



March 25, 2022

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
Attention: RIN 0955-AA04
De-PArtment of Health and Human Services
330 C Street NQ
Washington, DC 20201

RE: Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria (the “e-PA RFI”)

Dear Dr. Tripathi:

On behalf of the Regulatory Relief Coalition, we are pleased to have the opportunity to respond to the e-PA RFI. The RRC is a group of national physician specialty organizations advocating for regulatory burden reduction in Medicare so that physicians can spend more time treating patients. We aim to ensure that prior authorization (PA) is not a barrier to timely access to care for the patients we serve.

We applaud ONC for focusing on the pressing need to move electronic Prior Authorization (e-PA) forward. It is clear from the e-PA RFI that ONC has spent considerable time and effort to frame the highly technical issues that must be resolved in order to implement e-PA processes as expeditiously as possible, and we appreciate the ONC’s efforts to address this critical issue.

I. Background

There is a pressing need for change in health plans’ PA policies and practices. According to the most recent AMA survey on this topic:

- ❖ For those patients who treatment requires prior authorization, **93 percent** of physicians report care delays.
- ❖ **82 percent** of physicians report that prior authorization can sometimes lead to a patient abandoning treatment.

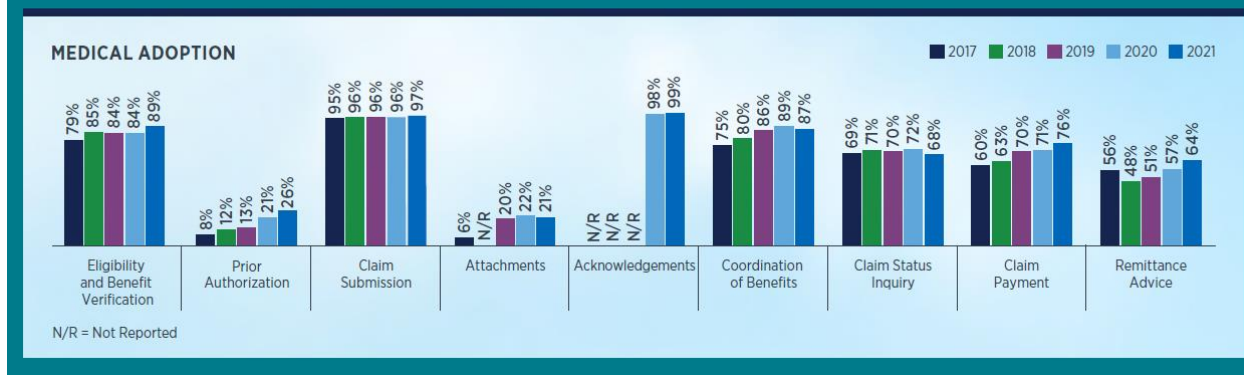
- ❖ **34 percent** of physicians report that prior authorization has led to a serious adverse event for their patient.
- ❖ **24 percent** of physicians report that prior authorization has led to a patient’s hospitalization.
- ❖ **18 percent** of physicians report that prior authorization has led to a life-threatening event or required intervention to prevent permanent impairment.
- ❖ **8 percent** of physicians report that prior authorization has led to a patient’s disability or permanent bodily damage.
- ❖ On average, practices complete **41 prior authorizations** per physicians per week.
- ❖ Physicians and key staff spend almost **two business days** each week completing prior authorization.
- ❖ **40 percent** of physicians have staff who work exclusively on prior authorization.

