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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted Electronically

Re: File Code CMS 0057-P
Proposed Rule on Advancing Interoperability and Improving Prior Authorization (RIN 0938–AU87)
(Vol. 87, No. 238, December 13, 2022)

Dear Ms. Brooks-LaSure:

On behalf of the over 200 hospitals and health systems in four states that make up the acute care membership of the Greater New York Hospital Association (GNYHA), we appreciate this opportunity to comment on the US Department of Health and Human Services Centers for Medicare & Medicaid Services (CMS) proposed rule on advancing interoperability and improving prior authorization.

We are greatly appreciative of CMS's efforts to streamline the prior authorization process and provide transparency for both patients and providers. Our comments focus primarily on the proposal to achieve this goal through adoption of a Prior Authorization Requirements, Documentation and Decision (PARDD) API. Prior authorization (PA) today is a heavily manual and inefficient process that is burdensome for providers and can frustrate patient care delivery. If done correctly, CMS's goal of automating PA has the potential to significantly improve the existing labor-intensive process and facilitate patient access to care. That said, the PARDD API, as currently proposed, raises questions for providers, particularly regarding technology and resource requirement specifications that need to be more fully understood prior to widescale implementation.

Importantly, certain elements of the proposed rule that foster key CMS goals around streamlining and transparency in the PA process are not dependent upon, and can be achieved prior to, the adoption of new technology. GNYHA urges CMS to expedite implementation of these important process improvement requirements, such as tighter timeframes for finalizing PA decisions and public reporting of PA outcomes, with the following modifications, as soon as possible and prior to 2026. Specifically, we believe that the timeframes proposed for payer response to PA requests (i.e., 72 hours for an expedited request and seven calendar days for a standard request) are too long and ask CMS to implement a timeframe of 72 hours for

standard services, and 24 hours for expedited requests and post-acute care services. Further, the proposed requirements for payers to publicly report on PA approval, denial, and appeal outcomes and the average median time elapsed between request and determination will provide much needed insight into payer PA practices and encourage associated payer accountability. We recommend CMS specify the level at which such data is to be reported, based on further stakeholder input, and require payer reporting of the required metrics at the line of business, individual plan, benefit category, and unique service level.

Regarding operationalizing the PARDD API itself, while GNYHA strongly supports CMS's aim to require payers to automate the PA process, the proposed technology "solution" has not been fully developed and tested and, thus, raises privacy and security questions that need to be more fully understood. We ask CMS to pursue further testing of the proposed technology and accompanying standards prior to finalizing the PARDD API requirements. It is critical that any solution be fully developed and tested before an industrywide implementation. Based on similar concerns, as more fully described in our detailed comments, we urge CMS not to adopt the proposed new measure titled "electronic prior authorization" in the health information exchange objective of the Medicare Promoting Interoperability Program at this time and as currently drafted.

We also note that GNYHA member hospitals have varying experiences and degrees of comfort with granting payers access to electronic health records (EHRs), and that it will be essential for CMS to clarify the extent to which EHR access will be necessary under the PARDD API, if at all, and to solicit provider feedback before expecting universal engagement among hospitals. Establishing clearly defined guardrails via rulemaking, informed by provider community input, will also be imperative with respect to any degree of contemplated access.

Moreover, CMS is separately seeking comments on a proposal that would adopt administrative simplification standards under the Health Information Portability and Accountability Act of 1996 (HIPAA) for health care transactions to support PA, among other things.[1] Both proposals seek to achieve similar goals; however, it is unclear how the proposals are intended to work together and, importantly, whether hospitals would have to duplicate efforts to facilitate the data sharing envisioned under both rules. It is also expected that the Office of the National Coordinator for Health IT (ONC) will be proposing a rule that may include requirements for certified EHR vendors to support the PA process between providers and payers. These requirements will go a long way in addressing some of our members' concerns, particularly the burden to create and implement new technology and a structure to oversee and audit privacy and security concerns. Thus, we urge CMS to not finalize these rules in a vacuum, but rather, work alongside ONC to finalize the rules together in a manner that reduces burden and cost.

Finally, GNYHA strongly urges CMS to incorporate payer oversight, enforcement, and dispute resolution mechanisms into the proposed rule. CMS should develop targeted audits focused on payer use of the PARDD API and compliance with decision timeframes and reporting metrics, clearly establish penalties

[1] *See* Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard; RIN 0938–AT38 (https://www.govinfo.gov/content/pkg/FR-2022-12-21/pdf/2022-27437.pdf).

and other consequences for violating the PARDD API standards, and identify the entities to which providers can report payer violations.

Our detailed comments are attached. Thank you for the opportunity to provide feedback on the proposed rule. We look forward to working with you to improve the PA process for beneficiaries and providers. Please direct any questions to Emily Leish, GNYHA's Senior Vice President for Health Finance and Managed Care, or Puja Khare, GNYHA's Vice President, Legal, Regulatory, and Professional Affairs.

