

March 25, 2022

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**Attention:** Request for Information: Electronic Prior Authorization Standards,  
Implementation Specifications, and Certification Criteria; RIN 0955-AA04

**Submitted electronically via [www.regulations.gov](http://www.regulations.gov)**

Dear Dr. Tripathi,

The Association for Clinical Oncology (ASCO) is pleased to submit comments in response to the Office of the National Coordinator for Health Information Technology's (ONC) request for information (RFI) on electronic prior authorization standards, implementation specifications, and certification criteria, which will be used to inform potential future rulemaking.

ASCO is a national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

As noted by ONC in the RFI, stakeholders have stated that the prior authorization process is a source of burden for patients, providers, and payers. It is a cause of significant burnout for providers and a health risk for patients when it delays their care. Disparate payer policies, provider workflow challenges, and technical barriers all contribute to this burden. ONC's *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*,<sup>1</sup> released in 2020, included a number of recommendations to strengthen electronic prior authorization processes, such as leveraging health IT to standardize data and processes around ordering services or

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<sup>1</sup> Office of the National Coordinator for Health Information Technology. Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs [PDF file]. February 2020. Available at [https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport\\_0.pdf](https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf).

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.

To further explore these and other stakeholder recommendations, and to build on recent efforts related to electronic prior authorization, the agency seeks public comment on how the ONC Health IT Certification Program could incorporate standards, implementation specifications, and certification criteria to advance electronic prior authorization.

ASCO is pleased to offer comments from a provider perspective, highlighting areas where standards and certification criteria could have a significant impact on the care of patients facing cancer.

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### **Prior Authorization Burden**

A recent survey of physicians by the American Medical Association<sup>2</sup> found that the reported burden of prior authorization (PA) is significant:

- On average, practices complete 41 PAs per physician, per week
- Physicians and their staff spend almost two business days each week completing PAs
- Forty percent of physicians have staff who work exclusively on PA
- Eighty-eight percent of physicians describe the burden associated with PA as high or extremely high

Requirements for prior authorization are also increasing, as shown by another recent survey released by the Medical Group Management Association (MGMA); this March 2022 survey found 79% of respondents saying said that prior authorization requirements increased over the past year.<sup>3,4</sup> MGMA members reported the following as their most significant challenges: lack of response or slow response from payers for approvals; increased time spent by practice staff working to obtain prior authorizations; and a lack of automation in payers' PA processes.

The manual nature of much of this process adds significantly to its burden and the impact on physicians and patients. While many prior authorizations may be initiated electronically via separate payer portals, subsequent interactions and requests for additional information are frequently conducted via fax or phone, leading to delayed communication, slower response times, and delays in patient care.

These manual processes are all set against a backdrop of increasing reliance on technology in the healthcare field more generally, but with caveats as to unintended consequences. The Clinician of the

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<sup>2</sup> The American Medical Association. 2021 AMA prior authorization (PA) physician survey. Available at <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

<sup>3</sup> Ernst, C. Virtually all medical groups say payer prior authorization requirements aren't improving. MGMA STAT, March 2, 2022. Available at: <https://www.mgma.com/data/data-stories/virtually-all-medical-groups-say-payer-prior-authorization>

<sup>4</sup> Southwick, R. Prior authorization demands are getting worse, survey finds. Chief Healthcare Executive, March 4, 2022. Available at <https://www.chiefhealthcareexecutive.com/view/prior-authorization-demands-are-rising-survey-finds>

Future study<sup>5</sup> found that 70% of clinicians agreed that the widespread use of digital health technologies will enable the positive transformation of healthcare; however, 69% of clinicians also agreed that digital health technologies will be a “challenging burden” and 64% agreed that the impact of health inequalities will be exacerbated by digital technology.

