



August 16, 2019

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
PO Box 8016  
Baltimore, MD 21244-8013

**Re: Secure Electronic Prior Authorization for Medicare Part D; CMS-4189-P**

Dear Administrator Verma,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule updating the standards for Medicare Part D electronic Prior Authorization (ePA) transactions. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 159,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Acting upon authority granted in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, CMS proposes that beginning January 1, 2021, Medicare Part D plan sponsors would have to support the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for four ePA transactions. Prescribers would have to use this standard when ePA transactions are performed for Part D-covered drugs being prescribed to Part D-eligible individuals. It does not require prescribers or dispensers to implement e-prescribing, just that those who do engage in ePA transactions comply with applicable standards for Medicare Part D beneficiaries. As proposed, implementing the SCRIPT standard conflicts with existing Health Insurance Portability and Accountability Act (HIPAA) law, which requires covered entities, including Part D sponsors, to use the X12 278 standard for this type of electronic exchange. However, CMS asserts they are able to circumvent this existing HIPAA mandate for specifically Part D plans using authority granted to the Secretary under the SUPPORT Act.

ACP appreciates the Administration's commitment to expediting patient's access to necessary prescription drugs and its recognition of the burden associated with prior authorization (PA). A 2018 survey of physicians found that 91 percent reported PA resulted in care delays for their patients and had a negative impact on clinical outcomes, with 28 percent indicating PA led to a serious adverse event for their patients. Further, 86 percent reported high burden associated with prior authorization.<sup>1</sup> A report from the Council for Affordable Quality Healthcare (CAQH) found that 88 percent of prior authorization transactions are completed either partially or completely manually, which is extremely inefficient and burdensome.<sup>2</sup> Moving to an electronic process for PA transactions would help streamline the disparate and burdensome manual processes in the current environment, and we support CMS' efforts to promote the use of the SCRIPT standard, which we agree is the technically appropriate standard to use for further implementation of and improvement to the ePA process.

The current X12 278 ePA standard is limited in functionality and does not allow for the submission of open text in some data fields, the ability to attach documents needed for PA requests, or the ability for real-time messaging. SCRIPT would reflect a marked improvement in the physician experience as it supports the automated collection of data required for a PA request from a patient's electronic health record (EHR) and facilitates a standard exchange of PA information while still allowing for customization. SCRIPT further offers support for both a solicited and unsolicited PA model. A transition to an automated ePA system holds the potential to improve clinical decision making and efficacy through real-time data exchange in determining a covered treatment while also decreasing physician burden by minimizing manual activities traditionally associated with PA such as printing, faxing, phone calls, and mailing.

While the proposal to update ePA standards is a welcome change, the College is concerned about the implications of applying this standard only to transactions with Part D plans. If the regulation is finalized as proposed, only Medicare Part D ePA transactions would use the SCRIPT standards and all other plans would still be subject to the less functional HIPAA-compliant standard, adding another layer of complexity in determining which standard to use based on the plan or payer. Disparate processes will inevitably result in unnecessary confusion for physicians as they deal with numerous different payers and would negate the benefits of ePA. While some vendors have developed ways to improve the workflow even within the constraints of the HIPAA-required standard, using the SCRIPT standard for ePA transactions across all plans would likely align and improve the efficiency of the transaction overall. The College would also like to emphasize that only some vendors have implemented these workarounds and even then, not all physician practices have access to these functionalities within their existing systems. We understand that existing law under HIPAA may not allow for the use of SCRIPT for ePA transactions; however, CMS states in this proposed rule that the SUPPORT Act allows them to circumvent this requirement for Part D payers. **ACP urges CMS to work with all stakeholders, including private payers and vendors, and similarly explore possible alternative options to obtain a technical fix for HIPAA that will allow everyone to utilize, and in turn, fully realize the potential benefits of the SCRIPT standard.**

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<sup>1</sup> <https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf>

<sup>2</sup> [https://www.caqh.org/sites/default/files/core/phase-v\\_CORE\\_RuleSet.pdf](https://www.caqh.org/sites/default/files/core/phase-v_CORE_RuleSet.pdf)

Thank you for considering our comments on this extremely important proposed rule. We appreciate CMS' ongoing commitment to reducing physician burden and this proposal is a crucial and necessary step in standardizing the health information technology (IT) experience and making it work better for both patients and physicians. Please contact Brooke Rockwern, MPH, Associate, Health IT Policy by phone at 202-261-4586 or by email at [brockwern@acponline.org](mailto:brockwern@acponline.org) if you have any questions or need additional information.

Sincerely,

A handwritten signature in blue ink, appearing to read 'ZAR', with a long horizontal flourish extending to the right.

Zeshan A. Rajput, MD, MS  
Chair, Medical Informatics Committee  
American College of Physicians