DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: January 13, 2012

TO: All Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: CY2013 Part D Reporting Requirements – Request for Comments

The purpose of this memo is to solicit comments and suggestions for some of the proposed changes to the Part D Reporting Requirements for CY2013. Your early feedback will help ensure a common understanding of specific data elements that effectively measure operational procedures, help foster consistency in the way data are reported by all Part D Sponsors, and ultimately help improve our monitoring of the prescription drug benefit provided to Medicare beneficiaries. Your initial comments will help us to prepare a more clearly defined version of requirements for the 60-day comment period under the Paperwork Reduction Act (PRA) process. All interested parties will have an opportunity to provide additional comments on these and any other changes pursuant to the PRA process in early 2012.

Specifically, we are soliciting comments on possible changes to the following two sections: Long-Term Care (LTC) Utilization and Waste (now Unused Drugs in Long-term Care) and Medication Therapy Management (MTM) Programs. The proposed changes are summarized below:

1. Unused Drugs in Long-Term Care (LTC)

On April 15, 2011, CMS published a final rule (76 FR 21432) implementing recent legislative changes affecting the Part C and D programs. Included in the final rule was a provision implementing section 3310 of the Affordable Care Act (P.L. 11-148) which addresses reducing wasteful dispensing of outpatient prescription drugs in LTC facilities. The final rule added a new regulation at §423.154 requiring that effective CY 2013 in-network LTC pharmacies dispense covered Part D brand name drugs in 14-day-or-less increments. With implementation of this provision, sponsors are required to collect information from their network LTC pharmacies to determine the amount of unused brand and generic drugs, as defined in Sec. 423.4.

In the preamble to the final rule, CMS explained that data would be collected from sponsors through Part D reporting requirements. We noted as well that we intend to use these data to determine the extent to which the new dispensing requirement reduces the amount of unused drugs and determine the cost effectiveness of expanding the requirement to generic drugs. The proposed data collection for collecting and reporting data on unused drugs is different from the data collection proposed during the 30-day comment period for the 2012 Part D Reporting Requirements (OMB Control No.

0938-0992) (these earlier requirements were prior to the implementation of this provision being delayed until 2013). The new data elements proposed for 2013 are underlined in Attachment A. Because no separate changes are contemplated to the data elements on LTC Utilization for 2013, these data elements are not included in this request for comments.

Note: Waivers are granted to LTC pharmacies that voluntarily adopt/a 7-day-or-less dispensing period for all solid oral doses (that is, both brand name drugs and generic drugs). Such pharmacies are exempt from the requirement that Part D sponsors collect data on unused drugs for reporting to CMS. For more information on available waivers for this requirement, and to view the finale rule please use the link below:
Http://www.cms.gov/PrescriptionDrugCovGenIn/PDR/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS1247014&intNumPerPage=10

2. Medication Therapy Management (MTM) Programs

To date, it has not been possible to fully demonstrate the value and success of Part D MTM programs. We propose to collect new data to allow for this analysis. The additional data elements proposed for 2013 are underlined in Attachment B. The collection of these additional data elements will enable CMS to perform more robust analyses to understand the level of MTM services received by the targeted beneficiaries and to monitor outcomes. Further, the collection of information for all beneficiaries participating in the sponsors' MTM program, whether based on CMS' specifications or other plan-specific targeting criteria, improves CMS' ability to examine MTM program outcomes and structure control groups.

Therefore, CMS proposes Part D Sponsors collect and report additional information on interactive comprehensive medication reviews (CMRs) offered and received by eligible Medicare Therapy Management (MTM) beneficiaries, and drug therapy problem recommendations and changes due to MTM services. This proposed reporting would include each Part D beneficiary included in the sponsor's MTM program, whether based on CMS' specifications or other plan-specific targeting criteria, and the corresponding MTM services delivered to each beneficiary, within the reporting period.

With these requirements to report on all Part D beneficiaries receiving MTM services we point out that we are also extending our reporting requirements to institutionalized individuals (as defined in 42 CFR §423.772 and otherwise referred to as beneficiaries in long term care (LTC) facilities). This may present new data collection challenges for sponsors and/or their contracted providers, so we are interested in receiving comments on any issues raised by this extension. We believe it is very important for sponsors to include all LTC beneficiaries in their MTM programs in order to provide additional scrutiny on the appropriateness of drug prescribing for our very vulnerable institutionalized beneficiaries in LTC facilities.

