March 10, 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

Submitted electronically at http://www.regulations.gov

In reference to: *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* – CMS-0057-P

Dear Administrator Brooks-LaSure:

Point-of-Care Partners (POCP) supports the above referenced proposed rule and believes the policy changes outlined will improve overall patient care, reduce payer and provider administrative burden and costs, and build trust amongst providers and payers. We commend the Centers for Medicare and Medicaid Services (CMS) and Department of Health and Human Services (HHS) for its efforts in bringing forth this proposed rule and appreciate the opportunity to provide our feedback.

As health IT consultants, Point-of-Care Partners (POCP) brings a perspective that is unique to those held by providers, payers, and health IT vendors because we provide consulting services for each. POCP is a nationally recognized health IT (HIT) consulting firm with associates who have frequently testified before the National Committee on Vital and Health Statistics (NCVHS), as well as provided technical assistance to both CMS and the Office of the National Coordinator for Health Information Technology (ONC).

POCP continues to be at the forefront of standards development to advance the convergence of clinical and administrative data and the advances being sought within the industry and by regulators to progress data fluidity, data sharing and health information technology.

POCP SMEs currently program manage the Da Vinci Project--a private multi-stakeholder initiative that is advancing HL7's FHIR standard to facilitate the exchange of clinical and administrative data in support of value-based care across payers, providers, technology vendors, and the entire healthcare industry. We also support the work of multi-stakeholder group, the FHIR at Scale Taskforce (*FAST*). *FAST* is aimed at helping identify and address infrastructure barriers to scalable FHIR solutions. In addition, the POCP team also is working to advance interoperability through extending the use of FHIR with project leadership, support, and guidance to advance standards within oncology and other domains through the HL7 FHIR Accelerator, CodeX. POCP is also the program management organization for the Gravity Project focused on identifying and harmonizing social risk factor data for interoperable electronic health information exchange.

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General Comments

The requirements within this proposed rule are exactly where patients need the industry to go. These policies, standards, data access, use and exchange rules and the technologies that will be enabled through this rulemaking will truly put the patient at the center of an efficient health care information ecosystem.

The ongoing lack of harmonized clinical and administrative data standards and policy has imposed burdens on the health care ecosystem, and especially on patients and their caregivers. The impacts of this lack of harmonization include inefficient provider and payer workflows that affect patient outcomes, time-consuming discovery of payer-specific requirements, as well as technical or financial barriers.

Electronic Prior Authorization

Prior authorization (PA) is a single point of data intersection long cited for its contribution to provider burden and care disruption.

It is critical to identify the appropriate plan-specific benefit to accurately understand the clinical, patient and provider-specific data required to quickly come to a prior authorization determination. The clinical data required can vary significantly from plan design to plan design, or among services and items being requested for the patient.

Payers increasingly are looking for ways to optimize their processes and return on investment (ROI). From the payer's perspective, the automation called for in this proposed rule (PARDD API) increases the trustworthiness of the review because the clinical data will be coming directly from the EHR, without human intervention. And when the automated process transfers the clinical values into the medical review, that additional transparency further enhances trust.

When done ethically and with good clinical rules, prior authorization can prevent unnecessary care, reduce cost, and improve quality. However, the lack of interoperability bogs down authorization of, access to and downstream payment. The lack of interoperability also makes it impossible for providers to understand the full impact of patients' member benefits on their care options. These burdens have serious impacts on timeliness, patient safety, and the quality of health care delivery, and can be a source of anguish for patients and clinicians alike.

Electronic prior authorization as laid out in this proposed rule represents an opportunity to solve the various challenges presented by prior authorization to reduce provider burden, minimize care disruption for the patient and provide a ROI for payers.

We appreciate that if adopted as final, the prior authorization process would be streamlined via the use of advanced technology. We agree with the requirements to use the health information technology (IT) API interoperability standards at 45 CFR 170.215, including the HL7 Fast Healthcare Interoperability Resources (FHIR) standard, the HL7 FHIR US Core Implementation Guide, and the HL7 SMART Application Launch Framework Implementation Guide. We believe this more advanced standard better aligns with the work underway to streamline prior authorization workflows by leveraging HL7's Fast Healthcare Interoperability Resources (FHIR) standard.

