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March 13, 2023

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 21244-8013

RE: CMS–0057–P. 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

On behalf of over 220 children's hospitals across the country, the Children's Hospital Association (CHA) appreciates the opportunity to comment on this proposed rule. We support this effort to provide appropriate access to complete health records for patients, providers and payers and improve prior authorization processes to reduce unnecessary administrative barriers to care. We are especially attuned to the value of, and need for, clear and uniform standards for the electronic exchange of information about prior authorizations across providers, plans and patients and for streamlined prior authorization processes.

Children's hospitals are a vital safety net for all children, treating children across the country regardless of insurance status or payer. A majority of the patients we treat are enrolled in the Medicaid program and many require highly specialized and complex care. Children's hospitals are regional centers for children's health, providing care across large geographic area. As leaders in local and regional pediatric health care, we are committed to electronic information exchange as a mechanism to improve administrative processes and advance high-quality children's health care and outcomes. Clear and uniform standards for the electronic exchange of information about prior authorizations are crucial to promoting the health of seriously ill children and the health of all children. Our comments below include several areas where we believe the standards proposed in this rule can be refined to reflect the uniqueness of pediatric care and ensure timely access to needed care.

- There are unique proxy and confidentiality considerations—particularly for adolescent patients and children and youth in volatile family situations—that must be addressed in the information exchange requirements and prior authorization processes.

- We strongly support shortened prior authorization timelines across plans to ensure patients' care plans are not delayed but urge CMS to establish more stringent requirements for payers to respond to both standard and expedited prior authorization requests.
- The requirements in this rule for electronic information exchange, transparency and timelines for prior authorizations should be applicable to out-of-state care provided to Medicaid beneficiaries. It is not uncommon for children with complex or chronic conditions to have to travel to another state for care. These standards will help streamline their access to needed services.

Our more detailed comments on the proposed rule are below.

II.(A) Patient Access Application Programming Interface (API)

We support the proposed requirement that plans add information about patients' pending and active prior authorization decisions to the Patient Access API standards established under the CMS Interoperability and Patient Access final rule. We also support the proposal to make prior authorization requests and decisions for items and services, along with administrative and clinical documentation information, available to patients no later than one business day after the payer receives the prior authorization request via the API. To ensure that patients and their families have all the information they need to support care decisions and ensure they receive timely care, payers should also be required to provide patients with information on necessary and/or optional next steps in the event of a denial, request for additional information, etc. It is important that patients have the information they need to be able to appeal on their own behalf, who to contact in the case of a denial, etc. Providing this information electronically to patients will not only empower those patients and their families with information they can use in the event of a denial but could also be helpful to those who switch plans and need to facilitate their own transition of care with new providers.

In addition, there are some unique proxy and confidentiality aspects and challenges related to the sharing of information with the patients and their families as well as with the design, adoption and use of a Patient Access API that must be considered for pediatrics. For example, there must be mechanisms in the API to manage parent/guardian involvement when situations arise that require their access to be discontinued, such as some circumstances related to the care of adolescents (e.g., reproductive health, drug use, etc.), and when there is potential significant harm in parents/guardians inadvertently being given access to that data without the adolescent patient's consent. This can be a particular concern when there are volatile family dynamics, such as contested guardianship situations. For example, children's hospitals work with—and obtain proxy consent from—parents, legal guardians or other authorized representatives when providing care to minor children and it is not unusual for a hospital to receive a request from a parent, non-guardian, foster parent or temporary court-ordered care provider—i.e., extended family, friends, etc.—for access to a child's records. Finally, the Patient API's functionality related to these confidentiality and proxy considerations must also reflect the varying state rules and regulations about parent/guardian access to sensitive adolescent data. States may have differing requirements and procedures related to the degree of confidentiality documentation (i.e., which types of information can or cannot be shared with family members) that will need to be incorporated into the API.

We also believe that it is critically important that the electronic information exchange enhancements and streamlined timelines within this proposed rule apply to prescription drugs and covered outpatient drugs via the API. In most cases, a patient requires a new medication as a critical part of the treatment regimen, in addition to any clinical intervention that these requirements would apply to. Therefore, improving the prior

authorization process for drugs is just as important as it is for services. We encourage CMS to include these drugs in the scope of the final rule or address the current cumbersome prior authorization procedures related to these drugs in subsequent rulemaking.

