

January 31, 2012

Centers of Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4157-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted via e-mail to: partd-planreporting@cms.hhs.gov

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Centers of Medicare & Medicaid Services (CMS) on proposed changes to the Part D Reporting Requirements for Contract Year 2013 (CY2013). Specifically, CMS has solicited comments on possible changes to two sections: Long-Term Care (LTC) Utilization and Waste (now Unused Drugs in Long-term Care) and Medication Therapy Management (MTM) Programs.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's more than 6,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

Unused Drugs in Long-term Care

In the final rule addressing reducing wasteful dispensing of outpatient prescription drugs in LTC facilities, CMS added a new regulation requiring that LTC pharmacies dispense covered Part D brand name drugs in 14-day-or-less increments. With implementation of the provision, CMS indicated that Part D plan sponsors would be required to collect information from their network LTC pharmacies to determine the amount of unused brand and generic drugs. The Academy understands that these data collection efforts are necessary and were requested by the industry. However, the data collection efforts place a significant reporting burden on both LTC pharmacies and Part D plan sponsors. CMS indicates that reporting on unused brand and generic drugs must be reported from Part D plan sponsors to CMS at least bi-annually. CMS has not specified the data collection methodology between Part D sponsors and network LTC pharmacies.

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However, this new provision would require that LTC pharmacies calculate the number of tablets or capsules remaining for each prescription considered to be discontinued and prepare reports for each Part D plan. Part D plan sponsors will aggregate the data and prepare reports to be shared with CMS bi-annually.

The Academy appreciates the definitions provided by CMS for reporting by LTC pharmacies. However, the definitions provide opportunity for various interpretations, and data will be based on a pharmacy's interpretation and estimates. While some data may be better than no data, the data reported from pharmacies to Part D plans and, subsequently, from Part D plan sponsors to CMS will not be precise. Absent a National Council for Prescription Drug Programs (NCPDP) reporting standard, each Part D plan sponsor must devise its own method of collecting such data. The quality and integrity of data reported suffers when there is not a standard format and infrastructure for reporting. AMCP asks that CMS work with NCPDP on development of a reporting standard. Until such a standard exists, CMS must understand that the data submitted will vary between each pharmacy and each Part D plan and cannot be considered precise.

As mentioned, AMCP appreciates the definitions provided by CMS; however, the Academy has a specific concern with the fourth situation identified:

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.

Based on the start of a therapeutic alternative, a pharmacy is to assume that the previous medication has been discontinued. There may be situations where a drug considered a therapeutic alternative is in reality a drug being added to therapy rather than a replacement therapy. For example, a second antipsychotic medication or a second medication to treat hyperglycemia may be either a replacement therapy or an addition to current therapy. The determination of whether or not the first medication is discontinued must be based on the judgment of the pharmacy staff. This assumption may lead to inaccurate reporting. The Academy asks that CMS use definitions not based on pharmacy staff assumptions.

The Academy asks CMS to continue to address challenges in data collection and data accuracy as it finalizes these reporting requirements. The reporting requirements will be administratively burdensome for pharmacies and plans and may not produce precise data. AMCP understands the need CMS has for such data and suggests that all stakeholders will need to be understanding of all challenges as this provision is implemented.

Medication Therapy Management (MTM) Programs

While the pharmacists and other health care practitioners involved in administering MTM programs and providing MTM services to patients have the opportunity to see the positive health outcomes as a result of MTM programs, the Academy recognizes CMS's need to fully demonstrate the value of Part D MTM programs. CMS has proposed new data to allow for this analysis.

AMCP agrees with the suggestion to collect data on the number of drug therapy problem recommendations made as a result of MTM services, using Data Element U. This is an important element in demonstrating the extent of a plan's Comprehensive Medication Review (CMRs) and the positive contributions provided by Part D MTM providers. However, the Academy has a concern with a potential use of this data element.

Data element 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.

AMCP anticipates that CMS may use element U in conjunction with exiting element V.

Data element 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)).

