November 15, 2012

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Office of e-Health Standards and Services
Department of Health and Human Services

Re: NCPDP Telecommunication Standard Implementation Guide Version D.Ø Enhancement Based on Regulatory Requirement

Dear Office of e-Health Standards and Services:

The National Council for Prescription Drug Programs (NCPDP) is submitting the following request to allow the enhancement of the NCPDP Telecommunication Standard Implementation Guide Version D.Ø named under HIPAA.

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization 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, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

Description of the problem
Government inspectors alleged in a report[1] based on 2009 data found three-quarters of contractors who processed prescriptions for the Medicare Part D program may have wrongly refilled some medications classed as Schedule II controlled substances, which include strong pain killers and other drugs considered at high risk for abuse. Those refills were worth a total of $25 million.

> "Paying for such drugs raises public health concerns and may contribute to the diverting of controlled substances and their being resold on the street," said the report by the U.S. Department of Health and Human Services inspector general.

The Centers for Medicare and Medicaid Services said in response to the report that the Inspector General was misinterpreting partial "fills" dispensed to patients in long-term care facilities as

[1] https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp

refills. Partial fills occur when a pharmacist does not dispense all doses of the prescribed medication at one time. The report indicated little evidence of actual partial fills.

The NCPDP Telecommunication Standard Implementation Guide Version D.Ø does not support the OIG's strict interpretation of the use of the Fill Number (4Ø3-D3) field. The Fill Number field is used in the industry to represent the fill number and not necessarily the refill number. NCPDP will work to clarify the definition to avoid further misinterpretation.

As such, the following question was submitted by the Centers for Medicare and Medicaid Services Medicare Drug Benefit Group to NCPDP's WG9 Government Programs Medicare Part D FAQ Task Group. This Task Group answers questions that are submitted from industry stakeholders to help with consistent application of Medicare Part D policy where claims or other applicable transactions, Prescription Drug Events (PDE) are involved.

> "We need to determine if there is a way to use the standard appropriately to distinguish incremental cycle fills of a controlled substance prescription in LTC claims from illegal refills. Some auditors, looking at the PDE data, are concluding that fill numbers greater than 0 are illegal refills. They believe that these should be indicated as partial fills.
>
> We believe that in long term care pharmacies, where prescribed amounts may be dispensed in multiple increments (i.e., "short cycle dispensing"), the dispensing status field may not be used on an electronic claim to indicate a partial fill in the sense of the term as used in 21 CFR §1306.13(b)[1]. The use of this field is dictated by the NCPDP (HIPAA) standards and is limited to "situations where inventory shortages do not allow the full quantity to be dispensed"[2]. Use of a field in contravention of the standard would be a HIPAA violation.
>
> We are not aware of another means of a LTC pharmacy distinguishing multiple partial fills of one controlled substance prescription for billing purposes (to avoid rejection as a duplicate claim) without using the fill number field. We would like to work with the pharmacy industry through NCPDP to determine if there is another acceptable use of the standard that utilizes a different field. If there is, we will explore our options for either encouraging or requiring the use of that alternative process to improve controls over fraud, waste and abuse. In the meantime, we believe use of a fill number greater than "0" on PDEs associated with LTC pharmacy short cycle fills of controlled substances cannot be relied upon to identify illegal refills."

[1] 21 C.F.R. § 1306.13(b) allows for the partial filling of prescriptions schedule II controlled substances in order to reduce the quantity of drugs on hand. "(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication."

[2] From version D.Ø Telecommunication Standard Data Dictionary (page 33):

Field:	343-HD
Name of Field:	Dispensing Status
Definition of Field:	Code indicating the quantity dispensed is a partial fill or the

completion of a partial fill. Used only in situations where inventory shortages do not allow the full quantity to be dispensed.

Recommendation
NCPDP's recommendation is to allow the Telecommunication Standard Implementation Guide Version D.Ø to specify the conditional use of field Quantity Prescribed (46Ø-ET) which is currently not in use in the claim billing transaction. During the review and approval of the Telecommunication Standard Implementation Guide Version D.Ø a business case for the use of this field was not brought forward and the situation for the use of the field was designated as "not used" in all billing transactions. Allowing the use of this field will communicate the actual quantity prescribed in the transmission of the claim. The data would be available to validate whether or not there are inappropriate fills in excess of the quantity prescribed.

Action
1. NCPDP requests OESS publish a notice by December 31, 2012 regarding approval of the use of the requested field.
2. NCPDP will republish the Telecommunication Standard Implementation Guide Version D.Ø, with an explanation in the "Editorial Corrections" section.
3. NCPDP would also publish this change in the Version D Editorial Document, which is a publicly available document containing editorial corrections, clarifications, and frequently asked questions.
4. Notification of the updated documents would be sent to all members (anyone that has purchased the Telecommunication Standard Implementation Guide Version D.Ø is considered a member).

Note, DSMO Change Request #1182 has been filed. A copy of this letter has been sent to the NCVHS Subcommittee on Standards. Thank you for your assistance in this matter.

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

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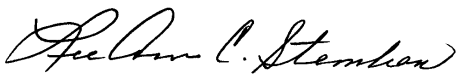
Sincerely,



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cc: NCPDP Board of Trustees