

April 24, 2017

Seema Verma  
Administrator

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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: 2017 Transformation Ideas***

Dear Administrator Verma 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 request for information (RFI) for Medicare Advantage (MA) and Medicare Part D programs included in the “*Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information*” released on April 3, 2017. AMCP commends HHS and CMS for seeking stakeholder feedback on how the MA and Part D programs can be transformed through innovation to best meet the individual health needs of Medicare beneficiaries. AMCP offers comments on the following elements of the MA and Part D programs that AMCP believes can be improved to better meet the needs of beneficiaries:

- I. Medication Therapy Management (MTM)
- II. Quality
- III. Formulary Design and Utilization Management
- IV. Health Information Technology and Data Interoperability
- V. Opioid Management
- VI. Fraud, Waste, and Abuse

AMCP's comments provide options for regulatory, subregulatory, policy, practice and procedural changes to meet the goals of CMS. Where applicable, AMCP's comments also provide options for statutory changes to the MA and Part D programs that would help to better meet the needs of beneficiaries.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

## **I. Medication Therapy Management (MTM)**

AMCP has established a MTM Advisory Group (MTMAG) to advise AMCP staff on critical issues in the delivery of MTM related services and provide practical recommendations for MTM practice and administration. The MTMAG is comprised of 40+ MTM stakeholders, including AMCP members and non-members who represent Medicare Part D sponsors, MTM vendors, technology vendors, community MTM providers, long-term care MTM providers, pharmacy professional organizations, EHR vendors, integrated delivery networks, and academia. One of the goals of the MTMAG is to evaluate how the current Medicare Part D MTM program can be modernized to maximize its intended benefit for Medicare beneficiaries. AMCP's comments related to MTM were developed with input from the MTMAG.

### ***CMS Should Include MTM Programs in the Medical Loss Ratio as Quality Improving Activities***

AMCP strongly encourages CMS to include MTM programs in the medical loss ratio (MLR) as quality improving activities. Medication-related problems are a significant public health issue within the healthcare system. The Food & Drug Administration's Adverse Event Reporting System estimates that more than 1.17 million prescription related-adverse events occur each year, resulting in \$3.5 billion in medical costs annually.<sup>1, 2</sup> MTM services help address the urgent public health need for the prevention of medication-related morbidity and mortality by contributing to medication error prevention, resulting in improved reliability of healthcare delivery, and enabling patients to take an active role in medication and healthcare self-management. In one significant example, a study of MTM programs in a large health system identified that 85% of patients had at least one medication therapy problem, and 29% of patients had five or more medication therapy problems.<sup>3</sup> A pharmacist-led MTM program in that health system saved \$2,913,850 (\$86 per encounter) over a ten year period. The total cost of MTM was \$2,258,302 (\$67 per encounter), for an estimated return on investment of \$1.29 per \$1.00 in MTM costs.<sup>4</sup> AMCP believes the inclusion of MTM programs in the MLR as a quality improving activity would further encourage and incentivize providers to strengthen their MTM programs, resulting in increased healthcare outcomes and decreased healthcare costs.

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<sup>1</sup> Food & Drug Administration's Adverse Event Reporting System Updated December 2013. <http://1.usa.gov/1W3FkGL>. Accessed April 24, 2017.

<sup>2</sup> Institute of Medicine. Committee on Identifying and Preventing Medication Errors. Preventing Medication Errors, Washington, DC: The National Academies Press 2006

<sup>3</sup> De Oliveria D, Brummel A, Miller D. "Medication Therapy Management: 10 Years of Experience in a Large Integrated Health Care System." J Manag Care Pharm (2010): 185-95

<sup>4</sup> *Ibid*

## ***CMS Should Work with the Pharmacy Profession to Modernize, Test, and Validate Alternate Formats of the Medicare Part D MTM Program Standardized Format to Maximize Its Intended Benefit for Medicare Beneficiaries***

