March 25, 2022

Dr. Micky Tripathi, M.D.
National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street, S.W.
Washington, D.C. 20201

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

Dear Dr.Tripathi:

Cohere Health, Inc. (Cohere) appreciates the opportunity to submit comments on the Office of the National Coordinator for Health IT (ONC)'s request for information (RFI) on electronic prior authorization standards, implementation specifications, and certification criteria that could be adopted with the ONC Health IT Certification Program.

Cohere is a patient-centric, digital health company committed to streamlining the prior authorization process for health insurers and physicians, with the ultimate aim of improving patient care and health outcomes. Launched in 2019, Cohere currently serves 5.5 million health plan members in all 50 states.

The Cohere platform is a digital prior authorization solution that leverages recent advancements in technology, machine learning, interoperability, and analytics to put patient clinical care at the center of prior authorization decisions by enabling a dramatically more efficient process by aligning utilization management with evidence-based clinical guidelines along longitudinal care paths. By reimagining the traditional, transactional approach to utilization management, Cohere enables greater collaboration between health plans,providers, and patients, driving improved quality and outcomes and reduced cost.

We are pleased to provide comments to ONC on standards for electronic prior authorization, implementation specifics, and certification criteria. We believe that transforming the prior authorization paradigm is a critical aspect of shifting the health care system to one that is value-based. Given the importance of data exchange and interoperability to the success of electronic prior authorization, we recognize ONC's important role in these efforts as it seeks to develop standards for electronic prior authorization programs and look forward to engaging with the agency on this work.

Our detailed comments follow.

In the following sections, we provide targeted feedback to ONC pursuant to specific questions it asked in its RFI. Overall, our hope is to help inform ONC's approach to developing standards for electronic prior authorization programs that facilitate seamless sharing of information across providers and between providers and payers; align with provider workflows and support the delivery of high quality, evidence-based care; and facilitate the transition to a value-based health care system.

Certified Health IT Functionality

I. Do the functional capabilities described above include all necessary functionality for certified Health IT Modules to successfully facilitate electronic prior authorization processes?

In our experience, even when all information required for the Health IT Modules is provided, there can still be discrepancies that prevent successful electronic prior authorization. These issues occur because payers need to interrogate the content of attachments to determine if there is sufficient

evidence to determine medical necessity. However, a problem often arises because providers do not understand, or have not provided sufficient clinical documentation in the attachments. This causes a burdensome process between the health plan and providers to collect the missing information, which drives delays in care. Additionally, problems sometimes occur when answers in questionnaires conflict with the information that a payer has, such as when a provider states in a questionnaire that a patient has certain surgical risk factors, but that is not corroborated by the clinical note, or where the provider does not state the surgical risk but evidence of the risk is present in the clinical note or in claims.

II. 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?

ONC proposes to include a FHIR Questionnaire resource for the DTR IG. We appreciate ONC's intention to include complete information but focusing on a more accurate set of functional capabilities would be a definite improvement to reduce burden and the risk of inaccurate or confusing information in the questionnaires. The questionnaires are typically filled out by non-clinical administrative staff to support interrogation of the clinical attachment, with varying degrees of clinical accuracy, which makes this information less useful for prior authorization. The ideal workflow to reduce burden would move beyond questionnaires and allow access to individual FHIR resources like Procedure or Medication with associated structured results and outcomes. This would allow a prior authorization vendor to review the relevant clinical information directly to make more efficient and accurate prior authorization decisions.

III. 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?

CMS and ONC allow payers and providers to request exceptions to using X12 for prior authorization if they use FHIR. Additionally, the Da Vinci project utilizes an exception to CMS's X12 requirement to show the ability of FHIR to improve efficiency and achieve administrative simplification in prior authorization. These policies as well as general industry movement towards FHIR show that the requirement to translate from FHIR into X12 is outdated. In our industry experience, FHIR is considered preferable to X12 because X12 only allows for minimal information transfer. In contrast, FHIR allows for more expressiveness and extensiveness in the information that is transferred which helps convey important clinical information about the patient and their history. Importantly, these data can be reused in other FHIR messages which lowers long term maintenance and development costs. Also, as new clinical data types become available FHIR can accommodate them without having to rebuild systems which again lowers long term costs and maintenance.

