AMCP Academy of Managed Care Pharmacy®

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

[Delivered by e-mail to: AdvanceNotice2013@cms.hhs.gov]

Subject: 2013 draft Call Letter

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the draft Advance Notice of Methodological Changes for Calendar Year (CY) 2013 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2013 Call Letter, which was released on February 17, 2012.

AMCP is a national professional association of pharmacists and other health care professionals with more than 6,000 members who provide services on behalf of the more than 200 million Americans served by managed care organizations, including health plans and pharmacy benefit management companies. Our members are responsible for managing prescription drug benefits on behalf of clients of the managed care organizations that employ them. They are responsible for implementing a broad and diversified range of clinical, quality-oriented services and strategies whose objective is to assure that individual patients receive the appropriate drug at the right time in a convenient, cost-effective manner.

AMCP offers comments pertaining to the following issues addressed in the draft Call Letter:

- 2013 Plan Ratings: New Measures
- Integration with ACOs and Other CMS Innovation Models
- Medication Therapy Management (MTM) Programs
- Improving Drug Utilization Review Controls in Part D

2013 Plan Ratings: New Measures:

Measure of quality improvement:
In the draft Call Letter, CMS describes the Agency's proposed methodology for a measure of quality improvement by MA plans and prescription drug plans (PDPs).

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The proposed methodology is to calculate improvement at the individual measure level and use statistical tests to determine whether there has been significant improvement or decline at the measure level prior to creating a measure of net improvement at the contract level. AMCP is pleased that CMS is working to account for contracts already achieving high scores and that CMS indicates that the methodology will not penalize high-performing plans and will not reward improvement over attainment.

The Academy is concerned that CMS is introducing a measure when it does not appear that this measure has been tested and thoroughly vetted by the Medicare plans and other stakeholders. AMCP recommends that CMS take the time to thoroughly test and evaluate this measure, and either delay its introduction to 2014 or implement it as a Display Measure for 2013. If CMS moves forward with the inclusion of the improvement measure within the 2013 Plan Ratings, AMCP encourages CMS to share detailed specifications with MA plans and PDPs and with experts in performance measurement so the appropriateness of the methodology and the potential impact on the plans can be assessed. In addition, the Academy recommends that CMS should weight this measure in a way to ensure that plans not performing well on a given measure are not significantly penalized twice for the same measure.

<u>High-Risk Medication (HRM) measure (Part D)</u>:
AMCP is pleased that the American Geriatrics Society has conducted a comprehensive update of the Beers Criteria for potentially inappropriate medication use in older adults**.** As part of a Pharmacy Quality Alliance (PQA) panel, AMCP staff was involved in efforts to revise the current High Risk Medication (HRM) in the Elderly measure's technical specifications. The Academy encourages CMS to work with PQA to explore any changes to the technical specifications such as accounting for transition fills or single prescriptions. AMCP is pleased that CMS will apply changes in specification and on the medication list beginning in 2014 and not retroactively for the 2013 Plan Ratings.

The draft Call Letter indicates that CMS will evaluate the inclusion or exclusion of benzodiazepines and specified barbiturates in the measure calculations at the time that 2012 and 2013 prescription drug event (PDE) data is reviewed for the 2014 and 2015 Plan Ratings. Due to the change in benefit structure and coverage of benzodiazepines and barbiturates, a significant number of beneficiaries will be on these medications beginning in 2013. This provision will increase Part D utilization for medications considered HRMs in the Elderly. The Academy is pleased that the Call Letter indicates that CMS will revise the previously-established star thresholds for the 2013 Plan Ratings and will instead base all of the star thresholds for this measure on statistical analysis and relative rankings of plans' scores.

<u>Integration with ACOs and Other CMS Innovation Models:</u>

The draft Call Letter indicates that CMS is interested in Part D sponsors of stand-alone PDPs playing a greater role in managing the care of beneficiaries in original (fee-for-service) Medicare and contributing to overall health outcomes. CMS indicates interest in considering business arrangements between the accountable care organizations (ACOs) (both Medicare Shared Savings Program [MSSP] ACOs and Pioneer ACOs) and Part D sponsors. The Academy supports efforts to remove silos between fee-for-service Medicare and Medicare Part D.

