue Cycle or Practice Management systems.
- SMART (i.e., SMART-on-FHIR) Applications may be used to support specific steps in the process.

³ See Attachment C.

⁴ See https://www.healthit.gov/sites/default/files/page/2021-02/2020-11-17_ICAD_TF_FINAL_Report_HITAC_508_0.pdf



The Resulting Landscape illustrated below depicts the various process flows between the functional components and capabilities that need to be considered in the development of health IT certification criteria as these capabilities are not necessarily performed as part of one, single health IT system. Health IT certification therefore needs to address the variety of configurations that may support the ePA workflow.





Recommendations

EXECUTIVE SUMMARY: LIST OF RECOMMENDATION TOPICS

The ePA RFI Task Force organized their discussion by the categories of questions described in the RFI and developed a list of recommendations in response. These recommendations, in the following 13 areas, seek to not only support the selection of health IT certification criteria, but move the healthcare industry toward streamlined, digitized electronic prior authorization processes with data-driven interoperability. The Task Force noted that a major goal of ePA is to eliminate burden, increase efficiency, improve care, and reduce redundancies and unnecessary effort.

1. Suite of Certified Health IT Capabilities to Support the Prior Authorization Workflow
2. Readiness of Implementation Guides to Support Functional Capabilities
3. Patient-Centered Inclusion in ePA
4. Prior Authorization Roadmap to FHIR
5. Adoption at Scale
6. Regulatory Coordination
7. Attachments
8. Prior Authorization Proving Ground For FHIR
9. Establishment of an Advisory Process
10. Accessibility of Health IT for ePA at Scale
11. Innovation around ePA Integration
12. Innovation around ePA Bundles
13. Multi-Stakeholder Engagement



DETAILED RECOMMENDATIONS AND DISCUSSION

Recommendation 1: Suite of Certified Health IT Capabilities to Support the Prior Authorization Workflow

The HITAC recommends that ONC create a suite of ePA health IT certification criteria for health IT systems supporting both providers and payers that can enable health IT developers (e.g., developers of EHRs, RCM/PMS systems, SMART Apps or other solutions), to certify to one or more specific functional capabilities that together, across participating health IT systems, enable the full ePA workflow.

- 1.1 All parties, including intermediaries, should use certified health IT to minimize the additional contractual obligations that might exist for electronic prior authorizations.
- 1.2 The ePA process should support prior authorization functional capabilities occurring in different systems and be capable of integration to allow for different systems to provide an integrated solution. Specific steps in the ePA process may not always involve interactions between payer and provider HIT systems but may instead involve intermediaries and applications. Health IT certification should encompass all these systems.
- 1.3 ONC should ensure new certification criteria for ePA provide for health IT systems that perform prior authorization on behalf of payers to ensure that their solutions are compliant to the standards and able to send and receive the information needed to meet the prior authorization business case and are therefore scalable.
- 1.4 ONC should ensure that systems and tools certified to support ePA processes allow capabilities to be incorporated within the existing provider workflow where appropriate.
- 1.5 ONC should develop criteria in a staged and tiered approach, providing initial baseline functionality that evolves through an iterative roadmap.
- 1.6 ONC should update the “e-prescribing” certification criterion in 45 CFR 170.315(b)(3) to change NCPDP SCRIPT transactions related to prior authorization from “optional” in the criterion to “mandatory,” to better support ePA processes for drugs covered under a prescription benefit.

(ID: EPARFI-TF-2022_Recommendation 01 – Suite of Certified Health IT Capabilities to Support the Prior Authorization Workflow)

Rationale and Additional Considerations

Payer-Provider Seamless ePA Information Exchange

Health IT Certification Program criteria should give guidance to all participants on what functional capabilities are needed to support a seamless ePA information exchange leading to a successful prior authorization process. It is imperative that what is being built on the provider side is compatible with what is being built on the payer side. If there is no compatibility across both stakeholder groups and their system partners, we will have not improved, nor automated the prior authorization process at all and have simply facilitated one-off, proprietary solutions. Payer workflows must be considered as well as provider workflows and patient needs. Payers weighed in heavily in the development of the three Da Vinci IGs and should continue to do so to ensure that standards are able to work with the broadest number of Health IT stakeholders.



Payers would like the option of using certified Health IT Modules, similar to providers. Payers would likely use the certified modules as reference implementations as a proxy for those clinical systems which are traditionally regulated by ONC. Although the payer is technically regulated by CMS and not ONC, both sides need to be compatible to achieve integrated care delivery. There is excellent value in seeking certification to ensure interoperability. There must be consistency and reciprocity across the EHR and payer sides based upon the IGs. Finally, ONC should consider its role in advancing and standardizing health IT modules that can be used by intermediaries, e.g., clearinghouses.

Recommendation 2: Readiness of Implementation Guides to Support Functional Capabilities

ONC should work with the Da Vinci Project and key healthcare stakeholders (e.g., providers, developers, patients) to develop appropriate health IT certification criteria that incorporate key functional capabilities for prior authorization.

