American Health Information Management Association®

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Micky Tripathi
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330 C Street, SW
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Washington, DC 20201

RE: Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria (RIN: 0955-AA04)

Submitted electronically via www.regulations.gov

Dear Mr. Tripathi:

Thank you for the opportunity to submit comments regarding ONC's *Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria.*

AHIMA is a global nonprofit association of health information (HI) professionals. AHIMA represents professionals who work with health data for more than one billion patient visits each year. The AHIMA mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and clinicians. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide.

AHIMA appreciates the ONC's continued work on integrating clinical and administrative data streams to improve the patient experience, enhance efficiency, and reduce burden for both providers and payers. Existing processes that require clinical data for administrative processes require a considerable amount of work including phone calls, faxes and use of multiple payer portals. In-patient authorizations, medical necessity reviews, and prior authorizations for tests, procedures, and medications impose significant burdens on providers and patients and raise administrative costs. In some cases, they can also delay treatments and negatively impact patient outcomes.

AHIMA offers general comments on the following issues followed by more detailed comments in response to certain questions in the RFI.

Factors Beyond Automation

AHIMA agrees that electronic prior authorization (ePA) transactions based on national standards has the potential to streamline existing processes for providers, payers, and patients. However, there are factors beyond

automating these transactions that must be addressed to improve efficiency and reduce provider and patient burden. Such considerations include addressing operating rules, data governance, and workforce training needs, including education on new standards, vocabularies, technologies, and processes. This includes working across the payer and provider communities to consider approaches to standardize the use of prior authorization and publish metrics regarding the extent to which prior authorization is used and with what results. Accurate and transparent mapping of the various code sets that are used for administrative and clinical purposes must also be considered to ensure consistency in meaning of the code sets and to promote trust between providers and payers during the transaction. Consideration should also be given as to whether a uniform and consistent set of data elements that enable a common information flow and format could be established across payers to minimize variation in prior authorization requirements and further streamline electronic prior authorization processes. AHIMA encourages ONC to place efforts to automate prior authorization within this fuller context and work with other agencies and stakeholders, and particularly the end-users of technology, to address the full range of issues at hand before moving forward. Otherwise, efforts to automate may not be successful or have less benefit than intended.

End-User Engagement

The development of new health IT standards and their adoption into regulatory requirements can bring benefits by addressing specific challenges and creating more uniformity in how health information is gathered, shared, and used. However, over the past ten years, end-users that deploy technology to care for patients have found that new technical approaches and regulatory requirements are not sufficiently grounded in real-world experiences or adequately consider the implementation pathway before mandating use. This includes issues such as how new approaches work with the existing infrastructure, workflow constraints in adopting new technology, technology costs, and how new requirements fit into the array of regulatory requirements health IT end-users face. As a result, end-users have experienced the following: (1) adoption of standards that require significant workarounds to implement, (2) a set of standards that are incomplete or too immature to accomplish the desired task, (3) policy mandate deadlines that are frequently changed, leading to confusion and poor resource allocation, (4) standards and policies that do not achieve their desired goals when deployed, (4) excessive burden added to health IT end-users, (5) wasted resources on failed implementations and (6) confusion from patients with respect to technological capabilities.

Leveraging health IT end-user input throughout the standards and policy development process and conducting real-world testing can help mitigate the above issues. It can also better align standards and policies to support the needs of front-line health workers and result in faster standards adoption as well as realization of the goals for collection, sharing, and use of health information to care for patients, and support individuals on their health journey.

Certified Health IT Functionality

Do the functional capabilities described in the RFI include all necessary functionality for certified Health IT Modules to successfully facilitate electronic prior authorizations processes?

Multiple systems are often involved in the workflow associated with prior authorization including registration systems, revenue cycle management systems and practice management systems. Many of these systems are not certified today. Conversely, under the Health Insurance Portability and Accountability Act (HIPAA), the HIPAA transaction standards apply to providers, payers, and clearinghouses but not health IT developers. It is unclear how certified health IT will support the full spectrum of communication for electronic prior authorization. To successfully facilitate electronic prior authorization processes, AHIMA suggests the same rules should apply to health IT developers, payers, and providers to ensure that all follow the same “rules of the road.”

