

March 23, 2022

Micky Tripathi
National Coordinator
Office of the National Coordinator for
Health Information Technology
Mary E. Switzer Building
330 C. Street, SW, 7th Floor
Washington, DC 20024

Re: Request for Information (RFI): Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria

Dear National Coordinator Tripathi:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Office of the National Coordinator for Health Information Technology's (ONC) *Request for Information (RFI): Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria*.

The AMA agrees with ONC that diverse payer policies, provider workflow challenges, and technical barriers create an environment in which the prior authorization (PA) process is a source of burden for patients, providers, and payers; a cause of burnout for providers; and a health risk for patients when it delays their care. The AMA appreciates ONC's Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs¹ (Strategy) to address these issues. The Strategy includes several recommendations to strengthen electronic prior authorization (ePA) processes such as leveraging health information technology (health IT) to standardize data and processes around ordering services or equipment; coordinating efforts to advance new standards approaches; and incentivizing adoption and/or use of technology that can generate and exchange standardized data to support documentation needs.

The AMA conducts annual physician surveys to evaluate PA's impact on patients and the health care system. Survey results have been cited in multiple public forums and in Health Information Technology Advisory Committee (HITAC) reports to ONC.² In 2022, the AMA released updated survey findings.³ With 93 percent of physicians reporting that the PA process delays access to necessary patient care, the AMA recognizes the importance of ePA to reduce delays. Yet, 82 percent of physicians report that patients have abandoned treatment due to the PA process itself. There are also serious questions about the validity of PA and impact on clinical outcomes. Nearly a third of physicians report health plans rarely or

¹ https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf

² https://www.healthit.gov/sites/default/files/page/2021-02/2020-11-17_ICAD_TF_FINAL_Report_HITAC_508_0.pdf

³ <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

never use evidence-based criteria in PA, and 91 percent of physicians report a negative impact on clinical outcomes due to the PA process. Most shockingly, **34 percent of physicians report PA has led to a serious adverse event for a patient in their care—with nearly one in 10 physicians reporting PA has led to patient disability/permanent bodily damage, congenital anomaly/birth defect or death.** Clearly, the PA *process itself* needs an overhaul.

The evidence is clear. More must be done to address the considerable burden and patient harm associated with the PA process. **As an overarching goal, the AMA urges ONC to think broadly and consider actions that promote PA reform.** While ONC may consider its role simply as a health IT certification body, its designated role as a National Coordinator for Health IT necessitates a holistic view of health IT's role—negative or positive—in the PA process. Health IT is integral in all aspects of health care delivery. Therefore, before new standards or guides are included within ONC's Health IT Certification Program (Certification Program), ONC should contemplate how those standards or guides will improve the PA process. **ONC should consider how standards and guides will reduce PA volume, denials, and delays; support the targeted application of PA; improve PA transparency; protect continuity of patient care; and eliminate PA-related patient harm or death—automation of PA processes and ePA alone will not accomplish these goals.** Moreover, the AMA agrees with the HITAC Intersection of Clinical and Administrative Data (ICAD) Task Force's 2020 recommendation that

[t]he process of reforming and improving prior authorization should be measurable so that progress can be tracked, and it should be meaningful for all stakeholders. Reforms should have a significant impact across the entire process and range of stakeholders, instead of having a marginally incremental impact or a significant impact for just a single stakeholder that leaves others behind or on the sidelines.⁴

PA reform requires an end-to-end evaluation of all proposed improvements to the PA process and a well-orchestrated national approach to implementing those improvements. Therefore, as ONC considers its role in promoting ePA, **the AMA strongly encourages ONC to evaluate new Certification Program criteria through the lens of the following PA reform characteristics:**

- How will the incorporation of new standards or implementation guides (IG) assist in the revision of PA requirements, PA program review, and PA volume reduction?
- How will the incorporation of new standards or IGs support transparency and easy accessibility of PA requirements, criteria, rationale, and program changes for physicians and patients?
- How will the incorporation of new standards or IGs support the evolution of PA criteria based on physician input, particularly those that participate in risk-based payment contracts?
- How will the incorporation of new standards or IGs protect continuity of care during changes in patients' treatment and/or change in health plans; minimize repetitive PA requirements; improve communication between physicians, health plans, and patients to facilitate continuity of care; and ensure patient health and safety?

Notably, the characteristics listed above reflect consensus of the nation's largest organizations representing health care providers (physicians, hospitals, pharmacists, and medical groups) and health plans.⁵ This includes the AMA, American Hospital Association (AHA), American Pharmacists

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

⁵ <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>

Association (APhA), Medical Group Management Association (MGMA), America's Health Insurance Plans (AHIP), and BlueCross BlueShield Association (BCBSA). Rather than evaluating new certification criteria based solely on one characteristic, e.g., PA automation, **ONC must consider how its Certification Program will leverage certified health IT to achieve comprehensive and much-needed PA reform across all of these critical areas.**

Specific considerations for health IT standards and guidelines

As detailed in the attached appendix, we believe ONC should consider two fundamental concepts before ONC's Certification Program can incorporate standards, implementation specifications, and certification criteria to advance ePA successfully.

- ONC should evaluate the “readiness” of all Health Level 7 (HL7) IGs and standards prior to including them in its Certification Program. Readiness means that IGs and standards are tested in real-world environments, i.e., not Connectathons or limited testing environments; across providers of all types, specialties, sizes, and resource levels; and the IGs themselves account for semantic and syntactic interoperability between certified and non-certified health IT products. In instances where IGs and standards are tested at Connectathons, ONC should request and review formalized reports of Connectathon testing, with particular focus on real-world aspects of IG and standards use.
- ONC should ensure that IGs and standards are certifiable and health IT can be tested to a level of conformance that ensures end-to-end interoperability. ONC's Certification Program tests for conformance to Certification Program criteria and federal agency requirements (e.g., the Centers for Medicare & Medicaid Services (CMS) reporting programs). **Testing for typical federal program compliance does not consider the innate complexity and variability in the PA process.** ONC should consider how its Certification Program will translate ePA standards and IG testing in a way that supports end-to-end PA process improvements. For example, successful ePA interoperability will require testing of health IT modules or products used by payers, clearinghouses, or other intermediaries that are not typically required to use certified health IT.

Health IT standards and IG readiness

The AMA believes that ONC and CMS are quickly coordinating an approach to promote the adoption and use of ePA through rulemaking. We believe CMS will likely release a revised PA proposed rule later this year. **The AMA has concerns about CMS proposing to require physicians to utilize ePA in the near term.** In our response to CMS' previously proposed PA rule in 2020 (RIN 0938-AT99), the AMA called on CMS to promote the pilot testing of ePA standards, to review industry-reported findings (including those of small and solo medical practices), and to consider lessons learned and gaps that should be addressed in the ePA standards space prior to codifying ePA standards in regulation.⁶ Our recommendations align and build on ONC's Strategy to:

[w]ork with clinicians, suppliers, payers, and other intermediary entities to support pilots for standardized electronic ordering of services/items. Maturing templates and sets of common clinical data elements for prior authorization and driving wider adoption across clinicians, suppliers,

⁶ <https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-1-4-Letter-to-Verma-re-CMS-NPRM-on-Provider-Burden-and-Prior-Auth-with-Table-of-Proposals.pdf>

health IT developers, the medical product industry, regulatory agencies, and payers will require a robust piloting effort across different stakeholders. HHS should actively engage with efforts to pilot these functionalities with other payers, health IT developers, and third-party exchange organizations to accelerate adoption. For instance, HHS could facilitate participation in pilots by participants in CMS APMs focused on increasing efficiency.⁷

The AMA actively participates in HL7 Da Vinci workgroup meetings and monitors Connectathons where Coverage Requirements Discovery (CRD), Documentation Template and Coverage Rules (DTR), and Prior Authorization Support (PAS) IGs are tested. ONC states in its RFI that it has “identified a number of issues that may be relevant to the use of these IGs in certified health IT,” including “concerns that the IGs lack maturity and have not yet undergone extensive testing in production and rely on other IGs and features in FHIR that are immature.”⁸ Based on the AMA’s experience with clinical and administrative implementation of health IT, our continued evaluation of the industry’s readiness to implement ePA, and our participation in Da Vinci efforts, we agree there are inadequacies and lack of real-world testing of the CRD, DTR and PAS IGs. The AMA supports the goals of reducing burden through the use of ePA and expects Da Vinci IGs to eventually meet those demands. Yet, Connectathon testing, which accounts for the vast majority of Da Vinci IG testing, relies on scripted testing scenarios and predefined input data—referred to as “happy-path” testing. **Happy-path scenarios exclude exception handling and do not test a system’s ability to handle incorrect values and validation errors; Connectathons do not test for or duplicate real-world conditions.**