- 2.1 ONC should use the Task Force's Health IT ePA Functional Criteria RFI Specifications guidance document (Attachment B) to assess maturity and readiness for adoption of the Implementation Guides for CRD, DTR and PAS and functional capabilities.
- 2.2 ONC should not be limited to requiring certification to a full IG or all IGs by one system, e.g., EHRs, rather we encourage ONC to define certification criteria that only require compliance with parts of the IGs initially.
- 2.3 HHS should work with Da Vinci Project leads and key healthcare stakeholders (e.g., payers, providers, HIT developers, patients) to determine functional requirements for health IT vendors acting on behalf of the payer to ensure that their solutions are compliant to the IGs and be able to send/receive the information needed to meet the prior authorization business case and therefore scalable.
- 2.4 Privacy and security of the data should be considered in criteria development along with the functional capabilities.

(ID: EPARFI-TF-2022_Recommendation 02 – Readiness of Implementation Guides to Support Functional Capabilities)

Rationale and Additional Considerations

The Task Force's Health IT ePA Functional Criteria Spreadsheet (Attachment B) is a visual tool that maps the implementation guides to events in the ePA workflow process. It includes the Task Force input on the maturity and readiness for adoption of the CRD, DTR and PAS IGs and functional capabilities needed to perform a successful prior authorization. The HITAC recommends working with the Da Vinci Project and key stakeholders to flesh out appropriate specifications, as this document is provided to convey examples only.

Maturity of Da Vinci IGs

The Da Vinci IGs are the best option in the healthcare industry for scalable solutions to improve payer/provider interoperability. We need to be directional, sound, and provide next phase guidance for innovators to ensure, at a minimum, that emerging solutions are built on emerging standards. The adoption of the FHIR base standard does not solve for the business case without the underlying functional



capabilities within the IGs clearly stated to define the specific content and workflows. Certified health IT systems should not be able to use proprietary solutions when standards are available for implementation as these solutions add burden to process and cost. The most important factor is to have standard APIs that can be implemented by health IT solutions supporting the prior authorization workflow.

The Task Force recognized that the complete suite of Da Vinci IGs is not yet ready for implementation at scale, and that there are different levels of maturity for each of the IGs. Today, early adopters are moving forward with the IGs as written in part or in whole based on the role of their respective health IT systems, which will provide more real-world testing. This testing is crucial, especially across physician practices of all sizes and specialties, to make sure the technology functions well across practice settings and in production.

Each of the Da Vinci IGs addresses a different phase of the prior authorization workflow and each can be implemented as a stand-alone solution which can provide incremental value. Based on what is ready and what is available, pieces of the IGs that are available and provide value should be identified in a certification strategy along with a timeline. Ultimately, however, the combined IGs must be implemented across the relevant health IT systems to fully digitize the prior authorization workflow and deliver an overall solution.

ONC certification criteria should not be based on the current, more “coarse” scope of the Da Vinci IGs, but instead should be based on a more granular approach that enables key interactions within each IG to cross various health IT solutions involved in the PA workflow. A baseline of functional criteria for prior authorization should be considered based on the required capabilities that support prior authorization in the majority of RCM/PMS, EMR and payer systems today. This baseline can then evolve to reflect the cutting-edge model of prior authorization that is laid out in the Da Vinci IGs.

Privacy and Security of Health Information

Privacy and security of protected health information must be considered in any IGs that are adopted for health IT certification. Implementations must capture the data required by payers to process a prior authorization for a particular service and safeguard against exposure of more patient health record information than needed by the payer for prior authorization processing.

Furthermore, there must be a way to ensure that patients choosing to self-pay for a particular service have the option to not share health information about that service with the payer. It is the patient’s right under HIPAA to have associated data withheld from their insurance plan. These are key protections to ensure patient trust in any adopted certification requirements. Sharing of health data in excess of what is needed for prior authorization processing, or sharing data of patients not using insurance for a particular service, could be highly distressing to consumers and cause distrust between clinicians and patients, and between patients and health plans.



Recommendation 3: Patient-Centered Inclusion in ePA

The HITAC recommends that ONC work with SDOs and other key stakeholders to build out standards to meet patient use cases and provide transparency.

- 3.1 Capabilities supported by standards for ePA should include: the ability for patients to opt-in to participate in the prior authorization process including status information related to making a prior authorization request; prior authorization status including relevant descriptions of where the prior authorization is in the process through to decision; and the ability to obtain the cost of the medical care connected to the prior authorization based on health plan coverage, including relevant cost information related to in-network status of treating physician(s), ancillary services related to the prior authorization, and desired place of care.⁵
- 3.2 Stakeholders should develop additional IGs or modify existing IGs, such as IGs supporting the Patient Access API policy finalized by CMS, to enable the prior authorization status updates for the patient and allow for voluntary patient inclusion in the ePA process.
- 3.3 Stakeholders should consider whether the Blue Button 2.0 API IG (and related IGs, such as PDex) should be amended to add the ability for patients to have access to prior authorization status and final determinations. Patients should also have access to the information that will guide them on how to handle denials and appeals.
- 3.4 Standards should be developed for electronic ID cards to support exchange requirements for patient matching.
- 3.5 The HHS roadmap described in Recommendation 4 should include plans within future ePA processes to enable patients to have the ability (but not be required) to submit to a payer a request for a prior authorization, participate in the prior authorization process, make a request, and obtain the cost of the medical care based on their health plan coverage, provider network and desired place of care.