IV. How should HHS address alignment between standards adopted for HIPAA transactions and standards adopted under the Certification Program?

FHIR needs to be recognized as an acceptable standard for both the Certification Program and HIPAA transactions in order to align the standards and support electronic prior authorization. FHIR

can characterize a patient record in a way that is reusable and extensible when there are advances in health care which would promote alignment and interoperability.

V. *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.*

We recommend that coverage requirements and prior authorization support standards be separate from DTR to allow for different levels of automation in support standards. DTR should have a base level of acceptable functionality for certification, but encourage greater innovation around automation. The basic functionality is largely what happens today where unstructured questionnaires and responses are exchanged. Adding more structured messaging around what the question semantically means and what the response can be coded as would be preferable

Implementation Specifications for Prior Authorization

VI. *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?*

We support adoption of all three IGs as part of certification criteria for health IT. Cohere has successfully implemented both PAS and DTR which are utilized on our platform hundreds of times each day in partnership with another prior authorization organization.

VII. *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?*

We appreciate that ONC is concerned about the burden of proposing certification criteria and adopting implementation standards at the same time, but we do recommend that ONC adopt the implementation specifications as quickly as possible. Without the implementation specifications, there is a risk that early work done by developers and the healthcare community to incorporate the FHIR Release 4 base standard will have to be refactored or restarted to meet the IG guidelines. If it is infeasible to quickly adopt the implementation specifications following the implementation of FHIR certification criteria, we recommend that ONC issue guidance about what could be expected in the IG guidelines to inform early work.

VIII. *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?*

The Da Vinci Project currently supports traditional attestation workflows where non-clinical staff answer the questionnaires on behalf of the clinician. To improve workflow and reduce burden, legal requirements should be used to encourage Health IT developers to exercise innovative approaches that do not perpetuate the suboptimal questionnaire process.

Instead of utilizing questionnaires, prior authorization administrators should interrogate the clinical documentation and only ask questions when the information cannot be automatically obtained. To achieve this, the government should focus on requiring that structured clinical outputs from the electronic medical record (EMR) be made available and that health plans be required to consume them. Using legal requirements to shift prior authorization processes to ones that limit questions to

those that can be answered with automatically available data would make electronic prior authorization more efficient and avoid the issues with involving non-clinical staff in clinical questions.

IX. *Are there simplified approaches to the workflows described in the Da Vinci IGs that ONC should consider as alternative approaches to support electronic prior authorization?*

Prior authorization workflows are typically handled by administrative staff, but the process could be simplified by directly connecting clinicians to prior authorization and using automated information when possible. We recommend that ONC prioritize CDS hooks that have a higher likelihood of engaging with providers. However, we recognize that would impose a significant burden and that this IG may not be detailed enough to allow the full automation of electronic prior authorization. ONC should consider how to develop the CDA attachment IG or others that prioritize engaging with providers and allow automation of electronic prior authorization.

We also recommend that ONC prioritize CDS hooks that have a higher likelihood of engaging with providers like the order-select hook. The order-select hook is fired when a physician selects one or more orders for a patient. Then a message would be sent to the health plan so the plan could invoke the CRD flow, and if prior authorization is required the PAS flow could be invoked followed by the DTR flow. This would be a more automatic process that is more directly related to the decisions of the clinician.

X. *Are there new IGs which need to be developed in order to integrate with other workflows relevant to prior authorization?*

As a health IT developer, we would appreciate IGs that cover CDS hooks to integrate with more automated workflows. A CDS hook is an automated push mechanism from the EMR to the health plan. This is helpful because the process is invoked by the provider or EMR and the health plan does not need to repeatedly poll the EMR. IGs for CDS hooks would promote automation and more efficient prior authorization workflows.

Healthcare Attachment Standards

I. *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?*

While it would be helpful to have upstream entities communicate with structured documents, Cohere believes this would ultimately impose a significant burden for requesting providers and other downstream providers such as radiologists. These requirements would pose a significant burden on providers to adopt and implement these standards, especially considering many of these entities (e.g., imaging labs and primary care providers) have varying degrees of IT capabilities. While we recognize the definitive need for more structured data, it is unclear how to accomplish this ubiquitously given the current variance in the range of data sources used today. In addition, CDA Attachments include long strings of text embedded within a structured message which do not enable structured data exchange by themselves.

