January 4, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9123-P
P.O. Box 8016
Baltimore, MD 21244-8016.

RE: CMS-9123-P, Reducing Provider and Patient Burden by Improving Prior Authorization Processes and Promoting Patients' Electronic Access to Health Information

Dear CMS Staff:

Point-of-Care Partners (POCP) is pleased to respond to the subject proposed rule from the Centers for Medicare and Medicaid Services (CMS). It aims at reducing provider and patient burden by improving prior authorization (PA) processes and promoting patients' electronic access to health data. To achieve those goals, payers would be required to implement and maintain application programming interfaces (APIs) using the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) standard. The proposed rule also contains a "rider" from the Office of the National Coordinator for Health Information Technology (ONC), which proposes the adoption of certain FHIR-based implementation guides. Additionally, five RFIs on various aspects of electronic data interchange are included.

POCP is uniquely positioned to respond to the proposed requirements. Since 2006, POCP has been a leader in the development of standards and transactions being adopted under the Health Insurance Portability and Accountability Act (HIPAA) and Medicare Part D. We have testified frequently before the National Committee on Vital and Health Statistics (NCVHS), as well as provided technical assistance to both CMS and ONC.

Most recently, POCP has been at the forefront of the development of standards for electronic prior authorization (ePA) and Real-Time Pharmacy Benefit Check (RTPBC). We currently are co-leaders of the Da Vinci Project--a private multi-stakeholder initiative for 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 a separate ONC-sponsored, 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 through the HL7 FHIR Accelerator, CodeX.

Before providing detailed comments (below), POCP would like to commend both CMS and ONC for issuing this proposed rule. We fully support the agencies' efforts to build on the CMS Interoperability and Patient Access final rule released in 2020 and the continued focus on driving adoption of interoperability standards across the industry. Not only will this result in helping meet the industry's needs for accelerated adoption of ePA, but it also will place medical electronic prior authorization (mPA) on the same footing and subject to the same rigor being applied to and in process across pharmacy ePA.

We also support the agencies' efforts to increase transparency around patient benefits through the adoption of the Real-Time Benefit tool.

POCP provides the following comments on selected aspects of the proposals and RFIs:

1. Medicare Advantage. If finalized, the proposed rule would apply to most CMS-regulated payers, but not Medicare Advantage (MA) plans. However, they should be included. It is important to apply similar requirements to MA, as it continues to be one of the success stories as a leading foundation to increased value-based care in the marketplace. We believe omission of MA plans will cause confusion in the industry and place a burden on payers. They will not want to have separate systems—and adhere to disparate requirements—for MA plans and other CMS-regulated entities with which they do business or operate as separate lines of business.

> **Recommendation 1:** We recommend that MA plans be required to adopt the requirements of the proposed rule in future regulation.

2. Supporting API innovation and adoption. The proposals in this rule are aimed at facilitating API innovation and adoption with respect to ePA. We note that the proposed implementation date of January 1, 2023, is ambitious. If that date is to be preserved, stakeholders will need government support to address the technical capabilities and workflow requirements needed to meet the deadline. We also note that CMS is well positioned to provide leadership in the roll out of Documentation Requirement Look Up Service (DRLS) in their own workflows with providers.

> **Recommendation 2a:** We recommend the government support stakeholders in adoption of the proposed requirements, such as through funding of early adopters and demonstration projects.
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> **Recommendation 2b:** It is critical that CMS and ONC coordinate adoption of the provider and payer use of APIs on these challenging workflows. This would help to ensure that both sides of the API are accountable for successful adoption.
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> **Recommendation 2c:** There is a clear need to coordinate and support organizations that are not just going through the technical adoption of APIs, but the underlying business transformation required to make the shift to focusing on value-based care. Examples include funding of dedicated staff and adoption-related convening activities.

3. Harmonization with HIPAA. The rule proposes that impacted payers must build and maintain a FHIR-enabled electronic Prior Authorization Support API, which has the capability to send prior authorization requests and receive responses electronically within their existing workflow, while maintaining the integrity of the ePA transaction standards named under HIPAA. Yet EHR workflows currently must use the HIPAA-named ePA transaction standards, the ASC X12N 278. These dueling requirements will cause confusion in the industry, burden on vendors, and create an enforcement conundrum.

> **Recommendation 3a**: The government could issue a waiver concerning the required use of the 278 for ePA transactions. As an alternative to a waiver, the government could consider discretionary enforcement.
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> R**ecommendation 3b**: The government should take this opportunity to revisit HIPAA requirements and harmonize them with the growing requirements and use cases based on FHIR. The relationship between the two standards for ePA is just another example of the blurred

usage lines between the two. Some consider the two standards as competing. Others consider the HIPAA-named 278 for ePA as a "floor." This problem will only accelerate as technologies and use cases rapidly evolve and future rulemaking is needed. We note that legislation may be needed to change or update HIPAA administrative simplification requirements in a rapidly evolving world of FHIR adoption.

4. Da Vinci and CARIN Implementation Guides. CMS and ONC propose to adopt named FHIR-based implementation guides (IGs) created by the Da Vinci Project and CARIN Alliance. Adoption of use case-specific FHIR-based IGs—which consider data available, roles, and workflows—will ensure that each API is built and implemented in a consistent and standardized way as well as transmit data that are mapped and standardized as expected by both the sending and receiving parties. The result will be increased efficiency and interoperability of the APIs. The role of a well-defined IG is one of many necessary steps to realize the promise of true semantic interoperability.