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?

AHIMA suggests ONC consider additional capabilities specific to patient access and engagement. Patients should have the capability at their discretion, to receive notification and/or query status updates of key activities throughout the prior authorization process, including being able to receive notification of denials and/or status of appeals. This also includes consideration of functionality to support electronic cost estimates for patients (e.g.—Advanced Eligibility of Benefits) to support successful prior authorization.

Functional capabilities should also consider the need for delegation of prior authorization related activities by a provider to back-office staff. Providers do not always have the bandwidth to manage all tasks associated with a prior authorization. As a result, certain tasks are handed off to non-clinical staff. Functional capabilities should recognize such workflows and allow for such flexibilities.

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 used to support prior authorization transactions?

Before adopting 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, AHIMA suggests ONC work with the Centers for Medicare and Medicaid Services (CMS) to share publicly the results of the HIPAA exception granted to the HL7 DaVinci Project to test FHIR standards to support prior authorization instead of X12 transactions. Public dissemination of comprehensive report-outs would allow for diffusion of learnings and identify opportunities for improvement prior to adoption of certification criterion.

With respect to how HHS should address alignment between standards adopted for HIPAA transactions and standards adopted under the Certification Program used to support prior authorization transactions, AHIMA suggests that the US Department of Health and Human Service (HHS) look to the Intersection of Clinical and Administrative Data Task Force (ICAD) recommendation that ONC, in collaboration with CMS and other federal agencies establish a single, consistent process for standards advancement that incorporates multiple rounds of development testing and production pilot use prior to adoption as national standards. As part of this singular approach, AHIMA recommends establishing a clear roadmap that lays out a clear path from our existing, bifurcated approach of setting clinical and administrative standards to one where these data steams converge. This includes ensuring that certain elements of the existing HIPAA transaction standards process are not cast aside including the establishment of clear roles and responsibilities of stakeholders involved in the process, consideration of the operating rules and how new standards may be used and implemented by the end user and the principles that all stakeholder can “move together” to promote consistency and certainty for all parties involved in the transaction. HHS should also consider as part of this alignment input from stakeholders beyond the federal government including payers and providers who would be responsible for implementing the standards from initial standard scoping to real-world testing to ensure such efforts support end-user workflows and maintain the stability of the revenue cycle.

Implementation Specifications for Prior Authorization

What is the current readiness of the three FHIR-based DaVinci Implementation Guides (IGs) 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?

Adequate, real-world testing is needed before establishing any timeline for the use of the three IGs. This includes real world testing across different care settings and practices sizes to understand the variety of configurations and to ensure the technology functions and the standards support end-user workflows across the full spectrum of clinical use. AHIMA recommends making public and broadly disseminating the results from piloting the IGs and current levels of adoption of the IGs in the production environment as a key determinant of readiness.

Additionally, given that prior authorization may occur across a number of health IT systems such as revenue cycle management systems, practice management systems, and payer systems that may not be certified health IT technology, prior to adoption as part of certification criterion, the IGs must provide additional granularity such that it is clear what is expected in each context and make it easier for certification criteria to point to what is required in a specific IG.

This question also raises the more general issue of the need for real-world testing of standards and greater engagement of end-users who use technology to care for patients before standards are included in federal regulations. Since passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, the federal government has played an increasingly active role in advancing health IT standards and mandating their use. By adopting specific standards, creating forums to identify needed standards, and funding standards development, the federal government is setting the path for standards adoption. The results of rigorous real-world testing that considers the impact on a range of end-users and is performed before standards are included in policy should help assess whether a standard is mature.

