March 13, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule CMS-0057-P

Dear Administrator Brooks-LaSure,

Cohere Health, Inc. (Cohere) appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services (CMS)'s Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule.

Cohere is a patient-centric, digital health company committed to streamlining the prior authorization (PA) process for health insurers and physicians, with the ultimate aim of improving patient care and health outcomes. Launched in 2019, Cohere currently serves 15 million health plan members in all 50 states.

The Cohere platform is a digital prior authorization solution that leverages recent advancements in technology, including AI/machine learning, interoperability, and analytics to put patient clinical care at the center of prior authorization decisions. Our offerings enable a dramatically more efficient process by using PA as a trigger to align health plans, their providers, and patients on evidence-based, longitudinal care paths - instead of treating PA as simply an individual transaction. 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 administrative costs.

We are pleased to provide comments to CMS on standards for electronic prior authorization and interoperability, implementation specifics, and turnaround times. We believe that transforming the prior authorization paradigm is a critical aspect of shifting the healthcare system to one that is value-based. Given the importance of data exchange, interoperability, and standards to the success of electronic prior authorization, we recognize CMS'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 CMS pursuant to specific topics outlined in the proposed rule. Overall, our hope is to help inform CMS's approach to developing standards for electronic prior authorization programs that facilitate seamless sharing of information across providers and between providers and health plans; align with provider workflows and support the delivery of high-quality, evidence-based care; and facilitate the transition to a value-based healthcare system.

1. Patient Access Application Programming Interface (API)

CMS proposes to require impacted health plans to report Patient Access API metrics to CMS on an annual basis. Cohere believes that notification APIs and applications designed specifically for patients would 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 would give patients better insight into any delays in their care on the part of the health plan or provider, for example. Patients may also be able to unlock key missing information that is delaying prior authorization decisions, resulting in more timely care and improved clinical outcomes.

2. Provider Access API

CMS believes it would be valuable for providers to have access to the same data available through the Patient Access API through a FHIR API, citing research that patients achieve better outcomes when their record is more complete and there is more data available to the provider at the point of care. CMS proposes to require that impacted health plans implement and maintain a Provider Access API to enable the information of current patients to be exchanged from health plans to providers that are in that plan's network, at the provider's request.

Cohere is supportive of CMS's proposal to require that impacted health plans implement and maintain a Provider Access API. A Provider Access API will not only reduce burden on the physician, but It can also reduce the burden on patients to recall information regarding prior care. Cohere believes that a fully interoperable healthcare system is necessary for electronic prior authorization to be successful and Cohere believes that it is imperative that FHIR is recognized as an acceptable standard 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.

Additionally, CMS can help ease the transparency with 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 certain institutions for specific purposes without adding overhead to their governance processes. A list of "trusted brokers" identified and maintained by CMS is a useful tool to help reduce the burden of vetting new information technology partners.

3. Payer-to-Payer Data Exchange on FHIR

The 2020 Patient Access final rule required payer-to-payer data exchange, effective January 1, 2022 for MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs. This rule required that affected health plans must maintain a process for the electronic exchange of the data classes and elements. Although the final rule did not specify an API standard, CMS encouraged health plans to consider using a FHIR API and signaled it could be a future requirement. Since the introduction of the 2020 rule, health plans have expressed concerns about the lack of technical specifications for the payer-to-payer data exchange and believe that it created implementation challenges. CMS attempted to address this in the December 2020 proposed rule, which would have required use of a FHIR API. CMS is withdrawing that proposed rule and, for purposes of the payer-to-payer data exchange, proposes rescinding the applicable portions of the May 2020 final rule.

The 2022 proposed rule again proposes requirements on impacted health plans to implement and maintain a payer-to-payer data exchange using a FHIR API and a patient opt-in policy. However, the approach to standards is different than in the December 2020 proposed rule. CMS notes that each health plan would only be responsible for its own side of a transaction. For example, if an impacted health plan is required to request patient data from another health plan that is not impacted, the impacted health plan must make that request regardless of the other health plan's status. CMS is hopeful non-impacted health plans will

implement the Payer-to-Payer API.