The cost of PA to the Nation’s healthcare system is significant, not only in terms of health care outcomes but also in dollars and cents. In fact, the cost per manual PA transaction (which constitute the plurality of e-PA requests) is about \$20 per transaction:

Average Cost and Savings Opportunity per Transaction by Mode, Medical, 2021 CAQH Index							
Transaction	Mode	Plan Cost	Provider Cost	Industry Cost	Plan Cost Savings Opportunity	Provider Cost Savings Opportunity	Industry Cost Savings Opportunity
Prior Authorization	Manual	\$ 3.54	\$ 10.95	\$ 14.49	\$ 3.47	\$ 7.52	\$ 10.99
	Partial	\$ 0.07	\$ 9.93	\$ 10.00	\$ 0.00	\$ 6.50	\$ 6.50
	Electronic	\$ 0.07	\$ 3.43	\$ 3.50			
Attachments	Manual	\$ 1.03	\$ 4.43	\$ 5.46	\$ 0.92	\$ 3.10	\$ 4.02
	Electronic	\$ 0.11	\$ 1.33	\$ 1.44			

According to the most recent CAQH Report (2021), the cost savings opportunity associated with fully electronic PA processes is \$437 million annually. Yet, adoption of fully electronic PA transactions falls considerably behind adoption of other electronic transactions tracked by the CAQH Index:

Medical Plan Adoption of Fully Electronic Administrative Transactions 2017-2021 CAQH Index



The inclusion of e-PA requirements in the ONC Health IT Certification Program (the “Certification Program”) has the potential to substantially increase the availability of technology that helps to redress these concerns.

II. General Comments

RRC supports efforts to better integrate PA into the clinical workflow through the incorporation of e-PA functionalities into Electronic Health Records (EHRs).¹ We believe that, to be maximally useful, e-PA functionalities should be designed for use at the point of care, should provide physicians and other providers with real-time information regarding the applicability of PA requirements to particular services as well as documentation requirements, and should facilitate the automatic pre-population of PA forms. The inclusion of e-PA functionalities in the Certification Program has the potential to substantially improve the efficiency of the PA process, and, most importantly, reduce delays in patient care and patient abandonment of medically necessary services.

At the same time, we caution that—if not done correctly-- automating the PA process has the potential to result in the further unnecessary and wasteful proliferation of PA requirements, and, over the short term, implementation of e-PA has the potential to increase, rather than decrease, providers’ administrative burdens. Over the past several years, PA requirements for physicians’ services and procedures have proliferated—apparently without regard to whether or not the service or procedure is overutilized-- and automating the PA process may further exacerbate the seemingly endless growth of payers’ PA lists. Automating PA, without more, is unlikely to

¹ While the suggestion has been made that ONC expand its oversight of e-PA to a broad range of IT systems utilized by physician practices (e.g. billing systems), we urge ONC to focus its efforts on the requirements that should be imposed on EHR systems. In this regard, the ONC’s approach to certification of PA functions must ensure that third party applications (“health IT modules”) can connect to EHRs via open, standards- based APIs to provide PA capabilities

achieve substantial patient benefit unless it is accompanied by reforms that ensure that PA is utilized only when there is some reason to believe that a service may be overutilized; that PA criteria reflect generally accepted clinical guidelines and standards; and that both PA criteria and health plan PA policies and practices PA are transparent to both providers and patients. If automating PA processes facilitates further additions to an ever-growing list of PA requirements and exacerbates existing variability in PA criteria, the time that health care providers will need to spend troubleshooting the process, responding to requests for additional information and pursuing appeals will increase, and delays in the provision of medically necessary patient care will continue. It is critical that CMS implement policy reforms of the PA process as a whole at the same time as ONC works on expediting the process and making it more efficient through e-PA.

We note that the CMS' 2020 e-PA Rule includes many of the provisions of the *Improving Seniors' Timely Access to Care Act* (H.R. 3173 and S. 3018), and we are hopeful that, during the upcoming rulemaking process, additional provisions will be added to the CMS e-PA Final Rule that further mirror the provisions of this legislation. This legislation is cosponsored by 255 House members and 16 Senators from both sides of the aisle. Among other things, this legislation requires that HHS establish an electronic prior authorization process and requires the agency to establish a list of items and services eligible for real-time decisions under an MA e-PA program.