II.(B) Provider Access API

We are pleased that CMS is expanding the standards for the Provider Access API to include new requirements that payers give providers a specific reason for a prior authorization denial and streamline timelines for prior authorization decision-making and notifications. These new requirements will reduce complexity related to the prior authorization process, decrease provider administrative burden and help ensure that patients receive the care they need when they need it.

Complying with unnecessarily complicated and time-intensive prior authorization processes creates additional stress for patients and their families, while placing undue burden on providers and impeding timely care. For example, children's hospitals have reported that payers can take up to 14 days to render a decision on a prior authorization request. An internal analysis by one children's hospital of prior authorization denial adjudications found that 99% of denials were ultimately overturned because the payer agreed with medical staff that the denied services were appropriate. That same hospital needed to increase their frontline prior authorization staff by 33% over the course of four years to keep up with those denials, at a cost of \$4 million. The delays in care that result from these types of complicated—and ultimately unwarranted—denial adjudications can have serious implications for children's long-term health and well-being and can drive up health care costs.

These two examples of the burden on children's hospitals from plans' prior authorization requirements demonstrate the need for the proposed rule's more streamlined and efficient adjudication processes, which will positively impact patient care. We support the rule's proposed requirement that plans include capabilities in the Provider Access APIs to allow providers to electronically locate the plan's prior authorization requirements and check the status of prior authorization requests. This will allow providers to ensure that they are submitting the necessary documentation when initially submitting requests, reduces administrative burden for re-submitting documentation and would prevent appeals.

We also support the proposed requirement that plans provide a reason in the Provider Access API for any denial, which would expedite needed corrections of administrative errors by the provider and support providers and patient families as they determine if and when to engage in an appeals process. We also encourage CMS to establish enforcement mechanisms to ensure that plans comply with these requirements and recommend that the final rule clarify that the denial reason from the payer includes all relevant information, such as appropriate clinical justification and information about appeals rights and deadlines. In addition, we support the proposal to allow patients to opt out of their information being shared with their provider. We recommend that this option include a mechanism to notify providers when a patient decides to opt out of having their health information shared via the Provider API. Since the information would no longer be shared with them, notice to the providers would allow them to track any existing prior authorization requests.

We also recommend several improvements to the Provider API to ensure that it further alleviates provider burden and enhances patient care.

- Require payers to standardize their prior authorization rules and requirements for third-party vendors. There are some unique issues that providers face when working with payers that outsource their prior authorization function to third party vendors. For example, providers face additional

administrative complications due to inconsistent and confusing rules when payers outsource prior authorization to multiple vendors for different service types that each use different systems and processes. In addition, once a prior authorization has been submitted, the vendor often does not communicate well with the primary payer, causing providers to have to go through burdensome follow-up processes. More effective communication between payers, their third-party vendors and providers will alleviate the need for providers to take the time to track the status of those requests.

- CMS should require payers that change their prior authorization requirements after a request has been submitted to use the requirements that were in place at the time of the submission to review that request. To implement this, CMS could establish a required grace period for payers to transition items on and off of their list of required prior authorizations. This would help ensure patient continuity of care.
- CMS should consider requiring payers to make patients' insurance coverage information more readily available to providers through the Provider Access APIs. to facilitate a simpler prior authorization request process. For example, a provider who is able to enter a patient's identifying information (name, date of birth, etc.) and quickly find that patient's coverage and eligibility status would be able to more efficiently determine whether prior authorization will be required for an item or service. Providers would also be better able to communicate with the patient about their prior authorization process. This is especially important for the pediatric patient population, where children cannot self-report and family dynamics may shift, making it more difficult for pediatric providers to get coverage information directly from patients and their families.
- All payers should have systems that enable providers to electronically differentiate between standard and expedited prior authorization requests. Eliminating the need for a provider to reach out to the payer directly to notify them that a request requires an expedited response would reduce provider administrative burden and further the efficiency of the prior authorization process.

Additional requirements for the Provider API that would help reduce delays in prior authorization decisions and the number of preventable denials include requiring payers to:

- Create and implement countermeasures in the event of an electronic information system outage and establish a minimum timeframe for repair.
- Address the limits on the size of attachments and documentation that providers have to submit as part of prior authorization requests.