The Medicare Part D MTM Program Standardized Format (standardized format) is a written summary of a comprehensive medication review (CMR). Part D sponsors must at least annually offer a CMR for targeted beneficiaries and provide written summaries. Currently, the summaries must comply with requirements as specified by CMS and include a CMR Cover Letter (CL), Medication Action Plan (MAP), and a Personal Medication List (PML). Existing flexibility in the presentation of CMR summaries is limited to the inclusion of supplemental information only. The format with the standardized information currently may not be modified which creates barriers to innovative approaches Part D plans may utilize to more efficiently and clearly communicate content to beneficiaries. These innovative approaches reflect effective delivery mechanisms for today's Medicare beneficiaries such as streamlined paper documents, emails, patient portals, text messaging, and mobile app technology. Furthermore, the lack of flexibility in the approach does not allow beneficiaries to designate their preferred format for the summary, which may decrease its usability and may not result in the intended benefit to patients and caregivers. Therefore, the development and testing of alternate formats is warranted to improve beneficiary outcomes.

Plans are at the forefront of developing innovative solutions to more meaningfully engage targeted beneficiaries in managing care plans developed through CMRs. Plans have invested in qualitative research, including in-depth in-person interviews with beneficiaries, retrospective surveys, and app usability testing, to better understand how to improve the beneficiary CMR experience. The research demonstrates that beneficiary CMR expectations are grouped around two major themes:

- First, the information provided in the CMR experience should focus on having utility when it is needed most, during transitions of care such as a hospital or emergency room admission or during a doctor's appointment.
- Secondly, the information should come from a clinician they value as a trusted source.

In order to bridge this gap between the limited utility of the standardized CMR format and beneficiary expectations based on research, AMCP believes CMS should permit plans to develop alternative CMR formats that deliver the summary in a more interactive and relevant manner to beneficiaries based upon their preferred delivery method. AMCP recommends that CMS permit plans to utilize alternatives to the standardized CMR format that duplicate the CL, MAP, and MPL content requirements and provide additional choices to beneficiaries including electronic, mobile application technologies, or other innovative communication mediums.

AMCP provided detailed initial suggestions to CMS on how the standardized format may be improved to align with updates in technology and the need for beneficiaries to have choice in how they receive this information, including options for a streamlined paper format and mobile app technology.<sup>5</sup> These recommendations were intended to serve as an opportunity to begin dialogue with CMS in this area to see how the pharmacy profession and CMS can work together to improve the standardized format to maximize the beneficiary experience.

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<sup>5</sup> AMCP Comments Re: CMS-10396 Medication Therapy Management Program Improvements. Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=22164>. Accessed April 24, 2017.

***CMS Should Consider the Inclusion of Alternate Records, Including Pharmacy Records and MTM Encounter Data Inclusive of MTM Vendor Platforms, to Satisfy the Medication Reconciliation Post-Discharge Measure***

The Medication Reconciliation Post-Discharge (MRP) measure requires documentation of medication reconciliation in the “outpatient medical record” within 30 days of discharge. This has historically been interpreted by CMS during the audit process to mean documentation in the electronic health record (EHR) or medical record, not the pharmacy record or MTM encounter/vendor record. This has caused problems since medication reconciliation may have been completed, but documentation of the medication reconciliation may not have been uploaded into the patient’s EHR or medical record. Therefore, Part D sponsors may be negatively scored on the measure even though they completed the medication reconciliation within the required timeframe. To combat this, many Part D sponsors, community pharmacy MTM providers, and MTM vendors are forced to maintain supplemental records, a time consuming process, to meet the needs of CMS. However, acceptance of the supplemental records to meet the requirements of the MRP measure has historically been auditor-specific and not consistent in application. The lack of consistency from one auditor to another raises parity concerns from one Plan Sponsor to the next when quality is being measured and financial rewards are linked to the measure(s). Furthermore, as the MRP measure is being considered for inclusion by NCQA as a component of a comprehensive transitions of care measure for implementation in the near future, it is imperative that the MRP measure be revised to properly capture the completion of medication reconciliation within 30 days of discharge. Therefore, AMCP urges CMS to work with NCQA to consider alternative records to satisfy this measure, including pharmacy records and MTM encounter data/vendor platforms, while the industry continues to move towards interoperability.