The proposed improvements to the prior authorization process, including the Prior Authorization Requirements, Documents and Decision (PARDD) API, will help reduce administrative burdens. Each of the FHIR-based implementation guides is designed for in-workflow support of the provider team to enable them to better understand patient-specific benefits.

We agree with requiring impacted payers to build and maintain a FHIR API (PARDD API) that would automate the process for providers to determine whether a prior authorization is required, identify prior authorization information and documentation requirements, and exchange authorization requests and decisions from their electronic health records (EHRs) or practice management system.

We are concerned about the carve out in the proposed rule of medications as a part of the PARDD API driven prior authorization process. Medications that are covered under a patient's medical benefit, should not be excluded from these requirements. Doing so creates a vacuum on drugs that are often lifesaving, quality of life altering therapies. To drive optimal provider adoption, ePA must be done across care events — diagnostics, procedures, specialty drugs, DME, etc. — and across their various payers, bringing a familiar, common workflow to the user, which is much more attractive than having to go to multiple systems for multiple payers depending on the care event or payer specific workflows.

Currently, use of the X12N 278 Request and Response standard is required by law and regulation per the Health Insurance Portability and Accountability Act (HIPAA) and we recognize that some in the healthcare community have invested in the X12 standard. To ensure that these requirements can be met, the HL7 FHIR Da Vinci PAS IG does include the ability to "translate" a FHIR transaction to the required X12N 278 transaction and back to FHIR. In this way, the required standard is appropriately supported, but the efficiencies of FHIR can also be simultaneously harnessed. This "translation" step also recognizes the investment that has been made by stakeholders and maintains the ability to use it accordingly.

It is necessary to have this "translation" step at this time given the current HIPAA regulations. For this reason, this "translation" is currently supported by both HL7 and X12 in the relevant PAS and 278 specifications, respectively. It is important to note that the HL7 FHIR Da Vinci PAS IG is written in such a way that if the requirement to use the X12N 278 was removed, the structure is there for a FHIR-only transaction – the "translation" step could be removed without degrading the integrity of the IG and the ability to complete the needed electronic prior authorization transaction. This is being illustrated by the fact that payers and their trading partners have the opportunity to use the PAS IG without the X12N 278 "translation" under the Da Vinci HIPAA Exception that was approved by CMS through July 14, 2024.1 This is further support for leveraging this IG now to begin to move toward a more efficient and effective current state, understanding it can also support a more streamlined future state FHIR-only prior authorization option.

We believe it is important to address questions around this "translation" step that have been raised by members of industry newly learning about the PAS IG, including if it is necessary to use a clearinghouse to leverage the PAS IG. The term "intermediary" in the PAS IG can refer to a clearinghouse if that is an entity a provider and/or payer is engaging with. But an intermediary could also be a business associate, a software service, or a payer front-end. Essentially, the "intermediary" is simply a step in the process that accepts the FHIR bundle, translates it to and from the X12N 278 as required, and returns a FHIR bundle. As such, a clearinghouse or outside intermediary is not needed to leverage the PAS IG.

The HL7 FHIR Da Vinci PAS IG supports existing federal and state requirements, supports sharing attachments by leveraging the HL7 FHIR Da Vinci Clinical Data Exchange (CDex) IG, and supports further transparency in the prior authorization process. In support of the proposals in this rule, the PAS IG facilitates receiving a response from a payer regarding whether a prior authorization was approved, denied (and if denied, a reason for denial), or the need for additional information. The PAS IG also allows a payer's system to be queried for updates on pending prior authorization requests, including a reason the prior authorization is pending. This transparency can assist providers and reduce burden by supplying valuable information to help providers submit increasingly successful prior

[1] https://confluence.hl7.org/display/DVP/Da+Vinci+HIPAA+Exception

authorizations over time with the right information the first time, and it can facilitate patients getting the information they need to be informed and active partners in their care. Burden is also reduced on payers who do not have to manage unnecessary or incomplete prior authorization requests from providers or frequent inquiries from patients.