To enhance the likelihood that beneficial new standards are adopted by a spectrum of health IT end-users, AHIMA recommends the following:

- Health IT end-users must be instrumental in establishing the goals and priorities for setting standards, across care settings and use cases, such as public health.
- Health IT end-user input should be included in every phase of standards development from initial standard scoping to real-world testing.
- Standards and policies to advance standards adoption should prioritize patient care and wellness and public health; secondary or supplemental requirements (e.g., reporting, quality measurement, compliance, etc.) should be derived from patient care.
- Real-world testing should inform whether the standard will:
    - Be implementable by healthcare organizations without significant effort beyond the value incurred by adoption.
    - Be effective at achieving its desired goals.
    - Encompass a complete solution to achieve the desired goals.
    - Not result in unintended consequences that would harm individuals (e.g., caregivers, patients, physicians, and other clinicians.)
    - Respect and accommodate the privacy needs of individual patients.
    - Not add extraneous work to the care team.
    - Ensure sufficient return on investment to justify the allocation of resources to health IT.
    - Disparately impact providers who care for communities that are underserved or marginalized.
- Health IT end-user engagement should be supported to maximize the end-user's ability to provide effective input.
    - Standards development organizations should assign resources for this purpose.
    - Clinical and operational informaticists should be called on to participate, while professional membership associations should encourage participation and serve as a liaison.
    - Providers caring for the underserved should be included and provided resources to participate otherwise they will be excluded.

    - The federal government should provide financial and technical support to ensure that end-user testing is a routine part of standards development and that testing methods are sufficiently rigorous and based on real-world needs of clinicians and patients. Federal support should also ensure participation by those who care for communities that are underserved or marginalized.
    - Payers and health IT vendors should also support testing, while avoiding sponsorship models.
    - Particular attention should be paid to ensuring that end-users caring for diverse populations and communities with the highest needs have support to participate.
- Health IT end-users or their professional organizations should commit to being active participants in standards development activities, consistent with their expertise. This should be viewed as a professional commitment, supported and recognized by organized medicine.
- Standards development organizations must take health IT end-user input seriously and not dismiss the input as "simply out of scope" or a "matter of policy" not appropriate to address through standards development. Granularity in standards implementation guides is increasingly necessary to ensure uniform development across vendors, interoperability, and achievement of the technology's end goals.
- The testing of standards must include real-world implementations, production pilots, and collection of metrics regarding the effort needed to implement, the training needs for staff, the extent to which the standard achieved the stated goal and estimates of the costs and benefits of implementation. This includes, for example:
    - Scoping
    - Conceptual development
    - Use Cases
    - Standards testing
    - Pilot testing
    - Return on investment
    - Assessment of impact on different provider types and with different resources
    - On-going monitoring
- The health IT community should work together to identify expectations for rigorous real-world testing, such as the needed metrics, methods of accountability, assurance that testing results are impartial, external expert review of testing methods and results, impact on health equity, and public reporting of the outcome.
- Standards should not be considered mature until real-world testing has been completed and comprehensive report-outs on the testing are made public. Standards maturity models should also not consider inclusion in regulation as a sign of maturity.
- Once in use, standards should be monitored to understand usability and other features.
- Policy proposals should build from the results of real-world testing and consider the implementation path for a range of providers settings, from small offices to large systems and across medical specialties and including end-users caring for diverse populations and communities with the highest needs.
- Standards that have not completed robust real-world testing are not suitable for mandated use in health policy. However, the federal government could support real-world testing of standards that support policy goals. This should be done in close coordination with end users and in a way that ensures that end-users serving diverse populations and communities with the highest needs are included.
- Standards and health policy must ensure equity and embrace diversity, including end-user involvement, conducting real-world testing, and the creation of resources for standards development.

If the existing IGs are not yet ready for addition, 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?

AHIMA suggests that adequate, real-world piloting and testing and implementation experience be performed before adopting any certification criteria. Defined metrics are also needed to measure readiness of the implementation. As part of testing and piloting, an implementation path or "roadmap to adoption" should be

articulated to encourage scaling and adoption by stakeholders. Such requirements are consistent with the ICAD Task Force's recommendation for HHS to develop and fund a national approach to have test data beds to drive innovation and ensure real-world functionality. Federal investment in the development of a proving ground for maturity of all IGs would help ensure the implementation specifications support end-user workflows.

