Omnicare

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May 9, 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:

Omnicare is a national provider of long-term care pharmacy services, serving Medicare beneficiaries residing in nursing homes and assisted living facilities throughout the United States.

We wish to comment on the second draft of the proposed Reporting Requirements for Medicare drug plans for calendar year 2012:

Issue Area: Long Term Care Utilization and Waste

1. CMS is under the impression that pharmacies serving long-term care facilities routinely receive notices from the nursing home of drugs discontinued for beneficiaries. While this may sometimes be true, it is not a universal practice. Exceptions include:

   - **On-demand dispensing systems**: This system relies on the nursing facility to order each refill. As a result, the pharmacy is unable to determine when the current dosing cycle began and would be unable to calculate when a drug was discontinued.
   - **Refused and "spitter" doses**: It is a common occurrence in nursing homes that residents will refuse or "spit" a scheduled order of medication. Facilities accommodate this by ordering in advance of scheduled supply exhaustion. Calculating the doses consumed becomes problematic under this scenario.
   - **Dosage changes**: At times, physicians will increase the dosage or frequency of medications and changes of unit dosages will not change. For example, increasing a dosage from 10 mg. to 20 mg. can be accomplished by doubling the pills dispensed rather than changing the order to a 20mg. dose. In these cases, tracking consumption becomes difficult.

- **PRN Medications**: Some medications affected by the rule will be administered "as needed". Accounting for pills no longer needed over time is uncertain.

We disagree that, with the discrepancies noted above, calculating unused doses from data currently in the pharmacy's system is "close enough to be a very good proxy".
We note that some LTC pharmacies, such as Omnicare, receive unused Part D drugs from LTC facilities for disposal and record information on such unused drugs in their computerized systems. Where available, this provides a much more accurate means of quantifying doses that have been dispensed but not consumed.

2. **Dosage forms subject to reporting**: Based on the provisions of the final rule, we understand that oral solid dosage forms, generic and brand, are the specific dosage forms subject to reporting.

3. **Application of Reporting by Pharmacy**: CMS appears to have limited unused drug reporting requirements to Network LTC Pharmacies, whereas there are many instances in which some residents are served by pharmacies not contracted with a particular LTC facility. CMS should emphasize that the reporting obligation applies to all pharmacies providing services to Medicare Part D enrollees in long-term care facilities.

4. **Reporting to Individual Plan Sponsors**: It appears that it is CMS' intention that pharmacies would report to each plan sponsor the number and value of doses that are not consumed. Given the large number of plans serving Medicare beneficiaries residing in long-term care settings, tracking and segregating individual drug orders by plan is a burdensome process. This will be especially problematic for smaller pharmacies without automated tracking capabilities.

5. **Formulary Status:** CMS proposes that statistics be reported separately for drugs which are "formulary" or "non-formulary". However, LTC pharmacies' systems do not maintain information on dispensed drugs on that basis; e.g., drugs which are non-formulary but covered through an exception or appeal are dispensed just like formulary drugs. It would be extremely burdensome for LTC pharmacies to determine formulary status of drugs dispensed/returned, by the Part D plan for the given patient. Instead, reporting should be limited to those drugs covered by the applicable Part D plan, without identification as "formulary" or "non-formulary".

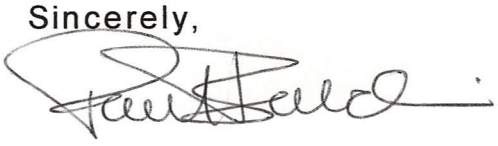
6. **Reporting of Number of "Claims", and " Units", as well as Ingredient Cost.** CMS seeks reporting of number of "claims" for brand and generic drugs, respectively. It is unclear to us what the benefit of this information would be, given that a claim could be for a days' supply of 1 day, 31 days, or any other value. Similarly, reporting of number of units

(tablets, capsules, etc.) dispensed and unused has little value, as these could be extremely expensive, or not expensive. The only metric we think has meaning is the dollar value of drugs dispensed vs. those unused.

7. **Missing Information**. CMS has failed to exclude antibiotics from reporting. More generally, however, the statistics CMS seeks to have reported will not demonstrate the value or folly of requiring short-cycle dispensing, since days' supply data is not collected. E.g., claims for a 1 day supply are commingled with claims for 31 days' supply. While certain data would be collected for each "dispensing methodology", that wouldn't reflect shorter or longer days' supply based upon prescriber orders, drug type or other factors, and the critical data on unused drugs would not be classified based upon "dispensing methodology". As such, we believe the collection of data CMS has proposed needs to be re-thought, in order to come up with data which can produce useful results for policy determinations.

Recommendation: The reporting requirements proposed by CMS for 2012 would be extremely burdensome for LTC pharmacies and would not produce accurate or useful data on "wasted" Part D drugs, for the reasons noted above. We believe that CMS should allow the industry time to work on a proposal for reporting of unused medications that would not be burdensome and would provide accurate and useful data to CMS, e.g., through the NCPDP process currently underway. We anticipate that this proposal would allow LTC pharmacies which receive unused Part D drugs from LTC facilities for disposal to report data based upon the actual drugs received; a different mechanism might be required for other LTC pharmacies. Implementation of this reporting requirement should coincide with the implementation of the 14-day or less dispensing requirement in January, 2013.

Sincerely,



Paul Baldwin
Vice President, Public Affairs