March 14, 2019

Alex M. Azar II
Secretary
Department of Health and Human Services,
Attention: CMS–0055–P

Dear Mr. Azar:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,500 members 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 is submitting the following comments to the CMS-0055-P NPRM. The comments are focused on when the Quantity Prescribed (460-ET) field would be used, alignment with the HIPAA process and the Transactions and Code Sets Rule, and an appropriate implementation timeline. While the immediate need is to address Schedule II medications, NCPDP also recognizes and provides comments on the need to address all controlled substance medications through the DSMO Request 1201 for adoption of the NCPDP Telecommunication Standard Version F2.

Use of The Quantity Prescribed (460-ET) Field
Page 635 of the CMS-0055-P NPRM

> *"In this proposed rule, we would require the Quantity Prescribed (460– ET) field in the August 2007 Version D.0 to be treated as a required field where the transmission uses the August 2007 Version D.0 standard for a Schedule II drug for the following three transactions: (1) Health care claims or equivalent encounter information; (2) referral certification and authorization; and (3) coordination of benefits. We would modify the regulations at §§ 162.1102, 162.1302, and 162.1802 to apply the new requirements. To ensure that the proposed definition of ''Schedule II drugs'' mirrors the DEA definition, we would specify that the term has the same meaning as the definition of that term at 21 CFR 1308.12.*
>
> *To be clear, our proposal would not modify the presently adopted Version D.0 in any way. Rather, it would require covered entities to treat a field in Version D.0 differently than the Version D.0 implementation specification requires. We further want to make clear that this proposal also does not propose to adopt the 2012 publication of Version D.0. There, the NCPDP changed the Quantity Prescribed (460–ET) field designation from ''not used'' to ''situational,'' and the situational circumstance is ''[r]equired for all Medicare Part D claims for drugs dispensed as Schedule II. May be used by trading partner agreement for claims for drugs dispensed as Schedule II only.'' By applying only to transactions involving Medicare Part D claims, the 2012 publication would not cover a huge swath of HIPAA covered entities and therefore we believe our proposal would yield much greater benefit than if we were to adopt that 2012 publication."*

NCPDP Recommendation

NCPDP recommends that in order to accomplish the objective of requiring the Quantity Prescribed (460–ET) field for all Schedule II drugs HHS should:

1. Adopt the November 2012 published version of the NCPDP Telecommunication Standard Version D.0; and
2. Include language within the Final Rule that states, "Covered entities must designate the situational field, Quantity Prescribed (460-ET) as Required for Schedule II Drugs, within applicable trading partner materials."

HIPAA Process and Transactions and Code Sets Rule

It is NCPDP's understanding that the changes as proposed in this NPRM do not follow the HIPAA process.

"*The rule*[1] *required the Secretary to consider a recommendation for a proposed modification to an existing standard, or a proposed new standard, only if "the recommendation was developed through a process that provided for: open public access, coordination with other DSMOs, an appeals process, an expedited process to address content needs identified with the industry, and submission of the recommendation to NCVHS*.""[2]

For the approach proposed in the NPRM to comply with the Transactions and Code Sets (TCS) Rule and the NCPDP ANSI process, the below steps would have to occur within the 180-day timeframe which is not feasible:

- Submit Data Element Request Form (DERF) to modify the situation for the Quantity Prescribed (460–ET) field as defined in the NCPDP Telecommunication Standard Version D.0 published November 2012.
- Obtain membership approval of the DERF
- Ballot the approved DERF
- Obtain consensus on the ballot
- Adjudicate ballot comments
- Recirculate ballot based on categorization of comments when applicable
- Initiate a 30-day appeal period
- Obtain the NCPDP Board of Trustees approval for ballot publication

The timeframe to achieve the above steps could range from 270 to 600 days. Once the modified standard is published, there is a minimum of an additional 180 days before implementation may occur.

NCPDP Recommendation

NCPDP recommends HHS adopt the 2012 publication of the Telecommunication Standard Version D.0 that was previously balloted and approved by the NCPDP membership and subsequently approved by

[1] The Transactions and Code Sets rule (TCS), published on August 17, 2000 (65 FR 50368) established the process for both the maintenance of standards as well as the adoption of modifications to standards (§162.910).

