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Mr. Alex M. Azar, II
HHS Secretary
Department of Health and Human Services
Attention: CMS–4189–P
P.O. Box 8013
Baltimore, MD 21244–8013

Ms. Seema Verma
CMS Administrator
Centers for Medicare & Medicaid Services
Attention: CMS–4189–P
P.O. Box 8013
Baltimore, MD 21244–8013

RE: Medicare Program; Secure Electronic Prior Authorization for Medicare Part D (CMS–4189–P)

Dear Secretary Azar and Administrator Verma:

PCMA appreciates the opportunity to comment on the proposed rule: Secure Electronic Prior Authorization for Medicare Part D (hereafter referred to as "Proposed Rule"), as published in the Federal Register (84 FR 28450) on June 19, 2019.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 270 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the exchanges established by the Affordable Care Act.

PCMA and its members support the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act), which was aimed at addressing the nation's opioid overdose epidemic. The legislation required, in part, the Department of Health and Human Services (HHS) to adopt standards for the Part D e-prescribing (eRx) program to ensure that electronic prior authorization (ePA) request and response transmissions are secure. PCMA has long-supported both eRx and ePA, and believes that both eRx and ePA are critical components in the fight against America's opioid epidemic. Electronic prescribing of controlled substances ensures that each prescription is written by a legitimate prescriber and filled by a legitimate pharmacy, leading to reduced medication errors and fraud. Electronic prior authorization helps ensure that patients' prescription drugs are dispensed accurately, safely, and quickly, leading to increased medication adherence.

PCMA is generally supportive of CMS's proposed methods for implementing the ePA provision of the SUPPORT Act. Moves such as these to modernize our health care system will improve patient care. We raise four points below for CMS's consideration as it moves to finalize these

regulations regarding: implementing other SUPPORT Act provisions, inconsistency with existing ePA standards, the timeline for implementation, and the need for additional guidance beyond what CMS has described in the Proposed Rule. Our comments and recommendations are below.

Implementation of Other Medicare Part D SUPPORT Act Provisions

There are many provisions of the SUPPORT Act that are specific to the Medicare Part D program that may interact with the Proposed Rule. For example, Section 2003 of the SUPPORT Act requires the use of e-Rx for opioids beginning January 1, 2021. This proposed rule, focusing only on ePA, misses an opportunity to align closely the related provisions of the statute to minimize confusion and disruption. The statute, however, allows the HHS Secretary to waive the eRx requirement in certain defined cases. While future rulemaking to implement Section 2003 likely will address this exception, there is no such exception in this ePA Proposed Rule, which may cause unnecessary confusion and inconsistency.

PCMA Recommendation**: **PCMA recommends that CMS address other Medicare Part D implementation issues arising from the SUPPORT for Patients and Communities Act, in addition to ePA, in order to reduce confusion, facilitate implementation, and ensure that related provisions are treated consistently.

Inconsistency with Other ePA Standards

CMS states that it believes the SUPPORT Act gives it the authority to require the use of an ePA standard under Medicare Part D that is different from the standard under the Health Insurance Portability and Accountability Act (HIPAA), as long as the different standard applies only to Part D-covered drugs prescribed to Part D-eligible individuals. CMS proposes to require Medicare Part D plans to use version 201071 of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for ePA transactions, beginning January 1, 2021. This standard is not currently used in other markets. CMS concludes that "the potential benefits of adopting user-friendly ePA for the Part D program outweigh any difficulties that may arise by virtue of Part D using a different standard than the rest of the industry."

While a "user-friendly" ePA standard would be welcomed, CMS does not give enough attention to this potential confusion and disruption that may result from the adoption of different standards in different parts of the industry. In other recent comment solicitations, we have recommended that HHS consider adopting a single standard for ePA – either HIPAA or NCPDP – with a reasonable transition period.

PCMA Recommendation**: **CMS should work to minimize the confusion caused by two similar but different standards and provide educational outreach to providers and

pharmacies, to ensure smooth transition to the new requirements. CMS should also use its best efforts to align the standards across federal health care programs.

Timeline

Implementation of the new ePA standard beginning January 1, 2021 may be challenging for some prescribers, particularly as it occurs at the same time as implementation of the real time benefit tool (RTBT) requirement under Medicare Part D.[1] While we support that these implementation dates are aligned, we note that the systems changes may be demanding. CMS should consider outreach and education efforts to assist prescribers and other stakeholders with these new, important requirements.

PCMA Recommendation: PCMA asks that CMS be aware of the challenges presented by these implementation deadlines and exercise enforcement discretion if PBMs and plans are not able to achieve success in getting the ePA and RTBT systems to work together. PCMA asks CMS to give PBMs and plans a reasonable amount of time to work out any systems and implementation problems after the January 1, 2021 deadline.

Interaction with Grievances and Appeals Guidance

PCMA notes that PBMs and plans have had to process the ePA transactions for several years without specific guidance from CMS. Thus, entities have made assumptions about how these transactions relate to the more traditional inquiries and requests discussed in the Part C & D Enrollee Grievances, Organizations/Coverage Determinations and Appeals Guidance.[2] PCMA believes it will be necessary for CMS to provide additional guidance following finalization of the Proposed Rule. Some examples of questions where guidance is needed are below:

- Does the Prior Authorization (PA) Initiation Request align with an "inquiry," as this step allows the prescriber and the payer to communicate?
- Does the PA Request Transaction align with what would traditionally be referred to as a request for a coverage determination? If so, would the date/time the PA Request transaction was received start the clock for the coverage determination timelines?
- How long should a PBM wait to receive a PA Request after the PA Initiation Response was sent to the prescriber? What should a PBM do if the PA Request surpasses the allotted timeline?
- Will all the Part D timelines be followed for ePA transactions?

[1] See 84 Fed. Reg. 23868, May 23, 2019.
[2] Available at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf, last revised February 2019.

<u>PCMA Recommendation</u>: When CMS finalizes the Proposed Rule, PCMA requests that CMS provide clear-cut sub-regulatory guidance that defines the transactions and expected turn-around times and includes the questions posed above. PCMA requests that CMS seek input from the industry, including PCMA and NCPDP, when developing such sub-regulatory guidance.

Thank you for the opportunity to provide comments. We look forward to working with you on the ongoing efforts to improve Medicare Part D. If you need additional information, please contact me at wkrasner@pcmanet.org or Tim Dube, Assistant Vice President, Regulatory Affairs at tdube@pcmanet.org.

Sincerely,

Wendy Krasner

Wendy Krasner
Senior Vice President, Regulatory Affairs

cc: Demetrios Kouzoukas, CMS Principal Deputy Administrator & Director of the Center for Medicare
Cheri Rice, Deputy Director, Medicare Parts C and D