***CMS Should Reconsider Targeting & Eligibility Criteria for MTM Services***

AMCP believes MTM targeting and eligibility criteria should be designed not on arbitrary mandates, but based on the needs of identified enrollees in a plan by utilizing appropriate patient selection criteria to meet the needs of individual members. As outlined in the consensus document *Sound Medication Management Principles version 2.0*,<sup>6</sup> CMS should establish a set of criteria to identify patients at risk for adverse events and those likely to be at risk for chronic diseases or other health problems. The criteria should be used to identify the patients at greatest risk and who could benefit the most from the provision of MTM services. Examples of criteria that can be used to identify at-risk patients should include patients, but not be limited to whom:

- Experience or are susceptible to medication related problems;
- Overutilize or underutilize medications;
- Visit multiple physicians;
- 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;

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<sup>6</sup> 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](http://www.amcp.org/data/jmcp/JMCPSuppB_Jan08.pdf). Accessed April 24, 2017.

- 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.<sup>7</sup>

In addition, AMCP believes the current dollar threshold requirement for MTM services should be revised. Currently, many patients do not become eligible for MTM services until late in the calendar year due to the dollar threshold requirement, placing undue pressure on Part D sponsors and MTM vendors to complete MTM services within a very short window before the end of the year. Patients would be better served if they could receive MTM services when identified as at-risk earlier in the year, versus waiting until deemed eligible by an arbitrary dollar threshold. Prescription dollar spending from a previous calendar year can help determine those patients who will likely meet a threshold amount in a current year.

AMCP urges CMS to work with stakeholders to identify a more efficient mechanism for identifying beneficiaries who could benefit from MTM services. Part D sponsors should have the flexibility to identify eligible patients based upon their individual characteristics (patient-centric) and at the greatest risk of adverse events. AMCP further urges CMS to recognize the growing importance of MTM services in accountable care organizations (ACOs), patient-centered medical homes, and other integrated delivery system models that seek to improve health outcomes while lowering costs. AMCP believes integrated delivery models, such as ACOs, are appropriate for the provision of MTM services and that health plans should be able to target beneficiaries who require MTM in these practice settings.

### ***CMS Should Reevaluate the Burden Estimate for Comprehensive Medication Reviews***

CMS currently estimates the burden for completing a comprehensive medication review (CMR) as 40 minutes.<sup>8</sup> AMCP believes this burden estimate is not accurate across all practice settings and therefore, CMS should reevaluate the estimate to better represent the amount of time and effort expended by Part D sponsors, MTM vendors, and pharmacists to provide this critical service to patients. AMCP encourages CMS to consider the following elements when establishing a revised CMR burden estimate, and encourages CMS to consider a multi-tier burden estimate dependent upon the factors below:

- Timing of the CMR (e.g. post-discharge versus an annual medication check-up)
- The venue of care (e.g. outpatient, inpatient, long-term care);
- Language barriers and cognitive ability of patients or their caregivers;
- Number of medications prescribed, including all non-prescription and herbal medications;
- Complexity of medications prescribed;
- Number of conditions/disease states;
- Complexity of conditions/disease states;
- Need to duplicate documentation in multiple records due to lack of interoperability; and
- Breakdown of clinical versus administrative costs (e.g. pre-work, patient time, post-work).

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<sup>7</sup> *Ibid* at 21.

<sup>8</sup> Revisions to the Medicare Part D Medication Therapy Management Program Standardized Format Available at: [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MTM-Program-Standardized-Format-Revisions-v071514-\[ZIP-2MB\].zip](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MTM-Program-Standardized-Format-Revisions-v071514-[ZIP-2MB].zip). Accessed April 24, 2017.