Having disparate workflows dependent upon care venue is burdensome. We encourage CMS not to carve out other critical care providers and partners, such as long-term, post-acute care and home health from these requirements. Regardless of the venue of care, the prior authorization process should be mechanically similar for both the clinician and their patient regardless of health plan.

We also encourage CMS to clarify that vendors, as those delegated to/from providers and payers, fall under these same requirements.

We commend CMS for adding an electronic prior authorization measure for MIPS eligible clinicians and hospitals and Critical Access Hospitals (CAHs). We believe this incentive will lead to greater adoption and use of ePA.

Provider Access API

POCP supports the addition of the proposed Provider Access API. Making the data as proposed in this rule available to providers will support care coordination and informed care that could lead to improved patient outcomes and help patients be an active partner at the center of their care journey. We are confident that the modifications to the CARIN IG for Blue Button needed to align with this proposal by supporting the ability to remove remittances and cost sharing data from the FHIR transaction can be readily accomplished to support this requirement.

Regarding attribution, with the final functional requirements, the Da Vinci IGs can be updated to provide the necessary tools to support implementation. At this time, as noted in the proposed rule, the Da Vinci IGs can support leveraging the Da Vinci Member Attribution List IG and/or the PDex IG can be used to support attribution. For instance, the PDex IG utilizes CDS-Hooks to enable providers to query to a payer and retrieve information about one or a panel of patients. Depending on the final requirements, Da Vinci can support identifying the best options to help industry implement a sustainable and scalable attribution approach.

POCP also supports the proposed requirement to leverage the HL7 FHIR Bulk Data Access IG for the Provider Access API so that if a provider has a panel of patients associated with a single payer, the payer can share those data asynchronously in one transaction. Use of the Bulk standard also supports sharing data for a single patient asynchronously, which may also be valuable to support this proposed data sharing.

Payer-to-Payer

The Payer-to-Payer API and exchange of information referenced in this proposed rule enables data to follow individual patients across disparate health plans, ensuring that no information is lost and therefore could very well be one of the most valuable interoperability policies for patients.

With Payer-to-Payer data exchange, continuity of care can be protected for patients on an ongoing, active treatment or a stable treatment regimen in the event of changes in coverage, health insurance providers, or PA requirements. The goal and breadth of content here paired with planned expansion of USCDI and USCDI+ will become critical to creating long desired historical records for patients.