(ID: EPARFI-TF-2022_Recommendation 03 – Patient-Centered Inclusion in ePA)

Rationale and Additional Considerations

Healthcare Consumerism

The Task Force discussed current barriers to and benefits of patient transparency and engagement in the prior authorization process. The Task Force identified a high priority need to increase focus on the consumer prior authorization experience and noted that healthcare consumers can be positively impacted by more rapid treatment approval; increased understanding of their healthcare options; ability to participate in their care decisions; increased patient satisfaction with their healthcare experience; and care delivered sooner to avoid unnecessary complications.

⁵ Specific functionality for consideration is found in the Attachment B Section Two - Impact to Patient, Recommendation.



ePA Patient-Specific Benefits

Prior authorization requests and responses must be for a patient-specific coverage benefit based on their plan coverage. Patient-specific coverage information through a standardized, end-to-end electronic prior authorization process widely implemented by physicians and health plans that provides patient-specific prior authorization requirements would have the clear benefit of preventing care delays.

“Exposing” patient-specific prior authorization requirements at the point of care in EHRs could support informed conversations between physicians and patients regarding treatment decisions and ensure that prior authorization is initiated when care is scheduled. Likewise, clear identification of the required documentation and automated exchange of information for a specific patient between providers and payers will speed time to care. Improving the prior authorization process can also prevent patients from abandoning treatment related to prior authorization-related slowdowns and discouragement.

Additionally, patients will be more likely to follow-up on diagnosis and treatment if prior authorization is approved (and visit scheduled) prior to leaving the practice, supporting patient goals to:

- Minimize delays in treatment due to prior authorization requirements.
- Avoid additional visits where additional tests or information gathering is required to support payment, which can be organized and captured as part of the initial visit rather than potentially requiring follow-up visits to satisfy prior authorization requirements; and
- Understand if something is covered and authorized, allowing the provider and patient to select services that are both appropriate and minimize the cost to the patient.

Ideally, prior authorization data sent to payers would be codified to minimize the need for human review and further reduce care delays. Treatment abandonment and care delays can have a negative impact on patient clinical outcomes, as shown by a recent AMA physician survey.⁶

Patient Price and Prior Authorization Transparency

ePA processes should include alignment to patient electronic cost estimates (e.g., Advanced Explanation of Benefits) for a successful ePA process. Price transparency of a procedure, service or item has the potential to drive patient engagement in their care. Physicians or their designees send a prior authorization to a payer when required by a patient’s health plan to obtain approval to perform a procedure or service, which typically does not include obtaining a price from the health plan for the services potentially to be performed.

Patients should not be *required* to participate in the prior authorization process; this could increase chances of prior authorization denials if patients are not able to comply with documentation requirements. The potential for conflicting data submissions from physicians/patients should also be considered, as it could impact the timeliness of the prior authorization process and decision outcomes. However, patients should be able to opt in to receiving updates on the status of in-process prior authorization requests.

⁶ See <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>



It is important to note that the ePA process needs to allow patients to direct their status updates to the application of their choice. A standard representation of prior authorization will enable patients to have better access to information and status of in-process and approved services that require prior authorization.

Testing and Vetting of Health IT

The Task Force considered and discussed extensively the patient's need for transparency and engagement including the following additional considerations related to patient-centered innovation. Because prior authorization is perhaps the only revenue cycle transaction that directly impacts patient care, it is crucial that any technologies considered for adoption under the Certification Program be adequately tested and vetted. Adoption of immature technology could exacerbate existing prior authorization-related care delays and patient harms through errors and lost transactions. With care quality and responsiveness at stake, we must be sure that standards have proven viability in real-world settings.

Benefits of Payer Metrics and Exposing Prior Authorization Requirements at Point of Care

“Exposing” health plan prior authorization requirements at the point of care supports informed conversations between physicians and patients during treatment selection and prevents care abandonment associated with patients being lost to follow up when care is delayed due to unknown/unmet PA requirements. Improving the transparency of prior authorization requirements and documentation needs in the scheduling and clinical documentation workflows will enable awareness of all the necessary data not yet available to be collected during the patient visit or stay, preventing additional appointments to obtain prior authorization-related data.

The Task Force anticipates that the guides/standards being proposed will reduce time to care, treatment abandonment, and PA denials. Patient-focused metrics should be included in any piloting/testing to ensure that we are achieving these important goals.

Recommendation 4: Prior Authorization Roadmap to FHIR

HHS should create and update a “Health IT ePA Roadmap” for health IT systems supporting providers, payers, and consumers that lays out an iterative path forward to move stakeholders to an integrated, automated prior authorization workflow.⁷

The roadmap should describe:

- 4.1 How capabilities and specifications should be mapped to the Da Vinci IGs.
- 4.2 A timeline that aligns the maturity of the capabilities within the Da Vinci IGs and the speed of the industry's ability to comply. The timeline should be informed by an environmental scan that assesses the readiness of the IGs and identifies the functionality that provides value to patients, providers, and payers.
- 4.3 A path for information exchange (i.e., C-CDA to FHIR) to lead stakeholders to move from a document-driven approach to an event-based and data-driven approach.

⁷ See Attachment B: ePA Functional Criteria RFI Spreadsheet.



- 4.4 A strategy for certification criteria to be adopted in a tiered and staged approach, providing baseline functionality as well as a roadmap for cutting-edge organizations.
- 4.5 A certification strategy only based on FHIR-to-FHIR endpoint transactions.