Additionally, data privacy considerations continue to factor in the development of ePA IGs and standards. At the time of this writing, several Da Vinci workgroups have only recently begun to consider data controls to protect patient data. Da Vinci IGs allow payers to access patient information on a broad scale without exception. For instance, when confronted with concerns about payers having access to data for those patients who are insured but will self-pay (i.e., not use insurance to pay) for certain services and have a right under the Health Insurance Portability and Accountability Act (HIPAA) to have associated data withheld from their insurance plan, workgroup members had not considered the need for IGs to limit automatic disclosure of patient electronic health information (EHI) for particular PA services. Moreover, some HL7 standards necessary to support ePA, e.g., CDS Hooks, have yet to implement controls limiting payer access. There is continued debate on whether to share patient EHI with a payer before a medical service is even ordered. Said another way, HL7 Da Vinci IGs may enable payers to monitor physician workflows and capture patient data prior to a physician even signing off on an order. We have heard the term “payer eavesdropping” being used to describe this act. **Clearly, there are still several data privacy considerations that have yet to be addressed. Physicians and patients should not be forced to choose between automating PA to reduce burden and forfeiting privacy rights and expectations.** Undoubtedly, payer leverage in the development of Da Vinci IGs has played a major role. We believe it is important for ONC to consider the significant deference given to payers as the main contributors to and funders of Da Vinci IG development.

More testing and refinement of ePA standards and IGs is necessary. Yet, the AMA cautions ONC and CMS on requiring the use of ePA to “work out the kinks.” Codifying ePA in regulation, at this time, will direct the industry’s attention to federal program compliance. The AMA is concerned forward momentum in PA process reform will cease. Standards development will inevitably turn to focus on federal requirements. ePA implementation specification and standards may become “locked” resulting in forward and backward compatibility issues. This cycle has occurred in every iteration of legacy health IT

⁷ https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf

⁸ <https://www.govinfo.gov/content/pkg/FR-2022-01-24/pdf/2022-01309.pdf>

programs such as the Meaningful Use Program. **We urge ONC and CMS to consider the unintended consequences of inadvertently focusing industry attention on federal program compliance rather than needed PA reform.**

To help address these concerns, and promote the maturity of ePA standards, the AMA recommends ONC coordinate with CMS in developing and promoting real-world PA testing programs. The AMA believes the following actions should be taken:

- ONC and CMS should identify specific and targeted PA scenarios where ePA would be most beneficial, after first eliminating PA requirements for services/treatments that are routinely approved (i.e., low-value PAs). Scenarios should include:
 - Services with the highest volume of PA requests, as automation will yield the most value across the industry
 - Services that are frequently deemed urgent by the ordering clinician, as ePA will speed time to care
 - Services for which claims are most frequently denied due to unmet PA requirements, as this suggests significant issues with transparency that could be addressed via implementation of the CRD IG
 - Clinical documents (i.e., electronic attachment standards) to reduce administrative burdens associated with PA; and
- ONC and CMS should consider methods to positively incentivize scenario testing across health care provider and health plan trading partners, such as intermediaries, clearinghouses, pharmacy systems, certified health IT, revenue cycle, and practice management system (PMS) vendors. ONC could consider establishing a voluntary ePA testing program similar to its voluntary certification of health IT for pediatric care and practice settings.⁹ This may act as an appropriate balance between the lack of real-world testing and requiring ePA use through rulemaking. CMS could promote physician participation in scenario testing through *positive incentives* such as reporting program (e.g., Promoting Interoperability program) bonus points or optional measures.

Gaps in health IT testing needed to support ePA

The PA process is more than physicians using certified health IT to communicate with payer systems. PA processes occur outside certified electronic health record technology (CEHRT) systems even within a medical practice. For instance, many of our members still utilize separate EHR, revenue cycle, and PMS. While EHRs are certified to federal requirements, stand-alone PMS are typically not. Da Vinci IGs are not sufficiently granular to enable certification criteria where multiple health IT systems on the physician side are involved to manage the workflow. Requiring EHRs to adopt ePA certification criteria only addresses a portion of the PA process within a health care organization.

Moreover, health care organizations interact with several trading partners, like intermediaries and clearinghouses, to exchange PA information with a payer or health plan. While CMS has oversight of health plans that fall under CMS' preview (e.g., Medicare Advantage plans), and can require the use of Da Vinci IGs, CMS does not require Medicare Advantage plans to use health IT systems tested and certified to conform with Da Vinci IG requirements. Sporadic use of Da Vinci IGs across the PA process

⁹ <https://www.healthit.gov/sites/default/files/page/2020-07/NPRMPediatrics.pdf>

could serve to increase PA administrative burden and harm patients. Additionally, intermediaries and clearinghouses are under no obligation to adopt, implement, or use federally-identified Da Vinci IGs. **The lack of PA process-wide adoption, testing, and conformance is a critical gap that should be addressed prior to federally mandating ePA use and participation.**

ONC's Certification Program tests and certifies health IT to program criteria and is a pass/fail paradigm. Da Vinci IGs have been developed to facilitate the *functional* needs of ePA but cannot easily be used to demonstrate conformance to ONC certification criteria or test procedures. ONC's Certification Program includes both pre-certification testing and post-certification reporting requirements. This includes Authorized Certification Bodies (ONC-ACBs) and Testing Labs (ONC-ATLs). It is unclear if ONC-ACBs and ONC-ATLs are capable of testing ePA workflows or support post-certification reporting given the vast array of administrative and clinical information exchange, variability in information, myriad of health IT environments, and uniqueness of health plan requirements used in thousands of PA processes nationally. **Da Vinci IGs are not at a sufficient level to support testing and certification to typical PA processes.**

Prior to including Da Vinci IGs in certified health IT, and prior to CMS requiring that physicians use or participate in an ePA program, ONC and CMS should consider and address the following issues:

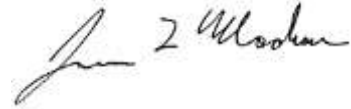
- How will gaps in the use of Da Vinci IGs be addressed between certified health IT and non-certified health IT like PMS?
- How will gaps in Da Vinci IG adoption and conformance be monitored and addressed across payers and health plans?
- How will FHIR-based application program interface (API) uniformity be assured across all payers and all payer PA programs?
- What role can federal regulators play in encouraging or requiring that all health plan trading partners (e.g., intermediaries and clearinghouses) use Da Vinci IGs in a consistent and conformant way? If federal regulations are insufficient, what federal legislation would be necessary to require intermediaries and clearinghouses to adopt and use certified health IT for ePA?
- What process is underway to translate HL7 Da Vinci IGs into ONC pre-certification testing and post-certification reporting requirements? How will HL7 workgroup analysis, Connectathon testing reports, individual health IT vendor experiences, independent ONC-ACB and ONC-ATL evaluation, and real-world pilot testing inform that translation?
- How will the Da Vinci IGs address payer goldcarding programs to ensure that any PA waivers/exemptions are clearly communicated to the clinician at the point of ordering?

The AMA reiterates its support of ONC and CMS' efforts to reduce the burden associated with PA. **ePA can function to address some of these burdens, but ePA is not a substitute for PA process reform.** ONC and CMS have important roles to play in PA reform—including identifying and prioritizing targeted uses of ePA and pilot testing. Requiring ePA participation too soon will make the PA process worse, increase burden, and ultimately lead to more patient harm when insufficiently tested standards lead to processing errors, lost requests, and care delays. ePA IGs and standards must be consistently utilized across all stakeholders, not just those that use certified health IT or are subject to CMS oversight. Testing must also validate strict conformance with IG use. The AMA has outlined several steps ONC and CMS should take prior to requiring physician use of ePA.

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In closing, thank you for this opportunity to share the views of the AMA regarding the proposals, issues, and questions that ONC has raised in its RFI. Additional comments are found in Appendix 1. If you have any questions, please contact Matt Reid, Senior Health IT Consultant, Federal Affairs, at matt.reid@ama-assn.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim L Madara". The signature is written in a cursive style with a large initial "J" and "M".

James L. Madara, MD

cc: Administrator Chiquita Brooks-LaSure , Centers for Medicare & Medicaid Services

Attachment

Office of the National Coordinator for Health IT

Request for Information Public Comment Template

Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria

Preface

This public comment template supports a specific request for information regarding Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria. The template is not intended to substitute for review of the Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria request for information: published in the Federal Register at 87 FR 3475. A PDF copy of the official version of the rule is available from the FederalRegister.gov website at <https://www.govinfo.gov/content/pkg/FR-2022-01-24/pdf/2022-01309.pdf>.