By letter dated October 28, 2021, 28 Senators requested that CMS take administrative action to adopt the provisions of this legislation in designing ePA requirements to be imposed on Medicare Advantage Plans. The ONC's e-PA certification requirements should be designed to include functionalities that enable providers to take advantage of trust and verify frameworks (i.e. gold carding); and automatic authorization frameworks for services that are routinely approved, as contemplated by this legislation. The inclusion of these functionalities in provider EHR systems has the potential of encouraging health plans to adopt gold carding policies and automatic e-PA policies and ensure that the focus is on services and procedures that pose a real risk of overutilization.

III. Responses to Questions Posed in the e-PA RFI

The RFI includes questions on a variety of topics, which are addressed below:

- ***How should electronic prior authorization capabilities be addressed in the ONC Health IT Certification Program?***

RRC believes that the e-PA capabilities adopted in the Certification Program should be carefully designed to ensure that providers are in a position to take full advantage of PA changes made by payers in response to CMS regulations. It is our understanding that CMS is currently considering potential changes to the 2020 e-PA requirements for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, which were subsequently withdrawn. RRC

has urged (and will continue to urge) that these requirements also be extended to Medicare Advantage Plans. We are hopeful that revised requirements will be set forth by CMS in a Proposed Rule this year. The primary elements of the e-PA requirements that ONC should include in the Certification Program should be designed to be consistent with the requirements imposed on payers under the CMS e-PA Final Rule.

In this regard, we believe that it is critical for ONC and CMS to coordinate closely with respect to timing of issuance of final rules and applicable effective dates. IT companies are unlikely to invest in the development of e-PA functionalities for EHR systems until a CMS e-PA Final Rule is issued that outlines payer requirements, and we urge the ONC wait until the CMS Final Rule is published before finalizing e-PA Certification Program requirements. Conversely, in order to ensure that providers are in a position to take advantage of e-PA when the CMS payer mandates become effective, the effective date of the ePA Certification Program requirement should be at least six months in advance of the effective date of CMS' e-PA regulations for payers.

Both during and following the ONC and CMS rulemaking processes, ONC and CMS should continue to work hand in hand to ensure that payer requirements are implemented in tandem with ONC e-PA Certification Program requirements to facilitate coordination of payer and provider information systems. In this regard, we concur with the e-PA RFI Task Force 2022, which stated, in its *Report to the Health Information Technology Advisory Committee* (March 10, 2022) (“e-PA Task Force Report”):

Although the payer is technically regulated by CMS and not ONC, both sides need to be compatible to achieve integrated care delivery. There is excellent value in seeking certification to ensure interoperability. There must be consistency and reciprocity across the EHR and payer sides based upon the [Implementation Guidelines]. ...

See e-PA Task Force Report at 8.

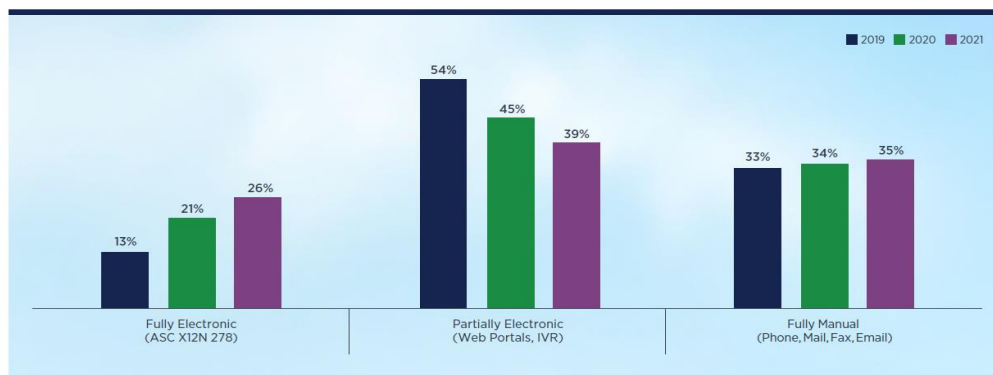
We also agree with the e-PA Task Force that ONC should work with the Da Vinci Project and key healthcare stakeholders (i.e., providers, developers, patients) to develop appropriate health IT certification criteria that incorporate key functional capabilities for PA at the site of care. However, we note that the Da Vinci Project “premium” members consist solely of health plans and vendors; that only three of the 19 Da Vinci Project members are Providers² and that all of the Provider members are large hospitals and health care systems that might be expected to have substantial resources beyond those available to individual physician practices. While the AMA is listed as a “Contributor,” the Da Vinci Project includes not a single physician organization member or any other physician practice representative. Under these circumstances, the RRC strongly urges ONC to establish a formalized mechanism for physician professional organizations to provide input into the process of developing e-PA requirements for adoption in the Certification Program. It is critical that the viewpoint of the physician community be incorporated into the process of establishing e-PA certification standards, in order to ensure that certified EHRs meet physicians’ needs and are scaled to accommodate physician practice resources.