Earlier studies<sup>6</sup> have shown the benefits of implementation of electronic prior authorization, including decreased faxes and phone calls and faster time to patient care. Moreover, according to a recent report from the Council for Affordable Quality Healthcare (CAQH),<sup>7,8</sup> the healthcare industry could save \$20 billion by handling 9 common transactions electronically. Of special note, only 26% of prior authorization requests are handled fully electronically. CAQH also found that 39% of prior authorizations were partially electronic in 2021, while 35% were still fully manual (submitted by phone, fax, e-mail, or mail). CAQH estimates that if all prior authorization claims were submitted fully electronically, the healthcare industry would save \$437 million annually.

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

ONC is seeking comment on functional capabilities for electronic prior authorization that should be considered for inclusion in certified health IT. Specifically, the agency seeks 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
- 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

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<sup>5</sup> Goodchild L, et al. Clinician of the Future Report 2020. Available at:

[https://www.elsevier.com/\\_data/assets/pdf\\_file/0004/1242490/Clinician-of-the-future-report-online.pdf](https://www.elsevier.com/_data/assets/pdf_file/0004/1242490/Clinician-of-the-future-report-online.pdf)

<sup>6</sup> America’s Health Insurance Plans. Press Release: New Analysis Shows Benefits of Electronic Prior Authorization for Patients and Providers, March 24, 2021. Available at <https://www.ahip.org/news/press-releases/new-analysis-shows-benefits-of-electronic-prior-authorization-for-patients-and-providers>

<sup>7</sup> 2021 CAQH Index. Working Together: Advances in Automation During Unprecedented Times. Available at: <https://www.caqh.org/sites/default/files/explorations/index/2021-caqh-index.pdf>

<sup>8</sup> Southwick, R. Healthcare companies do more electronically, but there’s room to improve, study finds. Chief Healthcare Executive, February 1, 2022. Available at: <https://www.chiefhealthcareexecutive.com/view/healthcare-companies-do-more-electronically-but-there-s-room-to-improve-study-finds>

ASCO agrees that all the functional capabilities listed above should be included in certified Health IT. The steps described are necessary to streamline the process and decrease unnecessary burden on providers and patients. Below we expand on some of the needed functionalities above, with an emphasis on “chokepoints” in the current system.

First, wherever possible, necessary documentation or data elements should be pulled directly from the EMR without additional manual entry from the user. The creation of additional forms or templates to complete within an electronic PA process simply shifts the burden from one portal to another without making any real difference to overall burden.

Second, while PA requests can often be submitted electronically (usually through a separate payer portal), it is much less common that responses are returned electronically. These manual responses (fax, mailed letters, calling for updates) add unnecessary delay to the process, especially when the response contains a request for additional information, which must also be exchanged manually. Electronic responses are critical to any electronic PA process. Third, if a response is a denial, the reason for the denial should be very specific. If, for example, an oncologist is adhering to NCCN guidelines in the care of a patient but is not aware that the payer uses non-NCCN guidelines in its determinations, this will significantly impact the appeals process and is something the provider should be made aware of immediately.

Many payers give status updates that simply read, “pending,” but with no indication of what further information might be needed for a final decision. An explanation of the cause of the delay and the information anticipated to be needed for a final decision would also help to streamline the process and potentially decrease the number of denials and appeals. Providers have noted that this lack of specific feedback earlier in the process plays a significant role in persistent denials for lack of relevant information, and that this same information provided later in the process often overturns a denial.

Finally, an element of PA not addressed by the core functionalities listed above is “peer-to-peer” communication, usually conducted over the telephone, with the physician sharing extra clinical information with a healthcare provider employed by the payer. For many providers, this is the step in the process that can be the most time-consuming and frustrating. We recognize that by their very nature, the “core functionalities” envisioned by ONC for certified Health IT would not specifically impact this step in the process; however, we believe that improving the more routine, earlier steps employed in the process could lead to a decrease in unnecessary peer-to-peer interactions with a corresponding increase only in those situations where they are truly needed.

