



National Association for the Support of Long Term Care

January 16, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health & Human Services (HHS)
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Via Electronic Submission

Re: Contract Year 2019 Policy & Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule (CMS-4182-P)

Dear Administrator Verma:

The National Association for the Support of Long Term Care (NASL) is pleased to share these comments on select provisions of the Center for Medicare & Medicaid Services' (CMS') *Contract Year 2019 Policy & Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program [Proposed Rule](#)* (CMS-4182-P).

NASL is a national trade association representing providers of both ancillary services and products to the long term and post-acute care (LTPAC) sector. NASL member companies provide health information technology (IT) systems and solutions; speech-language pathology, physical, occupational and respiratory therapy; portable x-ray/EKG and ultrasound; pharmacy; and deliver complex medical equipment; and other specialized supplies for the LTPAC sector. NASL IT vendor companies develop and distribute full clinical and point-of-care IT systems and other software solutions that serve the majority of LTPAC providers of assisted living, skilled nursing and ancillary care and services. In addition, NASL is a founding member of the Long Term & Post-Acute Care Health Information Technology Collaborative (LTPAC Health IT Collaborative), which formed in 2005 to advance health IT issues by encouraging coordination among provider organizations, policymakers, vendors, payers and other stakeholders.

NASL appreciates CMS' efforts to improve the e-prescribing process by implementing a new standard that allows for greater flexibility in accommodating complex directions from the prescriber and other measures that may improve patient safety. Even so, transitioning to new standards can be challenging, which is why we have focused our comments on two sections of this comprehensive

proposed rule, including:

1. Updating the Part D E-Prescribing Standards
2. Changes to the Days' Supply Required by the Part D Transition Process

Updating the Part D E-Prescribing Standards

CMS Proposal – Proposed adoption of NCPDP SCRIPT Version 2017071 as the official Part D e-Prescribing Standard for certain specified transactions, retirement of NCPDP SCRIPT 10.6, proposed conforming changes elsewhere in §423.160 and correction of a historic typographical error in the regulatory text which occurred when NCPDP SCRIPT 10.6 was initially adopted (see page 56439 of [Proposed Rule](#)).

NASL Comment – NASL agrees with the decision to move to the NCPDP SCRIPT Version 2017071, which includes several beneficial changes and improvements to the NCPDP SCRIPT 10.6 standard that we believe will help to improve patient safety.

CMS Proposal – §423.160(b)) – CMS proposes to require use of NCPDP SCRIPT Version 2017071 for the following transactions:

- Prescription drug administration message,
- New prescription requests,
- 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, and
- REMS response.

NASL Comment – NASL supports mandating the transactions listed above. We also suggest that CMS consider the comments of our colleagues with the American Society for Consultant Pharmacists (ASCP) with regard to these and other various items in this proposed rule.

CMS Proposal – CMS proposes to revise §423.160(b)(1)(iv) so as to limit its application to transactions before January 1, 2019 and add a new §423.160(b)(1)(v). The requirement at §423.160(b)(1)(v) would identify the standards that will be in effect on or after January 1, 2019, for those that conduct e-prescribing for Part D covered drugs for Part D eligible beneficiaries (see page 56440 of [Proposed Rule](#)). If finalized, those individuals and entities would be required to use NCPDP SCRIPT Version 2017071 to convey prescriptions and prescription-related information for the following transactions:

- Get message transaction.
- Status response transaction.
- Error response transaction.
- New prescription request transaction.
- Prescription change request transaction.
- Prescription change response transaction.
- Refill/Resupply prescription request transaction.
- Refill/Resupply prescription response transaction.
- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction.
- Fill status notification.
- Prescription drug administration message.
- New prescription requests.
- 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 initiation response.
- REMS request.
- REMS response.

NASL Comment – NASL supports requiring the transactions listed above except for the “Password change transaction.” We do not believe the “Password change transaction” is used in the industry today and therefore should *not* be mandated.

CMS Proposal – CMS proposes to add §423.160(b)(1)(v) to provide that NCPDP Version 2017071 must be used to conduct the covered transactions on or after January 1, 2019. CMS also proposes to amend §423.160(b)(2) by adding §423.160(b)(2)(iv) to name NCPDP SCRIPT Version 2017071 for the applicable transactions. Finally, CMS proposes to incorporate NCPDP SCRIPT Version 2017071 by reference in our regulations. CMS seeks comment regarding the proposed retirement of NCPDP SCRIPT Version 10.6 on December 31, 2018 and adoption of NCPDP SCRIPT Version 2017071 on January 1, 2019 as the official Part D e-prescribing standard for the e-prescribing functions outlined in our proposed §423.160(b)(1)(v) and (b)(2)(v), and for medication history as outlined in our proposed §423.160(b)(4), effective January 1, 2019. CMS also is soliciting comments regarding the impact of these proposed effective dates on industry and other interested stakeholders.

NASL Comment – NASL appreciates CMS’ solicitation regarding the impact of retiring NCPDP SCRIPT version 10.6 on December 31, 2018 and adopting NCPDP SCRIPT Version 2017071 on January 1, 2019 as the official Part D e-prescribing standard for the e-prescribing functions outlined in its proposals.

CMS is right to consider the impact that this transition will have. NASL respectfully requests that a transition period be added to the proposed implementation timeline, as has been done previously in successfully transitioning to a new standard. Specifically, NASL suggests that the effective date of the final rule be considered a voluntary use date for NCPDP SCRIPT Version 2017071, with a sunset date for SCRIPT Version 10.6 set for 24 months later.