² The other “provider” members of the Da Vinci Project are also payers (i.e. CVS and Kaiser Permanente).

In assessing how e-PA capabilities should be addressed in the ONC’s Health IT Certification Program, ONC should consider how to address rapidly changing technology. RRC believes that the ONC Certification Program should encourage the development and utilization of tools that use Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs) for the purposes of digitizing and automating PA within EHRs; however, it is also important to recognize that the development and adoption of these tools is likely to take years. The implementation of new tools like FHIR APIs are also associated with additional costs, training and resource use for physician practices that are already struggling with mandated uncompensated expenses. This should be taken into account in the adoption of new technology.

In the interim, the industry is moving forward with the tools that are available. Based on the 2021 CAQH Report, it appears that the HIPAA mandated Health Care Services Review Standard (ASC-X12N-278)(PA Standard) has doubled since 2019 and that over a quarter of PA requests currently utilize this standard:

**Medical Plan Adoption of Prior Authorization
2019-2021 CAQH Index**



As recognized in the CAQH Report for 2021, electronic processing of PA requests using the PA Standard saves providers 16 minutes per PA request and has the potential to save the system up to \$437 million annually. While a transition to FHIR-based systems is on the horizon, it is not yet here, and, in the interim, growing use of the PA Standard has the potential to substantially reduce the time and cost of ever-proliferating PA requirements. If the utilization of the PA Standard continues to grow at the present rate, its use may be commonplace by the time the Certification Program’s e-PA requirements become effective. Because the cost of engaging a clearinghouse to translate X12 into FHIR-enabled processes are costly and may be prohibitive for smaller and mid-size practices (and for smaller payers), we request that the any e-PA certification requirements mandate that FHIR-enabled processes should include functionality for translation to X12.

Finally, while it appears clear that many of the steps necessary to implement a fully electronic PA process will take some time, there is some “low lying fruit” that we urge ONC to adopt into the Certification Program immediately. For example, we urge the ONC to update the “e-prescribing” certification criterion in 45 CFR 170.315(b)(3) to change NCPDP SCRIPT

transactions related to prior authorization from “optional” to “mandatory,” to better support e-PA processes for drugs covered under a prescription benefit. This recommendation is consistent with the recommendation of e-PA Task Force Report.³

- **What implementation specifications should ONC consider for adoption in the Certification Program to support electronic prior authorization?**

It is our understanding that e-PA implementation specifications are at various stages of development. According to the e-PA Task Force Report, the Da Vinci Implementation Guidelines, which the e-PA Task Force characterizes as the “best option” for a scalable e-PA solution, are “not yet ready for implementation at scale.” This raises a number of issues and concerns.