(ID: EPARFI-TF-2022_Recommendation 04 – Prior Authorization Roadmap to FHIR)

Rationale and Additional Considerations

The aim of the roadmap should be to encourage standardization but also to encourage innovation. The certification process should be a user-friendly and simple mechanism to allow alternative solutions by cutting edge organizations. Criteria should be conveyed in a tiered and staged approach, providing baseline functionality that also supports innovation. This should be driven by continued testing in real settings to validate and improve the standards and the use of human-centered design to ensure patients would benefit from these advancements.

Recommendation 5: Adoption at Scale

HHS should develop an informed and vetted iterative roll-out plan for certification and adoption in collaboration with CMS, ONC, SDOs, and other healthcare stakeholders. The plan should allow for adoption and maturity at scale of a fully functional prior authorization workflow by setting/service, with no requirements rolled out until standards have been tested in that practice setting and for that type of service (e.g., imaging).

- 5.1 Initially roll out ePA for procedures that are most commonly subject to prior authorization and are being pilot tested through Da Vinci. Over time, additional procedures can be added that may take longer for less mature health IT systems to adopt.
- 5.2 Recommend that any provider requirements imposed by CMS or other payers to enforce use of ePA be put in place after standard(s) have been tested and adopted in that practice setting (e.g., ambulatory practices), and for that type of service (e.g., imaging).
- 5.3 Roll out individual components as they are ready and fully tested leading to implementation of the CRD, PAS, DTR and related IGs.
- 5.4 ONC should focus certification initially on the source of the information (e.g., payers for coverage determination and documentation requirements, and providers for access to supporting information).

(ID: EPARFI-TF-2022_Recommendation 05 – Adoption at Scale)



Recommendation 6: Regulatory Coordination

Given the emergence of new standards to support ePA, HHS should ensure that regulations allow multiple standards to at least temporarily co-exist as they are tested and used by stakeholders to meet specific business needs, while preserving widely used existing standards and addressing gaps.

- 6.1 The Certification Program should address the complete prior authorization workflow across one or more payer, provider or third-party HIT system(s). However, the individual components can be certified, implemented incrementally, and structured to allow both ONC and HIPAA regulations to update/change independently but remain harmonized with strong consideration of the status of the other regulations.
- 6.2 Certification requirements that allow a FHIR-enabled process for prior authorization transactions should not require the use of translation to X12.
- 6.3 An amendment should be made to the HIPAA exception approval process for testing emerging standards to be less burdensome for beta testers and more proactively supportive of innovation.
- 6.4 CMS should ensure compatibility with HIPAA transaction and code set regulations.
- 6.5 ONC should collaborate with CAQH CORE to add response times as contained in its Prior Authorization Operating Rule⁸ for the critical interactions that the ePA implementation guides are introducing.

(ID: EPARFI-TF-2022_Recommendation 06 – Regulatory Coordination)

Rationale and Additional Considerations

The Task Force agreed that certification requirements that allow a FHIR-enabled process should not require the use of translation to X12. For those stakeholders that do not have FHIR enabled, an intermediary acting on behalf of the stakeholder can expose FHIR endpoints to perform the X12 translations and interact directly with the stakeholders using either FHIR or X12. FHIR to X12 translation should not be required for compliance and/or HIPAA exceptions should be supported. The Da Vinci IGs support the exchange of attachments as FHIR-based RESTful transactions or using X12 275.

The translation between FHIR and X12 is an artifact of the previous standards and new standards colliding due to regulatory requirements. The Task Force encouraged consideration of an approach in which stakeholders do not have to translate between new and old standards to increase efficiency. Eliminating the X12 submission requirement for prior authorization would spur the use of FHIR as payers update their prior authorization processes.

Recommendation 7: Attachments

In considering standards for attachments, the Task Force emphasized the need to move the healthcare industry from a document-driven to data-driven information exchange.

- 7.1 ONC should prioritize criteria based on the PAS IG that allows data, C-CDA or FHIR documents be provided in a FHIR construct that is:

⁸ See <https://www.caqh.org/core/prior-authorization-referrals-operating-rules>.



- a. certifiable and testable as a unique process regardless of what larger workflow it is supporting.
 - b. developed based on movement of all stakeholders toward FHIR-based interactions that can include the variety of supporting information necessary to support an authorization request in the short term and aim for a more automated approach based on FHIR-based APIs to gather all relevant data.
- 7.2 Both the CDA Attachments IG and/or FHIR documents require further maturation and sufficient testing to be considered as an ePA minimum standard for adoption at scale before mandates should be established.
- 7.3 ONC should consider a “soft” timeline, e.g., when a specific quantitative testing threshold is reached, a specified timeline for adoption could kick in if there is still a need for document-based submission of attachment data.
- 7.4 Providers should have the option to either compile an attachment document that includes all supporting data or exchange the requested data gathered individually.
- 7.5 Any certification criterion addressing a CDA attachment functional requirement certification criterion should remain optional; innovators should not be locked down to the payload using a CDA Attachment IG approach only.

(ID: EPARFI-TF-2022_Recommendation 07 – Attachments)

Rationale and Additional Considerations

Stakeholders continue to need an attachment process which supports all the necessary business cases including prior authorization and claims. Attachments (and acknowledgements) are a complex issue that need to be addressed seamlessly across ONC certification and HIPAA regulations. Accordingly, the HITAC’s recommendations in this area are directed to both the HITAC and NCVHS.

