

## AMCP Summary of CY2013 Call Letter

Released April 2, 2012

### Items of Importance to Managed Care Pharmacy

This document identifies areas of importance to managed care pharmacy contained in the Centers for Medicare and Medicaid Services' (CMS) Medicare Part D 2013 Call Letter, which is available at:

<http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads//Announcement2013.pdf>.

#### Section III. Part D (pages 119-43)

**Preferred/Non-preferred network pharmacies:** Plan Finder will be updated to require beneficiaries to select a pharmacy for purposes of providing cost estimates that reflect the selected pharmacy's status as *preferred* or *non-preferred* in the plan's network. Also, plan sponsors should clearly designate their pharmacy contracts, including their standard terms and conditions available to any willing pharmacy, as either *preferred* or *non-preferred* Part D network contracts to improve transparency around these arrangements. (p 119)

#### Collaboration between Pioneer and Medicare Shared Savings Program Accountable Care Organizations (ACOs) and Part D Sponsors to Enhance Pharmacy Care Coordination

Collaboration Principles:

- Focus business arrangement on pharmacy care coordination and data sharing, such as innovative approaches to formulary and medication compliance, pharmacy counseling services, and medication therapy management (MTM) programs.
- Align financial arrangements with health outcomes and performance.
- Promote competition.

*Approach for facilitating collaboration between Medicare ACOs and Part D sponsors:* CMS encourages ACOs to find Part D sponsor partners through a request for proposals process and will provide upon request a list of Part D sponsor plans and contacts in the same market to the ACOs. (p 119-21)

**Low enrollment plans (stand alone Prescription Drug Plans only):** CMS will notify plans with fewer than 1,000 enrollees of available consolidation/withdrawal options in April 2012. CMS will not be enforcing specific criteria for CY2013 except with plans that were contacted last year about low enrollment status and have not yet consolidated/withdrawn these plans consistent with CMS discussions. (p 121)

**Benefit Thresholds:** CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered and tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory.

CMS established a minimum meaningful difference threshold that differed from the draft Call Letter. The minimum monthly cost-sharing out-of-pocket cost (OOPC) difference between basic and enhanced plan offerings will remain relatively stable at \$23. However, the minimum monthly cost-sharing OOPC difference between enhanced plan offerings will decrease to \$12. For CY2014, CMS is considering changing their approach to using OOPC or market basket approach to set thresholds for increases in cost-sharing and premiums whereby CMS would deny Part D plan bids with significant increases in either. (p 121-3)

**Medicare Plan Finder (MPF):** CMS is developing enhancements for the implementation on the MPF to include providing mechanisms to submit and display floor pricing, ceiling pricing, and pricing for 30, 60, or 90-day fills at both retail and mail order. While CMS will provide as much advanced notice as possible for these changes, sponsors are encouraged to take proactive steps to build logic to accommodate these changes. (p 124-5)

**Limiting Online Enrollment through the MPF:** In an effort to assist in guiding beneficiaries towards selecting higher performing plans, CMS will disable the MPF online enrollment function for Medicare health and prescription drug plans with the low-performing plan icon for CY2013 plan enrollments. Beneficiaries who still want to enroll in a low-performing plan or who may need to in order to get the benefits and services they require (for example, in geographical areas with limited plans) will be warned, via explanatory messaging of the plan's poorly rated performance, and directed to contact the plan directly to enroll. (p 125)

**Misuse of Five-Star Rating:** CMS was informed that certain sponsors are instead using their star rating in a lower category or measure to imply a higher overall plan rating for their marketing materials than is actually the case. CMS will scrutinize Parts C and D marketing materials to ensure they are not misleading in this manner. Additional guidance will be released with the Medicare Marketing Guidelines. (p 126)

**Complaint Tracking Module (CTM) Monitoring:** For CY2013, CMS is planning to update the Evidence of Coverage notice that is sent annually to beneficiaries to include a link to the online complaint form. (p 126-8)

*Complaint Survey:* In 2012, a web-based version of a beneficiary survey will be made available via message notification after a beneficiary's complaint is closed. This will provide an easier way for CMS to capture information on the complaint resolution process. (p 126-7)

*Medicare Online Complaint Form:* Per the Affordable Care Act (ACA), CMS implemented an electronic Medicare online complaint form. The online complaint form went live December 2010 and has been placed in three locations: 1) on the <http://www.medicare.gov> homepage; 2) on the Medicare Plan Finder homepage; and 3) on the Medicare Ombudsman homepage. Medicare Advantage organizations and prescription drug plan (PDP) sponsors are required to prominently display a link to this electronic complaint form on their websites. (p 127-8)

**MTM Programs:** CMS has stated concerns over low enrollment numbers in MTM programs. CMS is reexamining MTM eligibility criteria and emphasizes that the CMS requirements for targeting beneficiaries for the MTM program are the floor, not the ceiling. Therefore, sponsors may offer MTM

program services to beneficiaries who do not meet the eligibility criteria per CMS' specifications. (p 129-31)

For 2013, CMS is designating Alzheimer's disease and end-stage renal disease as two additional core chronic diseases for targeting. These chronic diseases were targeted by over 10% of MTM programs in 2011. Atrial fibrillation and chronic noncancer pain will be added to the list of non-core chronic diseases in the selection table in the HPMS MTM Program Submission Module. In addition, beginning in 2013, sponsors are expected to target at least *five* out of the nine core chronic conditions, which modifies the current criteria of at least four out of seven core chronic diseases.