The Academy is concerned about the calculations that could be made using elements U and V, and the assumptions that could be made based on such calculations. Using these two data elements to calculate the impact of MTM programs and services may be problematic. One could assume that the number of drug therapy problem resolutions (element V) divided by the number of drug therapy problem recommendations made (element U) would provide the percentage of problems resolved. However, some identified drug therapy problems may trigger a drug therapy problem recommendation but may not trigger a measurable resolution based on documented plan data. For example, an MTM provider may recommend an additional therapy (reported as a drug therapy problem recommendation "Needs additional therapy") such as an over-the-counter (OTC) product to treat a symptom or disease state. A successful drug therapy problem resolution involving an OTC medication cannot be documented using Part D plan data. CMS must use data from elements U and V in a way that appropriately measures the impact of MTM interventions.

CMS seems to be proposing changes to MTM in the LTC setting within this Part D reporting requirements document. CMS has caused confusion by instituting requirements for reporting related to interactive CMR in the LTC setting through adding data element S, before the regulations on changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 are finalized.

Data element 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.

AMCP understand that the Affordable Care Act (ACA) requires Part D plan sponsors to provide medication therapy management (MTM) programs for targeted beneficiaries. In previous contract years, CMS recognized that beneficiaries residing in LTC facilities who have cognitive impairment may be unable to participate in an interactive CMR. However, the ACA does not provide a basis for distinguishing the offering of MTM services based on settings. As indicated in AMCP's comments on the proposed regulations implementing regulations on changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013, the Academy realizes that CMS must revise the current regulation to comply with the ACA by requiring Part D plan sponsors to offer the annual CMR for target beneficiaries in an LTC facility. In our comments, AMCP asked that CMS indicate that, when the beneficiary cannot accept the offer to participate, the pharmacist or other qualified provider can perform the medication review without communicating directly with the beneficiary. This provision would give the pharmacist or provider the ability to perform the medication review without the encumbrance of attempting to communicate with a patient who cannot make decisions regarding their medical needs. In such cases, AMCP recommended that the pharmacist, or qualified provider, reach out to the beneficiary's prescriber, caregiver, or other authorized individual such as the residents' health care proxy or legal guardian, to receive the beneficiary's CMR. The proposed reporting requirements, as

indicated in data element S, seem to indicate that the decision has been made to do so; however, CMS has created confusion by creating a reporting element to measure a provision not yet in final regulations. AMCP suggests that this reporting provision be postponed until after the final regulations are in place.

Beneficiaries meeting MTM criteria who are also residents of LTC facilities are receiving services from their sponsors' MTM providers, as well as drug regimen reviews from consultant pharmacists in the LTC facilities. CMS has recognized that there is potential overlap in these reviews that could result in conflicting reviews and recommendations for prescribers and facility staff, as well as excess costs in the health care sector. CMS indicates 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. CMS asked whether arrangements including direct or indirect contracts between Part D plan sponsors and consultant pharmacists exist in the Part D market. AMCP is not aware of any Part D plan sponsor with such arrangements. The Academy opposes such a requirement. Part D plans have developed comprehensive MTM programs and contract with MTM providers to provide services that align with the Part D plans' MTM goals. The care provided to beneficiaries under a Part D plan's MTM program directly impact the Part D plan's overall performance results which are listed on the CMS Plan Finder website and on the display measures which CMS uses to internally evaluate plans. Part D plans must have the option to work with MTM providers with aligned goals and should not be required to use their limited MTM budget to pay providers that may or may not have aligned goals. Part D plans should consider LTC consultant pharmacists as important resources for providing MTM services; however, the ultimate decision on who is providing those services is a contract decision that should be made by the plan.

AMCP appreciates the opportunity to comment on CMS's proposed changes to the Part D Reporting Requirements for CY2013. If you have any questions, please contact me at (703) 683-8416 or erosato@amcp.org

Sincerely,

A handwritten signature in black ink, appearing to read "Edith A. Rosato". The signature is fluid and cursive, with the first name being the most prominent.

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer