March 7, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: AMCP Comments on *Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter*

Dear Ms. Tavenner:

The Academy of Managed Care Pharmacy (AMCP) respectfully submits comments to the Centers for Medicare and Medicaid Services (CMS) in response to *Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter* (call letter) issued on February 21, 2014. AMCP is a national professional association of pharmacists, physicians, nurses, and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's nearly 7,000 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 managed care pharmacy benefits.

Several provisions in the call letter, including those related to preferred networks and medication therapy management (MTM), intersect with other recent CMS Medicare Part D initiatives. AMCP also submitted comments in these areas in response to two CMS releases: the notice and comment period for Medicare Program; Contract Year 2015 *Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule* (42 CFR Parts 409, 417, 422, et al. January 10, 2014) (Part D proposed rule)[1] and a Center for Medicare and Medicaid Innovation (CMMI) Request for Information (RFI): *Evolution of ACO Initiatives at CMS* released in December 2013.[2]

AMCP offers comments regarding preferred networks and MTM, the Star Ratings provisions, and support for the use of utilization management, including prior authorization at the point of sale to determine whether a medication is eligible for Part D coverage. AMCP urges CMS to review our comments to the call letter and to the provisions in the proposed rule together.

Proposed Changes to Preferred Networks Should be Delayed until CMS Completes the Study Proposed in the Call Letter and Fully Analyzes the Results (page 123)

AMCP recommends that CMS delay changes to preferred cost sharing or preferred networks until CMS' study is conducted and the findings thoroughly analyzed. AMCP submitted comments in response to the proposed rule expressing significant concerns with the proposed restructuring of preferred networks and the negative impact on beneficiary costs and access. CMS' proposed rule suggested sweeping changes to the preferred network structure in 2015 and *then*, two months after the release of the proposed changes the Agency announced a study in the call letter. Given the timeframe for implementing such major changes for 2015, AMCP recommends that CMS not proceed with any preferred cost sharing changes until at least 2016 or later depending on the results of the study. AMCP believes that implementing preferred network or cost sharing standards would be unnecessary because like the proposed rule changes calling for any willing pharmacy provider, specific standards would undermine the true nature of competition and the ability of plans to aggressively negotiate with pharmacies for lowered costs.

Prior to the study commencement, AMCP urges CMS to publicly release the study design and questions that will be posed to allow public input. CMS should also release the composition of study participants, including the number of plans, retail community pharmacies, and chain pharmacies participating; Medicare Part D regions represented; and, the number of impacted beneficiaries. To ensure a fair review of preferred networks, CMS should ensure that plans with preferred networks are adequately represented in the study of preferred cost sharing. CMS should also seek consumer input on preferred networks and access to pharmacies.

Upon the release of preliminary study findings, CMS must provide an appropriate comment period of at least 60 days to allow plans and others to review the findings. CMS must provide assurances that it will review all comments in a timely manner and provide a response to commenters before publishing the final document.

CMS' Allowance for Utilization Management Edits to Determine Appropriate Part D Coverage, Including for Transition Supplies (Page 124)

AMCP supports CMS' clarification that the use of utilization management edits at the point of sale, including prior authorization (PA), is appropriate to establish whether Medicare Part D covers the medication or indication or whether the medication is covered under Part B.

Implementation and Adoption of Health Information Technology (HIT) Standards for MTM Could Result in Streamlined Service Delivery and More Useful Reporting of Medication Information to Beneficiaries and CMS (Page 131)

MTM Monitoring and HIT Standards
AMCP fully supports the provision of MTM by pharmacists, but is concerned that the current MTM program is not designed to meet the goals envisioned by CMS to improve health outcomes and reduce costs. AMCP believes that the proposed expansion in the Part D proposed rule would further jeopardize achievement of these goals, because it would stretch scarce resources to target and identify the expanded population set who may not want, need, or benefit from MTM.

AMCP comments to the Part D proposed rule contain an extensive explanation of our concerns with the MTM expansion. Rather than expanding a program that currently does not provide the infrastructure or support to ensure meaningful, useful pharmacists' MTM interventions, AMCP supports Part D plan flexibility to establish MTM programs to beneficiaries who truly need these interventions.

Findings from a recent CMS MTM monitoring "study" suggest issues exist with several plans in regard to conducting and reporting information on comprehensive medication reviews (CMRs) and targeted medication reviews (TMRs). AMCP encourages CMS to release additional findings from the study and provide more details on the methodology utilized. Many of the issues found by CMS relate to the lack of implementation of HIT standards to gather and report CMR and TMR findings. In addition to a small sampling of plans in the study, AMCP believes that implementation of HIT standards for MTM could help to correct some of the issues identified.

AMCP stands ready to work in collaboration with the National Council on Prescription Drug Programs (NCPDP), a designated standards development organization and the Pharmacy HIT Collaborative (the Collaborative) to lead the development of HIT standards through private sector initiatives. The Collaborative membership includes 9 national pharmacy organizations and associate members that include the NCPDP; HIT vendors; and MTM provider organizations.[3] According to a study completed by The Commonwealth Fund, health care providers have been slow to adopt electronic health records (EHRs). Despite nearly a 10 percent increase in EHR usage from 2011 to 2012, only 44 percent of physicians reported using a basic EHR in 2012. Most importantly, more advanced use of EHRs for information exchange among other providers, such as by pharmacists, for purposes of MTM, is reported to be a significant challenge among those that have already adopted an EHR.[4]

Recognizing the challenges associated with adoption of EHRs among pharmacy stakeholders, AMCP convened in 2013 a forum to help foster the development of electronic solutions to MTM service documentation and coordination for patients during transitions of care. AMCP and the American Society of Health-System Pharmacists (ASHP) are currently bringing together managed care organizations and hospital pharmacists to improve the uptake of electronic solutions to the medication reconciliation process during care transitions. This effort includes exploring more targeted inclusion of MTM in the care transition process.

AMCP believes that we can continue on this path to facilitate a similar process for advancing HIT solutions for MTM, by forging an important public-private partnership with CMS and other stakeholders. AMCP also supports the SNOMED CT MTM service documentation standards currently under development[5] and believes we can engage managed care stakeholders in developing actionable steps to ensure that the MTM documentation is integrated into plan MTM programs and within a patient's EHR. NCPDP has also approved standard transactions within the SCRIPT Standard that may be used for MTM. AMCP looks forward to working with CMS and other stakeholders in driving these efforts to widespread adoption.

To facilitate the standards adoption process through a public-private partnership, AMCP could explore alignment with CMS and others on barriers to HIT adoption in the MTM space, including:

- **Recognize pharmacists and pharmacies as eligible providers of EHRs that would facilitate information sharing with other health care providers and health information exchanges (HIEs).** AMCP strongly believes the use of standards that ensure interoperable documentation is integral to the future success of MTM programs and ultimately improving the lives of Part D beneficiaries. Currently, pharmacists are not meaningful users of EHRs and therefore generally do not have comprehensive EHR information readily accessible to read, share, edit, and exchange with other providers. If CMS encourages adoption of EHRs by pharmacies through the incentive programs and facilitates use of certain existing standards, then information sharing by pharmacies through HIEs may improve. The delivery of quality healthcare is largely dependent upon the quality of data or information that is available. As a result, AMCP encourages CMS to recognize pharmacists and pharmacies as eligible providers under EHR standards that will facilitate greater communication functionality. Accomplishing this issue of accessibility will equip pharmacists with more robust health information to improve health care quality using a team-based approach.
- **HIE funding.** Another potential barrier to MTM service documentation is the lack of funding for current HIEs. AMCP members have noted that large variability exists among states on the functionality of HIEs. HIEs receive various levels of funding and as a result implementation and participation vary on a state-by-state basis. Consequently, AMCP is concerned about the consistency in the availability of HIEs for sending and receiving MTM patient information including drug therapy problem (DTP) identification and resolution codes, especially Logical Observation Identifiers Names and Codes (LOINC) for laboratory data[6], patient disease scores (e.g., pain score) and Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) codes. Part of the initiative to implement HIT standards should be focused on efforts to implement and fund HIEs.
- **Lack of consistent access by pharmacists to prescription drug monitoring (PDMPs) for MTM reviews.** States vary in their level of pharmacist access to PDMP information and intrastate communications are not fully available via a seamless, single interoperable standard. PDMPs must be focused on providing clinical tools to pharmacists and others in making determinations about appropriateness of medication therapy and not simply a means to assist law enforcement in collecting evidence. AMCP supports CMS' efforts to improve oversight of opioid monitoring and therefore recommends that it support initiatives to ensure access to interstate, interoperable standards for PDMP data transmission.

AMCP has already taken steps to move managed care pharmacy and other stakeholders forward in adopting standards to streamline electronic communications and improve patient safety and outcomes. In April 2014, AMCP will convene a stakeholder focus group on the new NCPDP Electronic Prior Authorization (ePA) transaction set within the NCPDP SCRIPT Standard. Our goal with this forum is to define activities and programs AMCP should sponsor to facilitate a rapid adoption of ePA capabilities, to develop measurable goals for staged and full implementation of ePA, and encourage adoption of these goals by all stakeholders. AMCP can use this as a model template to promote implementation of MTM standards.