We are aware that beneficiaries meeting sponsors' MTM criteria who are also residents of LTC facilities are currently receiving services from their sponsors' MTM providers, as well as drug regimen reviews from consultant pharmacists in the LTC facilities. We believe that there is potential overlap in these reviews that could possibly result in conflicting reviews and recommendations for prescribers and facility staff, as well as excess costs in the health care sector. We believe that better care coordination and cost efficiencies would result from arrangements that include the LTC consultant pharmacist in the conduct of Part D MTM services for beneficiaries in

the long term care setting. Such arrangements could include direct contracts between the sponsor and consultant pharmacists (or their intermediaries), or indirect contracts between the sponsor's MTM provider or PBM and consultant pharmacists (or their intermediaries). We solicit comments on the extent to which such arrangements already exist in the Part D market and industry reactions to our suggestions that such arrangements could improve care coordination and other efficiencies.

We would appreciate feedback on these sections as we further refine the elements for the 2013 RR package. Please submit your feedback concerning the proposed CY2013 Part D Reporting Requirements to partd-planreporting@cms.hhs.gov. Please include "CY2013 Part D Reporting Requirements Comments" in the subject line and submit by January 31, 2011. We look forward to working with stakeholders, MA organizations, and PDP sponsors on the development of the CY2013 Part D Reporting Requirements.

ATTACHMENT A

Proposed Changes for 2013 Part D Reporting Requirements

Unused Drugs in Long-term Care (LTC)

We reviewed the comments received on the 2012 Part D reporting requirements on unused drugs in LTC. While we believe we have addressed those comments through the changes we propose here, we are providing this preliminary opportunity for industry comment on possible 2013 reporting requirements to make certain that our understanding of system data availability limitations is accurate. Further changes will be made based on the comments received from this solicitation and the revised requirements will be subject to subsequent public review and comment through the Paperwork Reduction Act (PRA) process.

As we stated in the preamble to the CMS-4144 Final Rule (76 FR 21432), pursuant to our authority under section 1860D-12(b)(3)(D) of the Social Security Act, we are requiring pharmacies servicing LTC facilities to report dispensing methodologies and report unused drugs to Part D sponsors. We noted that we would collect the data from sponsors and use it to determine the extent to which the dispensing requirements reduce the amount of unused drugs and to evaluate the implications of extending the requirement to generic drugs.

The requirements that the Part D sponsors provide information pertaining to unused drugs in LTC are described in Federal regulation at 42 CFR 423.154(a)(2). Specifically, this regulation requires that Part D sponsors collect and report information on the dispensing methodology used for the dispensing of solid oral doses of brand-name covered Part D drugs, and on the nature and quantity of unused brand and generic drugs dispensed by a LTC pharmacy to enrollees in a LTC facility. Per 42 CFR 423.4, "Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2))." Per 42 CFR 423.4, "Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved." Unused drugs are those drugs that have been dispensed to an enrollee in an LTC facility, but not used by the enrollee, whether returned to the pharmacy or not.

Similar to the manner in which medications are prescribed in the inpatient hospital setting, prescribing in LTC facilities requires the entry of a medication order in the resident's chart. Pharmacies dispense medications based on the pharmacy order system used and the payer (e.g., Medicare Part A, Part D, Medicaid or a commercial plan). We understand there are over twenty IT software applications (systems) in use in the pharmacy industry and, although there is some customization, all dispensing systems possess the functionality to accept cycle or chronic (standing order) and direct or acute (explicit day supply) order entry. The specific order entry method used is generally dependent upon the facility.

The possible new data elements for this reporting on unused drugs are listed below. Please note we are exploring adding two new fields to the PDE for 2013 for the reporting of place of service coding and submission clarification coding to identify the LTC dispensing methodology used. With this

additional coding on the PDE, we are able to propose a limited set of new data elements for the reporting of unused drugs in LTC.

1. Unused Drugs in LTC

A. Cycle (chronic) order entry:

1. Number of brand oral solid units (tablets, capsules, etc) dispensed;
2. Number of generic oral solid units (tablets, capsules, etc) dispensed;
3. The total number of unused brand solid oral units (tablets, capsules, etc); and
4. The total number of unused generic solid oral units (tablets, capsules, etc).

B. Direct (acute) order entry:

1. Number of brand oral solid units (tablets, capsules, etc) dispensed;
2. Number of generic oral solid units (tablets, capsules, etc) dispensed;
3. The total number of unused brand solid oral units (tablets, capsules, etc); and
4. The total number of unused generic solid oral units (tablets, capsules, etc).