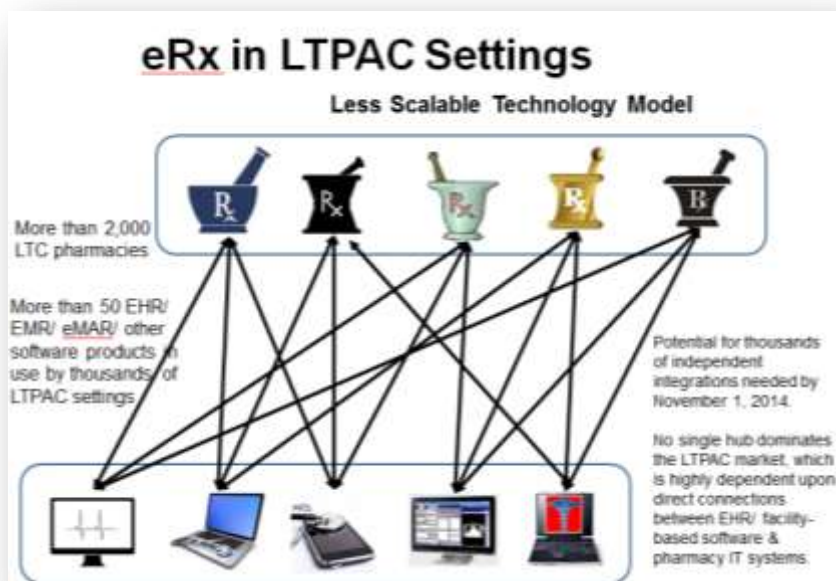
We believe that having a more robust transition period would decrease the risk of healthcare delivery delays and interruption. For example, the transition from SCRIPT Version 8.1 to SCRIPT Version 10.6 took approximately three years, which gave early adopters the opportunity to identify any possible issues with documentation or with the Standard itself.

A transition period is essential as myriad, time-consuming steps must occur prior to the mandated use of SCRIPT Version 2017071. For example, software must be designed, developed, tested and evaluated with respect to workflow by the various vendors – to include prescribing/EHR vendors, pharmacy software vendors, prescribers, pharmacies, payers and intermediaries that route transactions. Once new software is released, additional steps include end user testing, certification, EPCS auditing and training.

A 24-month transition period is critical for those operating in the long term and post-acute care

(LTPAC) sector. LTPAC EHR vendors must follow a lengthy process that involves coordinating releases, testing and certifying with each major pharmacy and pharmacy software system that integrate with LTPAC EHR vendors to ensure that patient safety is not compromised.

While these processes occur in many care settings, LTPAC has a less scalable technology model that involves many more stakeholders than the more streamlined approach taken by the acute and ambulatory care markets. The illustration below shows how implementing the e-prescribing standard when the LTC exemption from the *E-Prescribing Rule* was lifted in 2014 was exponentially more difficult than it was for retail and ambulatory care settings. Retail pharmacies that serve ambulatory care prescribers in the community already had hubs such as SureScripts® in place that allows a single physician practice management application to establish connectivity with the hub, which then gave immediate access to thousands of pharmacies with only one interface validation.



An LTPAC EHR vendor may have to recertify with ten different pharmacy chains and five different pharmacy software systems and/or networks in transitioning to the new standard. With more than 15,000 nursing facilities and an estimated 2,000 LTC pharmacies serving the majority of the sector, the amount of testing, time and resources quickly multiply. This multiplier effect can be overwhelming and divert

resources from LTPAC EHR and health IT vendors' existing software development efforts focusing on health information exchange and other patient care priorities.

In addition, we anticipate the transitioning to the new standard will mean that the Drug Enforcement Administration (DEA) will issue an update to the requirements for electronic orders and prescriptions under Part 1311 of Title 21 of the *Code of Federal Regulations (21 CFR 1311)*, which would trigger a new round of audits for vendors to verify the use of the new standard, which would require additional resources.

Lastly, NASL recommends that the regulatory compliance date for the NCPDP SCRIPT Standard Version 2017071 not fall on the first of January. Already there are operational challenges associated

with the normal processing and administrative changes that occur at the beginning of the calendar year. We also wish to note that the challenge of transitioning to a new e-prescribing standard becomes exponentially greater as LTPAC vendors are undergoing updates to reflect the updated *Requirements of Participation for Long Term Care Facilities* and other more routine updates as required for the *Minimum Data Set (MDS 3.0)*. Selecting an alternate date outside of January, and following a 24-month transition period, would be a more rational approach to implementation of this new standard.

Changes to the Days' Supply Required by the Part D Transition Process

CMS Proposal – CMS proposes to shorten the required transition days' supply in the long-term care (LTC) setting to the same supply currently required in the outpatient setting. Also, CMS now believes it could eliminate additional drug waste and cost by no longer requiring a longer transition days' supply in the LTC setting (see pages 56411 & 56412 of the [Proposed Rule](#)).

NASL Comments – CMS has had a longstanding policy of allowing long term care residents a 3-month supply of non-formulary medications during periods of transition. We have reservations about shortening the required transition days' supply and ask CMS to reconsider. We appreciate CMS' concern about drug waste, but believe the 90-day supply can be limited to 3, 30-day supplies, eliminating potential waste. NASL further agrees with comments of our colleagues at the American Society of Consultant Pharmacists (ASCP) and refers CMS to ASCP's comments for discussion on the unique challenges of managing medication regimens for this population.

Conclusion

As our nation's healthcare system continues to seek efficiencies through the use of emerging health information technologies, we are keenly aware of how federal policymaking can affect both innovation and business operations. We thank CMS for raising important questions about the implementation of a new e-Prescribing Standard. We stand ready to work with you in protecting patient safety as we transition to a new e-prescribing standard.

Should you have any questions or need additional information, please do not hesitate to contact Donna Doneski by calling the NASL offices at 202.803.2385 or by emailing donna@nasl.org.

Sincerely,



Cynthia Morton, MPA
Executive Vice President, NASL