May 31, 2017

Thomas E. Price, M.D.
HHS Secretary
HHS Office of the Secretary
Secretary@HHS.gov

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

Re: Partial Fills of Schedule II Controlled Substances

Dear Dr. Price and Mr. Rosenberg,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI)-accredited Standards Development Organization (SDO) consisting of nearly 1600 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, industry professional societies, service organizations, government agencies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry.

On July 22, 2016, the Comprehensive Addition and Recovery Act ("CARA") of 2016 (Public Law 114-198) was signed into law as a measure to help address prescription opioid abuse. Section 702 Partial Fills of Schedule II Controlled Substances amended the Controlled Substance Act to allow a pharmacist to partially fill a Schedule II controlled substance based on the request of the prescriber or the patient ("CARA Partial Fill Provision").

SEC. 702. PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.
(a) IN GENERAL.—Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

''(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.—

''(1) PARTIAL FILLS.—A prescription for a controlled substance in schedule II may be partially filled if—

''(A) it is not prohibited by State law;

''(B) the prescription is written and filled in accordance with this title, regulations prescribed by the Attorney General, and State law;

''(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

''(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

''(2) REMAINING PORTIONS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—

''(i) may be filled; and

''(ii) shall be filled not later than 30 days after the date on which the prescription is written.

''(B) EMERGENCY SITUATIONS.—In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in schedule II—

''(i) may be filled; and

''(ii) shall be filled not later than 72 hours after the prescription is issued.

''(3) CURRENTLY LAWFUL PARTIAL FILLS.—Notwithstanding paragraph (1) or (2), in any circumstance in which, as of the day before the date of enactment of this subsection, a prescription for a controlled substance in schedule II may be lawfully partially filled, the Attorney General may allow such a prescription to be partially filled.''

With implementation of the CARA Partial Fill Provision, the potential exists for a significant increase in the number of occurrences of a prescription for a Schedule II controlled substance being partially filled.

Background

In response to the Office of Inspector General Report, Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills[1], the Centers for Medicare and Medicaid Services (CMS) stated, "it is highly likely that OIG is misinterpreting partial fills dispensed to long-term care facility residents as refills of Schedule II drugs." 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.

NCPDP's recommendation to CMS was to allow the Telecommunication Standard Implementation Guide Version D.0 to specify the conditional use of field Quantity Prescribed (460-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.0 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 then be available to validate whether or not there are inappropriate fills in excess of the quantity prescribed.

In November 2012, NCPDP petitioned the Division of National Standards to adopt the revised Telecommunication Standard Version D.0 to address the need for additional data elements to support partial fills. The expansion of partial fills to all entities further exacerbates the industry's inability to meet the requirements of the legislation. Until such time the Division of National Standards adopts the revised Telecommunication Standard Version D.0 the industry will be unable to comply with the intent of the law.

Timeline and Actions to Date:

Quantity Prescribed (460-ET) - Based on the approval of the NCPDP membership in November 2012, a new publication of the Telecommunication Standard Version D.0 (November 2012) was posted on the NCPDP website. The enhancement is for the use of Quantity Prescribed (460-ET) in the billing

[1] Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills (OEI-02-09-00605)

transactions.

a. The original industry-requested implementation timeframe was January 2014. This is on hold pending regulatory processes. The Telecommunication Standard Version D.0 of August 2010 is still in place.
b. November 2012 – A request for HIPAA rule making notification was sent to the Office of e-Health Standards and Services (OESS) and the National Committee on Vital and Health Statistics (NCVHS).
c. November 2012 – Designated Standard Maintenance Organization (DSMO) Change Request 1182 was filed and approved.
d. March 2013 – NCPDP received approval from OESS. OESS thought they would publish a notice in the Federal Register per letter response to NCPDP.
e. NCVHS sent a recommendation letter to HHS.
f. Summer of 2013 – NCPDP was sent information that the Telecommunication Standard change would have to go through full rule making (Notice of Proposed Rule Making (NPRM) and Final Rule) process.
g. August 2013 – NCPDP requested reconsideration and clarification from HHS.
h. March 2014 – NCPDP received a response from HHS to the March 2013 letter. The change will go through NPRM and Final Rule process.
    1. September 2014 – Timeframe of NPRM publication has been reported as: "May 2015."
    2. October 2014 – WG1 Telecommunication Standard FAQ Task Group and the Strategic National Implementation Process (SNIP) Committee provided implementation timeline verbiage to OESS on Quantity Prescribed.
i. April 17, 2015 Update from National Standards Group (NSG) formerly OESS: At this time the Quantity Prescribed issue is going through the regulatory process. We will provide a revised target date for a regulation very soon.
j. July 21, 2015 Update from NSG: Our new target for this regulation is early 2016.
k. January 21, 2016 Update from NSG: This policy item is undergoing the rule making process, and at this time we are unable to give you a specific timeframe.
l. April 11, 2016 Update from NSG: The request is still in the rule making stage, so at this point I can't provide a formal comment on its status.
m. July 25, 2016 Update from NSG: Additional questions were received and documentation from 2010, 2012 and 2013 was provided to answer the questions.
n. October 14, 2016 Update from NSG: We are in the rule making stage of this policy item. We should have an NPRM out by Mid-2017.
o. February 2017 – NPRM release still on track for mid-2017. Once the final rule is promulgated, enforcement cannot occur until the implementation timeline requirement is completed.

Recommendation

Pharmacies have the quantity prescribed from the prescription and can determine appropriate utilization but cannot report the quantity prescribed to the payer using the current HIPAA-named standard. This lack of information prevents the payer from effectively monitoring and reporting Schedule II opioid utilization. The promulgation of this law increases the number of claims a payer cannot effectively monitor due to the missing Quantity Prescribed value.

Therefore, NCPDP recommends HHS and the DEA delay the enforcement of Section 702 Partial Fills of Schedule II Controlled Substances of CARA until after publishing a Final Rule adopting the revised NCPDP Telecommunication Standard Version D.0 and completing the implementation time period.

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

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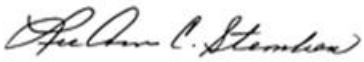
Sincerely,



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