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Re: Partnership to Communicate the Barriers in Processing Incremental Fills for Controlled Substance Prescriptions

Dear Sir/Madam,

National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-accredited Standards Development Organization (SDO) consisting of more than 1,400 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 members have been reviewing state and federal legislation that address dispensing of Control Substance medications in increments less than the amount prescribed. NCPDP appreciates and supports measures that are taken to improve patient health and safety; however, we have concerns some state requirements cannot be implemented within the current HIPAA guidelines. This outreach to your organization is an attempt to create a partnership in communicating to policymakers the current barriers and necessary actions to support collaborative and comprehensive solutions.

Barriers:

In an effort to mitigate the opioid epidemic and in support of CARA partial/incremental fills for Controlled Substances, policymakers have passed or are considering rules that may apply to the Original Fill or an Incremental Fill. For example, states that have adopted policy include, but are not limited to, CA, TN, and MA.

Some highlights of these policies include:

- Using non-HIPAA Standard mechanisms to identify an Incremental (partial) Fill

- Proration or adjustments of copayments and related data elements when dispensing less than the Quantity Prescribed
- Validation of total quantity dispensed does not exceed quantity prescribed
- Completion of entire prescription (all fills) within 30 days

In order to accurately validate and calculate the claim outcome for an Incremental Fill the payer must have access to the Quantity Prescribed during the adjudication process. The Quantity Prescribed would be used in conjunction with the Quantity Dispensed to identify Controlled Substance Incremental Fills, calculate total Prescribed Quantity, and adjust copayments and related data elements based on the prescribed and dispensed quantity ratio.

The Quantity Prescribed field is not available for use in the current HIPAA adopted version of the NCPDP Telecommunication Standard Implementation Guide, Version D.0 published August 2010. Since all covered entities communicating electronic prescription claim billing transactions must use the current HIPAA adopted version, there is a significant barrier for the industry to be able to support Controlled Substances Incremental Fill mandates and be HIPAA compliant.

NCPDP Actions:

Stakeholders identified the need for the Quantity Prescribed field in 2012 as a result of Medicare Part D audits that were not able to differentiate between a Refill and an Incremental Fill of a Controlled Substance. NCPDP initially submitted a request to the Department of Health and Human Services (HHS) to update the HIPAA named version to the Telecommunication Standard Implementation Guide Version D.0 published November 2012 and has subsequently contacted HHS multiple times regarding this issue. The specific timeline of activity regarding this request is available at <http://www.ncdp.org/Resources/HIPAA-Information> and selecting Implementation Guide Corrections.

NCPDP members continue to review state requirements and sends letters to the respective states addressing any Telecommunication Standard concerns. Additionally, NCPDP notifies HHS of the various states that have requirements that are not implementable until the Telecommunication Standard is updated as requested. As of the date of this letter, NCPDP has received minimal response from our state outreach.

We continue to attempt to educate the states and industry regarding the difference between Partial Fill and Controlled Substance Incremental Fill. NCPDP defines “Partial Fill” as situations where inventory shortages do not allow the full quantity to be dispensed.

Action Requested:

We believe your membership may be working to address state Controlled Substance requirements. NCPDP would like your assistance in this endeavor and is inviting you to join the WG1 FAQ Controlled Substance Guidance Update Sub-Task Group calls.

You do not need to be a member of NCPDP to join a task group. Information on how to join the NCPDP Collaborative Workspace, download calendar invitations, and join task group calls can be found at the following link: <http://ncpdp.org/NCPDP/media/pdf/EmailToExistingTaskGroups.pdf>

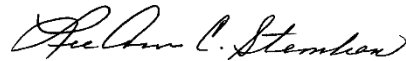
We also request that you involve us in your educational activities with states on the difference between a Controlled Substance Incremental Fill and a Partial Fill and that you reach out to HHS to support the adoption of the Quantity Prescribed field through the revised publication of the Telecommunication Standard. By joining the task group(s), we can assist you in the appropriate language necessary for your communication efforts.

Thank you for your consideration to work with NCPDP to remedy these barriers impacting patients, pharmacies, prescribers and payers as we address the Opioid crisis.

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

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Sincerely,



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