Expansion of MTM to Non-Targeted Populations in Administrative Bids (page 133)
As stated above, AMCP supports the use of pharmacist-provided MTM but remains concerned that the current structure of the program and proposed expansion will not ensure meaningful interventions to truly improve health outcomes. AMCP supports flexibility in providing MTM to patients and populations who truly need and require these services and therefore, appreciates CMS' statement in the call letter indicating that plans may expand MTM to beneficiaries beyond the targeted populations. However, given the challenges presented by the current infrastructure to target specific populations and the proposed expansion to more than 55% of beneficiaries, including non-targeted patient populations at this time would result in administrative costs that result in increases in costs to the government and to beneficiary premiums. Therefore, CMS' suggestion that plans may expand MTM beyond the targeted population is not feasible without changes to eligibility criteria.

In comments to CMS on the integration of Part D into ACOs, AMCP recommended that MTM efforts be targeted toward beneficiaries who are at risk for hospitalization, hospital readmissions, or experiencing a transition of care.[7] The Medicare Payment Advisory Commission agreed with AMCP's assessment that Medicare beneficiaries could be better served through MTM in ACOs and other integrated delivery models.

AMCP appreciates the work of CMS and CMMI on working to consider integration of pharmacists' services into new care delivery models and understands it might not happen immediately. Therefore, AMCP suggests consideration of the following alternative to the existing MTM infrastructure. Rather than relying on a regulatory mandated approach to MTM, AMCP supports the standards established in a consensus document, *Sound Medication Management Principles, version 2.0*.[8] This document, supported by key national pharmacy and patient advocacy organizations, including AARP, AMCP, the American Pharmacists Association, and the National Association of Chain Drug Stores, established a process to provide MTM based on the needs of identified enrollees in a plan, utilizing appropriate patient selection criteria and interventions to meet the needs of individual members rather than government mandates. MTM programs should identify appropriate outcomes and design measurements to assess the outcomes, while maintaining appropriate documentation and results. CMS should substitute the current Part D MTM requirements with the principles in this document.

According to the *Sound Medication Management Principles*, MTM programs should be based on enrolling patients at risk for adverse events and those likely to be at risk for chronic diseases or other health problems. Lists of eligible patients should be updated frequently. Patients at risk could include those who:

- Overutilize or underutilize medications;
- Visit multiple physicians (and/or pharmacies);
- Routinely are not adherent to or persistent with medication regimens;
- Do not understand how to use their medications and do not have a support system/network in place to guide their utilization;
- Have financial barriers to obtaining their prescriptions, including those who use very expensive medications or have very high total drug expenses; and
- Need multiple medications to treat complex comorbidities.[9]

Based on this list of criteria, plans may then develop MTM interventions toward the needs of the beneficiaries served and based on regulatory mandates. Again, AMCP urges CMS to use this approach based on a process for identifying specific beneficiaries rather than continue to rely on regulatory mandates.

AMCP Comments on Star Ratings Changes (Page 74)

CMS' Twice Yearly Comment Period for Star Ratings Changes
AMCP supports CMS' twice yearly comment period to allow for more comments and to introduce transparency into the process. AMCP also appreciates CMS' efforts to present the methodology two years in advance. Through this system, AMCP believes that CMS will receive more meaningful comments allowing more informed decisions by CMS and plans.

Reconsideration of Certain Measures for the Display Page if Guidelines Change during the Measurement Period
AMCP supports CMS' proposal because this allows measures to be appropriately updated and reviewed to ensure that the measures represent the most current guidelines and to ensure plans have the ability to implement current evidence-based clinical guidelines without the risk of penalty. If the Health Effectiveness and Information Data Set comments suggest changes to measures, then AMCP would support moving these measures to the display page.

Potential Changes to Measures Based on New Guidelines for Cholesterol Management, Diabetes, and Hypertension
AMCP supports reconsideration of these measures upon change in the guidelines. Specifically, for the diabetes measure, AMCP urges CMS to consider that while the clinical outcomes for DPP4 and GLP1 agents have been widely studied, the same cannot be said for the SGLT2 inhibitors, which have recently launched within the past 12 months. AMCP is promoting the conduct of observational trials of the SGLT2 agents and recommends not adding these drugs to the measure until more clinical evidence based on more widespread utilization is available.

Medication Adherence for Diabetes Medications for Medicare Part D
AMCP agrees with CMS' proposed changes to the measures. AMCP would like this measure to include adherence scores *and* outcome measures, for example improvements in hemoglobin A1C levels.