Sincerely,

Kenneth E. Raske
President
GNYHA

GNYHA's Detailed Comments

Introduction

GNYHA strongly supports CMS's proposal to require payers to automate the prior authorization (PA) process. PA can be a useful tool to ensure that services that are unlikely to benefit a patient are not pursued. Unfortunately, payers apply it routinely to a wide range of services. This volume of PA creates tremendous burden on hospital and physician office staff and can delay patient access to care. In previous comment letters, we expressed our support for CMS proposals to limit the purposes for which Medicare Advantage (MA) plans may use PA, and we also requested that PAs be more explicitly limited to services and procedures of unproven utility or subject to overutilization to ensure access to care. The labor-intensive manual nature of securing PA approvals only compounds provider workforce burdens. These concerns apply equally to commercial, Medicare and Medicaid managed care plans. Real-time PA decision-making will enhance patient access to care and advance time and cost-saving opportunities. However, the Prior Authorization Requirements, Documentation and Decision (PARDD) API, as currently proposed, raises unanswered provider concerns and questions. We share many of these below for CMS's consideration as it finalizes requirements and implementation timeframes.

The PARDD API Proposal

CMS proposes to require payers to implement an API that would allow a hospital to query a payer's system to determine whether a PA is required for certain items, identify necessary documentation, and ultimately exchange data to facilitate the PA. The API would require Fast Healthcare Interoperability Resources (FHIR)-based functionality and incorporate the currently applicable HIPAA transaction standards. The proposal also imposes PA transparency and timeframe requirements on payers. Finally, there are proposed requirements for hospitals, through the Promoting Interoperability (PI) Program, to participate in PARDD API with payers and report on that participation.

Provider Wariness/Guardrails Needed

It is important to note that GNYHA member hospitals have varying degrees of comfort with granting payers access to electronic health records (EHRs). While some have already done so to different extents, several of our member hospitals are wary of participating in electronic health data exchange with payers due to an historically adversarial relationship and a fundamental lack of trust. While many of the technical details of the PARDD API are not yet specified in the proposed rule, it is often assumed that hospitals will need to grant some degree of EHR access to payers to operationalize the exchange of medical records documentation to satisfy PA requests via the PARDD API. Whether this EHR access is direct or through technology, such as a link to a FHIR-based API, is not clear in the proposed rule. Regardless, hospitals may be hesitant to give this access or to enter into new technology arrangements, fearful that payers will leverage data for purposes unrelated to the specific PA request at issue and/or access data beyond the intended scope for the payer's advantage. One driver of this reluctance is the high percentage of medical necessity denials experienced by our member hospitals. For context, GNYHA surveyed a subset of our member hospitals in spring 2022 for the outcome of billed inpatient claims for services provided within the first six months of 2019. We collected data across a range of payer types. While we understand the proposed rule's PARDD API requirements would apply to a range of government and commercial plan types, we use MA plan data experience here for illustrative purposes.

For MA plans, 28% of billed inpatient claims for the first six months of 2019 were initially denied. Individual MA plan denial rates ranged from 43% to 19%. Of the 28% of MA billed inpatient claims initially denied, 71% were clinical, meaning the MA plan decided the services provided were not medically necessary. Strikingly, upon appeal, 37% of the initial denials of all types (i.e., administrative, clinical, and other) were overturned and an additional 23% were downgraded (e.g., from inpatient to observation care or to a lower-intensity Diagnosis-Related Group [DRG]). Clinical denials had a similar overturn rate of 36% and an even higher downgrade rate of 30%. Sixty-six percent of initial clinical denials were thus ultimately paid in part or in full[2].

While some of our member hospitals have granted EHR access to payers to varying degrees, and with a range of perspectives as to the impacts, **before expecting or requiring universal engagement among hospitals with the PARDD API technology it is essential for CMS to clarify the extent to which EHR access will be required, if at all, and to solicit provider feedback on a more detailed proposal. Additionally, with respect to any degree of contemplated access, it will be imperative for CMS to establish clearly defined guardrails via rulemaking prior to implementation.** Providers will want to have input into developing the operating rules and ensuring payers only access medical records when justified and as agreed. At minimum, providers must have the right to know when payers have accessed their systems, what data payers are taking, and for what purposes. A minimum necessary standard should govern all data access by payers.

Need for More Real World/End User Testing

Hospitals are already experiencing significant limitations on IT resources, and implementing new technology will be extremely resource intensive. As it currently stands, it is unclear what technology a health system or hospital would have to build or acquire to participate in a PARDD API with a payer. It is also unclear—even among industry experts—how the PARDD API will bring together the three HL7 DaVinci Project Implementation Guides (mainly, the PA support, requirements discovery, and documentation templates and rules). Importantly, it is also not understood what privacy and security controls are in place or must be set up by an end user to ensure the API only accesses specific information and that protected health information (PHI) is secure. If this proposal is finalized as written, our members will be using PARDD APIs widely for the first time without any meaningful testing.