Our belief instead is that health IT developers can be innovative here to adapt these unstructured documents into structured results. However, if this IG were to be adopted, we recommend that greater attention should be paid to the required metadata rather than only having the default being long strings of unstructured content.

II. *Would the use of FHIR Documents, if adopted as part of a certification criterion, support more effective exchange of healthcare attachments?*

We support the use of FHIR Documents to support more effective exchange of healthcare attachments. Specifically, we believe this would help at a high level to determine if the correct documents are being exchanged. However, we note that using FHIR Documents on its own does not enable automated decision making, and that these documents are more focused on meta data rather than the content of the document itself. Other FHIR resources such as DiagnosticReport, Imaging Study and Observation can expose more structured fields if implemented fully which would enable greater levels of automation.

III. *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?*

While we believe this is likely the necessary approach, we are concerned that this would involve a significant dependency on provider adoption and that this would complicate the timeline for implementing use of the CDA Attachments IG or FHIR Documents. If providers are able to adopt the standards at scale, we could have solutions available within months.

IV. *Healthcare attachments are used for a wide range of operations and administrative workflows beyond prior authorization. Are either of the standards discussed above commonly used in other administrative or operations transactions? Would there be a burden or benefit to using either, or both, standards in light of other administrative or operations workflows? Are there additional standards or implementation specifications ONC should consider that are in common use for healthcare attachments used in other administrative or operations workflows?*

In our experience, neither of the aforementioned standards are commonly adopted at the present moment. Instead, the *de facto* standard for exchanging attachments using the prior authorization process is via a PDF that is encoded and delivered to the payer. In addition, a requesting provider often has an assembly of reports from other providers which are not structured, which limits the ability for providers to exchange data. However, if the CDA Attachments were ubiquitously mandated for use in an inter-provider exchange, then more structured information would be available to send to payers as part of the prior authorization process. The FHIR standard beyond Attachments has broad applicability, particularly in the more administrative workflows where details of clinical information isn't entirely necessary.

Impact on Patients

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

Cohere applauds ONC's focus on ensuring possible changes result in meaningful improvements for patients. We believe changes to the Certification Program to better support prior authorization will lead to more timely decisions and greater adherence to evidence based clinical guidelines. This is critically important as timely decisions and reliance on evidenced based clinical guidelines are widely regarded as key drivers of high-quality care. When using the Cohere electronic prior authorization platform for example, on average, patients have access 70 percent faster, delays are reduced by 80 percent, and complications are 18 percent lower.

II. *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?*

The key to achieving out-of-pocket cost reductions is informing the patient and giving them options at the time of the prior authorization. If CDS hooks enable health plans to share out of pocket costs to the provider at the time of the decision and patient standards can enable communication of the prior authorization and alternatives to patients, Cohere believes that out of pocket costs can be lowered.

Over the long term, cost savings may also be realized thanks to the delivery of higher-quality care as a result of timelier care decisions and increased reliance on evidenced based clinical guidelines. High-quality care leads to improved outcomes which puts less strain on the health care system and reduces costs for patients.

Electronic prior authorization can also significantly reduce the time it takes patients to receive services, which is important for patient treatment plan adherence as well as reducing avoidable complications. Cohere sees 80% reduction in patient care delays when a physician uses Cohere's electronic prior authorization portal.

III. *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?*

Notification application programming interfaces (APIs) and applications designed specifically for patients could be added to the Certification Program to support patient participation in the prior authorization process. Patients are a key constituent and could use APIs and applications to take a more active role in managing their own care. The transparency that APIs and applications could provide would give patients better insight into any delays in their care on the part of the Payer or Provider, for example. Patients may also be able to unlock key missing information that is holding up prior authorization decisions, resulting in more timely care.