NCVHS has submitted letters to HHS requesting the adoption of an attachment standard to support claims and prior authorizations based on the urgent request through healthcare industry testimonies. These testimonies have highlighted the efforts of healthcare stakeholders in implementing attachments for claims that require additional information (X12 277 RFAI, X12 275, CDA carrying the clinical information and X12 999 acknowledgment).

Moving From Document-Driven to Data-Driven Information Exchange

As HHS develops an iterative ePA roadmap, the department should identify where attachments are used that could be improved with discrete information and pursue efforts to move away from attachments or documents. The HITAC recommends that providers should have the option to either compile an attachment document that includes all supporting data or exchange the requested data gathered individually as collected to avoid transformations, which still could include original source documents. Providing health IT criteria that are initially flexible and focus on the transition to the collection/pull of data rather than requiring only placement of gathered data in a document exchange format provides further flexibility for use of data in future exchanges.

The Task Force discussed the need for flexibility at the same time as establishing common basic standards. While certain attributes may be identified as optional to avoid data collection where data may be irrelevant,



interactions should have a base standard (typically an IG in HL7 context) that defines what all parties must do at a minimum. In discussion of C-CDA or FHIR, within supporting information (i.e., attachments), there should be flexibility that crosses standards (e.g., HL7 C-CDA vs. HL7 FHIR).

The HITAC recommends adopting the PAS IG which supports the FHIR questionnaireResponse and individual resources used to populate the questionnaireResponse. While the PAS IG can accommodate FHIR, CCDAs, and image documents via the FHIR documentReference, structured data is the preferred documentation approach. The healthcare industry needs to be forward-thinking and aim to avoid promulgating approaches that are dated. Health IT will not necessarily change based upon market demands for new contemporary interoperability.

C-CDA, FHIR-based, and Other Attachment Readiness

FHIR-based attachments are in development, while C-CDA based attachments may be used but are not widespread. The FHIR attachment process should be certifiable and testable as a unique process regardless of what larger workflow it is supporting. Both the CDA Attachments IG and/or FHIR documents would require further maturation and sufficient testing to be considered as a minimum standard for adoption at scale before mandates could be established. ONC might consider a “soft” timeline such that when some specific quantitative testing threshold is reached, then a specified timeline for adoption could kick in if there is still a need for document-based submission of attachment data. The HITAC suggests the primary focus should be on submitting the relevant data set (i.e., mix of documents, individual data, and unstructured formats).

While the CDex guide could be considered when a payer needs to request additional information from a provider following the submission of the initial PA request, the HITAC supports moving toward PAS IG Version 2 (currently in ballot) that is integrated within the provider and payer workflows that interact with the DTR IG that addresses data collection.

Optional C-CDA Criterion

The Task Force reviewed current regulations and programs that reference C-CDA capabilities⁹ and noted that while the C-CDA standard is a part of the current health IT certification criteria for certain C-CDA document types, the criteria do not address the CDA Attachment Implementation Guide: Exchange of C-CDA Based Documents (CDA Attachment IG).

The HITAC recommends that any CDA Attachment IG criterion remain optional for ePA. If used, there are other guides and standards that would need to be considered, including an X12 envelope (X12 275), and LOINC to request a specific document template and/or source data and X12 999 acknowledgement.

While the Task Force recognizes the interest to leverage current progress and investments made with the C-CDA documents to meet claim attachment and other business needs, we recommend innovators not be locked down to the payload using a CDA Attachment IG approach only. Health IT certification criteria should allow innovators to pilot the functionality within the Da Vinci PAS IG that articulates how to bundle a

⁹ See Attachment C: Additional Resources Reviewed by the Task Force.



collection of data using existing investments and inform future functional requirements as PAS becomes more mature without a need for an exception.

Recommendation 8: Prior Authorization Proving Ground for FHIR

ONC should develop and fund a proving ground to support maturation of IGs supporting ePA. This effort would:

- 8.1 Encourage and monitor the continued testing of these IGs in real-world settings to validate and improve the standards and the use of human-centered design to ensure patients would benefit from these advancements.
- 8.2 Require pilots and early implementers of the Da Vinci IGs to publicly report key metrics. Metrics examples include provider time spent on prior authorization before and after adoption; percentage of prior authorizations that were completed digitally (e.g., automatically); time to care delivery before and after adoption; cost savings; percentage of payer denials and both direct and indirect cost to providers of implementing the Da Vinci IGs. This will provide valuable data to the industry regarding the overall value of investing in this technology.
- 8.3 Require independent review of return on investment (ROI) and analysis to demonstrate improved metrics related to the ePA process.

(ID: EPARFI-TF-2022_Recommendation 08 – Prior Authorization Proving Ground for FHIR)

Recommendation 9: Establishment of an Advisory Process

ONC should work with relevant stakeholders to establish a review and advisory process similar to the Interoperability Standards Advisory (ISA) that advises on the ePA adoption lifecycle. This process should:

- 9.1 Evaluate ePA readiness and the maturity of the ePA implementation guides (CRD, DTR, PAS and others) and make recommendations for certification enhancements to support adoption, standard maturity, scalability from a multi-stakeholder perspective.
- 9.2 Identify gaps in current capabilities and encourage development of additional capabilities, such as patient-centered transparency.
- 9.3 Increase collaboration and extend federal funding to accelerate the movement toward adoption at scale (e.g., FHIR Accelerator).
- 9.4 Ensure standards and criteria are addressed and incorporated into the Interoperability Standards Advisory. Following adoption in the Certification Program, recommend updates to standards be addressed through the Standards Version Advancement Process.
- 9.5 Enable stakeholders to come together and match to the same requirements and ensure API conformity.

