August 16, 2019

Re: Medicare Program; Secure Electronic Prior Authorization for Medicare Part D—CMS 4189.

Dear Regulations Staff:

Point-of-Care Partners (POCP) is pleased to provide the Centers for Medicare and Medicare Services (CMS) with comments on the subject proposed rule.

POCP is uniquely positioned to comment on this proposed requirement. We are a nationally recognized consulting firm in the areas of electronic prescribing (ePrescribing); standards to support payers, prescribers and pharmacies; specialty pharmacy automation; electronic exchange of health and administrative data; interoperability of electronic health records (EHRs); and electronic medication management. POCP also provides related management and strategic consulting services in those areas to a wide range of stakeholders.

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 the Office of the National Coordinator for Health Information Technology (ONC).

Most recently, POCP has been at the forefront of the development of standards for electronic prior authorization (ePA) and the Real-Time Pharmacy Benefit Check (RTPBC). We currently are helping to lead a multi-stakeholder effort for use of HL7's FHIR (Fast Healthcare Interoperability Resources) standard to facilitate the exchange of clinical and administrative data among payers in support of value-based care. FHIR also shows promise for the development of application programming interfaces (APIs) for patients to access their data and better understand their financial liability for their health care and treatments.

Point-of-Care Partners applauds CMS in taking another step forward to stimulate adoption of ePA for drugs covered under the Medicare Part D patient's pharmacy benefit. We see two additional benefits to the proposal.

- **Bringing future consistency to the market.** If implemented, the proposal will help lay out a clear path to consistency to the market by driving states to adopt its requirements. States almost always follow Medicare's lead. Currently, states are interested in promoting ePA; about a quarter require it and another quarter allow it. However, requirements vary all over the map. That said, while CMS' requirements ultimately will gain traction in states, it's unlikely to be anytime soon. State legislatures operate on varying schedules (some don't even convene every year). Most are pre-occupied with addressing the opioid crisis, such as legislating electronic prescribing for controlled substances.
- **Supporting Real-Time Benefit Check (RTBC).** The proposed rule goes hand in hand with the final rule for Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of

Pocket Expenses (CMS-4180-P) that mandates use of an RTBC tool under Part D beginning on January 1, 2021. When used together, the two transactions deliver more accurate information about coverage and costs of drugs at the point of prescribing and allow physicians to help their patients get on therapy faster. Use of the newly-proposed ePA transactions would improve the ability for the prescriber to submit the required information in real time and increase patient-specific accuracy of whether PA is truly needed within the workflow. Together, these transactions will boost ePA adoption.

Outstanding issues in the proposal. While the proposed rule seems fairly straight-forward, we identified several issues that should be addressed, either in the final rule for this proposal and/or in future guidance. They are described below.

1. Addressing the scope of the mandate. The mandate is narrowly focused on use of drugs under Part D. We believe this is appropriate and will help drive adoption, since other public and private payers tend to follow Medicare's lead. We believe the agency could take this proposal another step forward and require ePA for drugs covered under the pharmacy benefit by Medicaid. This also will drive adoption. We do not believe this would be a heavy lift, since electronic health records (EHRs) are already equipped to handle NCPDP SCRIPT 20170701 and because this version of SCRIPT will be the official standard for Part D beginning on January 1, 2020.

Recommendation 1a: CMS should take the next step and require ePA for drugs covered under the pharmacy benefit by Medicaid and require state Medicaid agencies to adopt the same or similar ePA requirements. This will help accelerate real-time, standards-based ePA adoption in general and spur state legislatures to pass complementary legislation.

That said, we believe the scope of the proposed rule is unclear in several areas. For example, is the use of NCPDP SCRIPT transactions mandated for all ePA transactions for Part D, just those being ePrescribed or solely on electronic PA submissions? Will any electronic requirement extend to ePA portals? Clarification is needed. In addition, the proposed rule does not define terms, which may be unknown or unclear to some stakeholders.

Recommendation 1b: CMS should clarify the scope of the requirement, specifically whether it applies to all Part D covered drugs that are ePrescribed and its use in payer portals.
Recommendation 1c: The final rule should include a glossary of terms.

2. Overarching challenges with pharmacy and X12 278. The SUPPORT for Patients and Communities Act granted CMS an exception for the required use of the batch-oriented 278 for ePA, but only for Part D-covered drugs. The proposed rule's impact analysis noted some of the challenges with X12 278, such as the standard was designed to conduct batch transactions, which cannot be used to support real time prescribing, and is unsuitable for medications. It also cannot accommodate attachments even if one were required. So far, the HIPAA requirement for a claims attachment standard has not been promulgated. Resolving these challenges is important to stakeholders.