The 2013 MTM program annual cost threshold has been increased by 1.40% to \$3,144 (from \$3,100.20 in 2012).

Part D sponsors must begin using the standardized format for the action plan and summary that plan sponsors must provide to beneficiaries after their comprehensive medication review (CMR) no later than January 1, 2013. The standardized format, instructions for implementation, and frequently asked questions will be posted on the CMS MTM web page (<http://www.cms.gov/Medicare/Prescription-Drug-overage/PrescriptionDrugCovContra/MTM.html>) no later than April 2012. The implementation instructions include document, page, and field specifications; delivery requirements; additional guidance; and a completed sample.

To encourage industry to have clear and consistent service level expectations for the delivery of MTM and CMRs, CMS has provided clarifications based on Part D sponsor and industry questions:

- Targeted beneficiaries are auto-enrolled when they meet the eligibility criteria, so sponsors should not wait for beneficiary acceptance to offer the required minimum MTM services.
- The action plan and written summary in the standardized format requires certain minimum service levels for the CMR, such as discussion of the beneficiary's concerns with their drug therapy, collection of the purpose and instructions for using their medications, review of a beneficiary's medications including prescription, non-prescription drugs and supplements to aid in assessing medication therapy, and engaging beneficiaries in management of their drug therapy.
- Sponsors should offer to provide a CMR to newly targeted beneficiaries as soon as possible after enrollment into the MTM program, but no later than 60 days after being enrolled in the MTM program. For MTM enrollees who were enrolled in the MTM program during the previous contract year and continue to meet the criteria for the current contract year, sponsors should offer the CMR within one year of the last CMR offer.
- Sponsors are expected to use more than one approach when possible to reach all eligible targeted beneficiaries so they are able to receive MTM services and a CMR versus only reaching out via passive offers. Sponsors may increase beneficiary engagement by providing telephonic outreach after mailed outreach.

CMS plans to include the Pharmacy Quality Alliance MTM measure on the 2013 display page. This MTM measure calculates the percentage of beneficiaries in the MTM program who met the targeting criteria per CMS requirements and subsequently received a CMR. (p 129-31)

*Beneficiary Awareness:* In an effort to increase beneficiary awareness of MTM programs, starting in 2013, sponsors will be required to have information on their website about their MTM program. Customer service and the website should provide at a minimum: the plan's MTM eligibility requirements, who to

contact for more information, and a high level summary of services offered as part of the MTM program. Part D sponsors are encouraged to post a blank Personal Medication List from the CMR standardized format on their website or provide information to beneficiaries about how to obtain a blank copy. (p 131)

*MTM Program Submissions:* In the 2013 Part D reporting requirements and the MTM Program Submission Module for 2013, CMS will begin to capture information about programs and beneficiaries identified as being eligible for MTM, whether based on CMS or other plan-specific targeting criteria. The reported beneficiaries must receive MTM services that meet or exceed CMS' MTM program requirements. CMS will provide 2013 submission guidance before the end of April 2012. (p 131)

### **Improving Drug Utilization Review Controls in Part D**

Through discussions with the industry, CMS has determined that sponsors need to employ more effective concurrent and retrospective drug utilization review (DUR) programs to address overutilization of medications in order to protect beneficiaries, to comply with drug utilization management (DUM) requirements and to reduce fraud, waste and abuse in the Part D program. CMS is amenable to working with sponsors to achieve consensus on consistent metrics to identify overutilization of medications, particularly opioids. CMS emphasizes that Part D sponsors either already have, or should have, the existing expertise to address significant patterns of overutilization.

The improvements that CMS describes in this section do not change existing policy on quantity limits (QLs), prior authorizations, step therapy and protected class drugs, and are intended as improvements to formulary management processes that CMS expects sponsors to implement.

CMS is undertaking a communication and educational campaign about medication overutilization, particularly opioids, for physicians and pharmacies in the fall of 2012 to support sponsors' strengthened efforts to address this issue in the Part D program.

*Background:* A recent Government Accountability Office (GAO) report highlighted evidence that effective concurrent DUR has not been fully implemented across the Part D program and that there has been considerable overutilization of medications by Part D beneficiaries who were obtaining medications, primarily opioids, from multiple prescribers. Therefore, CMS is focusing on addressing overutilization of opioids beginning in CY2013. (p 131-43)

*Formulary Management Improvements:* Effective formulary DUM programs, when layered on concurrent DUR systems, should strongly diminish the likelihood of inappropriate overutilization. Thus, the processes described in the September memo were not meant to be a substitute for, but rather be a supplement to, effective DUR and DUM programs that should currently be implemented by sponsors.