This template is intended to provide a simple way to organize and present comments on the specific questions posed in the request for information. While use of this document is entirely voluntary, commenters may find it helpful to use the document in lieu of unstructured comments, or to use it as an addendum to narrative cover pages.

The following tables are organized according to the order of the requests for comment and questions in the request for information. All tables include the Federal Register page(s) of the request for information where the request for comment or question can be found. Each table provides a field for submitting comments on the request for comment or question. This field can be expanded as necessary for commenting.

To be considered, all comments (including comments organized using this document) must be submitted according to the instructions in the proposed rule. Electronic submissions are strongly encouraged and can be easily completed through the regulations.gov website (The request for information's docket is at https://www.regulations.gov/document/HHS_FRDOC_0001-0849). Look for the "Comment" button on the left.

Appendix 1

Functional Capabilities for Electronic Prior Authorization in Certified Health IT

We are seeking comment on functional capabilities for electronic prior authorization that should be considered for inclusion in certified health IT. Specifically we are seeking comment on a core set of capabilities that would enable a certified Health IT Module or Modules to:

- 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;
- Query a payer API for prior authorization requirements for each item and service and identify in real time specific rules and documentation requirements;
- Collect clinical and administrative documentation needed to complete prior authorization documentation (electronic forms or templates) from a health IT system;
- Electronically submit completed documentation for prior authorization to a payer's API, along with supporting information;
- Receive a response from a payer regarding approval, denial (including a reason for denial), or need for additional information;
- 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; and
- 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.

We invite further comment on whether these are the appropriate minimum capabilities needed for certified health IT systems to successfully interact with payer systems to complete key electronic prior authorization activities.

Preamble FR Citation: 87 FR 3477

Specific questions in preamble? *No*

Public Comment Field:

The AMA appreciates ONC's interest in considering necessary ePA functional capabilities in its Certification Program. As the AMA has discussed in the attached letter, ONC should consider ePA criteria that will improve the overall PA process beyond simply automating PA. In addition to the capabilities listed above, the AMA suggests health IT certification criteria promote the following capabilities:

- Payer functional capabilities should be sufficiently robust to convey comprehensive documentation requirements upfront. Any subsequent requests for additional information should be the exception instead of the rule.
- All medical/prescription PA requests should be triggered at the physician or designated health care staff discretion.
- Enable the care provider to choose preferred ePA system(s), internal/external app(s), or other solution based on preferred workflow.
- Enable the review of routine PA submissions and/or rules that are typically approved and support a trust and verify framework, i.e., gold carding.

- IGs should support PA renewal and appeal processes, in addition to initial PAs.
- IGs should support the capture of payer data and public reporting metrics, such as percentage of denials.
- At the time of ordering, physicians should have the 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.
- In addition to upholding general minimum necessary principles, EHR development must consider data privacy and security protections concurrently with functional capabilities.
- Certified health IT systems should ensure that APIs only be able to send data to payers needed for a particular PA request (vs. exposing the entire patient record) and allow clinicians to "shut off" the system if an insured patient wishes to self-pay for a particular service.
- Payers requesting supplemental information must identify the intended use of such information and communicate the desired goal of the particular PA.
- IGs should support detailed descriptions of payer 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.
- IGs should support provision of granular and actionable information regarding reasons for PA denials, any details about additional data needed to support/approve a PA request, and instructions for how to appeal a denial.
- IGs should enable the collection of clinical and administrative documentation needed to complete PA documentation (i.e., electronic forms or templates) from the appropriate source health IT system(s) to minimize the need for manual entry/re-entry of PA supportive data by clinicians and practice staff.

We are seeking comment on the appropriateness of the three Implementation Guides (IGs) listed below to support electronic prior authorization functionality within certified health IT systems used by healthcare providers and other stakeholders.

- HL7® FHIR® Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide.
- HL7® FHIR® Da Vinci Documentation Templates and Coverage Rules (DTR) Implementation Guide.
- HL7® FHIR® Da Vinci Prior Authorization Support (PAS) Implementation Guide.

Preamble FR Citation: 87 FR 3478

Specific questions in preamble? *No*

Public Comment Field:

The AMA actively participates in HL7 Da Vinci workgroup meetings and monitors Connectathons where Coverage Requirements Discovery (CRD), Documentation Template and Coverage Rules (DTR), and Prior Authorization Support (PAS) IGs are tested. ONC states in its RFI that it has “identified a number of issues that may be relevant to the use of these IGs in certified health IT,” including “concerns that the IGs lack maturity and have not yet undergone extensive testing in production and rely on other IGs and features in FHIR that are immature.”¹⁰ Based on the AMA’s experience with clinical and administrative implementation of health IT, our continued evaluation of the industry’s readiness to implement ePA, and our participation in Da Vinci efforts, we agree there are inadequacies and lack of real-world testing of the CRD, DTR and PAS IGs. The AMA supports the goals of reducing burden through the use of ePA and expects Da Vinci IGs to eventually meet those demands. Yet, Connectathon testing, which accounts for the vast majority of Da Vinci IG testing, relies on scripted testing scenarios and predefined input data—referred to as “happy-path” testing. **Happy-path scenarios exclude exception handling and do not test a system’s ability to handle incorrect values and validation errors; Connectathons do not test for or duplicate real-world conditions.**

Additionally, data privacy considerations continue to factor in the development of ePA IGs and standards. At the time of this writing, several Da Vinci workgroups have only recently begun to consider data controls to protect patient data. Da Vinci IGs allow payers to access patient information on a broad scale without exception. For instance, when confronted with concerns about payers having access to data for those patients who are insured but will self-pay (i.e., not use insurance to pay) for certain services and have a right under the Health Insurance Portability and Accountability Act (HIPAA) to have associated data withheld from their insurance plan, workgroup members had not considered the need for IGs to limit automatic disclosure of patient electronic health information (EHI) for particular PA services. Moreover, some HL7 standards necessary to support ePA (e.g., CDS Hooks) have yet to implement controls limiting payer access. There is continued debate on whether to share patient EHI with a payer before a medical service is even ordered. Said another way, HL7 Da Vinci IGs may enable payers to monitor physician workflows and capture patient data prior to a physician even signing off on an order. We have heard the term “payer eavesdropping” being used to describe this act. **Clearly, there are still several data privacy considerations that have yet to be addressed. Physicians and patients should not be forced to choose between automating PA to reduce burden and forfeiting privacy rights and expectations.**

¹⁰ <https://www.govinfo.gov/content/pkg/FR-2022-01-24/pdf/2022-01309.pdf>

Undoubtedly, payer leverage in the development of Da Vinci IGs has played a major role. We believe it is important for ONC to consider the significant deference given to payers as the main contributors to and funders of Da Vinci IG development.

More testing and refinement of ePA standards and IGs is necessary. Yet, the AMA cautions ONC and CMS on requiring the use of ePA to “work out the kinks.” Codifying ePA in regulation, at this time, will direct the industry’s attention to federal program compliance. The AMA is concerned forward momentum in PA process reform will cease. Standards development will inevitably turn to focus on federal requirements. ePA implementation specification and standards may become “locked” resulting in forward and backward compatibility issues. This cycle has occurred in every iteration of legacy health IT programs such as the Meaningful Use Program. **We urge ONC and CMS to consider the unintended consequences of inadvertently focusing industry attention on federal program compliance rather than needed PA reform.**

To help address these concerns, and promote the maturity of ePA standards, the AMA recommends ONC coordinate with CMS in developing and promoting real-world PA testing programs. The AMA believes the following actions should be taken:

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 - Services with the highest volume of PA requests, as automation will yield the most value across the industry
 - Services that are frequently deemed urgent by the ordering clinician, as ePA will speed time to care
 - Services for which claims are most frequently denied due to unmet PA requirements, as this suggests significant issues with transparency that could be addressed via implementation of the CRD IG
 - Clinical documents (i.e., electronic attachment standards) to reduce administrative burdens associated with prior authorization; and
- ONC and CMS should consider methods to positively incentivize scenario testing across health care provider and health plan trading partners, such as intermediaries, clearinghouses, pharmacy systems, certified health IT, revenue cycle, and practice management system (PMS) vendors. ONC could consider establishing a voluntary ePA testing program similar to its voluntary certification of health IT for pediatric care and practice settings.¹¹ This may act as an appropriate balance between the lack of real-world testing and requiring ePA use through rulemaking. CMS could promote physician participation in scenario testing through *positive incentives* such as reporting program (e.g., Promoting Interoperability program) bonus points or optional measures.