First, we support a phased-in approach to the inclusion of e-PA requirements in the Certification Program. The e-PA Task Force’s “Functional Capabilities Spreadsheet” suggests that the most critical and time consuming task involved in the PA process—“Collect clinical and administrative documentation needed to complete prior authorization documentation (electronic forms or templates) from a health IT system”—is not yet available (except possibly for FHIR US Core data, which is not sufficiently detailed to be of much use in responding to payer demands for supporting clinical documentation for specific services). At the same time, we believe that there are some extremely useful functionalities that are sufficiently mature to be implemented quickly. For example, we believe that the technology is sufficiently developed for a payer to respond in real time to queries regarding whether or not prior authorization is necessary for a particular service, since such queries could be answered with a simple “yes/no” response. Likewise, we believe that payers could provide lists of the data/documents necessary to support a PA request in machine readable format and in real-time. The response deadline for payers’ to respond to basic queries about whether or not PA is required and what data/documents are needed should be short (measurable in seconds or minutes), and this functionality could be required as the first stage of phased-in e-PA requirements.

More generally, we encourage ONC to establish a staged process for implementing e-PA certification requirements, so that the process begins to improve as soon as practicable and refinements can be made along the way. Formalized physician organization representation in the process of developing e-PA certification standards would help the ONC to prioritize those functionalities that can be implemented quickly, with the greatest cost and time saving impact.

Second, we also wish to emphasize the need for e-PA electronic processes (including the Implementation Guidelines) to be tested thoroughly before adoption into the Certification Program. Of all HIPAA transactions, e-PA are the only ones that impact patients directly, and the need for thorough testing cannot be overemphasized. The practicability of e-PA should be tested in a broad range of provider settings, including small practice settings, where resources that can be dedicated to IT may be limited. We anticipate that the initial adoption and implementation of e-PA itself may increase costs in the short term, and for that reason, e-PA

³ See e-PA Task Force Report at 7.

testing should include collection of data on the cost of implementation in each practice setting, including training costs for non-physician and physician personnel; the costs of IT support; equipment upgrade, and other costs. This analysis should evaluate how automating PA reduces documentation burden and can be tied to reductions in the delays currently associated with manual and payers' proprietary web-based PA processes.

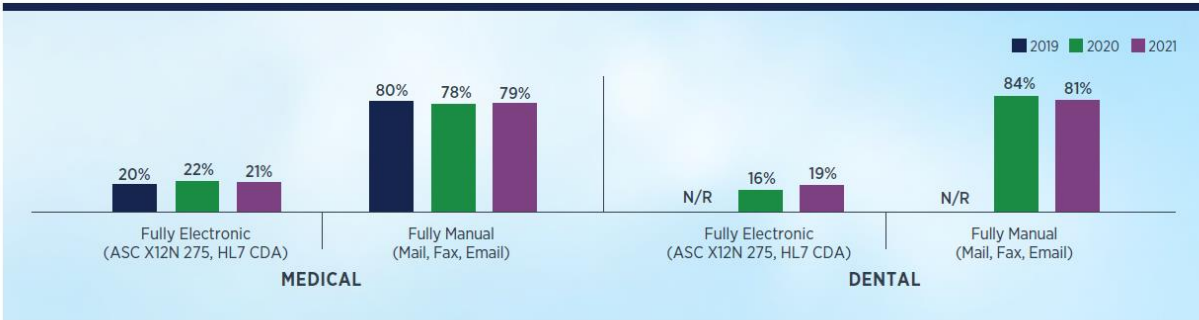
Third, in determining implementation specifications, ONC should carefully review the Da Vinci Implementation Guidelines to ensure that appropriate guardrails are placed on payer access to sensitive patient information that is not relevant to the PA process. We are concerned about the potential for allowing unprecedented access by payers to clinicians'/physicians'/providers' EHRs enabled by the Da Vinci Implementation Guidelines. If the Da VINCI IGs are adopted>

