

March 4, 2016

Sean Cavanaugh
Deputy Administrator, Centers for Medicare and Medicaid Services
Director, Center for Medicare

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Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
200 Independence Avenue, SW Washington, DC 20201

Re: Advance Summary of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter

Dear Deputy Administrator Cavanaugh and Director Lazio:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide comments in response to the notice titled “*Advance Summary of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter*” released on February 19, 2016. AMCP offers comments on the following sections of the notice:

- A. Medication Therapy Management (MTM)
- B. Opioids
- C. Point of Sale (POS) Pilot
- D. Star Ratings & Display Measures
- E. Tiers & Specialty Medications

AMCP is a professional association of pharmacists and other practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

A. Medication Therapy Management (MTM)

AMCP is pleased that CMS acknowledged AMCP in the 2017 Draft Call Letter and credits the important work that AMCP's Medication Therapy Management Advisory Group is doing to develop a framework to define drug therapy problems. AMCP will continue to collaborate with stakeholders in this area, such as the Pharmacy Quality Alliance (PQA) and the HIT Collaborative, to develop a standardized framework to allow for the shift towards outcomes-based measurements in Medicare Part D. AMCP will also work with CMS to share its work and recommendations for inclusion in future communications to plans, regulations, and Call Letters.

Part D Reporting Requirements for MTM

CMS Proposal

CMS proposes that element X, "Topics discussed with the beneficiary during the comprehensive medication review (CMR), including the medication or care issue to be resolved or behavior to be encouraged," be suspended for the 2016 Part D Reporting Requirements until a more standardized set of data can be collected. CMS notes that the industry, including PQA and AMCP, is working on a framework to define drug therapy problems (DTPs), and that sponsors should begin to develop the capacity to collect and report drug therapy problems using a standard framework and common terminology.

AMCP Recommendations

AMCP believes that the consistent use of structured universal codes is critical to the expansion of documentation of MTM services and supports the use and implementation of SNOMED CT codes for the exchange of information. SNOMED CT documentation for MTM services will allow the pharmacist to document the clinical care that is provided through encounter-based coding and intervention-based coding. Encounter-based coding elements for MTM services include reasons or indications for the MTM visits and a description of the services that were provided (e.g., referral to MTM service, complications with medication therapy, comprehensive medication therapy review, targeted medication therapy review, medication-related action plan, pharmacist consultation with health care provider, patient education). Intervention-based coding allows the pharmacist to document drug therapy problems identified during the medication regimen assessment, as well as provide the necessary SNOMED CT codes to document the patient's care plan or medication action plan. Use of standardized SNOMED CT codes, coupled with a framework for defining drug therapy problems, will allow for the shift towards outcomes-based measures versus the traditional process-based measures that are used today in Part D.

CMS-CMMI Enhanced MTM Model Test

CMS Commentary

CMS notes that the Center for Medicare and Medicaid Innovation (CMMI) has released a request for participation in an expanded MTM test model but does not offer any additional insight on the model or the status of plan participation.

AMCP Recommendations

AMCP encourages CMS to be transparent and flexible as the test models are implemented and as changes to the Star Ratings and display measures are considered for these test models. AMCP will continue to closely monitor the test model and provide feedback to CMS on possible areas of improvement.

Data Integrity of MTM Programs

CMS Proposal

CMS proposes that program audits will soon include review of Part D sponsors' MTM programs to determine bias outside of the Data Validation results. CMS proposes that audit criteria be developed and finalized based upon findings from pilot audits.

AMCP Recommendations

AMCP believes the proposed audits will provide data to help the industry understand how different practice models with positive results can be replicated across Part D sponsors. AMCP is pleased to see CMS perform pilot audits prior to finalizing audit criteria. AMCP encourages CMS to be transparent with sponsors during the pilot phase and provide timely information to sponsors on draft audit criteria.

B. Opioids

Formulary-Level Cumulative Opioid POS Edits

CMS Proposal

CMS expects sponsors to implement soft and hard formulary-level cumulative morphine equivalent dose (MED) at the point of sale (POS) edits beginning January 1, 2017. Sponsors' Pharmacy & Therapeutics (P&T) committees will be responsible for developing the specifications for the soft and hard cumulative MED POS edits. Beneficiaries with certain conditions, such as cancer, or those in hospice, would be exempted from the edits.

AMCP Recommendations

AMCP is concerned that CMS is focusing on POS edits to address the opioid epidemic. AMCP believes this is a reactive approach and that CMS should focus on adopting proactive means of identifying at-risk beneficiaries,

such as lock-in programs and expanding access of state prescription drug monitoring program (PDMP) data to health plans.