Additional considerations:

As ONC considers the appropriateness of the Da Vinci IGs, we encourage ONC to request and review status updates from Da Vinci participants/pilot testers. Detailed Connectathon report-outs may help ONC evaluate if the IGs are ready for widespread implementation. The AMA urges ONC to consider the following:

¹¹ <https://www.healthit.gov/sites/default/files/page/2020-07/NPRMPediatrics.pdf>

1. The guides are currently out for ballot, with comments due right before ONC's RFI comment deadline. How will ONC evaluate guides that are essentially in flux? Comments from the latest ballot cycle will be adjudicated in the coming months. The guides will undoubtedly change from the versions currently under review. The guides are a "moving target" which necessitates additional time for review and evaluation prior to including the IGs in health IT certification or CMS program requirements.
2. The guides are standards for trial use version 2 (STU2). They are not yet normative, meaning that they will continue to change. Issues will be identified during implementation and pilot testing—requiring additional updates to the IGs. Some changes may be "breaking," resulting in future versions not being backward compatible with any current version.

More real-world testing is needed in physician practices of all sizes and medical specialties. Before requiring the guides to be included in EHR certification, **the AMA urges ONC to make sure the technology functions well across practice settings and in the real-world verses "happy-path" demonstrations as discussed in our letter.**

PA is a signification burden to physicians and harms patients. The Da Vinci IGs may help address issues related to delays but cannot sufficiently address needed PA reform. There is an ongoing role for the HITAC ePA RFI Task Group (or similar group) to continue to meet several times a year to evaluate the status of the Da Vinci IGs, pilot results, etc. and continue to assess readiness for widespread implementation and certification requirements. Given CMS' presumed interest in the guides as well, and the AMA's belief CMS is considering reissuing a new PA NPRM, we believe a regular "check in" on IG maturity makes sense.

Additional Approaches to Support Electronic Prior Authorization: Healthcare Attachments

We are seeking additional information about the following standards and implementation specifications to support the use of healthcare attachments for prior authorization transactions.

- HL7 C-CDA R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1.
- HL7 FHIR Release 4, Section 3.3: FHIR Documents.

We are also requesting comment on any other additional areas we should consider in supporting the exchange of healthcare attachments in prior authorization workflows, and on the potential intersection with other administrative and operations processes. Finally, we are requesting public comment on other standards initiatives, pilot projects, or health IT resources that we should explore to identify promising best practices, emerging standards, or innovative approaches to advance interoperable health IT for healthcare operations use cases.

Preamble FR Citation: 87 FR 3479

Specific questions in preamble? *No*

Public Comment Field:

Proper review of the HL7 C-CDA and FHIR standards will require an update on current use and capabilities of C-CDA for PA. We recommend ONC conduct a survey of C-CDA and FHIR attachment use and analyze the pros and cons of using one standard over the other. We also recommend that ONC survey payers to determine how many PA rules/criteria sets have been mapped to C-CDA or FHIR attachments; this will ensure that a document-based approach to PA would meet actual payer information needs. From a physician perspective, supporting multiple standards and workflows for different payers (i.e., FHIR Da Vinci guides for some payers and C-CDA attachments for others) would be incredibly burdensome and expensive. **The AMA does not support an approach to use multiple attachment standards.**

General Request for Comments

We are seeking public comment on whether to adopt additional standards, implementation specifications, and certification criteria as part of the Certification Program to ensure that technology is available to providers for the automated, electronic completion of prior authorization tasks. We are also seeking general comment on the issues presented in the Request for Information.

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? *No*

Public Comment Field:

The AMA agrees with ONC that diverse payer policies, provider workflow challenges, and technical barriers create an environment in which the PA process is a source of burden for patients, providers, and payers; a cause of burnout for providers; and a health risk for patients when it delays their care. The AMA appreciates ONC's Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs¹² (Strategy) to address these issues. The Strategy includes several recommendations to strengthen ePA processes such as leveraging health IT to standardize data and processes around ordering services or equipment; coordinating efforts to advance new standards approaches; and incentivizing adoption and/or use of technology that can generate and exchange standardized data to support documentation needs.

The AMA conducts a yearly physician survey to evaluate PA's impact on patients and the health care system. Survey results have been cited in multiple public forums and in Health Information Technology Advisory Committee (HITAC) reports to ONC.¹³ In 2022, the AMA released updated survey findings.¹⁴ With 93 percent of physicians reporting that the PA process delays access to necessary patient care, the AMA recognizes the importance of ePA to reduce delays. Yet, 82% of physicians report that patients have abandoned treatment due to the PA process itself. There are also serious questions about the validity of PA and impact on clinical outcomes. Nearly a third of physicians report health plans rarely or never use evidence-based criteria in PA, and 91 percent of physicians report a negative impact on clinical outcomes due to the PA process. Most shockingly, **34 percent of physicians report PA has led to a serious adverse event for a patient in their care—with nearly one in 10 physicians reporting PA has led to patient disability/permanent bodily damage, congenital anomaly/birth defect or death.** Clearly, the PA process itself needs an overhaul.

The evidence is clear. More must be done to address the considerable burden and patient harm associated with the PA process. **As an overarching goal, the AMA urges ONC to think broadly and consider actions that promote PA reform.** While ONC may consider its role simply as a health IT certification body, its designated role as a National Coordinator for Health IT necessitates a holistic view of health IT's role—negative or positive—in the PA process. Health IT is integral in all aspects of health care delivery. Therefore, before new standards or guides are included within ONC's Health IT Certification Program (Certification Program), ONC should contemplate how those standards or guides will improve the PA process. **ONC should consider how standards and guides will reduce PA volume, denials, and delays;**

¹² https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf

¹³ https://www.healthit.gov/sites/default/files/page/2021-02/2020-11-17_ICAD_TF_FINAL_Report_HITAC_508_0.pdf

¹⁴ <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

support the targeted application of PA; improve PA transparency; protect continuity of patient care; and eliminate PA-related patient harm or death—automation of PA processes and ePA alone will not accomplish these goals. Moreover, the AMA agrees with the HITAC Intersection of Clinical and Administrative Data (ICAD) Task Force’s 2020 recommendation that

[t]he process of reforming and improving prior authorization should be measurable so that progress can be tracked, and it should be meaningful for all stakeholders. Reforms should have a significant impact across the entire process and range of stakeholders, instead of having a marginally incremental impact or a significant impact for just a single stakeholder that leaves others behind or on the sidelines.¹⁵

PA reform requires an end-to-end evaluation of all proposed improvements to the PA process and a well-orchestrated national approach to implementing those improvements. Therefore, as ONC considers its role in promoting ePA, **the AMA strongly encourages ONC to evaluate new Certification Program criteria through the lens of the following PA reform characteristics:**

- How will the incorporation of new standards or implementation guides (IG) assist in the revision of PA requirements, PA program review, selective application of PA, and PA volume adjustment?
- How will the incorporation of new standards or IGs support transparency and easy accessibility of PA requirements, criteria, rationale, and program changes for physicians and patients?
- How will the incorporation of new standards or IGs support the evolution of PA criteria based on physician input, particularly those that participate in risk-based payment contracts?
- How will the incorporation of new standards or IGs protect continuity of care during changes in patients’ treatment and/or change in health plans; minimize repetitive prior authorization requirements; improve communication between physicians, health plans, and patients to facilitate continuity of care; and ensure patient health and safety?

Notably, the characteristics listed above reflect consensus of the nation’s largest organizations representing health care providers (physicians, hospitals, pharmacists, and medical groups) and health plans.¹⁶ This includes the AMA, American Hospital Association (AHA), American Pharmacists Association (APhA), Medical Group Management Association (MGMA), America’s Health Insurance Plans (AHIP), and BlueCross BlueShield Association (BCBSA). Rather than evaluating new certification criteria based solely on one characteristic, e.g., PA automation, **ONC must consider how its Certification Program will leverage certified health IT to achieve comprehensive and much-needed PA reform.**

¹⁵ https://www.healthit.gov/sites/default/files/page/2021-02/2020-11-17_ICAD_TF_FINAL_Report_HITAC_508_0.pdf

¹⁶ <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>

Certified Health IT Functionality

Do the functional capabilities described above include all necessary functionality for certified Health IT Modules to successfully facilitate electronic prior authorization processes? Are there additional capabilities that should be included in certified Health IT Modules to address these needs? Should any of these functional capabilities not be included in certified Health IT Modules (please cite the reason they should be excluded) or should ONC focus on a more limited set of functional capabilities for certified Health IT Modules than those described above?

