

March 1, 2013

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

[Delivered by e-mail to: AdvanceNotice2014@cms.hhs.gov]

Subject: 2014 draft Call Letter

The Academy of Managed Care Pharmacy (AMCP) is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the draft Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter released on February 15, 2013.

AMCP is a national professional association of pharmacists and other health care professionals with nearly 7,000 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:

Section I: 2014 Plan Ratings and Measurement

Section II: Policy Recommendations and Changes

- Inappropriate Cost Shifting from Part B to Part D
- Inappropriate Use of Prior Authorization Forms
- Auto-ship Refill and Automated Fill Programs under Part D
- Improving Blood Pressure Control Through Anti-Hypertensive Adherence as a Component of the Million Hearts™ Initiative
- Expansion of Part D Policy on Improving Utilization Review Controls
- Medication Therapy Management (MTM) and Effects of Prescription Drug Use on Medicare's Spending for Medical Services
- Coordination of Care

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I. 2014 Plan Star Ratings and Measurement

High-Risk Medication (HRM) Use under Medicare Part D. This Pharmacy Quality Alliance (PQA) endorsed measure includes the percentage of Medicare enrollees age 65 and older who received 2 or more fills of a HRM during the measurement year. CMS proposes a technical clarification of its intent: “*This measure calculates the percentage of Medicare Part D beneficiaries 65 years or older who received two or more prescription fills for the same HRM drug with a high risk of serious side effects in the elderly.*”

CMS’ methodology already accounts for 2 or more fills of an HRM with the same active ingredient. PQA then updated the measure and national drug code (NDC) list as a result of recommended changes to the Beers List from the American Geriatrics Society (AGS). Based on CMS’ evaluation of both lists, it found approximately 50% overlap in drugs included in the previous HRM list and the updated list. Given this change, CMS proposes the following changes from its original proposal first published in the 2013 Call Letter:

- In 2014, the *original* PQA HRM list used as the basis for the 2013 Star Ratings will continue to be used with 2012 prescription drug event (PDE) data.
- In 2015, the *updated* PQA HRM list based on the revised Beers List recommendations will be used with 2013 PDE data.
- CMS will redesign the reports on its Patient Safety Analysis Website to include 2012 HRM rates using the original PQA HRM list. CMS anticipates this information will be released by May 2013.

Impact on barbiturates and benzodiazepine coverage. In January 2013, Medicare Part D began covering barbiturates (for the treatment of epilepsy, cancer, or a chronic mental health disorder) and benzodiazepines. The revised PQA HRM list includes barbiturates, but not benzodiazepines. Medicare Part D covered barbiturates will be included in the calculation for the 2015 Star Ratings using 2013 PDE data. CMS does not anticipate a pre-determined 4-star threshold for several years, and therefore, this measure will continue to be excluded from the overall quality improvement measure.

AMCP Comments and Recommendations

AMCP supports these measures. AMCP believes that the proposed methodology on HRM will allow plans to receive the new list in a timely manner. AMCP encourages CMS to provide additional reminders to plans regarding the procedures for the use of the original and new HRM list. AMCP also believes that because the new list will not include benzodiazepines, the new coverage requirements benzodiazepines will not have negative consequences. AMCP further recommends adding barbiturates to the HRM list because the only medically accepted indications are in rare diseases and are not considered first line for most seizure disorders.

Medication Adherence for Diabetes Medications. Currently defined as the percent of Medicare Part D beneficiaries age 18 and older who adhere to 4 classes of oral diabetes medications:

- Biguanides;
- Sulfonylureas;
- Thiazolidinediones; and,
- DiPeptidyl Peptidase (DPP)-IV Inhibitors.

(PQA specifications exclude beneficiaries who have one or more prescriptions for insulin.)

CMS proposes to adopt PQA's changes to this measure's specifications for the 2015 Star Ratings using 2013 PDE data, and adds two additional drug classes to the numerator and denominator: meglitinides and incretin mimetic agents. CMS also proposes renaming the measure to: *Medication Adherence for Diabetes Medications*.

The new proportion of days covered (PDC) calculation would determine if the beneficiary is covered by at least one drug from any of the six classes of diabetes drugs. CMS will determine if these changes are significant, and if so, this would necessitate the suspension of a pre-established 4-star threshold if established for 2014 Star Ratings.

AMCP Comments: AMCP supports these measures.

Medication Adherence Measures for Diabetes, Hypertension, and Cholesterol. CMS proposes 4 star measures in these areas for 2014. (Table 1 on page 93). CMS will continue to use a slightly modified PDC calculation to adjust for overlapping prescriptions for the same drug using generic name. PQA's specifications use Generic Code Numbers (GCNs), including strength. Considering medication adherence uses claim fill dates and days' supply as a proxy for utilization, GCN may be too restrictive in some cases. For this reason, CMS will continue using the broader interpretation of the PDC calculation using generic name.

AMCP Comments and Recommendation: AMCP agrees with CMS to use the modified PDC calculation and not the GCN from the PQA specifications.

Proposed New 4 Star Measures for 2015. These measures focus on CMS' Million Hearts™ Initiative to improve cardiovascular health, monitor blood pressure, and generally improve medication adherence to reduce the risk of heart attacks and strokes.

AMCP Comments and Recommendation: AMCP is concerned that increasing the 4-star threshold by 2 points may be a difficult percentage for plans to meet because of the level of requirements and timeframe for implementation. Therefore, AMCP recommends that CMS consider revisiting the stringency of this measure.

Measures Being Removed from Star Ratings and New Measures for Display Page. (page 100).

CMS is considering transitioning the following from the Star Ratings to the 2014 display page:

- Enrollment timeliness: being moved because of the lack in variation in scores across contracts with the scores being skewed very high.
- Getting information from drug plans: being moved to the display page because there is little variation in the scores across contracts with the scores being skewed very high.
- Call Center—Pharmacy Hold Time: being moved to display page because sponsor's performance has been consistently high for several years.

AMCP Comments: AMCP agrees with moving these measures to the display page because they are considered subjective measures.

Special Needs Plans (SNP) care Management Measure (Part C SNPs). (page 101). CMS requires SNPs to assess medical, psychosocial, functional, and cognitive needs.

AMCP Comments and Recommendations: AMCP is concerned that CMS has broadly defined the health areas, but has not defined a standard measurement tool for SNPs to use. Therefore, AMCP recommends that CMS provide further guidance regarding the tools that must be used to assess this risk.

MTM Program Completion Rate for CMR for Part D to continue on display page in 2014 with potential inclusion as a 2015 Star Ratings measure (page 101). This PQA measure assesses the completion rate for CMRs, the percent of non-long-term care beneficiaries who met eligibility requirements for MTM, and those who completed a CMR. This requirement will remain a 2014 display measure using validated 2012 beneficiary-level plan reported MTM data. CMS is concerned that some plans are reporting some beneficiaries as LTC for purposes of exclusion from the CMR completion rates. CMS believes that use of its LTC indicator is better than use of plan-reported LTC status and will begin providing plans with these reports on a quarterly basis beginning in 2013. CMS is also considering allowing continued use of plan reported LTC status for the 2014 display measure to exclude individuals eligible for MTM from the denominator as LTC status is confirmed.

Beginning in January 2013, MTM-eligible beneficiaries in LTC must receive a CMR and a written summary. CMS proposes to include the CMR requirements for all MTM-eligible beneficiaries, including LTC, in the 2015 Star Ratings using 2013 MTM data. CMS seeks comment on ways to appropriately weight or factor the percent of Part D sponsors' enrollment population eligible for the MTM program into the measure calculation to achieve a more fair comparison.

AMCP Comments and Recommendations: AMCP is concerned that the incorporation of CMRs for residents of LTC facilities is not appropriate or achievable in this setting. AMCP also recommends that CMS work with Part D plans to determine the source of the errors in assignment of beneficiaries.

CMS should consider removing the plan-focused MTM requirement for LTC beneficiaries and use the existing infrastructure of the federal nursing home regulations to conduct medication reviews using consultant pharmacists. Alternatively, rather than require the MTM for all residents of LTC facilities, AMCP recommends that CMS consider limiting the requirement to certain transitions of care, such as admission after hospitalization or from home.

CMS Provision: Inappropriate Shifting of Drug Coverage from Medicare Part B to Part D (page 113) CMS clarifies that enrollees in a MA-PD plan may elect, as a personal preference, to have a medication dispensed at a pharmacy for administration in the physician's office. In this case, the medication would be covered under Medicare Part D. However, CMS emphasizes that an MA-PD plan may not mandate Part D coverage when the medication would otherwise be available under Part B; rather, this determination must be between a prescriber and patient. This determination does not affect an MA plan's ability to contractually require network physicians to obtain Part B covered drugs for specified suppliers that bill the MA organization.