Impact on Providers

IV. *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?*

Cohere has observed substantial gains in efficiency among providers switching from analog forms of prior authorization to electronic prior authorization. The availability of these capabilities removes the need for time-consuming information retrieval and reliance on antiquated technology like the fax machine and reduces administrative expense. Further, decision making is expedited and is much more transparent to providers, allowing them to more quickly and easily address any issues with their requests. When using the Cohere electronic prior authorization platform for example, on average, providers report spending 38

percent less time on authorizations, a 63 percent lower denial rate, and a revenue cycle that is 4 days faster.[1]

V. *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?*

Cohere recognizes the key role providers play in interoperability and is concerned that analog channels will persist if the use of new technology capabilities are not incentivized in some way. One way to incentivize providers is to reward the best performers (high quality physicians) through greenlighting so they can enjoy reduced administrative burden and even faster authorizations, when clinically appropriate. Once providers have implemented these new capabilities and they are integrated into the workflow, Cohere has observed that providers consistently use electronic prior-authorization. For example, among providers with access to Cohere's musculoskeletal platform for electronic prior authorization in Medicare Advantage, there was 94 percent adoption. Further, the average time to decision was less than 9 hours and providers reported that delays in care due to prior authorization decreased by 80 percent, adding up to a reduction in provider administrative burden by nearly 40 percent.

A fully interoperable health care system is necessary for electronic prior authorization to be successful. ONC can help reduce the burden of adoption on providers by requiring electronic medical record (EMR) vendors to support the standards and instituting penalties for impeding adoption. Providers also may need support to ensure they are able to share data with specific institutions for specific purposes without adding overhead to their governance processes. A list of "trusted brokers" identified and maintained by ONC could be a useful tool to help reduce the burden of vetting new information technology partners. The Centers for Medicare & Medicaid Services (CMS) offer a similar resource to providers to help aid in the selection of a Clinical Decision Support Mechanism (CDSM).[2]

Prior authorization processes are currently determined by individual health plans and their third-party benefits management vendors. Cohere's electronic prior authorization platform integrates condition-based, high-value care pathways to support clinical decision making that relies on best practices identified by professional societies such as the American College of Cardiology (ACC) and American Academy of Orthopedic Surgeons (AAOS). To ensure implementation improves clinical workflows, ONC could require clinical standards of care be reflected in electronic prior authorization tools. Cohere also uses principles of behavioral economics to increase rates of first-time approvals and align care with clinical best practices by recommending adjustments to electronic prior authorization requests as they are entered into the system. ONC could require similar functionality to encourage improvements to clinical workflow in real time.

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[1] https://coherehealth.com/thought-leadership/case-study-humana/

[2] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM

Impact on Developers

I. *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?*

We estimate it would take approximately six months for health IT developers to support the Da Vinci IGs and bring services to production. Costs will vary based on the capabilities and readiness of the developers, which makes it more difficult to provide a definitive cost estimate.

II. *What would be the burden on health IT developers for prior authorization certification criteria referencing the base FHIR standard if there were not yet specific IGs adopted as well? How would potentially moving to criteria with use case specific IGs over time impact development burden? Would such a staged approach be detrimental or beneficial to the long-term development timeline and burden for health IT developers seeking to support electronic prior authorization?*

It is Cohere's view that the IGs have reached a point of stability and that they are a useful guide for industry. While not yet adopted, they do lay out a very sensible and developer-friendly path. If ONC were to move away from this approach, it would be very disruptive to early adopters who have already invested in this standard. Severe deviation from the IGs would therefore cause significant burden for early adopters. We recommend ONC encourage as much fidelity to these IGs as possible.

Payer Implementation

III. *Should ONC consider payer workflows in the development of certification criteria to support the potential use of certified Health IT Modules by healthcare payers?*

We appreciate that ONC is working to ensure that the Health IT Modules are feasible for payers to implement, but we recommend that ONC does not consider specific payer workflows in the development of certification criteria to avoid stymieing innovation. If ONC develops certification criteria based on specific payer workflows, the criteria could "lock in" suboptimal standards for workflows rather than allowing payers to continuously innovate on their prior authorization decision process.

We thank the agency for the opportunity to provide comment on how it may potentially act in effectuating new standards for electronic prior authorization programs. We are committed to supporting a policy environment that is favorable to an interoperable health system – a crucial component to the fruition of a streamlined prior authorization paradigm and, ultimately, higher quality care and improved patient outcomes. We are happy to provide any further support to ONC based on the feedback we have provided. Please reach out to Alina Czekai, Vice President of Strategic Partnerships by phone at 484-941-4465 or by email at alina.czekai@coherehealth.com.

Sincerely,

Siva Namasivayam

Siva Namasivayam
Chief Executive Officer
Cohere Health