Medication Adherence Measures for Medicare Part D
AMCP agrees that beneficiaries in skilled nursing facility (SNF) and hospice stays should be excluded from the measure. However CMS must be mindful that plans must perform the calculations necessary to remove SNF and hospice patients from the calculations for the measure. This process adds increased complexity to the measure and CMS should consider delaying the measure to ensure that plans have adjusted the calculations correctly for reporting purposes. Even minor mistakes in the calculations could result in percentage errors that result in implications to overall Star performance.

Pharmacy Quality Alliance Updated Specifications for Calculating Percentage of Days Covered in 2014
AMCP agrees with CMS' adjustments.

Consideration to Use Ingredient Name Flags to Perform Adjustments Programmatically Beginning in 2016
AMCP believes that CMS should make this change for the 2016 Star Ratings using 2014 prescription drug event (PDE) data.

Pharmacotherapy Management of Chronic Obstructive Pulmonary Disease (COPD) Exacerbation under Medicare Part C
AMCP agrees that this measure should remain on the display page .AMCP is concerned that this measure does not account for beneficiaries who have already received a 30-or 90-day supply dispensed before the event and still have days remaining on this supply. AMCP believes that if this issue is not considered, inappropriate overutilization may occur.

PQA Drug-Drug Interactions for Part D
AMCP suggests that this table undergo systematic review of clinical and scientific evidence by AHRQ to ensure that plans and others have access to the latest, most comprehensive clinical information on drug interactions most consistently associated with negative clinical outcomes. AMCP seeks this review to avoid "alert fatigue" that results when pharmacists are inundated with alerts and thus begin to ignore appropriate interventions. Alert fatigue is an important clinical concern and therefore, targeting the correct interactions is necessary to ensure patient safety.

Conclusion

AMCP thanks CMS for the opportunity to comment on the draft call letter. AMCP urges CMS to use AMCP comments provided herein and the comments on the proposed Medicare Part D rule to reconsider finalizing the proposed rule until outstanding provisions are resolved, namely, in the areas of preferred networks and MTM. If you would like to contact me, please call 703-683-8416 or erosato@amcp.org.

Sincerely,

Edith A. Rosato, RPh, IOM
Chief Executive Officer

[1] AMCP Comments to CMS on Medicare Part D Proposed Rule. March 2014. http://www.amcp.org/uploadedFiles/Production_Menu/Policy_Issues_and_Advocacy/Letters,_Statements_and_Analysis_-_docs/2014/CMS-AMCPComments_MedicarePartDProposedRule_March2014_FINAL.pdf. Accessed March 7, 2014.

[2] AMCP Comments to CMMI Request for Information (RFI): *Evolution of ACO Initiatives at CMS*. Feb. 2014. http://www.amcp.org/uploadedFiles/Production_Menu/Policy_Issues_and_Advocacy/Letters,_Statements_and_Analysis_-_docs/2014/CMS-AMCPComments_ACO_PartDintegration_Feb2014.pdf. Accessed March 4, 2014.

[3] In addition to AMCP, the founding members of the Collaborative are: American Association of Colleges of Pharmacy; Accreditation Council for Pharmacy Education; American College of Clinical Pharmacy; American Pharmacists Association; American Society of Consultant Pharmacists; American Society of Health-System Pharmacists; National Alliance of State Pharmacy Associations; and, National Community Pharmacists Association. Associate members are: Mirixa; National Council for Prescription Drug Programs; OutcomesMTM; Relay Health; ScriptPRO; and SureScripts. http://www.pharmacyhit.org/. Accessed March 4, 2014.

[4] C. M. DesRoches, A.-M. J. Audet, M. Painter et al., "Meeting Meaningful Use Criteria and Managing Patient Populations: A National Survey of Practicing Physicians," Annals of Internal Medicine, June 4, 2013 158(11):791–99.

[5] Medication therapy management services clinical documentation: using a structured coding system – SNOMED CT. Pharmacy HIT Collaborative. Accessed at http://pharmacyhit.org/pdfs/workshop-documents/WG2-Post-2014-02.pdf. Accessed March 4, 2014.

[6]LOINC. http://loinc.org/get-started/02.html. Accessed March 6, 2014.

[7] AMCP Comments to CMMI Request for Information (RFI): *Evolution of ACO Initiatives at CMS*.

[8] Sound Medication Therapy Management Programs v 2.0. *JMCP*. Vol. 14, No. 1, S-b. 2008. http://www.amcp.org/data/jmcp/JMCPSuppB_Jan08.pdf. Accessed March 2, 2014.

[9] *Ibid*.