II.(C) Payer-to-Payer Data Exchange

We support the proposed requirements for payer-to-payer electronic exchange of patient claims, encounter data and pending and active prior authorization decisions when a patient newly enrolls in a plan. This information exchange is key to care coordination and continuity.

However, we are concerned that the rule does not go far enough to ensure that ongoing care is not disrupted when a patient changes plans or moves between a QHP, Medicaid and/or CHIP. Specifically, we recommend that the final rule requires new plans to carry over and honor authorizations from the prior plan to assure care is continued. For example, the MassHealth ACO program has required all participating Medicaid ACOs to honor existing authorizations from patients' prior Medicaid plans for a continuity of care grace period of 30 days. The grace period has ensured that patients with ongoing care needs or procedures

that were already scheduled to occur after the plan transition did not have their care disrupted as they establish care with new in-network providers and secure prior authorizations with their new plans. We encourage CMS to establish similar carry-over policies for all payers in the final rule.

II.(D) Improving Prior Authorization Processes

II.(D)(4)(a) Requirements for Payers to Provide Status of Prior Authorization and Reason for Denial

We support the proposal that payers provide a specific reason for denied prior authorization decisions to providers. CMS should also require payers to include detailed information related to the denials, the clinical rationale in the case of a denial, an authorized treatment or service alternative, instructions for next steps including options for appeal, the timeframe to overturn a decision and an option to export the denial letter for the provider's internal use.

II.(D)(5)(b) Proposals to Address Timeframes

We are pleased that the proposed rule establishes standard expectations related to turnaround times for prior authorization decisions but recommend further tightening of these standards. Specifically, we recommend that plans be required to deliver prior authorization responses within 48 hours for standard requests and 24 hours for urgent requests, rather than the seven-day for standard/72-hour for urgent response timeline proposed under this rule. Furthermore, it is critically important that these timeframe requirements be in hours rather than days because hospitals provide care seven days a week, 24 hours a day. Timelines that are based on business days or business hours could lead to delayed responses from payers, reducing efficiency, delaying the initiation of treatment plans, and ultimately compromising care and outcomes.

We also recommend that CMS require payers to provide final (rather than "pending") prior authorization decisions within these tighter timeframes. This would mean that the final approval or denial, or a request for additional information must be provided by the payer within the 48 hours for standard/24 hours for urgent response timeframe. The technological capacity for the electronic exchange of prior authorization documentation and decisions that is established under this proposed rule makes these tightened timelines feasible. In addition, we note that appeals processes can be time-intensive and recommend that CMS adopt similar, standardized streamlined timelines for formal appeals in the final rule.

We recommend that these timeframe requirements be applied to all payer types to increase standardization in prior authorization requirements, rather than limiting them to Medicaid/CHIP FFS and managed care plans. Applying these requirements to all payers would reduce the inequitable outcomes of some patients receiving more timely care than others because of differing insurers.

II.(D)(6)(b) Fair Hearing Notices

We support the clarification in the rule that existing Medicaid beneficiary notice and fair hearing rights apply to prior authorization decisions for Medicaid FFS beneficiaries consistent with current regulations for notice and appeal rights for managed care prior authorization decisions. These clarifications will help ensure that patients receive equitable notice and have the same hearing rights related to their prior authorization requests, regardless of whether they are enrolled in Medicaid FFS or a managed care plan.

II.(D)(8) Public Reporting

We support the proposed requirement that payers publicly report data about their prior authorization processes, including a list of items and services that require prior authorization and specific data on denial and approval rates, the extent to which their prior authorization decisions are delayed, and reasons for

delays. We also recommend that CMS require payers to include their clinical criteria for prior authorization decisions, in addition to including data on provider types, type of items and services, case mix, patient age and plan use of third-party prior authorization vendors in their public reporting on their decisions. We also respectfully note that some plans are beginning to require prior authorizations on procedures that historically required no authorizations. Detailed public reporting of the above data categories, including any new authorization requirements, would help inform providers' prior authorization improvement efforts, assist patients and families choose which health plan is best suited for their health care needs, and facilitate CMS oversight to assess and address potential logjams related to certain clinical conditions, types of patients and providers.

