June 24, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Proposed Rule CMS-1716-P

The National Council for Prescription Drug Programs (NCPDP) appreciates the opportunity to respond to the CMS-1716-P proposed rule on behalf of industry stakeholders. NCPDP is a not-for-profit American National Standards Institute (ANSI) accredited Standards Development Organization (SDO) consisting of more than 1,600 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.

NCPDP recommends that CMS continue to work with ANSI-accredited SDOs that create standards using a consensus-based process among industry experts to develop standardized, workable solutions. Below are our comments to the proposed rule.

Opioid Use Disorder

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CMS:

"(2) Calculating 30 Cumulative Day Look Back Period
Another area where stakeholders have expressed concern is how to calculate 30 cumulative days of Schedule II opioid prescriptions in a 6-month period. One possible solution we offered was to utilize the NCPDP 10.6 Medication History query. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41655), we noted that the Medication History query does not contain a discrete field for prescription days and relies on third party data that may not be discrete. Since the FY 2019 IPPS/LTCH PPS final rule was published, stakeholders have continued to express this concern and impress upon us that the 30 cumulative day total in a 6-month look-back period cannot be automatically calculated, requiring health care providers to engage in a burdensome, manual calculation process if they wish to report on this measure…"

NCPDP Comments:

The *NCPDP SCRIPT Standard Implementation Guide Version 10.6* Medication History transactions are named in the Office of the National Coordinator for Health Information Technology (ONC) 2018 Interoperability Standards Advisory for querying and retrieving data from Prescription Drug Monitoring Programs (PDMP(s)). The Medication History transactions are used today and integrated into many Electronic Health Record (EHR) systems due to Meaningful Use. Therefore,

use of these transactions will expedite provider access to PDMP data. NCPDP supports encouraging the use of Medication History transactions. The *NCPDP SCRIPT Standard Implementation Guide Version 2017071* Medication History transactions have been enhanced for PDMP queries and response as demonstrated through the ONC Standards and Interoperability (S&I) Framework. This new version of the NCPDP SCRIPT Standard will be available for implementation beginning in January 2020. Any cumulative day total calculations must be completed through integration of Medication History into the EHR. NCPDP supports additional efforts to leverage existing technology and standards for effective use of the data for health IT-enabled Opioid Use Disorder (OUD) prevention and treatment.

Through the use of existing technology and standards, prescribers and pharmacists will be able to share real-time information to enable these providers to make clinical decisions prior to writing and dispensing medications for proactive intervention and to stop abuse before it starts. The burden on providers is reduced by incorporating drug abuse information within their workflows. Prescribers and pharmacists are already using NCPDP standards in their everyday operations to send, receive, and bill for prescriptions, making it easier for them to assess patient risk and ensure access for patients with a valid medical need.

NCPDP encourages the adoption of electronic prescribing of controlled substances (EPCS) via the NCPDP SCRIPT Standard as an important tool in OUD prevention. EPCS helps to prevent diversion of fraudulent prescriptions. Additionally, in order to facilitate appropriate electronic prescribing of opioids, NCPDP understands the importance of including the diagnosis/indication for which the opioid is being prescribed on an electronic prescription or a related message. The standard currently supports the voluntary inclusion of diagnosis/indication on a new prescription. EPCS will allow the prescriber to communicate prescription-related messages to pharmacies electronically, which will assist the pharmacist in appropriate opioid dispensing for acute and chronic conditions.

Page 19563

CMS:

"We welcome all comments, but we are seeking comment specifically on possible OUD prevention and treatment measures that include the following characteristics:

…

• Are based on well-defined clinical concepts, measure logic and timing elements that can be captured by CEHRT in standard clinical workflow and/or routine business operations. Well-defined clinical concepts include those that can be discretely represented by available clinical and/or claims vocabularies such as SNOMED CT, LOINC, RxNorm, ICD–10 or CPT; and

• Align with clinical workflows in such a way that data used in the calculation of the measure is collected as part of a standard workflow and does not require any additional steps or actions by the health care provider."