- We urge ONC and CMS to require adequate protections so that payers are only able to access EHR data relevant for a particular PA request and to ensure that physicians/providers have the opportunity to review any patient data before it is sent to the payer. EHR functionalities should support physician review, when desired, but it should not be required for each transaction
 - We strongly recommend that robust guardrails be imposed to ensure that payers are only accessing necessary protected health information when required for a prior authorization request and decision.
 - CRD/DTR technology should only be triggered when a physician initiates an order for a particular patient and for a particular item or service and when that item or services requires PA. Payers must be explicitly prohibited from “eavesdropping” or otherwise accessing EHR data for other use cases.
 - Finally, we urge CMS and ONC to limit/restrict payers' use of and ability to retain any EHR data or documentation obtained for PA.
- **How should the Certification Program support the use of health care attachments for prior authorization transactions?**

As indicated immediately above, it is the collection and submission of supporting documentation in response to iterative and repetitive demands of payers that is often one of the most cumbersome and frustrating aspect of the process for providers and that results in the most harmful delays in care for patients. For this reason, it is critical for any e-PA developed for adoption into the Certification Program include thoroughly tested functionalities that facilitate the identification and transmittal of Attachments or the identification and transmittal of EHR data in digital format.

At this stage, it appears that approximately 20-22% of Attachments required in conjunction with medical/surgical PA requests are submitted electronically using ASC X12N 275 or HL7 CDA:

**Medical Plan Adoption of Attachments
2019-2021 CAQH Index**



However, as the electronic submission of PA requests using the PA Standard continues to increase, it might be anticipated that the electronic submission of Attachments using the ASC X12N and HL7 CDA Standards also may increase. Since payer web-based systems may not be available for the submission of Attachments, approximately 80% are submitted manually, utilizing processes that are excruciatingly inefficient.

For these reasons, we urge the ONC to prioritize this aspect of the e-PA process and to put in place as soon as practicable a certification requirement that requires that all EHRs include a functionality that facilitates the electronic transmittal of Attachments to payers, whether based on the ASC X12N275, the HL7CDA, or some other standard. Progress in this area is critical to reduce the time and effort required for compliance with ever-expanding PA requirements imposed by payers.

What impact would support for electronic prior authorization within the Certification Program have on patients, providers, health IT developers, and payers?

While the RRC strongly supports the inclusion of e-PA requirements in the Certification Program, we believe that, without additional reforms outside the authority of ONC, the potential of digital technology to modernize and simplify PA will not be fully realized. Currently, the applicability of PA requirements and the documentation necessary to support PA requests are changed by payers frequently and without prior notice. PA requirements are imposed seemingly arbitrarily and without regard to whether or not a service has been shown to be overutilized and the entire process is entirely opaque. There is broad variability in the criteria used for the same service by different payers, and some of these criteria are viewed as proprietary by the payers involved. None of these problems can be solved simply by processing PE requests electronically. In fact, unless and until payers PA criteria are standardized, e-PA efficiencies are likely to be ephemeral.

For these reasons it is critical for CMS and ONC to continue to work hand in hand in addressing concerns related to PA. Through its authority to regulate Medicare Advantage Plans, Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, CMS has broad authority over health plans. We believe that CMS should use its authority for example, require health plans to standardize PA forms; establish uniform criteria for services and

procedures commonly subject to PA; identify the specific documentation or data elements necessary to support PA; identify services and procedures that are frequently approved or that are otherwise suitable for real time e-PA; and require that PA lists be transparent and updated no more frequently than annually. Such requirements would significantly simplify the task of designing workable e-PA requirements for adoption in the Certification Program.

We appreciate the opportunity to comment on this important RFI and look forward to working with you to ensure that e-PA can be incorporated efficiently and effectively into the workflow of physician practices.

Sincerely yours,

American Academy of Family Physicians
American Academy of Neurology
American Academy of Ophthalmology
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Radiology
American College of Surgeons
Association for Clinical Oncology
Congress of Neurological Surgeons
Medical Group Management Association
North American Spine Society
Society for Cardiovascular Angiography and Interventions