For reporting purposes, an important difference between these two order entry methods is the need in cycle (chronic) order entry for the pharmacy to either receive a discontinuation (D/C) order or be aware that an order has changed. The gist of the comments received on this proposed section in the 2012 Part D Reporting Requirements revolved around this difference and the need to determine a D/C date in those instances when none is received and/or stored by a pharmacy. We expect that in all cases, regardless of the order entry method used, when a medication is no longer being administered by the facility to the resident, the pharmacy receives information that causes the pharmacist to discontinue dispensing the medication. This information may be in the form of census data that informs the pharmacy that a resident has died or has been discharged from the facility, a D/C order, or a medication change order involving either a new dose for the same medication or a therapeutic alternative drug. In instances when a D/C order is not received and/or stored, the date of death, discharge, or date of the new medication order for a new dose for the same medication or a therapeutic alternative drug could be used as the D/C date. Thus, although D/C orders are unnecessary under the direct (acute) order entry method, the pharmacy could use these other dates to determine a D/C date when a facility uses direct order entry and compute the amount of unused drugs.

We believe that pharmacies have the data available in either their dispensing or billing systems to determine the quantity of medication dispensed and determine or approximate the date a medication order was discontinued or changed. Some pharmacies may have all the necessary information in their dispensing system and others may need to access both their dispensing and billing systems to capture the information needed to compute the amount of unused drugs. Using this information, the pharmacy can compute the amount of medication prescribed for the days prior to a discontinuation order, new medication order, or resident discharge or death and subtract this amount from the quantity dispensed to determine the amount of unused drugs. While this calculation may not precisely correlate with the amount of medication actually administered, we believe the result will be a close approximation of the unused amount, without the need for new data collection on the part of LTC pharmacies.

We remain convinced that this reporting is feasible, even when systems do not receive a formal "date of discontinuation" from the facility. While we believe all pharmacies can compute the amount of unused drugs, we are aware that in some instances the information may need to be imputed. To provide clarity on how these situations should be handled, thus ensuring consistency in reporting in these instances, we propose the following set of assumptions. We believe the vast majority of orders are covered under cycle order entry; therefore, the need to use these assumptions will be limited, but we solicit comment on the percentage of dispensing events that would require their use. We also seek comments on improvements that may be made to the proposed requirements or identification of any additional situations or issues that need to be addressed, and on the timeframe for systems enhancements necessary for all systems to collect and store D/C dates.

Situation	Assume	Count as Unused
Pharmacy receives a D/C order.	Assume all medications were administered on the date of the D/C order.	The unused amount will be the days supply remaining following the date of the D/C order.
Pharmacy does not receive a D/C order, but receives notice of resident death or discharge.	Use the date of death or discharge as the D/C date and assume all medications were administered on that date.	The unused amount will be the days supply remaining following the date of death or discharge.
Pharmacy does not receive a D/C order, but within 1- 2 days of the end of the current order, receives a new medication order for either the same drug, but different dose, or a therapeutic alternative drug.[1]	Assume the dispensed amount was used before the new medication was started, unless a refill has been processed and delivered. If a refill was delivered, assume the refill amount is unused.	There will be no unused amount, unless a refill was processed and delivered. If a refill was delivered, count the entire refill amount dispensed as unused.
Pharmacy does not receive a D/C order, but more than 2 days prior to the end of the current order receives a new medication order for either the same drug, but different dose, or a therapeutic alternative drug.	Assume new medications were begun on the first medication pass of day following the delivery of the medication to the facility. Any amount remaining when the new medication is started will be considered unused.	The unused amount will be the days supply remaining at the end of the day of the delivery of the new medication to the facility.

[1] Any new medication order received within 1-2 days of the end of the current order is probably administered. So, the entire amount previously dispensed is considered consumed, unless a refill for medication has already been processed and delivered to the facility.

The medication was ordered "held" by the physician or refused by the resident.[2]	Assume the pharmacy is unaware of the hold order or resident refusal and follow the prior assumptions that would otherwise apply.	Medications ordered held by the physician or refused will not be counted as waste.
The drug was ordered to be administered "PRN" (as needed) and the pharmacy has no knowledge concerning actual use.	Exclude drugs under "PRN" orders from reporting.	Drugs under "PRN" orders will not be counted as unused.
The medication was dispensed in greater than a 14-day increment because the census data initially showed a non-Medicare payer, but the data was retrospectively changed to a Medicare Part D plan.	Follow all applicable prior assumptions.	Count the amount of any unused drugs based on the amount actually dispensed.

If our understanding is incorrect or incomplete, we seek comments that better describe the pharmacy dispensing systems and explain how the system used might complicate the ability of a pharmacy to report the required data on unused drugs in LTC and how those complications might be overcome. We believe that that receiving and storing a D/C date is a best practice in the industry to maximize understanding of dispensing methodology efficiency. However, to the extent that some pharmacy systems do not currently collect and store a date of discontinuation, we need to develop consistent reporting requirements that best estimate the amount of unused drugs using data points that are available. As a result, we may need to refine our discussion in the reporting requirements to clarify requirements that address all pharmacies. Consequently, we solicit comments on whether the requirements proposed above addresses all questions.