NCPDP Comments:

NCPDP recommends that CMS continue to work with NCPDP and other SDOs to produce and promote standards that will further enhance the exchange of electronic health information to improve interoperability and usability and to reduce administrative burdens. Further, NCPDP requests CMS's support in calling out the importance of transparency and interoperability of patient clinical information (e.g. diagnosis codes, and other clinical measures). These values are currently available to be transmitted on an electronic prescription using the NCPDP SCRIPT Standard. Unfortunately, clinical information is not regularly communicated to pharmacies due to

a lack of understanding of their value. In addition, current EHR workflow limitations also impede transmission of the data. Without this clinical information, pharmacists are unable to perform appropriate clinical decision making regarding a patient's opioid use without first contacting the prescriber. Sending clinical information on an electronic prescription would reduce administrative burden and patient delay in obtaining their medication.

Patient Matching

Page 19568

CMS:

"(4) Patient Matching

ONC has stated that patient matching is critically important to interoperability and the nation's health IT infrastructure as health care providers must be able to share patient health information and accurately match a patient to his or her data from a different health care provider in order for many anticipated interoperability benefits to be realized. We continue to support ONC's work promoting the development of patient matching initiatives. Per Congress guidance, ONC is looking at innovative ways to provide technical assistance to private sector-led initiatives to further develop accurate patient matching solutions in order to promote interoperability without requiring a unique patient identifier (UPI). We understand the significant health information privacy and security concerns raised around the development of a UPI standard and the current prohibition against using HHS funds to adopt a UPI standard…"

"…CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information. We are also seeking comment on how we may leverage our program authority to provide support to those working to improve patient matching. We note that we intend to use comments we receive for the development of policy and future rulemaking…"

NCPDP Comments:

NCPDP encourages CMS to explore implementation of a patient matching solution that allows disparate healthcare organizations to exchange patient information across enterprise boundaries. Further, NCPDP recommends that CMS support industry-led efforts to have reliable identity matching. NCPDP's Universal Patient Identifier (UPI)® (https://ncpdp.org/Products/NCPDP-Universal-Patient-Identifier) could be used for this purpose.

There are numerous propriety patient identifier solutions besides NCPDP's UPI®. A patient identifier can be used to exchange information amongst different healthcare entities addressing patient safety, financial and operational challenges across the U.S. healthcare ecosystem. Through its real-time and interoperable Telecommunication Standard and the NCPDP SCRIPT Standard, NCPDP has the unique ability to propagate a patient identifier throughout the pharmacy system and ultimately throughout the entire healthcare ecosystem.

The intent of a patient identifier is to correctly identify the patient, therefore establishing the foundation for exchanging patient information across the healthcare ecosystem. This will provide the following benefits:

1. Reduced medical/medication errors and improved patient safety;
2. Improved care coordination, population health management, PDMPs; and
3. Reduced human and financial resources needed to reconcile duplicate records and billing/claims errors.

The following NCPDP Standards were identified as being applicable for communicating a patient identifier and were modified accordingly through the NCPDP consensus-based process:

1. Post Adjudication Standard
2. Prescription Drug Monitoring Programs (PDMP) Reporting Standard
3. Prescription Transfer Standard
4. Prior Authorization Transfer Standard
5. SCRIPT Standard
6. Specialized Standard
7. Specialty Data Reporting Standard
8. Telecommunication Standard
9. Uniform Healthcare Payer Data Standard
10. Batch Standard Subrogation Standard

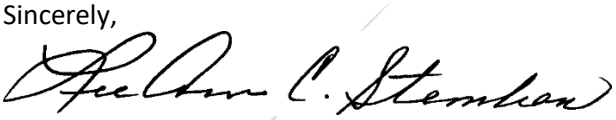
NCPDP recommends any identifier selected by CMS be openly available to any healthcare organization that exchanges patient data and address privacy protections. If CMS chooses not to name a specific vendor product for patient identification, NCPDP recommends CMS work with an ANSI-accredited SDO, such as NCPDP, to establish standards that facilitate the sharing of patient matching information across disparate healthcare organizations and provide the industry with a listing of endorsed identity matching services or products. Such a list could be made available in ONC's Interoperability Standards Advisory (ISA). The listing should only contain products that meet reliability standards set or adopted by CMS or ONC.

In conclusion, NCPDP and its members would like to thank CMS for the opportunity to provide written comments on CMS-1716-P.

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

Paul Wilson
Technical Analyst, Standards Development
NCPDP
E: pwilson@ncpdp.org

Sincerely,



Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000 x 108
lstember@ncpdp.org

cc: NCPDP Board of Trustees