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? Yes

Public Comment Field:

The PA process is more than physicians using certified health IT to communicate with payer systems. PA processes occur outside certified electronic health record technology (CEHRT) systems even within a medical practice. For instance, many of our members still utilize separate EHR, revenue cycle, and PMS. While EHRs are certified to federal requirements, standalone PMS are typically not. Da Vinci IGs are not sufficiently granular to enable certification criteria where multiple health IT systems on the physician side are involved to manage the workflow. Requiring EHRs to adopt ePA certification criteria only addresses a portion of the PA process within a health care organization.

Moreover, health care organizations interact with several trading partners, like intermediaries and clearinghouses, to exchange PA information with a payer or health plan. While CMS has oversight of health plans that fall under CMS' purview (e.g., Medicare Advantage plans), and can require the use of Da Vinci IGs, CMS does not require Medicare Advantage plans to use health IT systems tested and certified to conform with Da Vinci IG requirements. Sporadic use of Da Vinci IGs across the PA process could serve to increase PA administrative burden and harm patients. Additionally, intermediaries and clearinghouses are under no obligation to adopt, implement, or use federally-identified Da Vinci IGs. **The lack of PA process-wide adoption, testing, and conformance is a critical gap that should be addressed prior to federally mandating ePA use and participation.**

ONC's Certification Program tests and certifies health IT to program criteria and is a pass/fail paradigm. Da Vinci IGs have been developed to facilitate the *functional* needs of ePA but cannot easily be used to demonstrate conformance to ONC certification criteria or test procedures. ONC's Certification Program includes both pre-certification testing and post-certification reporting requirements. This includes Authorized Certification Bodies (ONC-ACBs) and Testing Labs (ONC-ATLs). It is unclear if ONC-ACBs and ONC-ATLs are capable of testing ePA workflows or support post-certification reporting given the vast array of administrative and clinical information exchange, variability in information, myriad of health IT environments, and uniqueness of health plan requirements used in thousands of PA processes nationally. **Da Vinci IGs are not at a sufficient level of maturity or granularity to support testing and certification to typical PA processes.**

Prior to including Da Vinci IGs in certified health IT, and prior to CMS requiring that physicians use or participate in an ePA program, ONC and CMS should consider and address the following issues:

- How will gaps in the use of Da Vinci IGs be addressed between certified health IT and non-certified health IT like PMS?

- How will gaps in Da Vinci IG adoption and conformance be monitored and addressed across payers and health plans?
- How will FHIR-based application program interface (API) uniformity be assured across all payers and all payer PA programs?
- What role can federal regulators play in encouraging or requiring that all health plan trading partners (e.g., intermediaries and clearinghouses) use Da Vinci IGs in a consistent and conformant way? If federal regulations are insufficient, what federal legislation would be necessary to require intermediaries and clearinghouses adopt and use certified health IT for ePA?
- What process is underway to translate HL7 Da Vinci IGs into ONC pre-certification testing and post-certification reporting requirements? How will HL7 workgroup analysis, Connectathon testing reports, individual health IT vendor experiences, independent ONC-ACB and ONC-ATL evaluation, and real-world pilot testing inform that translation?
- How will the Da Vinci IGs address payer goldcarding programs to ensure that any PA waivers/exemptions are clearly communicated to the clinician at the point of ordering?

Certified Health IT Functionality

Should ONC adopt a certification criterion for prior authorization that accounts for the full, HIPAA compliant workflow for prior authorization transactions including translation from FHIR to the X12 standard? Or should ONC adopt certification criteria that include only the workflows up to the point of translation? What ongoing challenges will stakeholders face if there is a need to translate between HIPAA-adopted standards and other standards that have only been adopted under the Certification Program used to support prior authorization transactions? How should HHS address alignment between standards adopted for HIPAA transactions and standards adopted under the Certification Program?

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? *Yes*

Public Comment Field:

ONC's Certification Program should support the complete PA workflow. Translation should be included in certification requirements if use of the X12 278 will continue to be required for HIPAA compliance. However, requiring X12/FHIR translation adds costs for all stakeholders and, even more concerningly, invites errors. CMS granted a HIPAA exception to Da Vinci participants who wish to pilot FHIR-to-FHIR workflows. ONC should request a comprehensive written status update on these exception implementations and, ideally, a comparison with those who are doing a X12/FHIR translation so ONC can better evaluate this issue.

Certified Health IT Functionality

If ONC were to propose to include these functional capabilities as part of the Certification Program, how should a new certification criterion (or multiple certification criteria) be structured, including technical requirements, attributed standards, and implementation specifications? ONC's experience adopting certification criteria suggests that, at times, combining related functions into a single Health IT Module is most appropriate, while in other cases, health IT functionalities are best represented by separate certification criteria, despite being functionally related. For instance, under a single criterion, different products and services in the market may be “tightly coupled” for the purposes of certification, even when they can be purchased and implemented separately. We seek the public's input on which functional capabilities for prior authorization should be tested and certified together as part of one certification criterion, and which capabilities should be separated into different certification criteria.

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? *Yes*

Public Comment Field:

The AMA strongly recommends that all the PA functional capabilities be incorporated in a single module. Physicians must be informed consumers and need guarantees that their EHRs support a seamless, “soup-to-nuts” fully automated PA process that does not rely on ancillary, and additional components. For example, physicians must determine if a particular service for a particular patient requires authorization. This functionality is provided by one of the three Da Vinci guides (e.g., Coverage Requirements Discovery). A practice with only the Prior Auth Support guide would miss out on this critical capability. **It is also unacceptable to impose or assume it is the physician’s responsibility to “mix and match” the right modules to support ePA.** Placing all the PA functionalities under a single module will also minimize variation between payers. A single module reduces chances of variation across payers and will reduce confusion, costs, and complexity of integration across disparate payers and EHR vendors. **ONC certification criteria should require health IT vendors provide an interoperable PA experience between one or more vendors so that physicians are ensured a full end-to-end electronic PA functionality.**

Implementation Specifications for Prior Authorization

What is the current readiness of the three FHIR-based Da Vinci IGs described above for adoption as part of certification criteria for health IT? Given limited testing of these specifications to date, what would be a feasible timeline for use of these IGs in production for prior authorization transactions? What, if any, additional changes are needed for these IGs prior to adoption as part of certification criteria for health IT?

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? *Yes*

Public Comment Field:

The AMA actively participates in HL7 Da Vinci workgroup meetings and monitors Connectathons where Coverage Requirements Discovery (CRD), Documentation Template and Coverage Rules (DTR), and Prior Authorization Support (PAS) IGs are tested. ONC states in its RFI that it has “identified a number of

issues that may be relevant to the use of these IGs in certified health IT,” including “concerns that the IGs lack maturity and have not yet undergone extensive testing in production and rely on other IGs and features in FHIR that are immature.”¹⁷ Based on the AMA’s experience with clinical and administrative implementation of health IT, our continued evaluation of the industry’s readiness to implement ePA, and our participation in Da Vinci efforts, we agree there are inadequacies and lack of real-world testing of the CRD, DTR and PAS IGs. The AMA supports the goals of reducing burden through the use of ePA and expects Da Vinci IGs to eventually meet those demands. Yet, Connectathon testing, which accounts for the vast majority of Da Vinci IG testing, relies on scripted testing scenarios and predefined input data—referred to as “happy-path” testing. **Happy-path scenarios exclude exception handling and do not test a system’s ability to handle incorrect values and validation errors; Connectathons do not test for or duplicate real-world conditions.**

Additionally, data privacy considerations continue to factor in the development of ePA IGs and standards. At the time of this writing, several Da Vinci workgroups have only recently begun to consider data controls to protect patient data. Da Vinci IGs allow payers to access patient information on a broad scale without exception. For instance, when confronted with concerns about payers having access to data for those patients who are insured but will self-pay (i.e., not use insurance to pay) for certain services and have a right under the Health Insurance Portability and Accountability Act (HIPAA) to have associated data withheld from their insurance plan, workgroup members had not considered the need for IGs to limit automatic disclosure of patient electronic health information (EHI) for particular services for which the patient will not seek coverage. Moreover, some HL7 standards necessary to support ePA, e.g., CDS Hooks, have yet to implement controls limiting payer access. There is continued debate on whether to share patient EHI with a payer before a medical service is even ordered. Said another way, HL7 Da Vinci IGs may enable payers to monitor physician workflows and capture patient data prior to a physician even signing off on an order. We have heard the term “payer eavesdropping” being used to describe this act. **Clearly, there are still several data privacy considerations that have yet to be addressed. Physicians and patients should not be forced to choose between automating PA to reduce burden and forfeiting privacy rights and expectations.** Undoubtedly, payer leverage in the development of Da Vinci IGs has played a major role. We believe it is important for ONC to consider the significant deference given to payers as the main contributors to and funders of Da Vinci IG development.

