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March 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

Haystack Project appreciates the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS') notice of proposed rulemaking on Advancing Interoperability and Improving Prior Authorization Processes. We appreciate CMS' dedication to ensuring patients receive timely access to care and have real-time access to their health records.

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease advocacy organizations to highlight and address systemic access barriers to the therapies they desperately need. Our core mission is to evolve health care payment and delivery systems, spurring innovation and quality in care toward effective, accessible treatment options for Americans living with rare or ultra-rare conditions. Haystack Project is committed to educating policymakers and other stakeholders about the unique circumstances of extremely rare conditions with respect to product development, commercialization, and fair access to care.

Haystack Project's rare disease communities struggle to navigate health system challenges in disease states where unmet need is high, and treatment delays and inadequacies can be catastrophic. Individually, these access challenges can present inconveniences, frustration, and delays in receiving care. Cumulatively, they can present an overwhelming burden for patients and their families. It is, therefore, imperative that beneficiaries have all relevant tools and information available as they seek out effective, efficient care.

Our comments offer insights and recommendations from Haystack Project's over-130 ultra-rare disease patient advocacy organization members so that CMS can continue to build upon its efforts to ensure that healthcare coverage and benefits confer equally to individuals regardless of their race, financial resources, health care needs, or the rarity of their health condition(s).

Haystack Project Urges Inclusion of Drugs in Prior Authorization Rule Scope

CMS' proposal states that because the processes and standards for prior authorization applicable to drugs differ from other items and services, the agency will not apply these improvements to prior authorization requests associated with drugs. Haystack Project strongly urges CMS to include both "medical" and "prescription" drugs.

Prescription drug coverage and access is critically important to rare disease patients. Since 90-95% of rare disease patients have no FDA approved treatment and must rely on off-label use of therapies approved for other conditions, they and their providers consistently face a labyrinth of claim denials, prior authorization requirements, reconsiderations, and appeals to access the care they need. The American Medical Association cites physician surveys indicating almost 1 in 5 prescriptions require prior authorization – and that ratio is almost certainly significantly higher for rare disease patients.

Rare disease patients and their providers find prior authorization particularly onerous when it is connected with utilization management strategies that fail to consider the nature of the patient's condition, the limited therapeutic options, or the urgency of the patient's need, including:

- **Step therapy protocols.** Step therapy is a frequently encountered utilization management strategy within commercial and Medicaid plans that was recently adopted by MA plans. Patients must "step" through older, less costly treatments before allowing access to newer, often more innovative or targeted, and inevitably more expensive options. Haystack Project strongly believes this utilization management tool is inappropriate for the highly complex needs of patients with extremely rare conditions for whom step therapy protocols may require failure on a treatment that is not useful (or may even be harmful) for their specific condition.
- **NDC "blocks" and "lock-outs"** – It is relatively common for plans to systematically block coverage of newly approved drugs for 6-12 months or longer under the rationale that formulary inclusion requires pharmacy and therapeutics committee review. These blocks apply to patients newly seeking treatment as well as to those who have benefited from the treatment through clinical trial participation, open label extensions, and expanded access programs. Haystack recognizes that the mechanism has utility and may be a reasonable approach for payers seeking to manage multiple treatment options for more common conditions. However, there is little chance of harm to patients. In rare conditions, there is no useful purpose for delaying access to what may be the only on-label treatment under the guise of needing to "review" whether it is medically necessary and should be covered.

Separately, prior authorization requirements for advanced diagnostic testing and surgical interventions frequently specify that the patient has received and/or failed to respond to medical treatments, including prescribed drugs. Payer claims processing systems, including prior authorization processes, should capture information on the full set of medical services and treatments, including prescription drugs and enable patients to easily understand where they are in the process of having their care approved. We urge CMS to include prior authorizations and coverage of prescription drugs in this rule.

