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January 10, 2018

Seema Verma

Administrator for the 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 Electronic Health Record Association (EHRA), we are pleased to offer our comments on the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.

EHRA's more than 30 members serve the vast majority of hospitals and ambulatory care organizations that use electronic health records (EHRs) and other health information technology to deliver high quality, efficient care to their patients. The Association operates on the premise that the rapid, widespread adoption of health IT and interoperability has and will continue to help improve the quality of patient care as well as the productivity and sustainability of the healthcare system.

Our comments focus on proposed changes to e-prescribing standards. We ask that the Centers for Medicare and Medicaid Services (CMS) delay requiring implementation of National Council for Prescription Drug Program's (NCPDP) SCRIPT 2017071 for 24 months after the Final Rule is released, to give health IT developers, Surescripts, pharmacies, clinicians and other stakeholders adequate time to develop, implement, test and widely deploy system upgrades.

In section II.B.8. E-Prescribing and the Part D Prescription Drug Program, CMS proposes to introduce a replacement standard to communicate prescriptions electronically as well as expand on the interactions that need to be supported electronically. Currently the supported standard is NCPDP's SCRIPT 10.6, which is required in ONC's 2015 Edition Health IT Certification Criteria (2015 Edition).

EHRA recognizes that the new proposed standard, NCPDP's SCRIPT 2017071, represents a reasonable progression to support e-prescribing interactions. However, EHRA is concerned that the January 1, 2019 deadline to adopt the new standard does not allow adequate time for development, implementation, testing, and deployment. With a finalized rule in early 2018, less than one year would be available to allow health IT developers to upgrade their systems and then work with their clients and Surescripts to implement the new capabilities. At the same time, Surescripts must upgrade its capabilities with pharmacies, Pharmacy Benefit Managers (PBMs) and other stakeholders. We are deeply concerned that there is not sufficient time to collectively be ready to support the proposed requirements.

Additionally, we are concerned that the proposed requirements are not aligned with the Office of the National Coordinator for Health IT's (ONC) initiatives. It is our understanding that the purpose of ONC's Interoperability Standards Advisory (ISA) is to provide insight into what standards and implementations should be considered for adoption in the near/mid-term. To date, there have been no indications that SCRIPT 2017071 is the new target for e-prescribing.

- As recently as December 2017, ONC's ISA does not include any reference to the emerging SCRIPT 2017071 standard, which would be an early indication to signal intent to move toward the new standard.
- ONC's 2015 Edition calls for support of SCRIPT 10.6, a continuation of the 2014 Edition. All systems have focused on supporting that version, in addition to the Surescripts implementation guide, to achieve the current level of e-prescribing.
- Surescripts does not yet have an announced date to adopt SCRIPT 2017071, nor is there any indication whether additional implementation guidance/requirements would need to be addressed in addition to 2017071 (as was the case for SCRIPT 10.6).

We also note that:

- SCRIPT 2017071 is not fully backward compatible with SCRIPT 10.6. There are changes to data definitions (e.g., increased data lengths and new formats), and while SCRIPT 2017071 requires use of XML, various implementations of SCRIPT 10.6 may still use EDI. Therefore, development efforts will be needed in order to upgrade existing transactions to the new standard.
- We disagree with the assertion that replacing current transactions using SCRIPT 10.6 with 2017071 is de minimis. Any change of standard involves re-mapping of data, development of code, testing, certification, deployment, and other efforts with all parties involved (health IT vendor, Surescripts, providers, and other entities) necessary to ensure the data continues to flow as intended. Such efforts are not trivial and involve investment from all stakeholders.
- Many EHR vendors and other stakeholders have already allocated development resources on their roadmaps to deliver customer-demanded functionality and innovation. Diverting these resources with less than a year to accommodate the adoption of SCRIPT 2017071 could result in a loss of functionality requested by clinicians. This is particularly true in a year following the development of a new certified edition, where customer demands might have had to be deprioritized to deliver certified functionality.

We urge CMS to delay the proposed adoption of SCRIPT 2017071 until at least 24 months after all requirements are available (Final Rule and Surescripts Implementation Guide) to address all aspects of development through deployment, across all stakeholders.

EHRA typically has asked for at least 18 months for proposed EHR capability upgrades, but we believe, considering the complexities and number of stakeholders involved, 24 months is more appropriate in this case. This effort requires coordination not just to roll out the updated and new transactions to prescribing clinicians, but to retail pharmacies that the clinicians interact with also. Additionally, care should be given to minimizing disruptions or inconsistencies in clinicians' workflows during the time window when not all of the pharmacies they interact with have adopted the new standards. This is particularly true for organizations that will just have begun the adoption to the 2015 Certified Edition.

Also, we suggest establishment of a one year transition period to migrate existing transactions from SCRIPT 10.6 to 2017071, beginning after the new transactions are supported by Surescripts (but does not complete until the earliest 24 months from release of the Final Rule and the Surescripts Implementation Guide). Such an approach will provide for a more orderly roll-out than requiring that all stakeholders convert on the same day, and would avoid deadlines falling on federal holidays.

We furthermore urge CMS to work closely with ONC to address the proposed change in the context of all interoperability initiatives that ONC facilitates across all stakeholders. We suggest that CMS work with ONC to use these interoperability initiatives to reduce certification burden (e.g., 2015 Edition certification and Surescripts certification) and focus on establishing with the industry robust testing tools; these tools should enable all interoperability partners (vendors, Surescripts, pharmacies, providers) who develop any of these transactions to thoroughly test the capabilities, and then self-attest to having passed those test tools.

We suggest that not all transactions need to be supported for all prescribing clinicians, as some transactions are specific to certain settings, e.g., long-term care facilities. We urge CMS to work with ONC and NCPDP to provide such clarification in the context of ONC's interoperability initiatives as well as to reduce development, certification, and implementation efforts where prescribing clinicians and health IT vendors are not active in those specific settings.

Thank you for this opportunity to comment.

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 www.ehra.org.