Recommendation 2a: We urge CMS to issue guidance concerning the HIPAA attachment standard or seek legislative relief from this requirement if it is unfeasible and has been overtaken by time, technology and industry efforts.

3. Addressing the potential for rich ePA content. The proposed rule deals with how PA information must be exchanged electronically under Part D. It stops short of addressing content requirements: that is, whether Question Sets, Coded Responses (CRs), or both must be implemented. The proposed rule states that the four types of ePA transactions must be supported and that there are benefits of implementing Coded References (without specifically using this terminology). We hope CMS will clarify which response types should be used. We think many payers would support mandated use of CRs, which would help automate the PA process on both sides of the transaction. Leaving the status of Question Sets and CRs unresolved could create problems for EHR vendors. The delay in use of coded references continues to miss the opportunity for deeper integration and automation between payers and provider systems.

> **Recommendation 3a: CMS should clarify content requirements for ePA transactions, specifically whether Question Sets, Coded Responses (CRs), or both must be implemented and how such implementations would work. If this cannot be done in the final rule, we urge CMS to issue clarifying guidance as soon as possible.**

4. Aligning HIPAA requirements with new standards and use cases. It is becoming increasingly evident that HIPAA requirements for ePA are outdated, unworkable and burdensome. This point was driven home recently by testimony at a series of sessions held this summer by the National Committee on Vital and Health Statistics (NCVHS). Many testifiers, including Point-of-Care Partners' CEO & Managing Partner, Tony Schueth, pointed out the challenges of using the 278 in an evolving, real-time world. At its core, the 278 was designed for batch transactions and is neither specific nor flexible enough to handle complexities of medication-specific prior authorization without significant efforts by all parties.

A statement from CMS' Health Informatics Office offered additional insights on the impacts of the 278's required use. It noted that, "CMS' HIPPA regulations for prior authorization require that every prior-authorization transaction between covered entities must use the ASX X12 278 standard. The Medicare Fee-For-Service (FFS) program expended considerable resources to comply with this regulation. It made modifications to its Electronic Submission of Medical Documentation (esMD) system to be able to accept 278s from providers. In the four years since the esMD system has been capable of receiving a 278 transaction, not a single one has been submitted by a provider."

The CMS team also drew attention to the work underway to streamline prior authorization workflows by leveraging HL7's Fast Healthcare Interoperability Resources (FHIR) standard, which is open source. CMS Fee for Service, in support of the HL7 Da Vinci Project, has developed a number of use cases to better create knowledge about PA requirements in workflows using FHIR-based ePAs. To facilitate forward progress and support consistency with existing HIPAA compliance, there is a subgroup of volunteer experts mapping FHIR to X12 resources. Outputs of this effort will available as a download under license by X12. Given widespread adoption of NCPDP SCRIPT ePA, it is unlikely that such a crosswalk is necessary.

Given the momentum and market adoption of ePA SCRIPT transactions, is legislative relief needed and available for pharmacy benefit covered items from HIPAA requirements?

> **Recommendation 4a: CMS should seek a path forward through legislative relief to eliminate the inconsistency with PA standards and the current HIPAA-named standards.** This will help eliminate confusion and further stimulate innovation, especially regarding development and use of FHIR-

based transactions and application program interfaces. This also will be important as the industry transitions to PA for drugs, devices and services covered under the medical benefit (mPA).

Recommendation 4b: CMS should continue to support and invest in the Da Vinci Project's efforts. These include implementation efforts and pilot activities by the industry. DaVinci's innovative approaches are creating new ways to develop collaboration and address long-standing and emerging issues in the industry, including ePA.

5. Transitioning to medical ePA. We believe the proposed rule is an excellent first step in promoting adoption of electronic pharmacy PA to reduce costs and improve outcomes. Substantial progress has been made in this area and adoption is already widespread. Now the industry is turning its sights on computerizing PAs for the drugs, devices and services covered under the patient's medical benefit (mPA). Initial efforts involve mPA for drugs covered under the medical benefit, such as under Medicare Part B. As these transactions become more robust and adoption accelerates, we urge CMS to undertake the following actions:

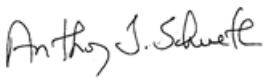
Recommendation 5a: CMS should support and invest in efforts for ePA for drugs covered under the medical benefit. This will take ePA to the next level.

Recommendation 5b: CMS should continue to work with stakeholders to develop the infrastructure and resolve the technical issues needed for standards-based ePA for medical devices, services and procedures.

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 on this draft regulation.

Sincerely,



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