October 5, 2020

Submitted electronically at: www.regulations.gov

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Re: CMS-3394-NC, Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI)

Dear Administrator Verma:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

For over 40 years NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy services industry as named in HIPAA. The NCPDP SCRIPT Standard, Telecommunication Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in MMA.

NCPDP submits the following comments in response to CMS-3394-NC, Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI).

CMS: II. Solicitation of Public Comment:

A. EPCS Compliance Assessments

- ***CMS Statement:*** *What types of challenges might discourage prescribers from incorporating electronic prescribing into their normal workflows? How could CMS structure its EPCS policy to remove roadblocks to effective adoption of electronic prescribing for controlled substances?*

  NCPDP comments: NCPDP acknowledges there could be rare instances where it is challenging or impossible to submit prescriptions electronically. We continue to update the NCPDP SCRIPT Standard through an iterative, consensus-based process to address

identified standard gaps. For example, the previously named NCPDP SCRIPT Standard Version 10.6 did not provide for transmission of compound prescriptions and patient directions were limited to 140 characters. The current mandated NCPDP SCRIPT Standard Version 2017071 now provides for the transmission of compound prescriptions and patient directions up to 1000 characters.

NCPDP supports the need for implementation waivers to allow exceptions to minimize barriers to patient care.

The Long Term and Post Acute Care (LTPAC) industry does have some unique challenges to broad adoption of EPCS.

- LTPAC obstacles for adoption:
  - Timeliness of prescribers to submit a fully compliant electronic prescription to the pharmacy through limited or lack of access to appropriate technology.
  - Prescribers access to a prescribing system with the capability to communicate with LTPAC setting/service systems that provide the medication administration services.
  - Pharmacies standards-based workflows to support electronic communication of EPCS received from prescribing systems outside of the LTPAC setting/service system.
  - Communication from prescriber to an agent that does not have the scope of practice to transmit a fully compliant EPCS prescription on behalf of the prescriber.
  - Lack of available guidance within the current standard is causing inconsistent implementation of relevant parts of the standards needed to be compliant with this regulation.
  - The unavailability of technology to support LTPAC services in rural communities could preclude compliance in these areas.
- NCPDP LTPAC Task Group recommendations to assist with increased adoption of EPCS:
  - Utilization of CMS' waiver policy when the prescriber does not have access to appropriate technology that can issue a prescription using EPCS without delaying patient care.
  - CMS support of the development of NCPDP guidance and/or standards that supports synchronization between prescribing, LTPAC, and pharmacy systems.
  - Allow an exemption for LTPAC services where the scope of practice is unable to provide fully compliant EPCS support through available technologies (see EPCS waivers section of the RFI).

- ***CMS Statement:*** *What time period (or periods) should CMS use to evaluate compliance (for example, quarterly, semi-annually, annually) and how should we communicate information on performance to the prescriber to drive improvement?*

NCPDP comment: NCPDP is not offering any recommendations on time period(s) or how CMS should communicate performance information to the prescriber. We do note the

Prescription Origin Code (419-DJ) field is available on the Prescription Drug Event (PDE) and is reported to CMS within 30 days of receipt of the claim. This field could be used to evaluate compliance as it indicates if a prescription was sent to the pharmacy electronically or received via other means.

C. EPCS Waivers

- ***CMS Statement****: A prescription issued when the practitioner and dispensing pharmacy are the same entity. We seek comments on whether this exception is necessary, and how these claims may be identified.*

  NCPDP comment: NCPDP agrees such a waiver is necessary and appropriate. Without a waiver, health IT teams developing integrated systems for entities acting as both the prescriber and the dispensing pharmacy could be required to rush to complete development to change their integrated prescribing and dispensing software to communicate using an NCPDP interface, rather than leveraging the single database to which they both have access to today. Requiring a system to "self-interface" rather than leverage its integrated database would have adverse impacts on health IT cost and performance and increase the potential for data corruption and patient matching errors. Meanwhile, such a requirement would not improve the security of the prescribing process since prescribers must adhere to the DEA's expectations for EPCS applications regardless of which electronic prescribing standard or communication method is used. Such an exemption would align with CMS' existing policy at 42 CFR 423.160(a)(1) from using the NCPDP SCRIPT Standard because the prescriptions and prescription-related information for covered Medicare Part D drugs for Medicare Part D eligible individuals is not transmitted using electronic media.

  Additionally, CMS should align such an exception with CMS' existing policy at 42 CFR 423.160(a)(3)(iii) which allows the use of HL7 messages for transmitting prescriptions and prescription-related information internally by clarifying that exemption's applicability to prescriptions for controlled substances. CMS could then leverage existing processes and procedures for Medicare Part D Prescription Drug Programs to indicate the applicability of an exemption on claims. The claim may be used to identify the prescriber and service provider. Prescriber ID (411-DB) and Service Provider ID (201-B1) fields are available on the PDE.

  Waivers should also be considered for prescriptions that cannot be transmitted during natural disasters or in rural areas that do not have sufficient connectivity and/or technology to send electronic messages. For example, without waivers, rural LTPAC settings may not meet the necessary timely exchange of data which could potentially delay critical patient care and therapy.