More testing and refinement of ePA standards and IGs is necessary. Yet, the AMA cautions ONC and CMS on requiring the use of ePA to “work out the kinks.” Codifying ePA in regulation, at this time, will direct the industry’s attention to federal program compliance. The AMA is concerned forward momentum in PA process reform will cease. Standards development will inevitably turn to focus on federal requirements. ePA implementation specification and standards may become “locked” resulting in forward and backward compatibility issues. This cycle has occurred in every iteration of legacy health IT programs such as the Meaningful Use Program. **We urge ONC and CMS to consider the unintended consequences of inadvertently focusing industry attention on federal program compliance rather than needed PA reform.**

To help address these concerns, and promote the maturity of ePA standards, the AMA recommends ONC coordinate with CMS in developing and promoting real-world PA testing programs. The AMA believes the following actions should be taken:

¹⁷ <https://www.govinfo.gov/content/pkg/FR-2022-01-24/pdf/2022-01309.pdf>

- ONC and CMS should identify specific and targeted PA scenarios where ePA would be most beneficial, after first eliminating PA requirements for services/treatments that are routinely approved (i.e., low-value PAs). Scenarios should include:
 - Services with the highest volume of PA requests, as automation will yield the most value across the industry
 - Services that are frequently deemed urgent by the ordering clinician, as ePA will speed time to care
 - Services for which claims are most frequently denied due to unmet PA requirements, as this suggests significant issues with transparency that could be addressed via implementation of the CRD IG
 - Clinical documents (i.e., electronic attachment standards) to reduce administrative burdens associated with PA; and
- ONC and CMS should consider methods to positively incentivize scenario testing across health care provider and health plan trading partners, such as intermediaries, clearinghouses, pharmacy systems, certified health IT, revenue cycle, and PMS vendors. ONC could consider establishing a voluntary ePA testing program similar to its voluntary certification of health IT for pediatric care and practice settings.¹⁸ This may act as an appropriate balance between the lack of real-world testing and requiring ePA use through rulemaking. CMS could promote physician participation in scenario testing through *positive incentives* such as reporting program (e.g., Promoting Interoperability program) bonus points or optional measures.

Additional considerations:

As ONC considers the appropriateness of the Da Vinci IGs, we encourage ONC to request and review status updates from Da Vinci participants and pilot testers. Detailed Connectathon report-outs and outcomes may help ONC evaluate if the IGs are ready for widespread implementation. The AMA urges ONC to consider the following:

- The IGs currently out for ballot, with comments due right before the deadline for response to ONC’s RFI. How will ONC evaluate guides that are essentially in flux? Comments from the latest ballot cycle will be adjudicated in the coming months; depending on the volume of comments, ballot adjudication could take a year or more. The guides will undoubtedly change from the versions currently under review. The guides are a “moving target” which necessitates additional time for review and evaluation prior to including the IGs in health IT certification or CMS program requirements.
- The IGs are currently under review are awaiting standards for trial use 2 (STU2) status, which is far from normative. The guides will continue to change as they are tested. Issues will be identified during implementation and pilot testing—requiring additional updates to the IGs. Some changes may be “breaking,” resulting in future versions not being backward compatible with any current version.
- More real-world testing is needed in physician practices of all sizes and medical specialties. Before requiring the guides to be included in EHR certification, the AMA urges ONC to make sure the technology functions well across practice settings and in the real-world verses “happy-path” demonstrations as discussed above.

¹⁸ <https://www.healthit.gov/sites/default/files/page/2020-07/NPRMPediatrics.pdf>

PA is a significant burden to physicians and harms patients. The Da Vinci IGs may help address issues related to delays but cannot sufficiently address all needed areas of PA reform. There is an ongoing role for the HITAC ePA RFI Task Group (or similar group) to continue to meet several times a year to evaluate the status of the Da Vinci IGs, pilot results, etc. and continue to assess readiness for widespread implementation and certification requirements. Given CMS' presumed interest in the IGs as well, and the AMA's belief CMS is considering reissuing a new PA NPRM, we believe a regular and formalized "check in" on IG maturity makes sense.

For example, CDS Hooks is a "nascent" specification that may undergo change, particularly as specifications related to its use for the CRD guide mature. Recent Da Vinci workgroup discussions have outlined some of the issues related to how CDS will trigger for CRD. Of particular concern is maintaining the privacy and security of patient EHI. It is critical that payers not receive more than the minimum necessary information needed to process the PA and that payers only receive information for ordered services for which the patient is seeking coverage. Protections must be in place to ensure that CRD does not trigger for services for which patients will self-pay.

Implementation Specifications for Prior Authorization

If the existing IGs are not yet ready for adoption, should ONC still propose certification criteria? Should ONC consider proposing certification criteria incorporating the FHIR Release 4 base standard but delay adopting implementation specifications until a later date? What are the potential risks of this approach?

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? *Yes*

Public Comment Field:

The IGs suggest a path towards full automation. The AMA recommends a phased approach by laying out an iterative path forward. Certification specifications should be based on IG maturity and the speed of the industry's ability to comply, as determined by an ONC environmental scan assessing current guide granularity and stakeholder readiness. ePA success will be realized only if all stakeholders have the functional criteria to share accurate and complete information required to complete a PA. Each stakeholder must match to the same requirements. **The AMA recommends ONC and CMS consider payer certification as a necessary component for ePA success and PA reform.** All stakeholders need the ability to match to the same requirements and ensure conformity. Proprietary capabilities and APIs increase burden and should be avoided and discouraged.

Implementation Specifications for Prior Authorization

If we were to adopt certification criteria referencing the base standard and then update those criteria to integrate implementation specifications in the future, how should these integrations be handled? When and how should the existing systems be replaced? All at once, or as a series of transitional steps?

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? *Yes*

Public Comment Field:

As indicated above, the Da Vinci IGs are in flux right now, making it difficult to suggest that they be included in ONC's certification criteria. As the AMA's research has shown, PA is a significant burden to physicians and harms patients. We strongly suggest there is an ongoing role for the HITAC ePA RFI Task Group (or similar group) to continue to meet several times a year to evaluate the status of the Da Vinci IGs, pilot results, etc., and continue to assess readiness for widespread implementation and certification requirements. Given CMS' presumed interest in the guides as well, and the AMA's belief CMS is considering reissuing a new PA NPRM, we believe a regular "check in" on IG maturity makes sense.

The AMA does not support adoption of a base standard in certification criteria as an initial step in moving the industry to ePA. To advance ePA implementation, use-case-specific IGs, such as those created by Da Vinci, are necessary. Adopting a general base standard will not support the uniformity in development and implementation of PA technology across a myriad of providers, health plans, and various HIT vendors, necessary to support widespread adoption.

Implementation Specifications for Prior Authorization

Do the Da Vinci IGs effectively support Federal and state legal requirements and/or health plan compliance requirements for clinical documentation, for example, signatures (or other indications of provider review and assent), record retention over long periods of time, and document security to ensure data integrity once stored?

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? Yes

Public Comment Field:

The PA process is more than physicians using certified health IT to communicate with payer systems. PA processes occur outside CEHRT systems even within a medical practice. For instance, many of our members still utilize separate EHR, revenue cycle, and PMS. While EHRs are certified to federal requirements, standalone PMS are typically not. Da Vinci IGs are not sufficiently granular to enable certification criteria where multiple health IT systems on the physician side are involved to manage the workflow. Requiring EHRs to adopt ePA certification criteria only addresses a portion of the PA process within a health care organization.

