May 6, 2011

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer
OIRA_submission@omb.eop.gov

Re: 42 CFR part 423, § 423.514
Medicare Part D Reporting Requirements 2012

Dear CMS Desk Officer:

The National Council for Prescription Drug Programs (NCPDP) submits the following comments regarding the Medicare Part D Reporting Requirements effective January 1, 2012.

Section XI Long-Term Care (LTC) Utilization and Waste

NCPDP would like clarification on the timeline for reporting of waste in the long-term care setting.

Based on the final rule for 42 CFR Parts 417, 422 and 423, the effective date of the dispensing and reporting requirements set forth in §423.154 has been delayed until January 1, 2013. However the requirement for reporting waste, as defined in 42 CFR part 423, § 423.514, is included in plan year 2012. Please confirm that requirements for reporting waste in the Long Term Care setting will be removed from the 2012 requirements.

NCPDP offers the following comments with regard to reporting waste in the LTC setting. Referring to the statement beginning on page 21,

> "we believe that pharmacies have data in their systems pertaining to quantities dispensed and the date a prescription was discontinued or changed. We understand that pharmacies routinely receive a discontinuation date (D/C date) from the LTC facility whenever a medication is discontinued for any reason. The pharmacy will receive a D/C date when a prescription is stopped altogether or if a prescription is changed. For example, when a dose is changed a pharmacy will receive a D/C date for the original prescription and a new prescription with the new dose. (Alternatively, the pharmacy may receive a new prescription for a new dose or substitute drug and would use the start date of the new prescription as the D/C date of the previous prescription.) These D/C orders prevent a patient from receiving the wrong drug or wrong dose or "extra" doses. The pharmacy may also receive census data that informs the pharmacy of when a patient dies or is discharged from the facility. Using this information, the pharmacy can subtract the days supply dispensed prior to the date of discontinuation, discharge, or death from the quantity originally dispensed to determine the quantity of drugs that go unused. While this calculation may not precisely correlate to unused doses, we believe it is close enough to be a very good proxy, and no new data collection would be required on the part of LTC pharmacies. Therefore, we believe pharmacies have the data in their own systems to calculate the difference between the quantity dispensed and the quantity consumed, which can be used to calculate the amount of unused medication."

CMS notes that data or lack of data can be used to reach conclusions on unused medication (waste). There are many situations in which the LTC pharmacy would not be made aware when a medication has been discontinued, changed or otherwise gone unused. There are also situations in which a calculation of unused doses could be grossly over or understated based on assumed information. Situations may include:

- Census data provided to pharmacies from nursing facilities is oftentimes retrospective to payer changes. If the pharmacy has recorded that a resident's payer is Medicaid or a commercial insurance, a greater than 14-day supply may be dispensed. The pharmacy may be notified after dispensing that the true payer at the time of dispense should have been a Medicare Part D plan. Facilities may or may not notify the pharmacy when a patient has died or is discharged. They may simply stop ordering medications.

- Medications that are ordered to be given "PRN". A 14-day supply may be sent to the facility but could actually last for 6 months or longer, until the medication expires. The pharmacy does not have the medication administration records that would show actual usage nor would they have knowledge of unused medication.

- Medications that are "held" based on physician orders or refused by the resident. The pharmacy again does not have the medication administration records that would show these situations to be able to determine consumed or unused medications.

- Medications provided via on-demand versus cycle-fill ordering systems. In an on-demand ordering system, the facility is re-ordering medications manually when the supply runs low. If a medication is discontinued, the facility would simply not reorder and pull any remaining medication from the cart. The pharmacy would not know if the medication was discontinued or how many doses were unused. If a facility were to report to the pharmacy a discontinuation date, the pharmacy may still not know how many doses were unused because the pharmacy would not know when the patient started using the most recently filled supply of medication. Facilities differ in their management of medication re-ordering. One facility may reorder when five days of medication is remaining while another facility may order when there is one dose of medication remaining. To assist pharmacies and plans in correctly reporting unused medications, NCPDP would like to recommend the industry adopt the following guidelines when medication orders are started or stopped.