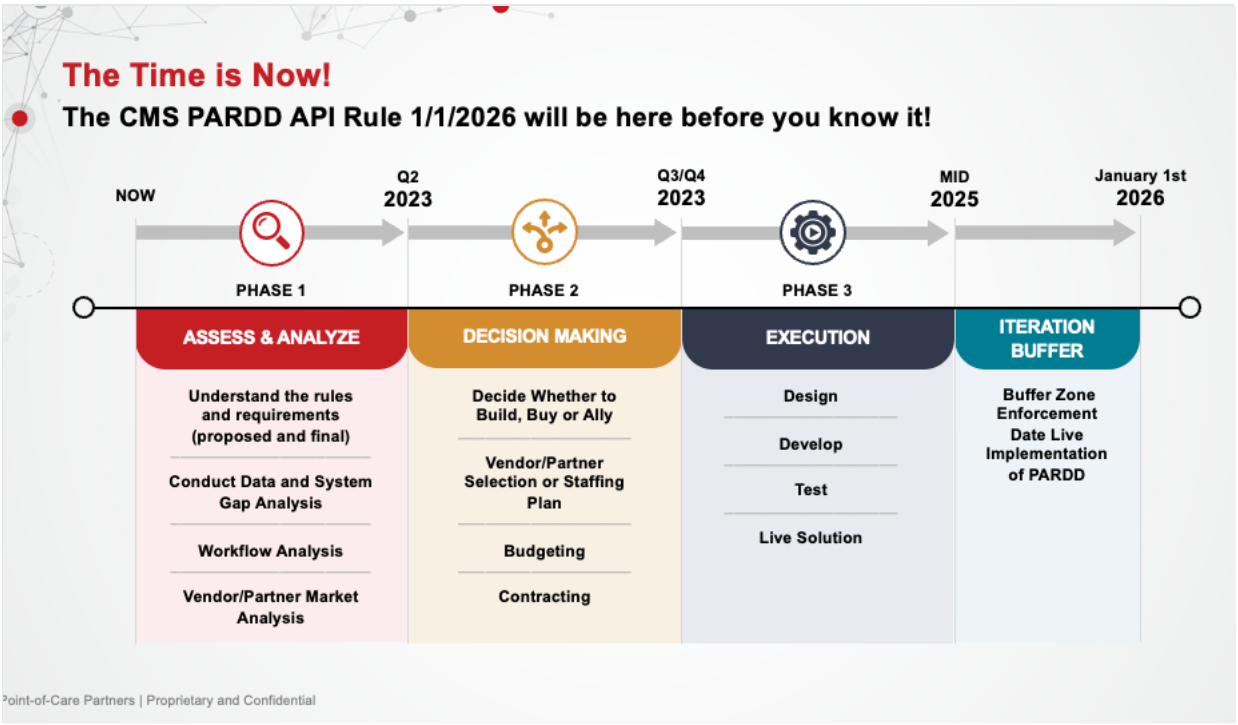
With Payer-to-Payer data exchange, patients shouldn't need to obtain relevant historic records or make multiple phone calls to the new health plan to inform them about chronic conditions and prior encounters. All they must do is provide consent to their past and present health plans, and the health plans manage the actual exchange of data. If what CMS

has proposed relative to Payer-to-Payer API remains intact in the final rule, with enforcement behind it, this will be a big win for patients.

Timeframe for Adoption and Effective Date

POCP understands that the January 1, 2026, proposed effective date for compliance with this proposed rule may be challenging for some stakeholders but not for others. Given the advances made in the industry by many, we believe numerous stakeholders will be prepared to execute on the various requirements by January 1, 2026, and therefore encourage CMS to keep the January 1, 2026, compliance date when issuing a final rule.

As HIT consultants, we have had the pleasure of working with many in the industry to identify the actions needed and anticipated timeframes in which to effectively execute on the PARDD API provisions of this rule. The following depicts an example of the phases and timeframes that impacted stakeholders and their partners should be taking into consideration as they prepare for implementation.



Other Comments

While we understand why CMS recommended vs. specifically required the use of certain implementation guides for the various APIs named in the proposed rule (Patient Access, Provider Access, Provider Directory, Payer-to-Payer and PARDD), alignment and continuity is desired. Without continuity and certainty, the provider experience from payer to payer and core services could be dissimilar. For true automation, alignment, and continuity to happen, there needs to be an approach developed by CMS, similar to SVAP, enabling partners to move to a newer version of a standard or implementation guide at their pace vs the regulatory pace.

We are befuddled by the release of the *Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard, i.e., Attachments NPRM*

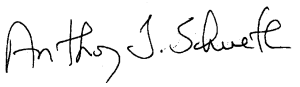
There are conflicts between this CMS proposed rule, the advancements HHS and the industry have been making to utilize codified, structured, standardized data and the Attachments NPRM. We encourage HHS to seriously contemplate pulling back the Attachments NPRM to continue to focus on advancing true interoperability via real-time, codified, structured data exchange, access and use.

Conclusion

Point-of-Care Partners is pleased to offer comments on the proposed regulation and welcomes any further inquiries. Please reach out to me at tonys@pocp.com if we can provide clarification or additional information.

Thank you for the opportunity to comment on this important interoperability NPRM.

Sincerely,



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