## ***CMS Should Monitor Successes from the Enhanced MTM Model and Implement Changes Across the Part D Program as Best Practices are Identified***

AMCP encourages CMS to closely monitor outcomes from the Enhanced MTM Model Test (eMTM), which is administered by the Center for Medicare and Medicaid Innovation (CMMI) and began a five-year model test in January 2017. AMCP believes these efforts begin the pathway to achieving the goal of ensuring MTM is a cornerstone of the Medicare Part D program through an inter-professional approach to providing services that will improve beneficiary outcomes and help to streamline health care costs in Medicare. The eMTM includes many of the provisions AMCP and other stakeholders have advocated for over the past several years, including flexibility with MTM criteria and changes to the payment system for MTM. As outcomes from the eMTM are made available, and as best practices are identified, AMCP encourages CMS to implement changes across the Part D program incrementally and not wait until the completion of the eMTM to introduce these changes program-wide as these changes have the potential to provide better care for Medicare beneficiaries, improve patient outcomes, and reduce overall healthcare costs.

## **II. Quality**

### ***CMS Should Support the Shift Towards Outcomes-Based Measurements in the Medicare Part D Program***

As the United States health care system begins the evolution from quantity and process-orientated payments to payment policies focused on rewarding higher quality and improved patient outcomes, AMCP urges CMS to support the shift towards outcomes-based measurements in the Medicare Part D program. Currently, most measurements used to assess quality in the Medicare Part D program are process measurements, which indicate what a health care provider does to maintain or improve health and typically reflect generally accepted recommendations for clinical practice. To align with the shift towards payment for value, however, measurements used to assess quality in the Medicare Part D program will need to shift to outcomes measurements which reflect the impact of the health care service or intervention on the health status of patients. To move the needle towards outcomes-based measurements, AMCP urges CMS to:

- Consider how data interoperability can aid in the shift towards outcomes-based measures. While the adoption of SNOMED CT codes may be the gold standard for documenting diagnoses, interventions, and other clinical information to provide the data needed to study and demonstrate value, adoption and implementation of SNOMED CT codes will be very costly for Part D sponsors and may be premature as results from the eMTM, which is using SNOMED CT codes, and other HL7 standards such as LOINC codes, for documentation, are unknown. In the interim, however, there are opportunities for CMS to drive clinical integration in programs and begin the shift towards outcomes-based measures. For example, if a patient is adherent on their diabetes medications based upon a Star Ratings measure, the patient should theoretically have an at-goal A1C level based upon a HEDIS measure. If the patient is adherent to their medications but does not have an at-goal A1C, there is opportunity to determine the causation such as perhaps the patient is adherent to the wrong medication regimen or the medication regimen was never optimized (i.e. appropriate titrated dosing) to achieve an at-goal A1C. Therefore, CMS has an opportunity to evaluate how current measurements can be integrated across the Part D program to begin to evaluate the impact of the health care service or intervention on the health status of patients.

- Consider the cost-effectiveness associated with new or revised measures before adding them to the Star Ratings or display page. AMCP believes measures should be utilized to demonstrate an improvement in patient outcomes and an overall reduction in health care costs to measure all three sectors of the “Triple Aim.” Therefore, AMCP urges CMS to ensure new or revised measures meet these goals and are assessed for cost-effectiveness prior to being added to the Part D program.
- Evaluate the current Star Ratings and display page measures for duplication and remove any overlapping measures. In addition, evaluate measures that are currently in the development process for duplication and that may compete with existent measures. AMCP believes measures should align and avoid duplication to minimize confusion and disruption for plans, providers, and patients.
- Continue to provide adequate advanced notice of changes to Star Ratings and display page measures to allow plans and providers to properly prepare and reallocate necessary resources to new or revised measures. AMCP believes adequate notice is essential for plans to properly prepare and educate providers about the changes.