Should ONC move forward with certification criteria, AHIMA recommends ONC work with CMS to ensure applicability across all stakeholders including health IT developers, providers, payers, and clearinghouses. Such alignment will encourage both agencies to "move together" to successfully facilitate prior authorization processes. This may require CMS to consider positive incentives to encourage participation by providers and payers.

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?

It is unclear how ONC certification would interact with the HIPAA transaction standards. For example, should HHS decide to adopt an attachment standard, would ONC certification still be necessary? Would both standards be included as part of the certification criterion? Attachments are a complex issue that need to be addressed seamlessly across ONC and CMS. We encourage ONC work with CMS to ensure alignment across both agencies.

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?

Adequate testing and implementation experience for the use of the CDA Attachments IG or FHIR Documents is needed before adoption. AHIMA also suggests broad dissemination of information regarding the results of real-world testing and piloting prior to establishing a feasible timeline for use of the CDA Attachments IG or FHIR Documents for prior authorization transactions.

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

It is unclear how exchange would work if both approaches are supported. Conversely, should ONC adopt certification criteria that references one approach over the other, it is critical that workflows that are working today are maintained to ensure the stability of the revenue cycle.

If the IGs developed by the DaVinci 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 attachment transactions for prior authorization alone?

Attachments today may be used for multiple administrative purposes and are contemplated as part of the HIPAA transaction standards. Should certification criteria be proposed to support healthcare attachment transactions for prior authorization alone, AHIMA recommends that ONC coordinate with CMS to ensure alignment.

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?

Patients should have the capability at their discretion, to receive notification and/or query status updates of key activities through the prior authorization process, including being able to receive notification of denials and/or status of appeals. This also includes consideration of functionality to support electronic cost estimates for patients (e.g., Advanced Eligibility of Benefits) to support successful prior authorization.

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?

Given the involvement of multiple systems in the workflow associated with prior authorization, including systems that may not be certified, it is unclear the extent to which having electronic prior authorization capabilities within certified health IT will reduce burden for healthcare. In addition, successful implementation would require that all parties engaged in the prior authorization process – providers, payers, and clearinghouses or other third parties – successfully adopt compatible technologies at the same time. Other considerations including business processes that are part of prior authorization activities but exist outside of certified health IT systems must also be accounted for in determining whether certified health IT is likely to reduce burden for providers engaged in prior authorization activities. This includes, for example, consideration of how to better standardize when prior authorization is needed and the data that are required to complete prior authorization, as well as data governance issues such as the amount of information that is shared to complete a prior authorization and possible limitations on further uses of the data in ways that could be detrimental to patients.

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?

The extent to which healthcare providers will use these new capabilities across their patient panels depends on whether the new capabilities will support end-user workflows. To ensure the effective use of these capabilities, standards must support these new capabilities comprehensively such that end-users can complete the task for which the capabilities were designed. Such new capabilities must also ensure that workarounds are minimized. Additionally, sufficient piloting and testing across settings and practice sizes must be performed prior to implementation with sufficient production of results and broad dissemination to demonstrate efficacy and to give confidence to provider that such new capabilities will support their workflow. Should such capabilities be available, AHIMA suggests that ONC avoid a "mixed model" approach where providers would be obligated to follow different approaches according to the requirements of different payers to minimize administrative burden on providers. AHIMA also suggests that positive incentives be implemented to encourage providers to adopt the new capabilities.

Thank you for the opportunity to offer comments on the RFI. We hope that ONC will continue to engage extensively with stakeholders on these critically important issues and we look forward to serving as a resource. Should you or your staff have any additional questions or comments, please contact Andrew Tomlinson, Director of Regulatory Affairs at andrew.tomlinson@ahima.org or Lauren Riplinger, Vice President, Policy & Government Affairs, at lauren.riplinger@ahima.org.

Sincerely,

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Chief Executive Officer
AHIMA