Coordinating the transfer of drug utilization information and partnerships in medication management between ACOs and PDPs should improve appropriate medication use and patient care. Such partnerships should help ACOs improve scores on the medication-related quality measures. However, such coordination will not address the fundamental concern that Part D expenses are the only health care expenditures not assigned to an ACO. Physicians have strong incentives to manage all health care expenditures except Part D drug costs.

Given the option to prescribe additional medications and increasing expenditures for PDPs, physicians have no reason not to do so, whether or not it provides better patient care. Some increases in Part D medication use, for example, improved medication adherence, will improve patient care and decrease overall cost. Other increases in Part D medication use will occur when a physician chooses to treat a condition with medications that may or may not be necessary or the most appropriate treatment. CMS should consider aligning incentives by including some measure of appropriate Part D drug utilization as part of the measures used to evaluate ACOs.

As CMS considers ways to incorporate appropriate medication management into the MSSP and Pioneer ACO programs, the Academy encourages CMS staff to refer to the AMCP document, *Pharmacists as Vital Members of Accountable Care Organizations*, (http://www.amcp.org/aco.pdf) as a resource in examining how pharmacists can contribute to appropriate medication use in an ACO setting. Current discussions related to ACOs focus primarily on the involvement of hospitals and physicians and seldom address pharmacists or medication management. CMS indicates in the draft Call Letter an interest in seeking feedback on innovative payment or service delivery models that promote improved medication adherence. *Pharmacists as Vital Members of Accountable Care Organizations* features six examples of integrated approaches to the delivery of care that incorporate medication therapy as an essential element.

Developing business arrangements between ACOs and the multitude of PDPs that may work with one ACO's beneficiary populations will be a challenge. The Academy looks forward to working with CMS staff to develop appropriate and feasible scenarios.

Medication Therapy Management (MTM) Programs

CMS indicates that the Agency is considering including the PQA-approved MTM Completion Rate for Comprehensive Medication Review (CMR), which measures the percentage of MTM-eligible beneficiaries who received a CMR. The PQA measure sets the denominator as the number of MTM eligible beneficiaries and the numerator as the number of beneficiaries in the denominator who received a CMR. AMCP supports the inclusion of this PQA-developed MTM measure as part of the CMS star ratings. Including the measure in CMS's star ratings will recognize the performance of Medicare Advantage (MA) and prescription drug plans (PDPs) in delivering MTM services to their eligible patients.

Improving Drug Utilization Review Controls in Part D

The Academy joins CMS in its concern about reports of fraud, waste and abuse within the Medicare Part D prescription drug benefit. AMCP has been a vocal proponent of the Medicare Part D program, which has provided much-needed prescription drug coverage to millions of Medicare beneficiaries, increasing their access to affordable prescription drugs. However, the program has unfortunately become a target for fraud, waste and abuse, costing taxpayers millions of dollars annually, and potentially threatening the integrity of the benefit as a whole.[1]

The Academy supports measures to prevent abuse of prescription drugs. Between 1999 and 2006, almost 14,000 deaths from prescribed opioids occurred annually.[1] Studies reveal that the drugs are being prescribed more widely for chronic non-cancer pain and that safety measures are needed to ensure proper prescribing. Pharmacists and prescribers have an obligation to assure that prescriptions are dispensed for legitimate medical conditions, including appropriate pain care.

[1] GAO, *Medicare Part D: Instances of Questionable Access to Prescription Drugs*, GAO-11-699 (Washington, DC: Sept. 6, 2011. http://www.gao.gov/products/GAO-11-699 (accessed October 25, 2011)

Managed care organizations must carefully balance the unique and varied needs of patients who are taking these medications against the susceptibility of abuse. In the commercial and Medicaid managed care markets, managed care organizations have successfully implemented many innovative programs designed to establish that balance. AMCP supports sensible changes to current regulations that would allow Part D plan sponsors to help combat the problem of prescription drug abuse.