Aggregate data on unused brand and generic drugs must be reported from Part D sponsors to CMS at least bi-annually. We are not specifying any data collection methodology between Part D sponsors and their network LTC pharmacies. However, we emphasize that from the CMS perspective this information does not need to be associated with the original claims transactions and can be provided through summary reporting. We restate that 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.

Proposed reporting timeline:

	Period 1	**Period 2**
Reporting Period	January 1 - June 30	July 1 - December 31
Data due to CMS/HPMS	August 31	February 28

[2] A prescribing physician may order a medication be "held" (i.e., not be administered for a specific number of doses). This may occur, for example, when diagnostic testing is to be performed and the drug would interfere with the test results.

ATTACHMENT B

Medication Therapy Management (MTM) Programs

The requirements stipulating that Part D Sponsors provide Medication Therapy Management (MTM) programs are described in Title I, Part 423, Subpart D, § 423.153. For monitoring purposes, Part D Sponsors will be responsible for reporting several data elements related to their MTM. Data will be uploaded in a data file.

Reporting timeline:

	YTD
Reporting Period	January 1 - December 31
Data due to CMS/HPMS	February 28

Sponsors are required to target beneficiaries for the MTM program who meet specific criteria as specified by CMS in § 423.153. Some sponsors also offer enrollment in the MTM program to other members who do not meet the specific CMS targeting criteria.

The following information will be collected for each beneficiary identified as being eligible for the Part D MTM program, whether based on CMS' specifications or other plan-specific targeting criteria, and for the corresponding MTM services delivered to each beneficiary, within the reporting period. Please note - all proposed new data elements are underlined below:

A. Contract Number.
B. HICN or RRB Number.
C. Beneficiary first name.
D. Beneficiary middle initial.
E. Beneficiary last name.
F. Beneficiary date of birth.
G. Met the specified targeting criteria per CMS – Part D requirements. (Y (yes) or N (no))
H. Long term care (LTC) enrollment (at any time in period). (Y (yes), N (no), or U (unknown)).
I. Date of MTM program enrollment.
J. Date of MTM program opt-out, if applicable.
K. Reason participant opted-out of MTM program (Death; Disenrollment from Plan; Request by beneficiary; or Other). Required if Date of MTM program opt-out is applicable.
L. Offered annual interactive comprehensive medication review (CMR).
M. If offered, date of (initial) offer.
N. Received annual interactive CMR. (Y (yes) or N (no))
O. Number of interactive CMRs received, if applicable. Required if received annual interactive CMR.
P. Date(s) of annual interactive CMR, if applicable. (If more than 1 CMR is received, up to 5 dates will be allowed.) Required if received annual interactive CMR.
Q. Method of delivery for the annual interactive CMR, if applicable. (Face-to-face; Telephone; Telehealth consultation; or Other). (If more than 1 CMR is received, report the method of delivery for the initial interactive CMR). Required if received annual interactive CMR.

R. Qualified Provider who performed the initial interactive CMR, if applicable. (Physician; Registered Nurse; Nurse Practitioner; Physician's Assistant; Community Pharmacist; LTC Consultant Pharmacist; Plan Sponsor Pharmacist; Plan Benefit Manager (PBM) Pharmacist; MTM Vendor Community Pharmacist; MTM Vendor In-house Pharmacist; or Pharmacist – Other).

S. Recipient of interactive CMR in LTC, if applicable. (Beneficiary, Beneficiary's prescriber; Caregiver; or Other authorized individual). Required if received annual interactive CMR in LTC.

T. Number of targeted medication reviews.

U. Number of drug therapy problem recommendations made as a result of MTM services. (For reporting purposes, a recommendation is defined as a suggestion to take a specific course of action related to the beneficiary's drug therapy. Examples include, **but are not limited to**: Needs additional therapy; Unnecessary drug therapy; Dosage too high; Dosage too low; More effective drug available; Adverse drug reaction; or Noncompliance).

V. Number of drug therapy problem resolutions made as a result of MTM recommendations. (For reporting purposes, a resolution is defined as a change or variation from the beneficiary's previous drug therapy. Examples include, **but are not limited to**: Initiate drug; Change drug (such as product in different therapeutic class, dose, dosage form, quantity, or interval); Discontinue or substitute drug (such as discontinue drug, generic substitution, therapeutic substitution, or formulary substitution)).