AMCP Comments: AMCP is concerned that this policy does not fully permit appropriate cost containment strategies because it does not always permit the use of plan management tools to provide the most affordable and appropriate medication.

CMS Provision: Inappropriate Use of Prior Authorization (PA) Forms (page 132)

CMS urges plans to discontinue inappropriate use of PA forms including the following reasons:

- Requirements that are more restrictive than CMS-approved PA criteria, including application of state-specific requirements.
- Limited access or step therapy restrictions not consistent with the CMS-approved formulary.
- Quantity limits (QLs) that are inconsistent with FDA maximum dosing or not consistent with the CMS-approved formulary.
- PA criteria not submitted for health plan management system (HPMS) approved formulary medications.
- Steering of physicians or beneficiaries to a sponsor's and/or PBM's own mail-order pharmacy.
- Steering of physicians or beneficiaries to a sponsor's and/or PBM's own specialty pharmacy for drugs which are not limited access eligible.

AMCP Comments and Recommendations: AMCP supports CMS' objective to ensure that PA forms be used to ensure appropriate clinical utilization of medications and not to determine delivery mechanisms or systems. AMCP recommends that CMS consider allowing the PA form to reflect state-specific requirements because this streamlines the approval process and decreases confusion and paperwork among beneficiaries, pharmacies, and plans.

CMS Provision: Auto-Ship Refill and Automated Fill Programs under Medicare Part D (page 133)

CMS proposes that Part D network sponsors require network retail and mail-order pharmacies to receive patient consent *prior to each delivery* of new or refilled prescriptions provided by auto-ship or automated fills programs. This is based upon complaints related to auto-shipment and auto-refill programs by mail-order and retail pharmacies.

AMCP Comments and Recommendations

AMCP cautions CMS from imposing additional burdensome requirements for beneficiaries, plans, and pharmacies that seek to provide patients with the most convenient delivery method that ensures adherence with medication regimens. AMCP suggests that CMS permit a beneficiary's prior consent to auto-shipments and auto-refills to continue until the beneficiary opts out. Alternatively, AMCP suggests that beneficiaries could be notified within a reasonable time prior to refills about the auto-shipment. This timeframe will allow them to opt-out of auto-shipments in a timely manner.

Rewards and Incentive Programs. (page 135) CMS currently allows Medicare Advantage organizations to offer enrollees de minimis rewards and incentives for participation in certain programs and achievement of health goals. Rewards and incentives may include zero dollar cost sharing or financial incentives of \$15 per item not to exceed \$50 per year. CMS also suggests that incentives might be added to encourage beneficiaries to submit all claims, including low-cost generic prescriptions, through the Medicare Part D plan to encourage proper tracking of adherence. CMS seeks comment on reward and incentive programs through Medicare Part D.

AMCP Comments and Recommendations: AMCP supports rewards and incentives under Part D as a means to improve adherence. In some cases, these rewards programs could help Medicare Part D plans achieve the necessary star ratings. As suggested by CMS, the use of incentives and rewards for submission of all claims to Part D plans would help to improve adherence but also ensure more accurate recordkeeping which then helps to ensure a more accurate electronic health record (EHR). The rewards programs may be incorporated into medication management services by pharmacists, but must be carefully structured to ensure that these programs do not include improper incentives and inducements that violate federal and state fraud, waste, and abuse laws and regulations.

CMS Provision: Improving Blood Pressure Control through Anti-Hypertensive Adherence as a Component of the Million Hearts™ Initiative (page 139)

CMS seeks comment on whether beneficiaries on anti-hypertensive medications should be offered \$0 co-payments or preferred tier cost-sharing on these agents. CMS also suggests that plans should offer MTM for beneficiaries who fill 1 or more prescriptions for these agents. This guidance is related to CMS' and the Centers for Disease Control's (CDC) Million Hearts™ initiative to provide a partnership among communities, health systems, nonprofit organizations, federal agencies, and the private-sector partners to prevent 1 million heart attacks and strokes by 2017.

AMCP Comments and Recommendations

AMCP supports the objectives of the Million Hearts™ initiative to reduce heart disease and in particular ensure adherence with anti-hypertensive medications. Medicare Part D plans often already provide beneficiaries' access to anti-hypertensive agents at little or no cost. However, cost of medications is a single factor among many that must be considered in ensuring compliance with anti-hypertensive regimens. AMCP is concerned that CMS does not currently have appropriate data to ensure that low cost sharing alone actually improves adherence.