To this end, we fully support ongoing development to ensure that technology meets the provider industry need and, importantly, is well understood. It is critical that any solution be fully developed and tested before the widescale roll out considered here, which comes with reporting requirements for hospitals. **We ask CMS to do more to test the API. We recognize provider participation in testing has historically been minimal and, as such, we encourage CMS to consider ways to incentivize provider participation in pre-implementation testing instead of imposing penalties after the fact for failure to implement. For example, there may be existing programs within CMS's Innovation Center that can be utilized for hospitals and payers to enter into arrangements where CMS oversees the activity. In addition, we ask CMS to educate the industry on FHIR-based API technology focusing on the guardrails that exist or must be set up by the end user to prevent improper access and secure PHI. This education should**

[2] Survey data reflects inpatient denied claims for the dates of service within the first six months of 2019 for 27 member hospitals.

consider all roles within a heath system that may have interactions with payers and the PA process, including IT professionals, legal counsel, billers and coders, and clinicians.

Prior Authorization Decision Timeframes

GNYHA strongly supports CMS's efforts to require payers to make the PA process more efficient and transparent. However, the proposed timeframes for payer response to a PA request (*i.e.*, 72 hours for an expedited request and seven calendar days for a standard request) are far too long. For context, New York requires commercial insurers to make non-urgent preauthorization determinations within three business days of receipt of necessary information, and within shorter timeframes for urgent and post-acute care requests[3]. We recommend CMS implement a timeframe of 72 hours for standard services, 24 hours for post-acute care services, and 24 hours for expedited requests. Additionally, payers should be required to approve services at a non-participating provider if a network provider does not agree to accept the patients within one business day of the approved authorization. (Securing plan approval for post-acute services is particularly challenging for GNYHA members, who report waiting days and even weeks for discharge planning approvals. Delays in post-acute discharge authorizations lead to increased length of stay and poor-quality discharges. Patients remain in acute settings when they should more appropriately be receiving post-acute care. At the same time, hospitals incur additional costs while caring for these patients awaiting discharge, generally with no additional reimbursement. We urge CMS to adopt rules implementing a 24-hour decision timeframe for post-acute care PA and to require plans to approve services at a non-participating provider if a network provider does not agree to accept the patient within one business day of the approved authorization.)

Tighter decision-making timeframes that facilitate access to care are critical to achieving CMS's goal of establishing a more efficient PA process. And, importantly, tighter timeframes are not dependent upon PARDD API implementation. **GNYHA urges CMS to implement the 72 hour requirement for standard services and the 24 hour requirement for expedited and post-acute discharge services as soon as possible and prior to the January 1, 2026 PARDD API implementation date.**

Transparency Metrics

Similarly, **we also believe that payers have the ability to generate the proposed transparency reporting today, and that it is not necessary to wait until 2026 or for the development of technology to implement the transparency contemplated by this rule.** The proposed transparency standards, particularly the requirements for payers to publicly report on PA approval, denial, and appeal outcomes and the average and median time elapsed between request and determination will allow providers and patients much needed insight into payer PA practices and encourage associated payer accountability and should be implemented as soon as possible. As for the scope of reportable metrics, the proposed rule does not specify the level at which data is to be reported. We ask CMS to require payers to report the required cited metrics at the line of business and individual plan level, and by benefit category and each individual service requiring a PA. CMS should solicit stakeholder feedback as to useful and meaningful categorizations of PA outcomes.

[3] NYIL section 4903.

Hospital Requirements

As previously mentioned, because the proposed rule does not specify what technology support is needed for hospitals to participate in the PARDD API (and track that participation), the financial and resource impact for hospitals is still unknown, but potentially costly and burdensome. Nevertheless, CMS proposes to add a new measure titled "electronic prior authorization" in the health information exchange (HIE) objective of the Medicare PI Program. To report the measure, hospitals must, as a threshold matter, be set up for and participating in the PARDD API. Additionally, hospitals must be able to track: the number of unique PAs requested; which of those PAs could not be requested via a PARDD API, because the payer does not offer one; and which of those PAs were requested via a PARD API. CMS notes eligible hospitals must report this measure beginning with the calendar year 2026, but the measure will not be scored in 2026.[4]