AMCP supports the concept of prescriber or pharmacy lock-ins under the Medicare Part D program for beneficiaries who are suspected of inappropriate utilization of controlled substances. Recent CMS data suggests that approximately 1-2% of Medicare beneficiaries inappropriately use controlled substances.¹ AMCP encourages CMS to advocate for legislative changes to the Part D program allowing sponsors to enroll patients identified as high-risk for opioid over-utilization in a pharmacy and/or prescriber restriction program, also known as lock-in programs. AMCP [commended](#) the Obama Administration and CMS for its support of Senator Pat Toomey and his leadership in addressing the opioid epidemic and being a champion for the expansion of lock-in programs to Medicare Part D beneficiaries. AMCP was pleased to see that an amendment offered by Senator Pat Toomey regarding lock-in programs was accepted into S. 524 – “*Comprehensive Addiction and Recovery Act of 2016*”. AMCP has worked with Senator Toomey’s office on the lock-in legislation and looks forward to working toward its passage.

Lock-in programs have successfully been used by state Medicaid programs and commercial plans for years, but are currently prohibited under Medicare Part D. Opioid misuse by elderly patients, the primary population covered by the Medicare Part D program, is a growing concern in the United States and it is unfortunate that drug management programs, along with other clinical and psychosocial interventions, may not be used to allow these individuals to receive the help they need. Furthermore, Medicare beneficiaries who are disabled and under 65 are at greatest risk for overutilization or inappropriate utilization of opioids thereby strengthening the need for drug management programs under Medicare Part D.

In 2009, the Oklahoma Medicaid department found that its lock-in program reduced doctor shopping, utilization rates of controlled substances, and emergency room visits with an average savings of \$600 per person in costs.² A recent study evaluating the clinical outcomes of drug management programs for Medicaid patients found that the proportion of stable patients increased from 31% at 6 months to 78% at 36 months.³ In addition, a study evaluating the impact of a single-provider drug management program on health care utilizations and costs within a Medicaid Managed Care Organization in Maryland found that enrollment in a single-provider drug management program decreased opioid prescriptions and associated costs among health plan members who exhibited signs of opioid overuse.⁴ In addition, a recent consensus document released by the Johns Hopkins Bloomberg School of Public Health highlights the benefits of drug management programs and recommends

¹ Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Centers for Medicare and Medicaid Services, April 2, 2012 Available at <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=15078> Accessed March 4, 2016.

² SoonerCare Pharmacy Lock-in Program Promotes Appropriate Use of Medications. September 9, 2009 [press release]. <http://okhca.org/about.aspx?id=10973>. Accessed March 4, 2016.

³ Theresa R. F. Dreyer, Thomas Michalski, and Brent C. Williams. Patient Outcomes in a Medicaid Managed Care Lock-In Program. *Journal of Managed Care & Specialty Pharmacy* 2015 21:11, 1006-1012.

⁴ Sarah G. Kachur, Alyson B. Schuster, Yanyan Lu, Elizabeth Patton-LeNoach, Hugh Fatodu, Peter J. Fagan, and Chester W. Schmidt. Impact of a Single-Provider Lock-In Program for Opiates in a Managed Medicaid Population. Johns Hopkins University School of Medicine, Baltimore MD.

expansion of the drug management programs to Medicare Part D beneficiaries.⁵ Therefore, as demonstrated in Medicaid and other programs, and recommended by the General Accountability Office in 2011, CMS should consider restricted access to certain prescribers and pharmacies for Medicare beneficiaries to reduce incidence of doctor or pharmacy shopping.⁶

AMCP is also concerned that POS edits would be based only upon information available to the Part D sponsor via claims data available to the plan, and not take into account patients who choose to pay cash for their prescriptions. While forty-nine states and the District of Columbia have PDMPs that collect dispensing data for all opioid medications, including prescriptions paid for by insurance and cash, only five states provide PDMP access to Medicare plan sponsors and three states to commercial third-party payers.⁷ The current legislative scheme at the state-level is a barrier to Part D sponsors' ability to properly assess the true opioid overutilization of their members. If the POS edits are limited to adjudicated prescription claims data only, CMS risks falsely rewarding plans for their successful implementation of POS edits while in reality many of their patients may be opioid over-utilizers but appear as a false negative because of limitations in data availability. Prior to finalizing these POS edits, CMS must address how patients paying cash for their prescriptions, and the inability of plan sponsors to access this information, will be factored into these edits. Furthermore, CMS must address how opioids that are administered in physician offices will be accounted for because this information is also traditionally not available to plan sponsors.