Beneficiaries with hypertension also often have access to low-cost medications at the pharmacy. This often results in beneficiaries not submitting claims to Part D plans and thus tracking for adherence and health outcomes is more difficult. This could also result in situations where a plan's star rating is inadvertently affected because it appears as though the beneficiary is not adhering to their medication regimen.

To improve overall adherence and more accurate recordkeeping for purposes of quality measurement, beneficiaries with hypertension also need support to encourage adherence. As CMS suggests, MTM might be one alternative to provide support to ensure adherence. AMCP generally agrees that MTM should be offered to beneficiaries who would receive better hypertension control from such a program. However, AMCP does not support arbitrary determinations for MTM qualification, including disease-state specific approaches or spending thresholds. Rather, plans should be permitted to develop MTM programs based on the needs of an individual beneficiary.

Based on prevalence data from the CDC suggesting that approximately 68% of Medicare beneficiaries have hypertension, offering MTM to all individuals on a hypertensive medication could open MTM programs to the majority of individuals in many plans. This could result in unnecessary costs and interventions that CMS and the government seeks to reduce in health care. Since the implementation of the Medicare Part D program, some

plans have found value in voluntarily expanding the MTM program beyond the minimum requirements and CMS should encourage plans to voluntarily expand MTM to patients who require it, not make recommendations arbitrarily based on disease state or cost.

CMS encourages plans to offer MTM programs to individuals with hypertension but notes that additional payment will not be provided. The lack of a formal payment structure for MTM is a shortcoming of the program. This lack of payment discourages the development of new and innovative programs especially because plans must currently focus time and resources on MTM programs for the mandatory targeted beneficiaries and disease states required under Part D. These arbitrary mandates may not necessarily result in the provision of MTM to beneficiaries that improve outcomes or add value to the program. As CMS gathers evidence of the value that MTM provides, it should consider a structured payment mechanism for MTM and other pharmacists' services that improve outcomes and provide value to the program.

AMCP also supports incorporation of MTM into the medical loss ratio (MLR) as a component of the "qualifying health improvement activity" under proposed §423.2430 of the proposed rule, *Medicare Program; MLR for MA and the Medicare Part D Program* (42 CFR Parts 422 & 423). While this is not direct compensation to pharmacists for MTM, it is a means to allow plans to incorporate MTM as a component of the care of beneficiaries and removes it from the uncompensated administrative component of plans Part D programs.

CMS Provision: Expansion of Part D Policy on Improving Utilization Review Controls (page 139)
CMS seeks to expand upon requirements to improve utilization controls for opioid overutilization to other categories of medications, including antipsychotic medications, amphetamines derivatives, benzodiazepines, and non-benzodiazepine sleep aids.

AMCP Comments and Recommendations

AMCP has previously offered comments regarding CMS' efforts to improve utilization review controls for opioids. As CMS considers other areas to expand utilization review to other medications, AMCP recommends that CMS first consider the outcomes associated with the expanded opioid utilization management. CMS should allow plans to develop tools that are successfully utilized in the commercial and managed care markets. These strategies have been successful in ensuring utilization, access, and lowered costs. Unfortunately, plans in Medicare Part D often have greater restrictions on utilization controls, particularly in the protected classes, which include antipsychotic medications and benzodiazepines in the proposed expansion.

AMCP suggests that CMS convene a technical expert panel (TEP) composed of representatives from plans, prescribers, pharmacies and pharmacists, long-term care, mental health, consumers, federal and state agencies, association and advocacy groups, and other experts to consider the options available. CMS may then publish the recommendations from the TEP to offer suggestions to plans to implement utilization controls.