To improve CMS oversight of payer practices, we urge CMS to require payers to report their data to CMS—rather than only on their own websites—and that this data be published on a CMS website. This will ensure that payers are following these reporting requirements and will also provide a central location for providers and patients to locate the data. We also recommend that CMS establish benchmarks to assess plan practices, with specific enforcement and oversight mechanisms to address low performance.

Finally, we recommend that CMS phase in reporting requirements for payers starting at an earlier date than the 2026 proposal. For example, payers could be required to report some, but not all, of the required metrics soon after this rule is finalized, and the other requirements could be phased in over time. This would help to identify any issues with the reporting process earlier on in order to make necessary improvements as needed. In addition, we propose that CMS establish a more frequent reporting schedule for payers (e.g., twice a year) so problematic trends and issues can be identified addressed in the same plan year rather than the year after.

II.(D)(9) Gold-Carding Programs for Prior Authorization

We urge CMS to include pediatric care in any proposed standards related to gold-carding in order to reduce unnecessary delays in pediatric care. By allowing providers with a good track record to forgo prior authorizations, gold card programs facilitate more timely care for routine services without added administrative burdens. However, many existing gold-card programs are not inclusive of pediatric medical services. The application of gold carding to certain routine pediatric medical services, such as pediatric echocardiograms, MRIs and CT scans, which still require prior authorization would expand the program's intended efficiencies to pediatric care.

Additional recommended improvements to prior authorization processes

There are several other ways to support care continuity and reduce patient and provider administrative burdens related to prior authorizations and, ultimately, improve care and outcomes.

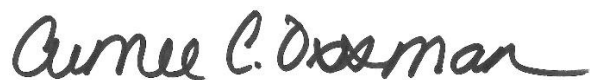
- We encourage CMS to apply electronic information exchange, transparency and timelines for prior authorizations to care that must be provided in another state to Medicaid beneficiaries because the care is not available in the home state. It is not uncommon for children with serious, complex or chronic conditions to need to travel out of state for care given the regionalization of pediatric specialty care. However, state Medicaid programs may impose additional prior authorization requirements on children who must cross stateliness and more frequently deny services, which leads to delays in needed care. Applying the electronic information exchange, transparency and timelines of this rule to these necessary out-of-state care situations will improve children's access to essential specialty medical services.
- We urge CMS to limit plans' imposition of prior authorization requirements for nationally recognized, evidence-based standard-of-care services for chronic and acute conditions. CMS should

also require plans to reduce or eliminate repeat prior authorizations for specific services and procedures that are part of an already-approved plan of care.

- We encourage CMS to require payers to allow providers to submit a range of CPT codes for similar services that require prior authorization. Payers often require specific CPT codes in prior authorization requests, which can be difficult for providers that need to perform a slightly different service after the authorization request was submitted. For example, it is common in diagnostic imaging for a radiologist to make changes to the specific imaging (and related CPT code) that is ordered by the referring provider to ensure the best image for the diagnostic need. Very few payers will allow submission of a range of codes or retrospective authorization updates; most will deny claims when the authorized service CPT code does not exactly match the delivered service code. Allowing for a range of related CPT codes to be submitted would reduce the administrative burden on providers, who would otherwise have to appeal these denials.
- We propose that CMS establish a set of standards, best practices, or requirements for payers to utilize when making prior authorization decision. It is not uncommon for individual plans to continually change and expand their prior authorization requirements, adding to the overall administrative complexity without necessarily improving care. Consistent standards across plans on which items and services require prior authorization would help providers know what they will have to submit prior authorization requests for. Standardization of documentation requirements across plans will simplify and reduce the burden of administrative processes and support timely patient care.
- We also recommend that payers be required to give the same information related to a prior authorization request to both patients and providers. Typically, patients receive basic information from the plan's member services while the provider receives more detailed information from provider services. Providing the same level of information to both patients and providers would remove this burden for patients and improve the patient care experience.

In conclusion, we appreciate your work to improve the prior authorization and electronic information exchange processes between payers, between payers and providers, and between payers and patients. We look forward to working with you to further reduce the complexity of these systems to improve patient care and outcomes and reduce costs. Please contact Milena Berhane at milena.berhane@childrenshospitals.org or (202) 753-5521 with any questions.

Sincerely,



Aimee Ossman
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Children's Hospital Association