The PARDD API utilizes three separate HL7 implementation standards and requires use of both FHIR and HIPAA transaction standards. This creates a situation where a hospital may have to use more than one technology solution to not only facilitate participation with the payers' PARDD APIs, but also track PARDD API activity for reporting purposes. Some health systems may have sophisticated certified EHR technology that will be able to do this on their behalf, although this is not currently a required EHR core function. However, for other providers, like community hospitals and physician offices, necessary documentation to support PA decisions may exist in revenue cycle platforms or other similar billing systems. The EHR systems used by these providers may not yet offer the functionality to communicate with the payers' PARDD API, let alone track PARDD API activity. Additionally, to accurately report the measure, hospitals must know which payers offer and which payers do not offer PARDD APIs. **Thus, we urge CMS not to impose any PI requirements on hospitals. Given the already significant burden on hospital IT resources, the burden of reporting outweighs benefits of use. If CMS moves forward with the proposal, we ask CMS to create a pass/fail measure that is reported using an attestation as to PARDD API functionality and utilization. This would strike a better balance of ensuring that hospitals are using the technology against the burden of developing infrastructure for purposes of tracking activity.**

Enforcement

CMS is proposing robust technology, infrastructure, process, and transparency requirements for payers, which taken together will have a much needed effect of streamlining the PA process, reducing associated provider burden, and improving patient access to care. However, it is imperative that CMS also establish a mechanism for oversight and enforcement of payer compliance with the new standards. Developing and implementing the appropriate level of categorization for PA outcomes public reporting will be important.

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[4] It is unclear from the proposal whether this measure is one option within the HIE category of PI that will be scored a certain number of points (to be determined in later rulemaking), or if a hospital's entire PI performance hinges on meeting this measure. In this regard, CMS states "[i]f the MIPS eligible clinician, eligible hospital, or CAH does not report a numerator of at least one for the measure or claim an exclusion, they would receive a zero score for the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program, respectively." See Advancing Interoperability and Improving Prior Authorization Proposed Rule, pg. 76313 (https://www.govinfo.gov/content/pkg/FR-2022-12-13/pdf/2022-26479.pdf) The portion of this statement relating to MIPS appears to be tied solely to a particular category, while the portion on the PI appears to be tied to the program as a whole. **If the proposal is finalized as written, CMS should clarify this is an optional measure within the HIE category of PI for hospitals and, therefore, a hospital's entire performance for the PI program does not hinge on this measure.**

CMS should make public access to the reported data patient-friendly and enable comparison of metrics. CMS should also develop targeted audits focused on plan use of the PARDD API and compliance with decision timeframes. Penalties and other consequences for violating the PARDD API standards should be clearly identified. Further, CMS must identify the entities to which stakeholders, including providers and enrollees, can report violations and establish a process for doing so. Clarity in this area will be particularly important given the range of payer types subject to the new requirements and the different regulatory bodies to which they answer. We have previously suggested that, with respect to MA plans, CMS might consider dedicating regional office resources responsible and accountable for handling provider concerns. **We strongly urge CMS to incorporate oversight, enforcement, and dispute resolution mechanisms into the proposed rule.**

Administrative Simplification: CMS has also proposed a HIPAA transaction standard for attachments in a separate proposed rule. While not the subject of these comments, it is important to note the potential overlap and/or inconsistencies with proposing both FHIR-based PARDD API capabilities for communicating PA requests and transmitting clinical documentation, and also a HIPAA X12 standard for PA attachment transactions. The proposals seek to achieve similar goals but it is unclear how they are intended to work together and, importantly, whether hospitals would have to duplicate efforts to facilitate the data sharing envisioned under both rules. Additionally, the Office of the National Coordinator for Health IT (ONC) is expected to soon propose a rule that may include requirements for certified EHR vendors to support the PA process between providers and payers. These requirements will go a long way in addressing some of our members' concerns, particularly the burden to create and implement new technology and a structure to oversee and audit privacy and security concerns. **Thus, we urge CMS to not finalize the proposed Administrative Simplification rule in a vacuum, but rather, work alongside ONC to finalize the rules together in a manner that reduces burden and cost.**

Provider Access API

We have focused our comments on the PARDD API as that is the proposal with the greatest technology build and process redesign implications for hospitals. We would however like to express our general support for a Provider Access API that would facilitate hospital access to patient information held by payers. In establishing the requirements for a Provider Access API, we note the following for CMS's review and input:

- The proposed rule does not specify how payers will attribute members and enrollees to specific providers, which can be particularly challenging with plan designs that do not require designation of a primary care provider or other gatekeeper. It will be important for providers to understand when they have access to a patient's information and how this will be determined by payers.
- The rule proposes that patients be permitted to opt-out of providing access to their providers. Providers need to understand how they will be made aware of patient opt-outs and the mechanism for determining whether they have access to information for one or more of their patients.
- It is unclear whether providers will need certain technology to access the provider API. Providers need to understand the required technology to develop associated cost estimates.
- Out-of-network treating providers could also benefit from having access to the range of patient data available through the Provide Access API, particularly with respect to PA requests and status