Finally, AMCP cautions CMS to carefully consider the timing of requiring the POS edits to be in place by January 1, 2017. It will be challenging for plans to complete their Pharmacy & Therapeutics Committee review and approval of MED-based POS edits for CY 2017, given that the final Call Letter with the final requirements will be released close to the date by which the CY 2017 formularies must be finalized and uploaded in HPMS. Therefore, AMCP requests that CMS consider delaying the implementation date to January 1, 2018 to allow additional time for the necessary P&T review and approvals, programming, and testing.

CDC Guidelines for Prescribing Opioids for Chronic Pain

CMS Commentary

CMS states it is monitoring the release of Centers for Disease Control and Prevention (CDC) prescribing guidelines for opioids and will consider potential revisions to CMS overutilization guidance and the OMS opioid overutilization methodology in the 2018 Call Letter.

⁵ Alexander GC, Frattaroli S, Gielen AC, eds. *The Prescription Opioid Epidemic: An Evidence-Based Approach*. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015.

⁶ Academy of Managed Care Pharmacy. *Role of Managed Care Pharmacy in Managing Controlled Substances for Medicare Part D Beneficiaries*. 2014. Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=18556>. Accessed March 4, 2016.

⁷ Alexander GC, Frattaroli S, Gielen AC, eds. *The Prescription Opioid Epidemic: An Evidence-Based Approach*. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015

AMCP Recommendations

AMCP provided detailed [comments](#) to the CDC on the draft opioid prescribing guidelines in January 2016 encouraging the CDC to adopt a holistic, comprehensive, and multi-stakeholder approach among health care providers and patients to truly address the opioid epidemic. While AMCP believes the CDC's draft guidelines are a step in the right direction, AMCP has concerns with some of the recommendations and believes many important elements are either missing from the draft guidelines or can be improved upon, including:

- Patient risk evaluation and assessment;
- Lock-in programs;
- Electronic prescribing;
- Inter-professional team approach;
- Prescription drug monitoring programs;
- Opioid overdose antidotes; and
- Safe storage and disposal of opioids.

AMCP recommends that CDC consider these elements before finalizing and adopting the guidelines to ensure that the guidelines include the benefit of the experience gained from managed care pharmacy and the patient population it serves.

Finally, AMCP encourages CMS to work collaboratively with CDC to develop a robust education strategy for prescribers once the opioid prescribing guidelines are finalized. AMCP believes educating prescribers of the new guidelines and their implications should be the primary responsibility of the agencies, and not of the individual plan sponsors or their P&T Committees.

C. POS Pilot

CMS Commentary

In 2015, CMS initiated a pilot program aimed at identifying opportunities for reducing the volume of rejected pharmacy claims for payment by resolving issues that occur before a prescription is sent to a pharmacy. CMS provides preliminary results from the POS pilot including issues identified as well as a representative list of areas CMS may explore for addressing them. CMS also invites stakeholders to provide comments to the pilot program.

AMCP Recommendations

As a way to increase the use of electronic prior authorization (e-PA), earlier this year AMCP published results of a survey it conducted in late 2015 to identify potential outreach strategies that could be undertaken to speed and improve the adoption of e-PA. The findings suggest that many prescribers who use electronic prescribing (eRx) systems do not necessarily use the e-PA standard approved by the National Council of Prescription Drug Programs (NCPDP). Furthermore, the survey found that in many cases, prescribers do not distinguish the NCPDP standard e-PA from proprietary systems, such as non-standard email systems, web portal systems, or

electronic fax systems and therefore, may not be fully assessing the benefits of using standard e-PA. AMCP is working to proactively provide educational efforts on the benefit of standard e-PA to provide prescribers with more insight to evaluate the benefit and cost savings associated with using the NCPDP e-PA standard. Until prescribers appreciate the difference and see the value of the use of standard e-PA, AMCP predicts that adoption rates will be low. Simply asking Medicare Part D plans to encourage eRx and e-PA is not enough. AMCP recommends that CMS call attention to precisely the version of e-PA they would like to see adopted, and acknowledge that there may be marketplace confusion as to the differences. Only use of standard e-PA will help reduce POS rejections and improve the Medicare Part D member experience.

D. Star Ratings & Display Measures

AMCP provided detailed [comments](#) to CMS in response to the memorandum titled “*Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond*” in December 2015 outlining the AMCP’s position on several of the proposed changes to the Star Ratings and display measures as proposed. AMCP is pleased to see that many of its concerns were addressed in the Call Letter and that no drastic changes to the Star Ratings or display measures are proposed for CY 2017. AMCP encourages CMS to continue to provide advanced notice of proposed changes to Star Ratings and display measures prior to release of the Call Letter. In addition to the comments AMCP offered in December 2015, it offers the following additional comments for consideration.

Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer

CMS Proposal

CMS proposes developing three new safety opioid overutilization measure reports to provide to Part D sponsors on a monthly basis through the Patient Safety Analysis website. CMS will consider adding these measures to the 2019 display page after gaining at least one year of experience with the measures and pending new guidelines. CMS does not recommend including these measures in the Star Ratings at this time because of lack of consensus on clinical guidelines for opioid prescribing and pending additional data.

AMCP Recommendations

AMCP remains concerned that the proposed opioid measures require clarification prior to implementation. AMCP urges CMS to clarify the timeframe for Measure 2 (Multiple Prescribers and Multiple Pharmacies) and Measure 3 (Multi-Provider, High Dosage). Depending on the timeframe, it may be reasonable that a patient receives prescriptions for opioids from four or more prescribers and four or more pharmacies. Therefore, defining a timeframe to accompany the measures is necessary to alleviate both false positives and false negatives. Furthermore, as detailed in the comments above, AMCP urges CMS to consider proactive means of identifying at-risk beneficiaries such as expanding lock-in programs to Medicare Part D beneficiaries and allowing health plans to access state PDMP data.

Medication Reconciliation Post (MRP) Discharge

CMS Proposal

CMS proposes to expand MRP to all MA plans and members 18 years and older and include it the display page for 2017. CMS believes expansion of the MRP measure is an important step to measure the quality of care coordination post-discharge for MA beneficiaries as well as ensuring patient safety. CMS plans to include the expanded MRP measure in the 2018 Star Ratings.

AMCP Recommendations

AMCP appreciates that CMS intends to expand the MRP measure, but remains concerned that this may be duplicative with other post-discharge measures in place for areas outside of pharmacy and the patient confusion, alert fatigue, and disruption that may result. AMCP encourages CMS to develop mechanisms to decrease redundancy and overlap, and encourage team based care.

High Risk Medications (HRM)

CMS Proposal

CMS proposes the HRM measure be removed from the Star Ratings and moved to the display page for 2017 based on a recommendation from the American Geriatrics Society (AGS) that the Beers Criteria not be applied in a punitive manner and the recognition that identification as a HRM is not a contradiction to use, but rather an encouragement to avoid use without first considering the risks and benefits to the individual. CMS would continue to provide HRM measure reports to Part D sponsors on a monthly basis through the Patient Safety Analysis website and continue to identify outliers. CMS may consider the HRM measure for Star Ratings again in the future.

AMCP Recommendations

AMCP appreciates that CMS recognizes the AGS' recommendation that the Beers Criteria not be applied in a punitive manner and the recognition that identification as a HRM is not a contradiction to use, but rather an encouragement to avoid use without first considering the clinical risks and benefits to the individual patient. However, AMCP cautions CMS to carefully consider the timing of when this change should be made and recommends that CMS revise the timeline for removing the HRM measure from the Star Ratings from 2017 to 2018, to allow sufficient time to develop additional measures that examine overuse and inappropriate use of prescription drugs. Furthermore, AMCP encourages CMS to be transparent with sponsors and provide advanced notice as future changes to HRM, or measures intended to replace HRM, are considered and to ensure that the perspective of geriatricians, managed care pharmacy, and other health care providers that are experts in this area are taken into consideration prior to finalization.

E. Tiers & Specialty Medications

Tier Labeling and Composition

CMS Proposal

CMS proposes a non-preferred drug tier option that will allow for a drug mix regardless of brand/generic status. Sponsors will have the option of selecting a non-preferred drug tier or non-preferred brand tier but not both. Although sponsors using a non-preferred drug tier have the option of choosing either copay or coinsurance cost sharing with the same thresholds as the non-preferred brand tier, CMS encourages Part D sponsors to consider using a coinsurance for the non-preferred drug tier instead of a copay.

AMCP Recommendations

AMCP believes the creation of a non-preferred drug tier is a step in the right direction to encourage innovation in plan design. AMCP encourages CMS to be transparent and share results from outlier tests to help determine the benefit of the new tier to patients, including the benefits of coinsurance over copay.

Specialty Tiers

CMS Proposal

CMS proposes increasing the specialty tier threshold from \$600/month to \$670/month.

AMCP Response

AMCP believes this change will probably have a negligible impact as the number of specialty medications that fall between the \$600/month and \$670/month thresholds is limited. However, AMCP will monitor the impact of this change to determine the true impact and any unintended consequences associated with the change.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer