Centers for Medicare and Medicaid Services

U.S. Department of Health and Human Services

Attention: CMS-4182-P

Mail Stop C4-26-05

7500 Security Boulevard

Baltimore, MD 21244-1850

Dear Sir or Madam,

Cerner Corporation (Cerner), a leading supplier of electronic health record, clinical and revenue cycle information systems appreciates the opportunity to submit comments on certain of the provisions of 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 Benefits Programs and the PACE Program,* Proposed Rule CMS-4182-P. We offer comments specifically on section *II.B.8. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards*.

Cerner hopes these comments will be of value to CMS in considering possible update to the CY 2019 Medicare Part C and D Program Updates NPRM. We are happy to help clarify any of the comments should CMS wish to pursue any such conversations with us during the period of public comment review.

Sincerely.



John Travis

Vice President and Compliance Strategist

Cerner Corporation

# Section II.B.8 – E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

Cerner praises the Centers for Medicare and Medicaid Services (CMS) for its forward thinking in proposing an upgrade in the E-Prescribing Transaction Standards to Version 2017071, as recommended by the National Council for Prescription Drug Plans (NCPDP) recognized by CMS as the Standards Development Organization (SDO) for electronic prescribing. As the last officially mandated standards upgrade took place in 2013, it is our belief that an upgrade will benefit the industry and is a logical step in the progression of Health Information Technology. Additionally, Cerner applauds the agency’s foresight in addressing the 9 additional transactions which allow for the additional efficiencies within the electronic prescribing process.

As a vendor of software that contains functionality for both prescribing and dispensing, we would like to provide the following comments in support of influencing strong policy- making.

* **ONC Interoperability Standards Advisory**

The proposal to officially update the electronic prescribing standard to SCRIPT 2017071 did not surface through ONC’s Interoperability Standards Advisory (ISA), and we feel it necessary to call attention to the absence of inclusion in ONC’s 2017 or 2018 ISAs. We understand that there is no requirement that new standards adoption first be identified through the ONC ISA, but we feel strongly that the industry should be able to rely on ONC’s ISA as an advanced barometer for new standards adoption. We encourage CMS to work with ONC in this manner in the future.

* **Transition Period/Voluntary Adoption**

Within subsection b. Regulatory History, CMS steps through the previous adoptions of E-Prescribing Standards, which has consistently provided, in the past, a 24 month transition period beginning upon release of the final rule for voluntary adoption and upgrade to the new version, while allowing for use of the previous version as well. Finally, a 12 month notification was provided for the retirement of the previous version, and mandatory adoption of the new version. For instance, final rulemaking on June 23rd, 2006 recognized SCRIPT 8.1 as an update to SCRIPT 5.0, with a voluntary adoption, and final rulemaking released on April 7, 2008 mandated retirement of 5.0 on April 1, 2009. Subsequently, on July 1, 2010, SCRIPT 10.6 was recognized as the successor of version 8.1, with version 8.1 being retired on November 1, 2013. CMS has requested comment on the retirement of version 10.6 on December 21, 2018 and the official adoption of 2017071 on January 1, 2019. Cerner offers the following comments and perspective regarding this expedited timeline for adoption without consideration for a “dual use” of SCRIPT 10.6 and SCRIPT 2017071.

Cerner suggests CMS provide a voluntary 24-month adoption and transition period, effective on the date the final rule is released. While we understand the desire of the agency to expedite adoption of SCRIPT 2017071, and further streamline the adoption process to avoid interim rule-making as was included in previous upgrades, we believe the industry will be unable to undertake the enormity of this upgrade in the proposed period that is less than 12 months after a final rule would be issued. There are many dependencies within the electronic prescribing process, across multiple stakeholders, that require additional time for an effective upgrade.

Additionally, in terms of transaction adoption, previous transitions allowed the opportunity for providers to deliver feedback to vendors on what transactions would be needed for their practice, reducing the burden of adoption as only applicable transactions need be supported by vendors, and implemented by providers. For this transition, feedback must be obtained at a much faster pace, lest all transactions are deployed to all providers.

* + **De-minimis Effort of Upgrade**

Cerner would like to comment on the usage of the phrase “deminimus cost” and other indications that upgrade to SCRIPT 2017071 would provide minimal burden to the stakeholders involved in e-prescribing for the Medicare Part D Program. As there are 25 versions that have been publised between the current SCRIPT 10.6 and the proposed adoption of SCRIPT 2017071, and CMS is proposing the adoption of 10 additional transactions, we believe the actual cost and effort of the upgrade will be considerably greater than is indicated by the current language in the proposed rule. Costs incurred will stem from 12-18 months of vendor development work, followed by the cost of training end-users, client consumption of a sizeable upgrade, collaboration with trading partners for timely adoption, and other costs associated with implementation efforts such as potential new licensing. Additionally, vendors who have certified, or gone through external security audits for e-prescribing of controlled substances with the Drug Enforcement Agency (DEA) will be required to repeat those efforts with the SCRIPT 2017071 version updates after any such vendors have completed those updates. This represents a set of activities that CMS does not appear to have accounted for in their proposed rulemaking.

As evidence of burden associated with upgrade, we offer the following reference materials regarding the effort undertaken by Cerner in the upgrade from SCRIPT 8.1 to SCRIPT 10.6 on behalf of its clients several years ago:

Core uplift from SCRIPT 8.1 to SCRIPT 10.6 has been approximated to have taken the following work effort from a software vendor development perspective, which would not include the amount of time needed for a customer to test and implement the software package. As a note, the following estimation is inclusive of support to ensure e-prescribing for controlled substances meets the requirements set forth by the DEA. While this is not directly attributable to the effort needed to perform the SCRIPT 2017071 uplift, it will be action required of the software vendor beyond the primary impact of this rule.

Core Work Effort for Uplift to SCRIPT 10.6

* Development project duration: June 2011 to December 2012 (18 months)
* Approximately 53 Development Team Months
* Approximately 30,500 hours of development

In addition to the above core uplift, it will also be required for software vendors to perform a Medication History uplift from SCRIPT 10.6 to SCRIPT 2017071. To provide an estimation of work effort for this portion of the project, we have included information below from the SCRIPT v10.6 uplift from SCRIPT 8.1. Again, these numbers include some ancillary development work which is not directly attributable to the SCRIPT version upgrade.

Medication History Work Effort for Uplift to SCRIPT 10.6

* Development project duration: August 2011 to November 2012 (15 months)
* Approximately 22 Development Team Months
* Approximately 12,000 hours of develpment

Finally, SCRIPT 10.6 required development to implement the Cancel/Change/Fill transactions; a requirement of 2015 Edition Certification with the Office of the National Coordinator for criterion 170.315(b)(3) which will remain a requirement upon client upgrade to SCRIPT 2017071, and therefore will require development work. As a note, the work effort documented below is relative to creating these net new transactions; it stands to reason that work to uplift them to SCRIPT 2017071 would be less onerous. However, we ask that CMS consider these figures as they are relevant to work effort required to develop each of the 10 new transactions.

* Development project duration: January 2016 to September 2016 (8 months)
* Approximately 18 Development Team Months
* Approximately 34,000 hours of development

When considering the work effort to upgrade from SCRIPT 10.6 to version 2017071, we ask that CMS please consider the sum of all three of the above projects, and also consider the additional work effort that will be required to develop the 10 new transactions which have been mandated with the proposed rule. In light of this information, we recommend that CMS refrain from referencing miminal cost or effort of the upgrade. The real costs of adoption will come when organizations elect to engage in the use of the new standards, and while compliance is voluntary in the sense of providers, pharmacies and prescription drug plans electing to use the transactions in the place of other means of communication, the costs to be borne will be realized incrementally as they elect to engage in electronic transacting. This is also why we ask CMS to consider the complexity of an aggressive compliance period In their final rule, and to give full consideration to allowing the industry a 24 month transition period.

* **Insulation of Trading Partners During Transition**

The upgrade to SCRIPT 2017071 is so substantial that we are not convinced that all stakeholders will be able to transition to the version by January 1, 2019, whith less than 12 months to prepare and execute. We understand that certain intermediaries for electronic prescribing such as Surescripts are considering plans to insulate trading partners from the challenges of using different NCPDP versions during the transition. We understand that other actions may be possible, as well, to help during the transition, such as the intermediary nulling values of any new required fields only required by NCPDP 2017071 and addressing field length differences between the versions (e.g. by truncating values that exceed 10.6 field lengths if the sender is sending in 2017071 or by conveying guidance to trading partners to not to send values in 2017071 transactions that exceed the field length of a 10.6 enabled trading partner). These are examples of some of the variables that must be considered if the transition is to involve two versions in use at once until the end of the transition period for that transaction. We also understand that Surescripts has yet to develop their own implementation guide for SCRIPT 2017071 which will inform their certification of HIT vendors of Surescripts’s business rules for transacting in the new standards. Surescripts vendor certifaction activities can only be completed after vendors finish their software development which also depends upon the availability of this same implementation guide. Unless CMS recommends adoption of a binary compliance date generally or even transaction by transaction (i.e. all stakeholders starting to use the same transaction set on the same day), which we would advise against. These are factors that must be accounted for in the final rule. Cerner recognizes that these scenarios are currently being considered and planned for by industry leaders (i.e. Surescripts), but none-the-less calls this out for agency attention in recognition that a transition period, as recommended above, would be to the benefit of all stakeholders.

* **Transition Timeline**

Again, in support of an extended timeline for adoption of SCRIPT 2017071, Cerner would like to call attention to the effort required to undertake the transition to the new standard. Cerner has been involved in many standards related upgrade efforts including all three of the ONC criteria edition adoptions for EHR certification for the EHR Incentive Program, adoption of ICD 10 CM and ICD 10 PCS, adoption of all iterations of HIPAA EDI standards, adoption of the National Provider Identifier (NPI) and numerous other federal initiatives that involve standards adoption for HIT. In almost every single case, there have been extensions or relaxing of enforcement to allow the industry to come into compliance. There have also been transition periods where old and new versions of standards have been permitted to co-exist. For a vendor of the scale of Cerner to design, develop, test, deploy and bring into production use across its client base a software change of the magnitude of the SCRIPT 2017071 adoption, the effort from start to finish is minimally 24 months. The Electronic Health Records Association (EHRA) has frequently laid out a well established timeline of effort for such large scale adoptions involving 18-24 months. These timelines are necessary to assure as smooth a transition as is possible for HIT vendors and their clients. The proposed timeline does not adequately account for the time needed for vendors to develop, test, certify (with Surescripts), and deploy code. Additionally, after vendor deployment of code, clients must be given adequate time to test the code, train end-users on the updated code, and adoption of the new transaction capabilities.

* **2015 CEHRT E-Prescribing Requirements for 2019**

We observe that use of 2015 Edition CEHRT is first mandated as of January 1, 2019 both for the EHR Incentive Program and for the Quality Payment Program under the Medicare and CHIP Reauthorization Act (MACRA) of 2015. As a part of those requirements, CEHRT is to be certified to the ability to transact in the SCRIPT 10.6 version of electronic prescribing standards. We note that as a result, the first mandated use of 2015 Edition CEHRT will occur in the same calendar year as what CMS proposes for the use of SCRIPT 2017071 with an obvious difference in the electronic prescribing standard that is required. While we are certain CMS has already considered this matter, the proposed rulemaking does not account for this difference nor does it propose any implications for 2015 Edition CEHRT. We ask for clarification on the application of SCRIPT 2017071 E-Prescribing Standards against the 2015 CEHRT requirements that will be in effect for 2019. We believe that the current CMS proposal obsoletes the use requirement for 2015 Edition CEHRT, thus not requiring vendors to certify against the 2015 Edition CEHRT electronic prescribing criterion.

* **Enforcement and Support of SCRIPT Versions 10.6 and 2017071**

Enforcement of this rule seem to be not penalty or audit driven; however, the rule sets a firm requirement for any entity that currently utilizes electronic prescribing to use SCRIPT 2017071 based transactions on January 1, 2019. Should such an entity prove unable to meet the upgrade deadlines, one must conclude they must cease all electronic prescribing transactions where they do not use SCRIPT 2017071 based transactions, and prescribing processes must regress to manual methods until the complete set of transactions applicable to the entity are upgraded to SCRIPT 2017071. This would be in violation of at least some [State law](http://www.op.nysed.gov/prof/pharm/pharmelectrans.htm) where electronic prescribing is mandated. Cerner asks CMS for clarification on the effects for industry stakeholders who fail to undertake the upgrade to SCRIPT 2017071 on a timely basis. Absent an enforcement regime similar to that in place for [HIPAA EDI](https://www.hhs.gov/hipaa/for-professionals/special-topics/enforcement-rule/index.html), Cerner fears that extended support of two versions of NCPDP standards (SCRIPT 10.6 and 2017071) until such time as all stakeholders transition to SCRIPT 2017071 could provide an exceptional burden from a support and cost perspective. Aside from stakeholder complaint and contractual remedies, what sanctions exist or will exist to push adoption?

In regards to enforcement, Cerner would like to ask for further clarification if the January 1, 2019 effective date represents a starting point, or a binary requirement (requirement for stakeholders to upgrade on the same date), as this differentiation will greatly impact current interpretation and planning for implementation of SCRIPT 2017071. Also, due to the difference in approach for this upgrade to SCRIPT 2017071 from previous upgrades to SCRIPT 8.1 and 10.6, Cerner seeks clarification if the effective date represents the start of a transitional period and if it is at the trading partner discretion to transact in one version of the standard or the other during that transition period, or whether the effective date represents a common date for all stakeholders to upgrade all at once.

* **Mandatory Adoption of New Prescribing Transactions**

Cerner also wishes to comment on the proposal which mandates the adoption of the following new transactions:

* Prescription Drug Administration Message
* New Prescription Request
* New Prescription Response Denials
* Prescription Transfer Message
* Prescription Fill Indicator Change
* Prescription Recertification
* Risk Evaluation and Mitigation Strategy (REMS) Initiation Request
* REMS Initiation Response
* REMS Request
* REMS Response

As currently stated, the above transactions are listed as voluntary adoption requirements within the SCRIPT 2017071 implementation guide, which mirrors much of the pre-existing SCRIPT transactions. However, within the proposed rule, strong language is utilized suggesting that where an organization is participating in e-prescribing for Part D beneficiaries, and where processes are undertaken which could be completed using the new transactions, the new transactions must be utilized. In this situation it comes into question if CMS is suggesting mandated use of transactions that NCPDP has otherwise offered as voluntary. Additionally, the majority of the above added transactions are in support of residential, as well as coordinated community care activities, which do not impact a large portion of active Medicare Part D Program participants and key stakeholders. Cerner requests CMS’s clarification on this point that organizations participating in e-prescribing only need to support the transactions applicable to their setting and circumstances and therefore HIT vendors only need to support and be potentially certified to by Surescripts to the transactions that their clients need.