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August 16, 2019

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma,

On behalf of the 32 member companies of the Electronic Health Record (EHR) Association, we are pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed rule for the *Medicare Program; Secure Electronic Prior Authorization for Medicare Part D* (CMS-4189-P.). We appreciate CMS' objective to align the standards for e-prescribing with those used for prior authorization through Medicare Part D.

EHR Association members support the adoption of version 2017071 of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for electronic prior authorization (ePA) for prescription drugs. While in the short term this will create a discrepancy with other programs for non-Part D plan payers, our members believe that aligning the use of NCPDP SCRIPT 2017071 e-prescribing and prior authorization standards across use cases is a positive step.

To further align prior authorization for e-prescribing across other federal programs, we recommend that HIPAA be updated to reference the same standards, with the aim of upgrading any subsequent standards in concert.

Also, the EHR Association understands that some states are pursuing different standards for electronic prior authorization. We recommend that CMS work with states to align on common standards, in order to reduce redundant development and maintenance efforts for the same capabilities.

The proposed rule states (page 28451):

"An ePA transaction standard would allow a prescriber using an electronic prescribing (eRx) system or an electronic health record (EHR) with eRx capability to determine whether the beneficiary's plan requires a PA for a given medication. If the prescriber enters such a prescription into an eRx system, a message will be returned to the provider indicating that a PA is required. Use of the ePA transactions would then enable the prescriber to submit the information required to fulfil the terms of the PA in real time" (emphasis ours).

The ability to enable real-time interaction as the clinician prescribes is a reasonable goal; however, it depends upon a number of factors, including the ability of the payer to respond to the query in a timely manner that is acceptable to the prescribing clinician. The EHR Association recommends clarifying this expectation, such that it does not require solely the implementation of a real-time e-prescribing module fully integrated into the e-prescribing workflow. Rather, other workflows, not necessarily real-time, should be permissible to optimize the user experience.

To align expectations of providers and payers on real-time availability of prior authorization, it would be important to establish industry-accepted guidelines, such as those established by CAQH-CORE (the Council for Affordable Quality Healthcare's Committee on Operating Rules for Information Exchange) for similar use cases.

The proposed rule designates January 1, 2021, as the target date for e-prescribing requests and responses using NCPDP SCRIPT 2017071 to be operational between prescribers and Part D plan sponsors. In light of the necessary software changes and deployment across our client bases, our assessment is that this timeline is not realistic. The EHR Association recommends a target date based on a 24-month development and deployment window, *after* the final rule is published.

Additionally, EHR Association members suggest a transition period, during which it is clearly permissible for e-prior authorization services to translate transactions from previously available standards to the NCPDP SCRIPT 2017071 standard.

We are pleased that the proposed rule does not call for certification requirements. We appreciate this approach as we anticipate that the electronic prescribing services will have appropriate certification tests in place before enabling the services. We encourage CMS to work with ONC to align the Interoperability Standards Advisory and other potential initiatives on any standards around prior authorization, and urge CMS and ONC to avoid duplicative certification requirements, should ONC consider inclusion in a future certification edition.

While the EHR Association supports the use of the NCPDP SCRIPT 2017071 standard for electronic prior authorization for prescriptions under Medicare Part D, we note the various current and candidate standards being used, particularly as HL7® FHIR® is playing an increasing role in web-based APIs that enable real-time interactions using more current technology. These technologies are not yet sufficiently mature, but efforts by HL7, Da Vinci, NCPDP, and X12 should be looked at for future direction in this space.

Thank you for this opportunity to share our perspective as CMS updates the Part D transaction standard for e-prescriptions to ensure secure electronic prior authorization request and response transmissions. EHR Association members look forward to continuing to support CMS' efforts to streamline physicians' use of health information and technology.

Please contact Sarah Willis-Garcia, EHRA Program Manager, at swillis@ehra.org or 312-915-9518 with questions or if we can provide additional information.

Sincerely,

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit $\underline{\text{www.ehra.orq}}$.