Recommendation 4a: POCP supports the adoption of these IGs, recognizing that they will continue to mature and evolve to meet market and regulatory demands. We note our leadership of the Da Vinci Project.

Recommendation 4b: It is critical that CMS does not create a gray area for PA for medications and pharmacy-related services that are dispensed in a facility or reside on the medical benefit. POCP applauds the Medicare Program; Secure Electronic Prior Authorization For Medicare Part D final rule. CMS must deliver clear guidance, inclusive of these non-retail pharmacy and prescribed services to ensure they are covered by the same standards as other order entry services and procedures.

5. USCDI. The rule proposes expanded exchange of clinical data using a subset of the U.S. Core Data for Interoperability (USCDI) standard. It is clear that the USCDI will continue to mature and expand in the coming years. The emergence of the Standards Version Advancement Process (SVAP) is a first step, but it is important to note that many of the payer-to-provider uses of existing FHIR resources are maturing as well. Therefore, the use of IGs is important to accommodate the nuanced use cases between these trading partners.

6. Quarterly data reporting. Comments were requested on the proposal to require impacted payers to report metrics about patient use of the Patient Access API to CMS on a quarterly basis, instead of annually. We believe this will be excessively burdensome, especially in the early days as the APIs are rolled out and payers, patients, and providers become accustomed to their use. In addition, CMS should determine what metrics are most important and will move the dial on burden. Otherwise, CMS runs the risk of creating unintended consequences for the industry through the selection of the wrong or problematic metrics. An example is the development of several of today's quality measures, which some believe don't measure the right thing in the right way.

Recommendation 6a: CMS should work with stakeholders to identify what metrics are key to providing the needed data as well as reduce burden. It is critical that we ensure we are measuring the new desired workflows and not just digitizing existing friction and burden.

Recommendation 6b: We recommend reporting of patient usage metrics on an annual basis.

7. RFI: Electronic Exchange of Behavioral Health Information. The RFI is a much-needed first step to allow the electronic exchange of behavioral health information, which is largely prohibited under 42 CFR

Part 2. This change is needed to address the ongoing impacts of the COVID-19 crisis and the opioid crisis. According to recent research, the drastic increase in the prevalence of behavioral health conditions ivn the U.S. due to Covid-19 will drive an estimated $140 billion in additional healthcare costs by the end of 2021. At the same time, other statistics show that drug overdose deaths continue to skyrocket. More than 81,000 people died from overdoses in the year ending in May 2020. In addition, suicides in the military, veteran, and civilian populations continue to rise.

Having behavioral health data available in the electronic health record (EHR), and sharable across platforms and users, will promote a more holistic picture of the patient's health. This will result in more comprehensive, cost-effective and accessible care and prevent unnecessary deaths.

> **Recommendation 7:** The federal government should work with stakeholders to update the provisions of 42 CFR Part 2, to allow the secure, electronic sharing of behavioral health information.

8. RFI: Reducing the Use of Fax Machines. The proposed rule asks for information on how fax technology is still being used and how it could be replaced by electronic data interchange (EDI). Fax machines are still widely used in PA workflows between providers, payers/PBMs, and third-party entities. An American Medical Association **2019 study** reported by Fierce Healthcare found that 60% of 1,000 doctors surveyed use a phone and 46% use a fax machine for submitting PAs. We hope that the efforts outlined in this RFI to identify and remediate fax-based processes (including PA and beyond) will help accelerate the adoption of standards and transition to interoperable EDI.

> **Recommendation 8a:** We support these efforts. Once input has been received through the auspices of this RFI, we recommend that the government follow up with stakeholders to develop an action plan or roadmap to eliminate antiquated and non-interoperable phone/fax transactions across the industry.

> **Recommendation 8b:** POCP has been an early and long-standing participant in digital prior authorization adoption and the development of standards. As such, we firmly believe that all parties involved in APIs need incentives and/or regulation to move to electronic workflows. It is critical that we simply do not transform existing fax-based forms into a digital format and digitize a flawed, burdensome, fax-based workflow. This is important as we shift toward increasing transparency of benefit coverage and automation where prior authorization is required.

9. RFI: Accelerating Adoption of Standards Related to Social Risk Data. The proposed rule requests information on standards related to social risk data. The COVID-19 crisis brought the need for such information into sharp focus. We note that the term "social risk data" is used in place of "social determinants of health (SDOH)," which is what is commonly used by CMS and the industry. Is this RFI proposing alternative terminology in place of SDOH?

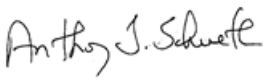
> **Recommendation 9a:** The government should work with stakeholders to identify what risk factors are of interest with respect to social risk and determinants of health; prioritize the need to address them; and work to create specific standards.

> **Recommendation 9b**: Clarification is needed on the definition of "social risk data;" its intended use going forward; and its relationship to social determinants of health.

Conclusion. Point-of-Care Partners is pleased to offer comments on the proposed regulation. Please do not hesitate to ask for clarifications or additional information. You can reach me at tonys@pocp.com.

Thank you for the opportunity to comment.

Sincerely,



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