(ID: EPARFI-TF-2022_Recommendation 09 – Establishment of an Advisory Process)



Rationale and Additional Considerations

The Task Force believes the complete suite of DaVinci IGs (CRD, DTR, PAS) are not yet ready for implementation at scale. However, it believes that establishing an advisory body that performs the above duties would increase ePA system development, stakeholder engagement and the speed of adoption.

Recommendation 10: Accessibility of Health IT for ePA at Scale

The HITAC recommends HHS explore additional incentives and supports to ensure ePA processes are effectively adopted and implemented across the care continuum.

- 10.1 ONC should partner with other agencies to establish positive incentives for stakeholder groups (providers, payers, other health care stakeholders) to reach adoption at scale and enable stakeholders to choose preferred system/systems, internal/external app, or other solutions to manage or initiate an ePA.
- 10.2 To ensure the widest beneficial impact of ePA technology and protect against further exacerbation of current health disparities, HHS should explore incentives to support smaller, under-resourced providers in adopting and implementing standard ePA technology.
- 10.3 The Certification Program, specifically ONC's Certified Health IT Product List (CHPL) should inform and support providers' ability to mix and match components they use in their practice setting. Many providers will be unaware of which health IT products are necessary to fully support ePA. The CHPL should clearly identify and group together complementary health IT products into suites of modules that support ePA.
- 10.4 Supporting overall reduction in the volume of prior authorization requirements will also be necessary for widespread ePA implementation. Exploring policies such as a trust and verify framework for prior authorizations that are routinely approved (e.g., gold carding), can help to reduce overall burden and ensure uptake of ePA for high priority procedures, services, and items.

(ID: EPARFI-TF-2022_Recommendation 10 – Accessibility of Health IT for ePA at Scale)

Rationale and Additional Considerations

We cannot leave patients in underserved communities behind in the ePA process; it would exacerbate the health care disparities that already exist in our country. We should hold all stakeholders accountable for the functional criteria needed for each successful ePA and apply levers for adoption. Success will be realized only if all stakeholders have the functional criteria and access to technical capabilities to share accurate and complete information required to complete a PA.

The Task Force discussed the value in adding performance measures to the Promoting Interoperability program and MIPS. Providers who choose to opt in can earn points towards meeting the programs' objectives, while payers set up standards-based APIs that conform to the Da Vinci implementation guides. Providers who have an opportunity to use ePA-enabled health IT systems can begin to interact with these payer APIs through optional program requirements as the interactions across various health IT configurations is further developed and matured, culminating in a set of clearly defined interaction sets or



building blocks within each of the Da Vinci implementation guides. Over time the functional criteria and APIs can be certified to by all payer and provider health IT systems interacting with the prior authorization workflow.

Payers should support prior authorization while processes are put in place to implement a trust and verify framework (i.e., gold carding), or other authorization approaches at a more general, (chronic) condition level and review prior authorization lists to remove requirements and/or rules that are approved a significant percentage of the time to reduce prior authorization burden. This will enable payers to realize efficiencies and effectively implement ePA for the remaining procedures and services requiring prior authorizations.

Recommendation 11: Innovation around ePA Integration

ONC should require health IT systems to provide inter-provider communication and workflows associated with the ePA certified processes with the goal to allow “pass-offs” between physicians and other practice staff and ability for physicians to save an initiated PA to complete later and/or delegate to staff.

- 11.1 Tools should be made available to trigger a new/renewal PA that may be submitted by an expanded group of stakeholders to enable ePA processes based on best practices (e.g., patients, DME providers, etc.).

(ID: EPARFI-TF-2022_Recommendation 11 – Innovation around ePA Integration)

Rationale and Additional Considerations

The Task Force discussed that physicians do not typically perform a complete prior authorization, but delegate to their designee to handle the supplemental information request and other follow-up required. Therefore, the prior authorization process must be incorporated within the existing workflow and allow role-based delegation to the back-of-the-office staff and/or patient to complete prior authorization request and/or respond to payer supplemental information requests.

The Task Force recognized that prior authorizations may be submitted by an expanded group of stakeholders and tools will need to be developed to enable ePA processes based on best practices. For example, systems or patients may begin to trigger the prior authorization in certain instances. Initial DME ePA requests are currently ordered by a system, however, we envision a third-party intermediary should be able to trigger a DME request in the future.

Recommendation 12: Innovation around ePA Bundles

HHS should encourage expansion of authorizations from a single procedure or service within a “single medical episode” to one where authorizations cover services performed concurrently that may be bundled into an established protocol or complex treatment plan to improve transparency, reduce complexity/administrative burden, and improve coordination of care.

- 12.1 Encourage further study of the required capabilities/additional code options for concurrent care authorizations that need to be included in the future Da Vinci CRD IG to meet the business need.



- 12.2 Encourage payers through various levers to continue to move toward episode of care, complete treatment plan or bundled services including ancillary services required to complete the service for prior authorizations review and decision.