We appreciate that CMS is concerned about the burden of technical specifications requirements, but we do recommend that CMS and ONC specify, as opposed to recommend, API standards. 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 healthcare, which would promote alignment and interoperability.

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 Implementation Guide (IG) guidelines. If it is infeasible to quickly adopt the implementation specifications following the implementation of FHIR certification criteria, we recommend that CMS and ONC issue guidance about what could be expected in the IG guidelines to inform early work.

Cohere believes that the IGs have reached a point of stability and that they are a useful guide for the industry. While not yet adopted, they do lay out a very sensible and developer-friendly path. If CMS and 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 a significant burden for early adopters. We recommend CMS encourage as much fidelity to these IGs as possible.

4. Improving Prior Authorization Processes

A. Prior Authorization Requirements, Documentation and Decision (PARDD) API

CMS is proposing to require impacted health plans to build and maintain a FHIR API that would automate the process for providers to determine whether a prior authorization is required, identify prior authorization information and documentation requirements, as well as facilitate the exchange of prior authorization requests and decisions from their electronic health records (EHRs) or practice management system. CMS notes that under HIPAA, covered entities are required to use the currently adopted standard for prior authorization transactions, which is the X12 278 version 5010. This proposed rule does not propose to modify the HIPAA rules in any way, nor would they hinder the use of that standard.

Cohere is supportive of the agency's proposal to require impacted health plans to build and maintain a PARDD API. Cohere's core solution is focused on automating the process for providers to determine whether a prior authorization is required, identify prior authorization information and documentation requirements, as well as facilitate the exchange of prior authorization requests and decisions from their EMR or practice management system.

B. Denial Reason

CMS is proposing to require impacted health plans to include a specific reason when they deny a prior authorization request, regardless of the method used to send the prior authorization decision, to both facilitate better communication and understanding between the provider and health plan and, if necessary, a successful resubmission of the prior authorization request.

Cohere is supportive of CMS's proposal to require impacted health plans to include specific denial reasons. This type of transparency is important so that patients and their caregivers can be involved in the prior authorization process and understand their healthcare journey. Generally, Cohere is supportive of increased transparency around authorization requirements. The Cohere platform delivers a specific reason for a prior authorization denial and we publish our decision and care path guidelines for users.

C. Prior Authorization Timeframes

CMS is proposing to require impacted health plans to send prior authorization decisions within 72 hours for expedited (i.e., urgent) requests and seven calendar days for standard (i.e., non-urgent) requests. CMS is, however, also seeking comment on alternative time frames with shorter turnaround times, for example, 48 hours for expedited requests and five calendar days for standard requests.

Cohere is supportive of CMS's proposal to require faster turnaround times, however, we encourage the agency to focus on automation and consider placing requirements on just prior authorization requests that can be automatically adjudicated. Cohere believes at least 60 - 70% of authorization requests can be instantaneously adjudicated by technology. This will not only allow clinicians and manual review to focus on more complex cases, but it will allow patients to receive faster access to care, which drives adherence to their care protocols.

CMS also sought stakeholder feedback on "gold carding" or similar programs to relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance. Cohere believes that, while well-intended, programs like gold carding have the potential to increase PA complexity, effectively hindering one of a health plan's most important tools for impacting value and quality. This is significant as it will drive higher costs for the system which will ultimately impact patients in the form of higher premiums.

Indiscriminate approvals prompted by gold carding will likely have a negative impact on patients over time, as forcing health plans to allow medically unnecessary services may require health plans to use the claims process to deny inappropriate utilization after services have been rendered. This has the capacity to not only cause distress for patients and providers, but it may ultimately drive up healthcare costs and lead to higher premiums. Additionally, because the current gold carding programs (e.g., Texas regulations) apply only to specific types of health benefit plans, providers will be confused over whether gold carding applies for a specific patient's insurance product, making it difficult to administer the rules. According to a November 2022 industry-wide study conducted by America's Health Insurance Plans (AHIP), 75 percent of surveyed health plans that reported a discontinuation of gold carding reported that they stopped the program due to administrative difficulty associated with implementation.