Moreover, health care organizations interact with several trading partners, like intermediaries and clearinghouses, to exchange PA information with a payer or health plan. While CMS has oversight of health plans that fall under CMS' purview (e.g., Medicare Advantage plans), and can require the use of Da Vinci IGs, CMS does not require Medicare Advantage plans to use health IT systems tested and certified to conform with Da Vinci IG requirements. Sporadic use of Da Vinci IGs across the PA process could serve to increase PA administrative burden and harm patients. Additionally, intermediaries and clearinghouses are under no obligation to adopt, implement, or use federally-identified Da Vinci IGs. **The lack of PA process-wide adoption, testing, and conformance is a critical gap that should be addressed prior to federally mandating ePA use and participation.**

ONC's Certification Program tests and certifies health IT to program criteria and is a pass/fail paradigm. Da Vinci IGs have been developed to facilitate the *functional* needs of ePA but cannot easily be used to

demonstrate conformance to ONC certification criteria or test procedures. ONC's Certification Program includes both pre-certification testing and post-certification reporting requirements. This includes Authorized Certification Bodies (ONC-ACBs) and Testing Labs (ONC-ATLs). It is unclear if ONC-ACBs and ONC-ATLs are capable of testing ePA workflows or support post-certification reporting given the vast array of administrative and clinical information exchange, variability in information, myriad of health IT environments, and uniqueness of health plan requirements used in thousands of PA processes nationally. **Da Vinci IGs are not at a sufficient level to support testing and certification to typical PA processes.**

Prior to including Da Vinci IGs in certified health IT, and prior to CMS requiring that physicians use or participate in an ePA program, ONC and CMS should consider and address the following issues:

- How will gaps in the use of Da Vinci IGs be addressed between certified health IT and non-certified health IT like PMS?
- How will gaps in Da Vinci IG adoption and conformance be monitored and addressed across payers and health plans?
- How will FHIR-based application program interface (API) uniformity be assured across all payers and all payer PA programs?
- What role can federal regulators play in encouraging or requiring that all health plan trading partners (e.g., intermediaries and clearinghouses) use Da Vinci IGs in a consistent and conformant way? If federal regulations are insufficient, what federal legislation would be necessary to require intermediaries and clearinghouses adopt and use certified health IT for ePA?
- What process is underway to translate HL7 Da Vinci IGs into ONC pre-certification testing and post-certification reporting requirements? How will HL7 workgroup analysis, Connectathon testing reports, individual health IT vendor experiences, independent ONC-ACB and ONC-ATL evaluation, and real-world pilot testing inform that translation?

Implementation Specifications for Prior Authorization

What alternative approaches to designing certification criteria should ONC explore that are not based on the three Da Vinci IGs described herein?

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? *Yes*

Public Comment Field:

The AMA recommends ONC adopt the NCPDP SCRIPT ePA transactions for prescription drugs as part of certification requirements, shifting this criterion from optional to mandatory.

Implementation Specifications for Prior Authorization

Are there new IGs which need to be developed in order to integrate with other workflows relevant to prior authorization? In particular, what IGs may still need to be developed in order to integrate with HIPAA administrative transaction standards?

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? *Yes*

Public Comment Field:

ONC should consider the need for patient transparency, including price and prior authorizations. This is a gap within standards development today. This could be realized as a complementary IG with separate certification requirements, schedule, and implementation timeframe. At a minimum, the Patient Access API could be used to provide the patient with the status of a PA. We reiterate that patient participation in the PA process should be **voluntary** rather than mandatory.

Healthcare Attachment Standards

Would the specifications within the CDA Attachments IG, if adopted as part of a certification criterion, support more effective exchange of healthcare attachments for prior authorization? Would any changes to the IG be needed, or would additional functionalities or standards be required for effective implementation of the CDA Attachments IG in certified health IT?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

Proper review of the HL7 C-CDA and FHIR standards will require up-to-date information on the current use and capabilities of C-CDA for PA. We recommend ONC conduct a survey of C-CDA and FHIR attachments and analyze the pros and cons of using one standard over the other. In addition, ONC should seek information from health plans regarding the sufficiency of C-CDA and FHIR attachments to provide all of the necessary data needed to evaluate a PA request for a specific service. In other words, ONC should seek confirmation that attachments, which capture data in general, non-service-specific document templates, meet the information needs for evaluating PA criteria for a particular procedure. From a physician perspective, supporting multiple standards and workflows for different payers (i.e., FHIR Da Vinci guides for some payers and C-CDA attachments for others) would be incredibly burdensome and expensive. **The AMA does not support an approach to use multiple attachment standards.**

Healthcare Attachment Standards

Given limited testing of these approaches to date, what would be a feasible timeline for use of the CDA Attachments IG or FHIR Documents in production for prior authorization transactions?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

The CDA Attachments IG or FHIR Documents must be mature and sufficiently tested before successful adoption at scale. ONC and CMS could consider a “soft” timeline informed by specific quantitative testing. The AMA encourages ONC to develop a proving ground for the maturity of all IGs and development of phased in criteria. Testing results and proving ground “lessons” should be independently evaluated (i.e., by an entity not directly involved in the product being tested) and publicly reported.

Healthcare Attachment Standards

Which of these approaches would better accommodate improvements over time to meet payer and provider needs? Should ONC consider adopting certification criteria referencing one approach over the other, or should ONC consider supporting both approaches within certified health IT?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

From a physician perspective, allowing multiple approaches is extremely concerning. Different payers could require different document types as a condition of network contracting. This is not sustainable, particularly for smaller practices with fewer resources and little negotiating power with payers. It would also be more expensive for the industry to support multiple approaches.

Healthcare Attachment Standards

If the IGs developed by the Da Vinci Project, or an alternate set of IGs addressing the full scope of prior authorization workflows, are not yet ready for adoption in certified health IT, should ONC propose certification criteria to support healthcare attachments transactions for prior authorization alone?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

The ePA workflow is complex and typically spans multiple health IT solutions within physician and payer health IT environments. A single health solution, e.g., EHRs, cannot support all ePA workflows. SMART apps and/or intermediaries also enable aspects of PA workflows. ONC should ensure that all relevant actors in the ePA workflow are adopting the necessary standards. ONC's Certification Program should provide assurances to physicians that all pieces of the ePA puzzle, including attachments, are present and can interoperate. Moreover, an iterative approach is needed to allow for adoption and maturity of a fully functional PA workflow. Physicians need a unified attachment process—not one specific to PA or specific to claims. It is also worth noting that an attachment standard would only address one piece of the PA workflow (i.e., transporting supportive clinical data between providers and health plans). Exposing PA requirements in physician EHR workflows and clearly communicating all required supporting clinical information needed to evaluate a PA request are critical to support a fully automated PA process. An attachment standard alone would not address these other key stages in the PA process.

Impact on Patients

How could potential changes to the Certification Program to better support prior authorization positively impact healthcare consumers?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

A standardized, end-to-end ePA process may help prevent care delays. "Exposing" PA requirements in EHRs at the point of care could support informed conversations between physicians and patients regarding treatment decisions and ensure that PA is initiated when care is scheduled. Likewise, clear identification of required documentation and an automated exchange of information between physicians and payers may reduce care delays. Improving the PA process can also prevent patients from abandoning treatment related to PA-related slowdowns and discouragement. Treatment abandonment and care delays can have a negative impact on patient clinical outcomes, as shown by the AMA's physician survey.¹⁹ Ideally, PA data sent to payers should be codified to minimize the need for human review.

There is widespread assumption that implementation of the Da Vinci IGs will speed patient time to care and reduce treatment abandonment. These patient-centric metrics should be included in any pilot evaluations to ensure that this technology is achieving its promise.

¹⁹ <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

The privacy and security of protected health information must be maintained in any IGs that are adopted for EHR certification. IGs should limit—and certification should validate—use of patients’ data to a particular PA service alone. In other words, patient data accessed for PA should not be used for any other purpose. IGs should safeguard against the overexposure of the patient health record beyond what is needed for PA processing. Furthermore, patients choosing to self-pay for a particular service, and who do not want their EHI disclosed to a payer, should have their HIPAA rights protected. Sharing more EHR data than what is needed for PA processing can be highly distressing to patients and cause distrust between clinicians and patients or patients and health plans. A patient should never be unpleasantly surprised or shocked by where their data shows up.

Finally, it is critical that any technology proposed for certification be affordable and accessible to physicians from all locations, settings, sizes, and resource levels. Patients in underserved communities cannot be left behind in PA reform; it would exacerbate the health care disparities that already exist in our country.

Impact on Patients

How could potential changes reduce the time for patients to receive needed healthcare services, reduce patient non-adherence, and/or lower out-of-pocket costs?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

As previously indicated, “exposing” health plan PA requirements at the point of care supports informed conversations between physicians and patients during treatment selection and prevents care abandonment. Improving the transparency of PA and documentation requirements in the EHR workflow will ensure that all the necessary data are collected during the patient visit. Yet, assumptions are being made that Da Vinci IGs and standards will reduce PA processing time, treatment abandonment, and PA denials. To validate these assumptions, ONC should require patient-focused ePA piloting and testing to ensure that these important goals can be achieved.

Impact on Patients

Besides the provider to payer interactions discussed in this RFI, is there additional functionality that could be added to the Certification Program that would better support patients' participation in the prior authorization process?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

Patients should not be required to participate in the PA process. This could increase chances of PA denials if patients are not able to comply with payer documentation requirements. The potential for conflicting data submissions from physicians and patients should also be considered as this could impact the timeliness of the PA process and decision outcomes. Patients should, however, be able to opt in to receiving updates on the status of in-process PAs.