CMS Provision: MTM Programs and Effects of Prescription Drug Use on Medicare's Spending for Medical Services (page 149)

CMS provides updated information regarding the status of the MTM program and the new data gathered from a 2-year project examining the impact of Part D MTM on Medicare Part D, particularly in high-risk populations who require continued maintenance of medication therapy. The study used 2010 MTM data on high cost beneficiaries with congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD). The findings suggest that beneficiaries with these conditions who received annual comprehensive medication reviews (CMRs) experienced significant improvements in drug therapy outcomes compared to beneficiaries who did not receive any MTM services. The data also found that Part D plans and Medicare Advantage Prescription Drug Plans (MA-PDs) achieved cost savings associated with all-cause hospitalization but not necessarily CHF or COPD-specific admission rates. CMS suggests that MTM is a comprehensive, not disease-specific, approach to improve medication utilization, adherence, and reduce the risk of adverse events. CMS intends to expand on the initial findings through a quantitative analysis to evaluate the effect of MTM on narrowly defined drug therapy interventions in beneficiaries with diabetes. CMS will also perform qualitative analyses of the implementation and effectiveness of MTM, specifically procedures that support delivery of CMRs. This study seeks to examine best practices for more standardization of MTM service definitions and requirements. CMS will provide findings to the public.

AMCP Comments and Recommendations

AMCP has supported CMS' data collection efforts for MTM since the inception of the program. This process will assist in analyzing MTM effectiveness and areas where improvement is necessary. AMCP agrees that CMS should continue efforts to collect data, but believes that CMS should examine the impact of MTM broadly rather than using disease specific approaches. CMS' own findings when studying CHF and COPD MTM data indicate that MTM appears to be more effective using a more comprehensive approach, particularly in the delivery of CMRs. Some AMCP members have also expanded MTM to beneficiaries not included in the targeted populations defined by Medicare Part D. This voluntary expansion of MTM suggests that it offers value and that CMS should consider more flexibility in the approach to MTM.

To enhance the CMS' study of MTM, AMCP offers the following additional recommendations:

- CMS should consider allowing plans to develop a customized approach for targeted patients and disease states rather than relying on the current approach of arbitrary assignments based on disease state or threshold Part D spending. CMS' qualitative and quantitative analyses should focus on the broad implications of MTM rather than disease specific implications.
- CMS' efforts to study MTM must incorporate input from a broad array of entities, including prescribers, plans, pharmacies and pharmacists, other health care practitioners, professional and trade associations, and consumers.
- CMS should develop guidelines for best practices for the establishment of appropriate plan-based MTM programs that meets the needs of beneficiaries.
- CMS should consider a payment mechanism for MTM programs and adopt the allowance for MTM to be a component of the MLR that result in positive health outcomes, including reduced hospitalizations and other medical conditions.

CMS Provision: Coordination of Care (page 150)

CMS indicates that MTM helps to promote quality of care and encourages beneficiaries to complete the annual CMR prior to the annual wellness visit. CMS also encourages beneficiaries to take their standardized medication action plan and personal medication list from the CMR to the wellness visit or other medical encounter. CMS believes that the patient medication summaries can serve as a valuable tool to reduce duplicative therapy and drug-drug interactions and will include information on CMRs in the 2014 *Medicare & You Handbook* and other communications.

CMS suggests that the provision of CMRs may be beneficial after a transition of care or a hospitalization. CMS encourages Part D sponsors to communicate this information in plan notification for MTM enrollment or when offering or scheduling CMRs.

CMS encourages plan sponsors to adopt the use of health information technology (HIT) for documentation of MTM services, including the use of standard coding systems supported by industry standards. These systems should also enable sponsors to update and print summaries of CMRs in a standard format in EHRs rather than in free-form documents.

AMCP Comments and Recommendations

AMCP supports CMS' strategies to communicate the value of this important benefit to all beneficiaries. AMCP also supports CMS' efforts to expand the use of the CMR as a component of patient's comprehensive EHRs for use in all health care settings and in all health care encounters. AMCP supports the work of the Pharmacy e-Health Information Collaborative to produce the CMR in standard electronic format.

AMCP believes that performing a CMR at a transition of care could be appropriate considering medication related problems often occur at this time. However, AMCP cautions CMS from mandating the specific timing of the CMR, particularly because it will now be used to calculate Star Ratings. A CMS-mandated timing for CMRs may result in data reporting issues that could negatively impact Star Ratings without a plan being at fault.

AMCP members have indicated that beneficiary CMRs are often multiple pages in length and often contain information that might be unnecessary for the individual. CMS should focus on encouraging plans to provide CMRs that include comprehensive medication information in a user-friendly format that is easily adaptable to EHRs and other HIT systems.

The Academy appreciates the opportunity to submit these comments on the 2014 Call Letter. If you have any questions, please contact me at (703) 683-8416 or at erosato@amcp.org

Sincerely,



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