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 "green lighting", as opposed to gold carding, 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.

D. Prior Authorization Metrics

CMS is proposing to require impacted health plans to publicly report certain prior authorization metrics by posting them directly on the plan's website or via publicly accessible hyperlink(s) on an annual basis. Generally, Cohere is supportive of increasing transparency in the delivery system and around processes like prior authorization and requirements. Today, Cohere facilitates transparency with health plans and network providers by annually publishing specified prior authorization on a quarterly basis.

Currently, some prior authorization technology vendors prohibit other vendors from embedding their licensed clinical criteria used in PA determinations. Because there are only two vendors who provide this content to the vast majority of health plans, this refusal is monopolistic and creates an unfair advantage in the market. Most importantly, however, refusal of these vendors to comply limits health plan and provider choices in how they will comply with CMS regulations. We urge the agency to consider this unforeseen consequence when considering pushback against transparency around prior authorization metrics.

5. Interoperability Standards for APIs

CMS proposes modifications to the standards for APIs at 45 CFR 170.215 that apply to previously finalized API requirements. It also proposes changes to those standards tailored to each new set of API requirements proposed in this rule. The proposed language changes specify the use of each standard at 45 CFR 170.215 that would apply to a given set of API requirements at the sections of the regulations identified in Tables 8 and 9 in the proposed rule. Table 10 summarizes the standards applicable for each set of API requirements.

With respect to IGs to support API requirements proposed in the rule, CMS had proposed in the December 2020 CMS Interoperability proposed rule requiring the use of FHIR IGs, including the CARIN IG for Blue Button®, HL7® FHIR® Da Vinci PDex IG, HL7® FHIR® Da Vinci PDex U.S. Drug Formulary IG, HL7® FHIR® Da Vinci PDex Plan Net IG, Da Vinci Coverage Requirements Discovery (CRD) IG, Documentation Templates and Rules (DTR) IG, and Prior Authorization Support (PAS) IG for this purpose. The December 2020 CMS Interoperability proposed rule has been withdrawn and CMS declines to require the use of those standards. At this time, it only recommends their use, while acknowledging that it could limit interoperability.

Cohere supports the adoption and mandate of the IGs to support API requirements.These IGs are extremely important to set the parameters for interoperability. Without standards that are widely accepted across the industry, it will perpetuate the proprietary exchange of information, which will stifle innovation and interoperability.

Cohere has successfully implemented both PAS and DTR which are utilized in our platform hundreds of times each day in partnership with another prior authorization organization. As previously stated, we appreciate that CMS is concerned about the burden of proposing certification criteria and adopting

implementation standards at the same time, but we recommend that CMS adopt and require implementation specifications as quickly as possible. Without the implementation specifications, there is a risk that early work done by developers and the healthcare community will have to be refactored or restarted to meet the IG guidelines. If it is infeasible to quickly adopt the specifications following the implementation of FHIR certification criteria, we recommend that CMS issue guidance about what could be expected in the IG guidelines to inform early work.

We appreciate CMS's intention to include complete information but focusing on a more accurate set of functional capabilities would be a definite improvement to reduce the burden and risk of inaccurate or confusing information in the questionnaires. The questionnaires are typically filled out by non-clinical administrative staff to support the 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 the 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.

Finally, Cohere also strongly encourages CMS to support policies that end information-blocking practices of EMR companies which will promote interoperability. With these policies in place, it will be much more feasible to carry out the agencies' initiatives around healthcare technology and healthcare innovation in the private sector will flourish.

We thank the agency for the opportunity to provide comments 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 CMS based on the provided feedback. 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