Impact on Providers

To what degree is availability of electronic prior authorization capabilities within certified health IT likely to reduce burden for healthcare providers who currently engage in prior authorization activities?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

The 2021 AMA Prior Authorization Physician Survey clearly illustrates the physician burdens associated with PA: practices reported completing an average of 41 PAs per physician, per week. The weekly PA workload for a single physician consumes almost two business days of physician and staff time. An overwhelming majority (88 percent) of physicians reported PA burdens as high or extremely high, and 40 percent of physicians have hired staff exclusively to complete PAs.

The 2021 CAQH Index estimates that the medical industry could save \$437 million annually (\$87 million for health plans; \$350 million for providers) by adopting a completely automated electronic PA process using standard transactions. This is based on a comparison of manual vs. fully electronic per PA transaction costs, respectively: \$3.54 vs. \$0.07 for health plans and \$10.95 vs \$3.43 for providers. CAQH estimates that providers could save 16 minutes per transaction by adopting electronic PA, with an average provider time per PA averaging 23 minutes for manual and 7 minutes for electronic. Note that these numbers are only based on adoption of the HIPAA-mandated X12 278 (not FHIR APIs) and do not include any additional savings related to electronic attachment adoption, as the CAQH data on attachments was aggregated for claims, PA, and appeals use cases. CAQH data do not account for the initial technology investment needed to adopt ePA. The 2021 Index reports data for 2020, the first year of the COVID-19 pandemic, which impacted adoption, volumes, and costs of administrative transactions.

The AMA notes a few important caveats:

Automation is only one piece of fixing our industry's PA problem. The overall volume of drugs and services requiring PA must also be addressed, as the trend towards ever-increasing requirements in recent years is simply not sustainable. In addition, it would take years to digitize the current volume of current PA rules; a more manageable workload is needed for developers to build out this technology.

We need to ensure that any certification requirements will not impose undue financial burdens on smaller practices and payers that are already struggling to stay afloat, particularly during a pandemic.

Implementation costs are a huge consideration—we cannot leave practices in under-resourced areas that serve vulnerable historically marginalized communities or rural populations behind—this will exacerbate existing health disparities. In addition, we need to be sure that physicians will gain efficiencies from ePA technology. This should be measurable as **PA process reform**. Piloting of the technology under consideration should measure clinician and staff time required to complete PAs before and after implementation to ensure that ePA is achieving the desired efficiency goals.

EHR privacy and security issues apply for physicians as well as patients. For physicians to feel comfortable using any new technology, they need to be confident that payers will only access the parts of a patient's EHR relevant for a particular PA.

The AMA's concerns extend to non-physician providers being able to participate in the PA workflows and technology under consideration. For example, DME suppliers do not have EHRs. How will ONC and CMS ensure that all providers benefit from the proposed workflows and technology? It is unclear if the Da Vinci IGs adequately address complex PA workflows where multiple providers (ordering and rendering) are involved. While these scenarios are more complicated, it is important to consider them now.

ONC must evaluate if Da Vinci IGs support inter-provider communication and workflows associated across all PA processes. As previously mentioned, ONC needs to ensure that any technology proposed for certification allows "pass-offs" between physicians and other practice staff; we do not want to build a process that forces physicians to take on more administrative tasks. Similarly, physicians must be able to save an initiated PA to complete later and/or delegate a PA to staff.

The available estimates of cost savings for implementing ePA do not address the Da Vinci IGs (i.e., CAQH data only analyzed X12 278 implementation). There is no information available on initial technology investment costs of FHIR-based ePA. The AMA recommends that ONC request pilot sites and early implementers of Da Vinci IGs to publicly report this information so that the industry can assess an accurate return on investment. In addition, cost data should include a variety of potential implementation scenarios (e.g., estimated cost in various possible provider setups using SMART apps, intermediaries, etc. along with their EHRs).

Impact on Providers

To what degree are healthcare providers likely to use these new capabilities across their patient panels? Will additional incentives or requirements be needed to ensure healthcare providers effectively use these capabilities? What accompanying documentation or support would be needed to ensure that technology capabilities are implemented in ways that effectively improve clinical workflows?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

Physicians will need *positive incentives* to adopt the ePA capabilities of certified health IT given that adoption may result in significant cost and time (in the form of training and workflow alteration) to implement. Many physicians do not have the sophisticated software needed to support FHIR. Physicians may need to contract with intermediary services to support end-to-end ePA. Additional support will be required to help medical office staff capture patient information in accordance with Da Vinci IG requirements. For instance, data needed for ePA are often recorded in free text EHR fields rather than in the FHIR-enabled resources necessary to drive CRD/DTR workflows.

Physicians need ePA technology that supports **all health plans for all services requiring PA and for all patients in their panel**—spotty implementation across payers or services will discourage adoption. The ePA process must also be easier and faster than the process used today. For example, if completion of a FHIR questionnaire is more time-consuming than a payer portal (or even a phone call or fax), medical practices will choose the more efficient process.

Physicians need accurate coverage information in their EHRs. If physicians discover that a PA was required, even if the CRD function said it was not, physicians will lose trust in ePA technology and stop using it. **It will be critically important for payers and vendors to ensure information is accurate and up to date.**

ePA should not create additional burdens and must align with the workflow of clinical care. Physicians should experience a reduction in the total cost of managing PA through documentation automation and reduced PA rework, PA denials, and PA appeals. The AMA again stresses that PA reform is necessary. **ONC should ensure that any ePA certification criteria leads to increased support for clinical workflows and the reduction in overall PA burden on the practice.**

Impact on Providers

What estimates can providers share about the cost and time (in hours) associated with adopting and implementing electronic prior authorization functionality as part of care delivery processes?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

As suggested above, the AMA recommends that ONC require piloters and early implementers of the Da Vinci IGs to publicly report key metrics, including physician time spent on PA before and after adoption; time to care delivery before and after adoption; percentage of all PAs capable of being completely in a completely electronic workflow; cost savings; and both direct and indirect cost to physicians implementing Da Vinci IGs. This will provide valuable data to the industry regarding the overall value of investing in this technology.

Impact on Developers

What estimates can health IT developers share about the cost and time (in hours) of developing electronic prior authorization functionality within certified health IT products?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

The high volume of current payer PA rules and criteria—which are highly variable—will be a challenge for developers. Our experience indicates that since many EHR systems are supporting multiple payer versions of PA, and require customization, implementation of ePA technology will be expensive and time consuming. Implementation often requires unique payer connections and customizations. **ONC must assure that ePA certification criteria eliminates proprietary solutions between payers and EHR vendors.**

Impact on Developers

What factors would inform the burden for health IT developers to develop certified Health IT Modules for electronic prior authorization based on the three Da Vinci IGs described above?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

EHR vendors often struggle to develop functionality in response to their clients' needs. Federally requiring ePA will push those requirements above client-requested functionalities. ONC should consider the opportunity costs associated with requiring ePA criteria over important changes or improvements requested by physicians that are already in developer queues.

Payer Implementation

How could the Certification Program support the technology needs of healthcare payers in implementing electronic prior authorization? Should ONC consider payer workflows in the development of certification criteria to support the potential use of certified Health IT Modules by healthcare payers? Would the availability of certified Health IT Modules supporting these workflows reduce the burden for healthcare payers of engaging with healthcare providers in prior authorization processes?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

It is unclear if any information is available on payer support for FHIR-to-FHIR PA workflows. We urge ONC to evaluate real-world implementation of Da Vinci guides. ONC should investigate and make its findings public.

Moreover, health care organizations interact with several trading partners, like intermediaries and clearinghouses, to exchange PA information with a payer or health plan. While CMS has oversight of health plans that fall under CMS' purview (e.g., Medicare Advantage plans), and can require the use of Da Vinci IGs, CMS does not require Medicare Advantage plans to use health IT systems tested and certified to conform with Da Vinci IG requirements. Sporadic use of Da Vinci IGs across the PA process could serve to increase PA administrative burden and harm patients. Additionally, intermediaries and clearinghouses are under no obligation to adopt, implement, or use federally-identified Da Vinci IGs. **The lack of PA process-wide adoption, testing, and conformance is a critical gap that should be addressed prior to federally mandating ePA use and participation.**

Prior to including Da Vinci IGs in certified health IT, and prior to CMS requiring that physicians use or participate in an ePA program, ONC and CMS should consider and address the following issues:

- How will gaps in Da Vinci IG adoption and conformance be monitored and addressed across payers and health plans?
- How will FHIR-based application program interface (API) uniformity be assured across all payers and all payer PA programs?
- What role can federal regulators play in encouraging or requiring that all health plan trading partners (e.g., intermediaries and clearinghouses) use Da Vinci IGs in a consistent and conformant way? If federal regulations are insufficient, what federal legislation would be necessary to require intermediaries and clearinghouses adopt and use certified health IT for ePA?