Overall, while ONC as a regulatory agency has little influence over payer decisions related to the need for prior authorizations, certification of Health IT related to the PA process could at least make the process less burdensome and more predictable. In this vein, we also agree with ONC’s *Electronic Prior Authorization RFI Task Force’s* recommendations<sup>9</sup> on this overarching issue, as submitted to ONC’s Health Information Technology Advisory Committee (the HITAC):

*Supporting overall reduction in the volume of prior authorization requirements will also be necessary for widespread ePA implementation. Exploring policies such as a trust and*

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<sup>9</sup> Electronic Prior Authorization RFI Task Force 2022. Report to the Health Information Technology Advisory Committee. March 10, 2022. Available at: [https://www.healthit.gov/sites/default/files/facas/2022-03-10\\_ePA%20RFI%20TF%20Recommendations%20Report.pdf](https://www.healthit.gov/sites/default/files/facas/2022-03-10_ePA%20RFI%20TF%20Recommendations%20Report.pdf)

*verify framework for prior authorizations that are routinely approved (e.g., gold carding), can help to reduce overall burden and ensure uptake of ePA for high priority procedures, services, and items. [Recommendation 10.4]*

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

ASCO strongly agrees with this recommendation and has long supported regulations and draft legislation that seek to set a threshold for prior authorizations where the item or service is approved a vast majority of the time. These types of prior authorizations accomplish nothing in the way of improved patient care or healthcare savings and simply place roadblocks between a patient and the patient's needed treatment.

Finally, we highlight here another recommendation from the Task Force in the section titled, "Accessibility of Health IT for ePA at Scale" (Recommendation 10). Specifically, the Task Force recommends:

*To ensure the widest beneficial impact of ePA technology and protect against further exacerbation of current health disparities, HHS should explore incentives to support smaller, under-resourced providers in adopting and implementing standard ePA technology [Recommendation 10.2].*

We are pleased that the Task Force recognizes the potential for an exacerbation of health disparities and strongly support its recommendation that HHS assist these smaller, under-resourced providers, and urge ONC to adopt this recommendation in any future rulemaking.

### **mCODE<sup>®</sup> and CodeX<sup>™</sup>: Prior Authorization in Oncology**

As ASCO has discussed with the agency previously, mCODE is a focused set of data elements selected based on their broad applicability to cancer patients and survivors and to support a variety of cancer care and research applications across a variety of cancer types. mCODE elements were developed by a collaboration of oncology experts, and as a Health Level 7 (HL7) Standard for Trial Use these elements were refined with broad input and review through the ballot.

The mCODE Initiative Collaborators have submitted a response to this RFI under separate cover, which we refer the agency to for more details. Here, we briefly highlight that many organizations are already collaborating on pilots to enable, test, and advance mCODE use. Several of these activities are being coordinated through the CodeX HL7 FHIR Accelerator,<sup>10</sup> including the ICAREdata<sup>™</sup> study, Integrated Trial Matching for Cancer Patients and Providers, Cancer Registry Reporting, Radiation Therapy Treatment Data for Cancer, and a Prior Authorization in Oncology use case.<sup>11</sup> A target outcome of the prior

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<sup>10</sup> Please see <https://confluence.hl7.org/display/COD/CodeX+Home>

<sup>11</sup> CodeX Use Cases: Prior Authorization in Oncology. Available at <https://confluence.hl7.org/display/COD/Prior+Authorization+in+Oncology>

authorization project is to provide a standard method to supplement the Da Vinci Coverage Requirements Discovery (CRD), Document Template Rules (DTR) and Prior Authorization Support (PAS) FHIR-based information exchange framework with cancer specific data as defined by mCODE, to enable prior authorization auto-approvals.

We encourage ONC to explore the use of mCODE as the agency considers how to incorporate certification criteria to advance electronic prior authorization through potential future rulemaking. Data elements that are critical to the care of patients with cancer must be a piece of the larger solution to ensure these patients get the timely care they need.

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We thank ONC for the opportunity to submit this response to the RFI. If you have any questions or need additional information, please contact Karen Hagerty ([karen.hagerty@asco.org](mailto:karen.hagerty@asco.org)).

Sincerely,



Howard A. Burris III, MD, FACP, FASCO  
Chair of the Board  
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