*Level One: Improved Use of Concurrent Claim Edits (Safety Controls at POS):* CMS indicates that all drugs (including the six protected classes and controlled substances) should be subject to DUR safety controls, such as early refill edits, maximum dose limitations (as described in the Food and Drug Administration (FDA) approved label for most drug products), and therapeutic duplication. CMS indicates that as long as safety edits are consistent with FDA labeling, they can be implemented without submission to or approval by CMS.

Also, sponsors should apply safety edits that minimize the risk of overutilization of individual medications contained in combination products, such as opioid products containing acetaminophen (APAP), which does have maximum dosing limits when the ingredient APAP is considered across all unique combination products. (p 134-5)

*Level Two: Improved Use of Formulary Utilization Management Designs (QLs at POS):* Includes quantity limits (QLs) applied to medications that do not have a clear maximum dose, such as opioids that do not contain APAP, or QLs applied below the FDA labeled maximum dose. (p 135-6)

*Level Two: Improved Use of Formulary Utilization Management Designs (QLs at POS):*

- A) QLs/FDA Maximum Dose: CMS indicates that Part D sponsors are permitted to apply QLs at the FDA maximum approved dosing to covered Part D drugs, including drugs within a protected class, in order to promote safe use by not allowing dosages beyond maximum dose. CMS notes that current regulations permit exceptions to the protected classes requirement for “utilization management processes that limit the quantity of drugs due to safety.” (p 135)
- B) QLs/No Maximum Dose: CMS indicates Part D sponsors may also apply QLs to medications for which there is no clearly defined maximum dose in the approved labeling, such as most opioid analgesics, to ensure safety, promote cost effectiveness, and to decrease fraud, waste and abuse. CMS indicates that, in such cases, sponsors’ Pharmacy and Therapeutic (P&T) committees should consider existing best practices to control overutilization through formulary management. CMS notes that QLs below the FDA labeled maximum daily dose must be included as part of the HPMS formulary submission and are subject to approval. (p 135-6)
- C) QLs/Below FDA Maximum Dose: CMS also indicates that Part D sponsors may apply QLs, as appropriate, below the FDA maximum approved dosing to encourage cost-effectiveness through dose optimization, and to decrease fraud, waste and abuse, if the optimal dose is included on the plan formulary. An example of dose optimization identified by CMS would be to promote use of one 80mg controlled release (CR) tablet rather than two 40mg CR tablets to achieve an 80mg CR tablet dose through QL restrictions on the 40mg CR tablets. CMS indicates that it would not be permitted for protected class drugs since such QLs would not be due to safety. (p 136)

*Level Three: Improved Retrospective DUR Programming and Case Management:* Part D sponsors are to identify patterns that suggest drug overutilization based on number of prescribers and doses, patterns of prescribing, and cumulative dosing, and then employment of clinical case management intervention strategies. (p 136-43)

CMS has indicated that Part D plan sponsors must have retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate use of medications or of medically unnecessary care.

As CMS indicates, using opioids as an example, the application of utilization management tools, such as maximum dose safety edits at POS, approved QLs through formulary review process, or therapeutic duplication logic, may not be as effective in identifying overutilization of opioids when compared to other classes of medications. Therapeutic duplication edits at the POS may not be programmed to the level of sophistication to prevent overutilization for opioids, and are often overridden at the pharmacy. POS edits may not distinguish between drugs within a therapeutic class, or may be overly sensitive and identify

regimens that are commonly used for pain management. CMS indicates that sponsors should have DUR programming that identifies patterns which suggest that the identified patients may be at risk of overutilization, so that these cases may be further analyzed clinically for possible fraud, waste and abuse across all sponsors' formulary medications, including opioids.

Beneficiaries receiving multiple opioid products, from multiple providers, dispensed from multiple pharmacies, may be at risk for harm and overutilization. For CY 2013, for those sponsors who are not already employing utilization management tools as part of a drug utilization review system, or are not doing so with respect to opioids, CMS expects these sponsors to implement this level to address opioid overutilization, at a minimum. CMS indicates that case management should be employed and include outreach to prescribers and beneficiaries. Other examples could also trigger a referral for retrospective review/case management. CMS indicates that when a beneficiary is identified as at risk for safety and overutilization, sponsors should develop beneficiary centered utilization controls that can be implemented at POS to address safety issues that are not captured through level one and two controls. (p 136-41)  
*CMS expects to see the improvements outlined in Level One and Two applied to all medications for CY 2013, and Level Three applied to opioids.*

*Data Sharing Between Sponsors:* CMS clarifies that for CY2013, sponsors could share the record and actions generated by an overutilization review with the successor sponsor to prevent the beneficiary from re-engaging in overutilization. (p 141-2)