(ID: EPARFI-TF-2022_Recommendation 12 – Innovation around ePA Bundles)

Rationale and Additional Considerations

Coordination of care for a patient may consist of multiple complex medical procedures and services, DME and other services provided by multiple care providers which should not require additional approvals if the bundled protocol is approved. Similar to dental treatment plans, knowing the costs and expected medical care for the complete treatment plan allows patients to engage in determining their finalized treatment plan that makes the most sense for their situation and their desired place of care.

The Da Vinci CRD guide potentially would need to add an option to flag the need for concurrent authorization. This would alert the clinician that he/she could proceed with ordering the service/treatment, but that additional documentation would need to be submitted for the claim to be paid.

Recommendation 13: Multi-Stakeholder Engagement

ONC should solicit multi-stakeholder feedback, including feedback from other departments, agencies, programs across HHS (i.e., CMS), and key stakeholders, throughout the development of the health IT certification criteria and roadmap for the acceleration and adoption of the ePA process.

(ID: EPARFI-TF-2022_Recommendation 13 – Multi-Stakeholder Engagement)

Rationale and Additional Considerations

Additional input from provider organizations leading or engaged in this effort will provide valuable feedback to determine the timing and scope of health IT certification criteria and roadmap. Putting a stake in the ground will lead all stakeholders (payer, provider, system(s), etc.) toward adoption at scale. ONC should partner with CMS for the acceleration and adoption of the ePA process to leverage the learnings of CMS recent pilot activities. The Da Vinci IGs were named in the 2020 CMS and ONC proposed rules and are supported by CMS and ONC. CMS has engaged in pilot testing of the ePA process and can provide valuable input and insight on real-world use and related issues, with particular focus on ePA implementation and use in under-resourced facilities such as small, solo, and rural medical clinics.



Attachments

Attachment A – Electronic Prior Authorization RFI Task Force Roster

Attachment B – Health IT ePA Functional Criteria Spreadsheet -
<https://docs.google.com/spreadsheets/d/12mEQISaGivkDo5aOBK4unqabq97iTnH3/edit#gid=1761603277>

Attachment C – Additional Resources Reviewed by the Task Force

**ATTACHMENT A: ELECTRONIC PRIOR AUTHORIZATION RFI
TASK FORCE ROSTER**

Name	Organization
Sheryl Turney (Co-Chair)	Anthem, Inc.
Tammy Banks (Co-Chair)	Individual
Hans Buitendijk	Cerner
Dave DeGandi	Cambia Health Solutions
Rajesh Godavarthi	MCG Health
Jim Jirjis	HCA
Rich Landen	NCVHS
Heather McComas	AMA
Patrick Murta	Humana
Eliel Oliveira	Dell Medical School, University of Texas at Austin
Debra Strickland	NCVHS



ATTACHMENT B: HEALTH IT EPA FUNCTIONAL CRITERIA SPREADSHEET

This spreadsheet provides a visual tool that maps the implementation guides to events in the ePA workflow process. It includes the TF input on the maturity and readiness for adoption of the Implementation Guides for CRD, DTR and PAS. This document is for example only.

ONC RFI	TASK FORCE Functional Capabilities Suggestions (From Compiled Comments)	Ready for Certification Focus	Criteria Perspective	HITAC Recommendations to ONC to investigate the feasibility of including the following specific standards or functionality specifications to meet identified functional criteria.
Ensure Correct Patient Information & Eligibility for Benefits				
	Digital ID cards be considered to increase successful ability to match patient identity. [Included in ICAD recommendation]	Mention in report		
	Electronically support patient requests for Advanced EOB to provide estimated cost for approved Prior Authorizations and if prior authorization is required.	Future (is a need whether ePA is in play or not)		
Identify if Prior Authorization Needed				
Identify when prior authorization is applicable for an item or service, using clinical decision support and/or user input, and for receiving notifications of changes in such applicability;			Criterion A: Initiate authorization necessity process	CDS Hooks within CRD to initiate AND/OR SMART App plus FHIR US Core + Coverage
	Identify when prior authorization is necessary for an item or service being requested or to be performed for a specific patient and based on necessary data to determine whether a PA is needed (data may include procedure modifiers, patient, provider, patient coverage). This may be performed by using clinical decision support, user input or payer API. <i>Note: Certified technology should ensure that APIs are only able to send data to payers needed for particular PA request (vs. expose entire patient record) and allow</i>	Minimum	Criterion B: Request authorization necessity from payer	CRD



	<i>clinician to "shut off" system if insured patient wishes to self-pay for a particular service.</i>			
	Automatic trigger of CRD to determine if a PA is needed and if there are any documentation rules	Minimum		
			Criterion A: Notification to initiating system	CDS Hooks within CRD to receive update AND/OR new notification method to be defined not dependent on CDS Hooks
Request supporting documentation requirements				
Query a payer API for prior authorization requirements for each item and service and identify in real time documentation requirements;	Recommend adding specific rules to ONC definition. "Query a payer API for prior authorization requirements for each item and service and identify in real time specific rules and documentation requirements"		Criterion C: Request documentation requirements	DTR (Query for documentation requirements interactions)
Capture/Submit Supplemental Documentation – workflow varies depending on when payer information/document requirements are captured (X12 278 response, payer portal, FHIR enabled API or prior experience.				
Collect clinical and administrative documentation needed to complete prior authorization documentation (electronic forms or templates) from a health IT system;	Reduce denials and human burden by automatically populating a payer's authorization request criteria for a specific patient and provider with the requisite clinical and administrative data captured by the patient's care team as it becomes available.	Minimum	Criterion D: Electronically gather source data	Requester: DTR (Translate CQL and Questionnaire into data queries, at least FHIR US Core, but may be proprietary, and accommodate manual collection for that that cannot be automatically collected)
	Allow healthcare stakeholders to capture required information for and submit a query to a payer's system for updates on a pending prior authorization request for a patient and have a specific reason returned as to why a request is still pending.	Minimum ((suggest that the request for why a request is pending be included in B23)	Criterion E: Accessible to data requests	Source: FHIR US Core



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.	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 transaction. <i>(From a technology perspective the digital signature step adds a barrier to automation. Recommend further ONC's investigation into when a signature or other method to determine accountability for accuracy of DME, medical procedure/service request and documentation is required. When move toward automated collection and exchange of requested data to support payer ask, will digital signature of the requested data pulled from the data repository need to be approved?)</i>	Requiring further study.	Review & Sign supporting data (if truly needed)	Not available yet.
Electronically submit completed documentation for prior authorization to a payer's API, along with supporting information;	Capture payers required documentation criteria using technology, such as FHIR, CQL, X12 278 and manual document selection by clinical staff for each item and service and identify in real time specific rules and documentation requirements for the coverage determination for the specific patient. Include detailed description of the predefined rules that must be satisfied for a particular PA Request to be approved, including the data the payer requires for approval to be granted. <i>Note: To minimize patient care delays and provider burdens, the payer functional capabilities should be sufficiently robust to convey comprehensive documentation requirements upfront; subsequent requests for additional information should be the exception instead of the rule.</i>	Minimum	Criterion F: Submit authorization request	PAS (Submission interactions)
	Automatically retrieve/pull clinical information attachments and electronically export (i.e., electronic claim/PA attachments) in response to external request. Include data elements and documentation	Minimum		Current DTR functionality



	(internal and external systems where applicable) to payer that enables payers to run predefined rules for determination.			
	Receive and record an acknowledgement of receipt from a payer.	Minimum		Supported in CRD & PAS
	Ability to access authorization status using a patient level indicator/flag. Includes information related to the status of the PA Request for a specific patient and, ultimately, the PA Determination. The intent is to enable providers, care team members, and patients to understand the status of a PA Request; obtain detailed information about the medication, treatment, procedure, service, or product approved; and reduce the number of duplicate PA Requests in process. This includes ability to identify if a plan's PA requirement for a particular patient's service is waived due to the ordering physician being gold carded.	Minimum		Supported in PAS
Receive Final PA Determination				
Receive a response from a payer regarding approval, denial (including a reason for denial), or need for additional information;	Receive and record response from a payer regarding approval, denial (including specific reason(s) for denial and any required action) or need for supplemental information (including detailed description of the documentation or required action).	Minimum	Criterion G: Monitor request status	PAS (Status lookup)
			Criterion C: Request additional supporting information	PAS/DTR (Guidance is being balloted)
			Criterion D: Electronically gather source data	DTR (Translate CQL and Questionnaire into data queries, at least FHIR US Core, but may be proprietary, and accommodate manual collection for that that cannot be automatically collected)
			Criterion E: Accessible to data requests	FHIR US Core



			Criterion H: Communicate authorization request response	
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	Role-based workflows that support non-provider / back-office staff to complete PA and/or respond to payer requests to finalize PA.	Minimum	Criterion G: Monitor request status	PAS (Status lookup)
	Allow patients to capture required information for and submit a query to a payer's system for updates on a pending prior authorization request for a patient and have a specific reason returned as to why a request is still pending.	Next phase		Da Vinci Payer Data Exchange (currently in ballot)
Post Final PA Determination				
	Triggers (alert) for expiring PA to prompt renewal activities	Minimum		
	Automatically forward copies of all submissions and responses (in plain English or designated language) to those patients who have affirmatively opted in to receive such messaging.	Next phase		
	All health IT systems, including business associate shall implement procedures and utilize mechanisms to ensure the confidentiality of medical information submitted on electronic claims for payment of medical services, subject to the federal Health Insurance Portability and Accountability Act	Minimum (unclear what is unique to ePA as this seems already covered through existing HIPAA constructs - covered entity, business associate)		



ATTACHMENT C: ADDITIONAL RESOURCES REVIEWED BY THE TASK FORCE

The Task Force reviewed several resources and regulatory citations to augment the discussions and assist in its review and compilation of recommendations, including several for attachments that reference C-CDA

- Final Report of the Health Information Technology Advisory Committee’s Intersection of Clinical and Administrative Data Task Force to the National Coordinator for Health Information Technology
 - https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf
- ONC Health IT Certification Program Guidance and Regulations
 - <https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method>
- CMS Promoting Interoperability Regulations
 - <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms>
 - <https://qpp.cms.gov/>
- 21st Century Cures Act
 - <https://www.congress.gov/bill/114th-congress/house-bill/34/text>
- Trusted Exchange Framework and Common Agreement
 - <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement-tefca>