    - New Medication Orders
        - The new medication will be administered beginning on the first medication pass following the delivery of the medication to the facility.
    - Discontinued Medication Orders
        - The medication order will be discontinued on the first pass following the physician discontinuance of the order.
    - Discharge Discontinued Medications
        - The patient's medications will be discontinued at the time the physician has set for the patient's discharge.

- The following example demonstrates why making assumptions, programmatically or by manual methods, about consumed and unused medication could result in inaccurate reporting of waste.

    Information available in pharmacy dispensing system: A 14-days supply of Drug X 40mg was filled on April 1, 2011. On April 6, 2011 a new order was received and a 14-days supply of Drug X 60mg (same medication) was filled. No discontinuation order was received by the pharmacy for the 40mg medication.

    Different scenarios that may have occurred at the facility:

    - Six days of the 40mg medication was consumed and eight days worth of medication was unused.
    - The facility continued to administer the 40mg medication until completely used and then started the 60mg medication on the first med pass after the last dose of the 40mg medication was given.
    - The physician wrote orders to give the resident 100mg of medication for eight days and then drop the dose back to 60mg.
    - The 40mg dose was discontinued and the nursing facility gave one and one-half tablets of the 40mg medication to equal 60mg based on physician orders. The nursing facility began to use the new order filled for 60mg medication on April 11, 2011.

Due to the widely varying amounts of waste that may occur with each scenario above we recommend that waste only be reported when the pharmacy has the necessary information (discontinue order, death or discharge) within their dispensing system to accurately report waste.

Because plans must audit the waste reported and ensure that pharmacies have accurate processes to calculate waste, we respectfully disagree that making assumptions is a "close enough" proxy.

Section XI states "reporting on unused drugs is waived for Part D sponsors for any of their network pharmacies that dispense both brand and generic drugs, as defined in §423.4 in no greater than 7-day increments."

NCPDP understands that if one claim comes in from a network pharmacy for a dispensing methodology greater than 7-days the pharmacy is obligated to report on all dispensing for all unused drugs. To meet the needs of CMS' intent and to ensure clarity for the reporting requirement, we recommend that the requirement to report information on unused drugs be based upon the dispensing methodology identified in the claim for each prescription. Whereas those prescriptions dispensed in quantities greater than 7-day would be reported, the reporting for those prescriptions dispensed in 7-day or less would be waived.

Section XI lists two types of reports:

1. **LTC Utilization**
2. **LTC Waste**

Sections A through D under *2. LTC Waste* ask for reporting of unused brand and generic oral solids.

NCPDP recommends changing *2. LTC Waste* to *2. Reporting for Appropriate Dispensing in LTC* and inserting another heading as demonstrated below:

2. Reporting for Appropriate Dispensing in LTC
    a. Waste
        i. The total number of unused brand solid oral units (tablets, capsules, etc.)
        ii. The total ingredient cost of total reported in i,
        iii. The total number of unused generic solid oral units (tablets, capsules, etc.)
        iv. The total ingredient cost of the total reported in iii.

Section E under *2. LTC Waste* asks for reporting based on dispensing methodology.

NCPDP recommends Section E become *b. Dispensing Methodologies used to Report Waste* under *2. Reporting for Appropriate Dispensing in LTC.* Based on industry understanding, generic medications are exempt from the rule requiring dispensing in 14-day or less increments. Therefore, a dispensing methodology would not be recorded on a claim and reporting for numbers 7 through 12 would not be available. NCPDP recommends CMS delete the requests for dispensing methodology reporting on generics (7-12 under E) and as such, the section would be written as demonstrated below:

b. Dispensing Methodology used to Report Waste
    i. Number of brand oral solid units (tablets, capsules, etc) dispensed;
    ii. Number of brand claims;
    iii. Number of formulary brand claims;
    iv. Cost of formulary brand claims, where cost should be calculated using total ingredient cost only;
    v. Number of non-formulary brand claims;
    vi. Cost of non-formulary brand claims, where cost should be calculated using total ingredient cost only.

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NCPDP appreciates the ability to respond. Given this organization's role in providing pharmacy standards for multiple practice settings including long-term care, we have chosen to respond only to those reporting requirements that relate specifically to long-term care utilization and waste.

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

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cc: NCPDP Board of Trustees