[2] From the NCVHS Predictability Roadmap Narrative Report September 2018

American National Standards Institute (ANSI). This will result in the shortest time period to implement the Quantity Prescribed (460–ET) field. This version eliminates the 270 to 600 days.

NCPDP believes the November 2012 publication of Version D.0 would satisfy the need for all covered entities to require the use of the Quantity Prescribed (460–ET) field for all claims or equivalent encounters, prior authorization transactions and coordination of benefits, where the drug dispensed is defined as a Schedule II drug.

To be clear, the only modification within the November 2012 publication is the change to the Quantity Prescribed (460-ET) field. Refer to Appendix A: "Quantity Prescribed (460-ET) for claim billings was changed from "not used" to "situational" for Schedule II dispensing under the following situational circumstance "Required for all Medicare Part D claims for drugs dispensed as Schedule II. May be used by trading partner agreement for claims for drugs dispensed as Schedule II only."

NCPDP publishes payer sheet templates (companion guides) that are used to define the required use of situational fields. These payer sheets may be included as part of trading partner materials. To comply with the proposed rule, payers would require the submission of the Quantity Prescribed (460–ET) field for all claims or equivalent encounters, prior authorization transactions and coordination of benefits, where the drug dispensed is defined as a Schedule II drug. These payer sheets are used to define required field submission.

Payer Sheet Example:

460-ET	QUANTITY PRESCRIBED	*Imp Guide:* Required for all Medicare Part D claims for drugs dispensed as Schedule II. May be used by trading partner agreement for claims for drugs dispensed as Schedule II only. *Payer Requirement: Required for all Schedule II drugs*

Implementation Timeline

The NPRM references the implementation timeline as "*we are proposing that covered entities would be required to comply with the modification 180 days after the date the modification is adopted in a final rule (to be clear, this would be 240 days following the date of publication of a final rule)*."

NCPDP is estimating this compliance date could result in a January 2020 impact to the industry. This is also the same timeframe as the implementation of the NCPDP SCRIPT Standard Version 2017071, the 2020 Medicare Part D rules and normal annual benefit plan changes. Additionally NCPDP interpreted the NPRM to require all entities to be compliant on the same day (hard cut-over). This may result in patient access to care risks and unnecessary administrative burdens.

NCPDP Recommendation:

To mitigate the risks with a hard cut-over implementation, NCPDP recommends the below transitional implementation timeline as outlined in the letter dated October 9, 2014.

"The Quantity Prescribed (460-ET) field shall be allowed to be submitted on a NCPDP Telecommunication version D.0 claim as of the first day of the month that is at least 180 days after the final rule is published. The compliance date for Payers/Processors/PBMs to impose point of sale edits on the Quantity Prescribed field shall not be earlier than 90 days after the Quantity Prescribed

field is allowed to be sent. This additional 90 day period allows incremental CII prescriptions and claims already in process to complete. Due to end of year industry processing requirements this compliance date should not fall between December 1 and January 31."

Additional Comments:

Quantity Prescribed Field for All Controlled Substances:

NCPDP agrees with HHS that Schedule III through Schedule V drugs not be included with this NPRM. We encourage HHS to expedite the NPRM for the Telecommunication Standard Implementation Guide Version F2 (DSMO request 1201). The enhanced transparency within Version F2 improves patient safety measures for all controlled substances.

Typographical Errors

On page 633 of the proposed rule, there are two places where NCPDP is referred to as the National Council of Prescription Drug Programs. Please correct the name to be the National Council for Prescription Drug Programs.

In summary NCPDP recommends HHS adopt the November 2012 published version of the NCPDP Telecommunication Standard Version D.0. To ensure streamlined implementation, we also recommend the final rule include language that states, "Covered entities must designate the situational field, Quantity Prescribed (460-ET) as Required for Schedule II Drugs, within applicable trading partner materials." We also recommend as outlined above a transitional implementation timeline.

NCPDP appreciates the opportunity to comment on this important and long-awaited rule and HHS's consideration of our recommendations to ensure a streamlined implementation and support industry efforts to mitigate the opioid epidemic.

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

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cc: NCPDP Board of Trustees