Through the Call Letter, CMS has introduced three levels of acceptable drug utilization review (DUR) controls:

- Level One: Improved Use of Concurrent Claim Edits (Safety Controls at POS)
- Level Two: Improved Use of Formulary Utilization Management Designs (QLs at POS)
- Level Three: Improved Retrospective DUR Programming and Case Management

Level One: Improved Use of Concurrent Claim Edits (Safety Controls at POS):
In the Call Letter, 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 (i.e., patient receiving same drug or drug within the same class two days prior). CMS indicates that as long as safety edits are consistent with FDA labeling, they can be implemented without submission to or approval by CMS. AMCP is pleased that CMS has clarified that safety edits to prevent dispensing of unsafe dosing of drugs are to be part of the concurrent DUR requirements for all Part D drugs. Specifically, the Academy is pleased that CMS noted that the DUR safety controls at point-of-service (POS) apply to all medications and do not require submission to or approval by CMS.

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

A) Quantity Limits (QLs)/FDA Maximum Dose: In the Call Letter, 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." AMCP appreciates the clarification that utilization management processes due to drug safety are permitted for all drugs, including the six protected classes, and agrees that measures to prevent excessive and unsafe use of medications should be prevented through QL edits.

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. AMCP notes CMS's reminder that QLs below the FDA labeled maximum daily dose must be included as part of the HPMS formulary submission and are subject to approval.

   AMCP supports this provision allowing such edits to help ensure appropriate medication use and supports CMS's clarification exceptions to the protected classes requirement are permitted for "utilization management processes that limit the quantity of drugs due to safety." AMCP supports CMS's clarification allowing the use of QL edits within the protected classes.

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, 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.

The Academy is pleased that CMS is clarifying that Part D sponsors may apply QLs to encourage cost-effectiveness through dose optimization. However, AMCP believes that CMS is misguided in not allowing similar dose optimization edits for drugs within the six protected classes. Allowing dose optimization would not prevent any beneficiary from getting a medication within the protected classes. Such dose optimization provisions should be allowed within the protected classes in the same way such provisions are allowed within all other classes.

Level Three: Improved Retrospective DUR Programming and Case Management:
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. In the Call Letter, 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.

Implementing Beneficiary Level Edits:
In the Call Letter, CMS addresses the concern that many prescribers are non-responsive to retrospective DUR requests, and that this non-responsiveness and Part D plan sponsors' lack of authority over prescribers reduce the impact of overutilization review activities. The Academy supports CMS's decision to allow Part D plan sponsors to implement beneficiary-level edits at POS at all pharmacies, to include the rejection of claims or rejection of quantities in excess of plan established limits of opioid analgesics. Similar beneficiary-level edits are commonly used in commercial and Medicaid benefits.

Although the language in the Call Letter further clarifies CMS's intent and expectation in this area, it is still not entirely clear what plans may and may not do without being in danger of being cited for impeding beneficiary access to medications. AMCP encourages CMS to continue to work with Part D plan sponsors to define scenarios that may or may not be acceptable for beneficiary-level edits. AMCP encourages CMS to allow plans to develop their own best practices; however, the Agency must acknowledge that it is requiring plans to make decisions in how to balance two important but conflicting CMS priorities.

As mentioned previously, in the commercial and Medicaid managed care markets, managed care organizations have successfully implemented many innovative programs designed to establish that balance. One such method is restricting patients suspected of abuse to receiving medications from one prescriber and one pharmacy or chain of pharmacies. Unfortunately, within the Medicare Part D prescription drug benefit, plan sponsors have been prohibited from restricting pharmacy and provider access, denying payment to pharmacies that are suspected of aiding and abetting individuals abusing drugs, and from communicating information about suspected beneficiaries with other Part D plan sponsors. The Academy encourages CMS to consider such measures as an allowable method to appropriately manage overutilization and abuse.

The Academy appreciates the opportunity to submit these comments on the 2013 Call Letter. If you have any questions, please contact me at (703) 683-8416 or at erosato@amcp.org

Sincerely,

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