June 11, 2020

RE: CMS-0055-F: Administrative Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard

Dear State Medicaid Director:

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.

NCPDP, as an industry standards resource, is offering guidance on the implementation of the Department of Health and Human Services (HHS) final rule CMS-0055 published on January 31, 2020, effective March 24, 2020, with a compliance date of September 21, 2020.

The final rule adopts a modification of the requirements for the use of the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs, by requiring covered entities to use the Quantity Prescribed (460-ET) field for retail pharmacy transactions for Schedule II drugs. This change constitutes a modification to the ***use*** of the adopted standard, not a modification to the standard itself. Per the final rule:

> *"The modification enables covered entities to distinguish whether a prescription is a "partial fill," where less than the full amount prescribed is dispensed, or a refill, where the full amount prescribed is dispensed, in the HIPAA retail pharmacy transactions. This modification is important to ensure the availability of a greater quantum of data that may help prevent impermissible refills of Schedule II drugs, which will help to address the public health concerns associated with prescription drug abuse in the United States."*

In an effort to streamline the implementation of the Quantity Prescribed (460-ET) field for all Schedule II drugs, NCPDP offers the following recommendations:

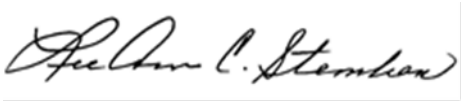
1. Refer to NCPDP's Strategic National Implementation Process (SNIP) Committee guidance documents below:
   - NCPDP Quantity Prescribed (460-ET) Implementation Timeline Guidance
   - NCPDP Payer Sheet Template

2. Coordinate system enhancements to accept all claims submitted with the Quantity Prescribed (460-ET) field, but only require the field for Schedule II drugs.
3. Support the use of the NCPDP External Code List values (e.g., reject codes) designated for Schedule II claim adjudication business cases.
4. Refer to NCPDP's "Recommended Use of Quantity Prescribed (460-ET) in NCPDP Telecommunication Standard Version D.0" white paper which provides information and guidance on the use of the Quantity Prescribed (460-ET) field and associated External Code List values. Below are a few examples of the topics addressed in the white paper:
    - Incremental versus Partial Fill Billing Concepts
    - Claim Processing Guidance, Claim Request and Claim Response
    - Processing Recommendations for Time Limits on Incremental Fills
    - Proration of Copays
    - Frequently Asked Questions
    - Claim Billing Examples
5. Review, update and distribute pharmacy manuals, implementation guides, payer sheets, etc., to reflect the updated use of the Quantity Prescribed (460-ET) field.
6. Support appropriate testing to ensure readiness prior to the September 21, 2020 compliance date.

NCPDP encourages Medicaid programs to share this information with all applicable stakeholders and trading partners and to participate in NCPDP Task Group discussions and the development of any additional industry guidance. If you or a member of your staff have questions or are interested in participating in the Medicaid Frequently Asked Questions (FAQ) Task Group where issues of this nature are discussed, please contact Kittye Krempin, NCPDP, standards@ncpdp.org.

Thank you for allowing NCPDP to bring awareness to the HHS Quantity Prescribed final rule and the significant impact on all pharmacy industry stakeholders. With your collaboration we can help ensure a streamlined implementation while supporting national and industry efforts to mitigate the opioid epidemic.

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