Haystack Project Urges CMS to Develop a PA Proposal for Medicare Fee for Service (FFS)

Since this proposed rule generally does not apply to Medicare fee-for-service, Haystack Project strongly encourages CMS to implement additional policies for Medicare FFS patients. Medicare Administrative Contractors (MACs) can be just as burdensome to work with as private payers. Due to the nature of the National Coverage Determination/Local Coverage Determination coverage system, policies can vary between MACs, and providers have trouble obtaining transparent coverage and prior authorization guidelines. Accordingly, more oversight of the prior authorization process in Medicare FFS is warranted.

Haystack Project Supports CMS' Proposal to Add Prior Authorization Information to the Patient Access Application Programming Interface (API)

Haystack Project supports adding prior authorization information to the categories of data required to be made available to patients through the Patient Access API. Making prior authorization requests and decisions for which the payer has data (whether the decision is still pending, active, denied, expired, or is in another status) available to patients no later than 1 business day after the payer receives the request or another type of status change (and remain available for as long as the authorization is active and at least 1 year after the last status change) is important. Patients are often left in the dark on the status of the prior authorization requests and information exchanges between the plan and the provider. This results in considerable uncertainty, stress, and confusion for patients awaiting needed care. Additionally, patients may be able to identify and correct errors or supply additional information that could speed up the process and reduce inappropriate denials. Most importantly, this proposal could empower patients with the information they need to hold payers accountable. Once again, this should be extended to drugs.

Haystack Project Support CMS' Proposal to Create a Data Exchange Between Plans and Providers (Provider Access API)

Requiring plans to create and maintain a similar data exchange with providers is also an important step forward. The Fast Healthcare Interoperability Resources (FHIR) API envisioned in CMS' proposal will, as the agency notes, be valuable for providers to request patient care data (except for provider remittances and enrollee cost-sharing information) through a FHIR API as it would provide clinicians with important information on care received from other network providers. CMS's proposal includes a requirement that payers allow patients to opt out of the Provider Access API. CMS is considering, but is not at this time imposing, a requirement for patient data sharing with out-of-network providers.

Haystack Project notes that most patients rely on their providers to make recommendations for care, submit and monitor prior authorizations, and ensure timely access to prescribed and recommended interventions. Provider access to data is, therefore, critical. **We strongly encourage the agency to move quickly to determine how out-of-network providers can gain access to this information.** Health care for individuals with rare and ultra-rare conditions can be relatively high-cost and often requires highly specialized clinicians to deliver quality care. Patients with rare diseases must frequently seek out-of-network providers in order to obtain quality treatment. In addition, we expect that the unduly long patient journey from symptom onset to diagnosis could be shortened if all providers have access to the same information.

Haystack Project Supports Efforts to Improve Prior Authorization Processes *Prior Authorization Requirements, Documentation and Decision (PARDD) API*

Finally, CMS proposes steps to address some of the systemic issues with prior authorization generally. Specifically, CMS proposes requiring payers to:

- implement and maintain an API to support and streamline the prior authorization process; respond to prior authorization requests within certain timeframes;
- provide a clear reason for prior authorization denials; and,
- publicly report on prior authorization approvals, denials, and appeals;

The PARDD API would streamline the prior authorization process for the provider or office staff by automating certain tasks, thereby mitigating some of the obstacles of the existing prior authorization process. The API would allow a provider to query the payer's system to determine whether a prior authorization was required for certain items and services and identify documentation requirements. It would also automate the compilation of necessary data for populating the HIPAA-compliant prior authorization transaction and enable payers to provide the status of the prior authorization request, including whether the request has been approved or denied.

Providers struggling to efficiently and effectively treat their patients spend countless hours wrestling with the myriad requirements, processes and procedures payers implement – hours that would be better spent with patients. Especially in very rare diseases where there are only a few experts, this wasted time means they see

fewer patients and handle fewer requests for consults with their colleagues who may never have seen a patient with that condition. Ultimately, these processes not only contribute to significant waste in terms of provider effort, but also delay and can even prevent medically necessary care.

Haystack Urges CMS to Provide Additional Information on What Constitutes a Denial (Denial Reason Proposal)

CMS proposes requiring payers to transmit a reason for denial so that the provider would know what steps to take next— whether to request a different service for the patient, to submit additional information, or to appeal the decision.

Haystack supports this provision and urges CMS to provide additional detail in the final rule on what constitutes a denial. For instance, we know that many payers limit the types of requests a provider may make. For example, a prior authorization request may only allow a provider to request the service be approved but not allow the provider to include information on duration, frequency or dosage. This is particularly true for therapies requiring multiple sessions or visits over an episode of care. Insufficient granularity on both the request and its approval leads to uncertainty and inappropriate lapses in care. For example, the payer may approve an inadequate frequency or duration of services. Because the payer decision is deemed an approval, the patient and provider do not have automatic appeal rights. Providers must repeatedly resubmit prior authorization requests for the same services. Some payers do allow providers to include “dosage” information but their approval of a lower dose, frequency, or duration is handled internally as an approval without appeal rights.

We encourage CMS to clarify that payers must allow providers to request specific amounts and frequencies of services and that any approval of a reduced set of services is subject to appeal. Patients and their treating clinicians should be able to appeal any payer decision diverging from their providers’ clinical judgement.

Haystack Project Urges CMS to Impose Consequences on Payers Who Do Not Meet Proposed Prior Authorization Time Frames

CMS proposes that plans subject to this rulemaking must provide notice of prior authorization decisions as quickly as a patient’s health condition requires. For “standard” requests, CMS proposes no later than 7 calendar days. The agency proposes Medicaid FFS and CHIP FFS programs must provide similar notice within 72 hours for expedited requests unless state law provides for a shorter time frame. If a payer fails to meet these timelines, providers should contact the payer to obtain the status of the request and determine if supporting documentation is needed to complete processing of the authorization or if there are other reasons for the delay in a decision.

Haystack Project supports’ CMS’ efforts to require timely payer responses to prior authorization requests. We remain concerned that without any consequences for plans failing to meet the required timeframes (e.g., approval is “deemed” or appeal right is triggered), the policy will have little impact on payer response times. As drafted, the burden of payer failure to meet these timelines falls on the providers requiring them to contact payers to determine next steps. The burden should clearly reside with the plans and without sufficient “teeth,” this important policy refinement will be meaningless. Haystack Project suggests CMS consider deeming a failure to respond to requests within the applicable timeframe as an approval. Alternatively, CMS could impose monetary penalties on payers failing to comply.

Haystack Project Supports Measures to Encourage Interoperability of Prior Authorizations

CMS proposes a new electronic prior authorization measure for providers eligible for the Merit-Based Incentive Payment System (MIPS). Under the Promoting Interoperability performance category of MIPS (for clinicians) and the Medicare Promoting Interoperability Program (for hospitals and CAHs), CMS aims to address stakeholder concerns regarding possible low provider utilization of APIs established by payers for electronic prior authorization. The measure would require providers to request prior authorization electronically through the technology, thereby encouraging them to adopt the technology (from a PARDD API using data from certified electronic health record (EHR) technology (CEHRT)).

While we are supportive, we note that many providers were excluded from CMS' EHR Incentive Program—also known as Meaningful Use or MU— which initially provided incentives to accelerate the adoption of EHRs. So it will be important for CMS to revisit its' EHR Incentive program to ensure all provider types are given the appropriate financial support to adopt CEHRT.

Conclusion

Haystack Project appreciates that CMS recognizes and seeks to address the significant burden associated with prior authorization processes on both patients and providers. This burden is ever-increasing and exponentially more burdensome in rare diseases. CMS' proposed policy refinements have the potential to provide enormous value to patients and their treating clinicians.

If you have any questions or need additional information on the impact that current prior authorization mechanisms have on patients and caregivers living with ultra-rare conditions, please contact our Haystack Project's policy advisor, Kay Scanlan, at 410-504-2324.

Very truly yours,