- ***CMS Statement:*** *A prescription issued that cannot be transmitted electronically under the most recently adopted version of the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard. We believe that the current adopted standard NCPDP SCRIPT version 2017071 allows for most electronic prescribing transmissions. <u>We seek comment on this assumption and on any specific circumstances in which a prescription for a controlled substance could not be transmitted electronically under this standard</u>.*

NCPDP comment: While the NCPDP SCRIPT Standard version 2017071 can successfully transmit the vast majority of prescriptions, there are several situations in which limitations of the standard or communication conditions will result in an inability for the prescription to be transmitted including:

- Network/internet outages or system downtime
- Patients with names longer than 35 characters
- Patients whose names contain extended ASCII characters (common examples include the 'ñ' and 'é' characters)
- Prescriptions with notes for the pharmacy that exceed 210 characters
- LTPAC settings/services in rural communities that service vulnerable populations that do not have sufficient capabilities to support NCPDP message transmission by agents with the appropriate scope of practice or through available technologies.

In these situations, the NCPDP standard cannot be used by the prescriber to complete the electronic prescribing transaction requiring the practitioner to use an alternative method of prescribing, such as paper. CMS' waiver policy should allow prescribers the flexibility to use alternative prescribing workflows for all of these situations and any others where a prescription is technically unable to be transmitted using the NCPDP SCRIPT Standard.

- ***CMS Statement:*** *A prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use. We seek comment on whether there are any drugs currently under risk evaluation and mitigation strategies for which prescriptions are not conveyed electronically or cannot be modified for electronic transmittal.*

  NCPDP comment: It is rare that a prescription for a medication subject to risk evaluation and mitigation strategies that include elements to assure safe use (REMS ETASU) could not be transmitted electronically using the NCPDP SCRIPT Standard. NCPDP does not believe there should be a categorical waiver for such prescriptions. Further, additional requirements for REMs drugs will be added to future NCPDP SCRIPT Standard versions to address any identified gaps. Currently, NCPDP is only aware of Xyrem and Sodium Oxybate (generic shared REMs) that have specific requirements (type of dose and co-morbidities) that cannot be transmitted in discrete fields using the current version of the NCPDP SCRIPT Standard. These prescriptions could fall under a general waiver for prescriptions that can not be ePrescribed, due to limitations of the NCPDP SCRIPT Standard.

- ***CMS Statement:*** *A prescription issued by a practitioner—*
  ++ For an individual who receives Medicare hospice care; and
  ++ That is not covered under the Medicare hospice benefit.
  We seek comment on the circumstances in which this exception is necessary, and how this information would be conveyed to CMS.

NCPDP comment: If the prescription is not covered under the Medicare hospice benefit, but the individual is receiving Medicare hospice care, there may be some limited situations where the hospice provider is unable to electronically send a prescription. In those rare cases, a waiver is warranted to ensure patient care is not disrupted. The claim may identify patients residing in a hospice facility via Patient Residence (384-4X) field, value 11 (Hospice) when that information is known to the pharmacy. However, patients outside of a hospice facility would not be identifiable through the claim. NCPDP recommends CMS confirm hospice enrollment through sources other than the PDE.

- ***CMS Statement:*** *We recognize that electronic prescribing for residents in nursing facilities can be challenging due to necessary three-way communication involving the prescriber, the facility and the pharmacy. Waiting for the prescriber to transmit controlled substance prescriptions electronically for new admissions could create delays in initiating urgent medication therapy because a prescriber could be required to log in to the electronic health record or other health IT system to enter a complete and compliant prescription and may not have immediate access to the system if not on site at the nursing facility. We also recognize that early versions of the NCPDP SCRIPT Standard, such as NCPDP SCRIPT Standard version 5.0 and 8.1, did not support the workflows in the long-term care setting that require prescribers to issue a prescription for a patient to a non-prescriber (such as a nursing facility) that in turn forwards the prescription to a dispenser (LTC pharmacy). Nonetheless, many key Part D initiatives such as electronic prior authorization are anchored within the NCPDP SCRIPT Standard version 2017071. CMS recognizes and is encouraged by the NCPDP's efforts to ensure that e-prescribing standards accommodate the unique needs of nursing facility residents. As these efforts progress, we believe that electronic prescribing will become more widely adopted in these settings. Additionally, as nursing residents are at high risk for infection, serious illness, and death from COVID–19, we are especially interested in how to assure streamlined and timely prescribing. <u>We seek comments on our understanding of the persistence of such challenges for EPCS in the nursing facility setting and on any other specific circumstances which would support this exception</u>.*

  NCPDP comment: NCPDP agrees with the above recognition of the obstacles to ePrescribing. In addition to the previously mentioned LTPAC obstacles for adoption, NCPDP also recognizes the following:
  - Fundamental ePrescribing standards are not wholly aligned to actual practice in the LTPAC settings. NCPDP is currently working on a solution for the multi-party synchronization of communications.
  - Additional time will be needed for the creation of specific guidance and proof of viability through a pilot to gain industry support and identify any outstanding gaps where a new NCPDP SCRIPT Standard would be needed to gain adoption and compliance. (See EPCS compliance section).

NCPDP would like to thank CMS for the opportunity to submit comments on the CMS-3394-NC RFI document. NCPDP looks forward to working with CMS to find solutions for the concerns and issues raised in the above comments.

For direct inquiries or questions related to this letter, please contact:
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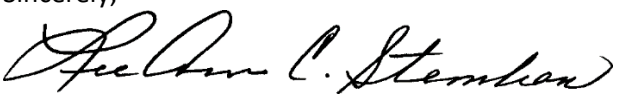
Sincerely,



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cc: NCPDP Board of Trustees