***CMS Should Work with Medicare Part D Plans, Medicare Advantage Networks, and Retail and Community Pharmacies to Establish Preferred Pharmacy Networks that Reward the Provision of Improved Outcomes for Beneficiaries***

AMCP supports the use of preferred pharmacy networks as a tool to ensure quality of care and access to pharmacies that may influence health outcomes and lower costs as part of integrated delivery models, ACOs and other emerging payment models.

Preferred pharmacy networks may be leveraged to help improve overall outcomes and quality measures. First, risk-sharing arrangements with pharmacy networks and incentives to increase generic utilization rates increases pharmacist and pharmacy participation in patient health care management and may help to improve medication adherence and utilization by ensuring that patients receive the appropriate medications at a reasonable cost. Second, preferred pharmacy networks may also incorporate pharmacists patient care services and interventions into accountable care arrangements and other integrated care delivery to achieve better health outcomes at a lower cost. Pharmacies and pharmacy chains that help to achieve better health outcomes should receive incentives to continue these practices through preferred network arrangements. AMCP understands recent potential concerns with the structure of preferred pharmacy networks and urges CMS, Part D plans, and pharmacies to work to establish mechanisms that reward positive health outcomes for beneficiaries and reasonable costs for the Medicare program.

The Center for Medicare and Medicaid Innovation (CMMI) issued a RFI in December 2013 to consider integration of Medicare Part D into ACOs,<sup>9</sup> including information related to Medicare Part D integration into ACOs and the possibility of enhanced risk sharing by ACO participants. In comments responding to the RFI, AMCP supported integration of Part D into ACOs so long as certain conditions were met, including the ability of pharmacies to participate in risk sharing. AMCP is concerned that CMS’ current Part D structure would

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<sup>9</sup> CMMI Request for Information. Evolution of ACO Initiatives at CMS. December 2013. <http://innovation.cms.gov/Files/x/Pioneer-RFI.pdf>. Accessed April 21, 2017.



undermine the ability for pharmacies to ever fully participate in ACOs as full partners because of restrictions on the ability to enter into insurance risk contracts.

### III. Formulary Design and Utilization Management

#### *CMS Should Reconsider Criteria for Managing Medications in the Medicare Part D Six Classes of Clinical Concern (Protected Classes)*

AMCP has long supported the ability of plans to manage medications in all categories and classes, including medications in the six classes of clinical concern (protected classes). The six protected classes are: anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, and immunosuppressants. In June 2016, the Medicare Payment Advisory Commission (MedPAC) recommended removing immunosuppressants and antidepressants from the classes of clinical concern.<sup>10</sup> In its analysis, MedPAC indicated that it “generally supports objective criteria in determining classes of clinical concern while balancing the goals of beneficiary access and welfare with Part D plans’ tools to manage the drug benefit and appropriately restrain costs.” MedPAC noted that these two classes of medications contain a number of generic products available on commercial formularies with different products and strengths.<sup>11</sup>

In a 2014 proposed rule, *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.), CMS also proposed eliminating immunosuppressants and antidepressants from protected class status with a consideration for eliminating antipsychotics at a later time.<sup>12</sup> CMS indicated that the costs associated with the requirement for these protected classes added approximately \$720 million or more in costs for plan years 2015-2019. In making its determination to remove these classes of medications, CMS assessed the risk of significant harm or hospitalization and whether more specific requirements are necessary to ensure sufficient beneficiary access to these classes of medications. CMS noted that allowing additional management of immunosuppressant and antidepressant classes would not result in serious harm or hospitalization to beneficiaries if not all medications in the class are included on the formulary. Further, CMS noted that these protections reduce the ability of plans to negotiate lower prices for these medications, thereby increasing costs to beneficiaries and the government.<sup>13</sup> This finding is consistent with findings from a 2008 report commissioned by AMCP to determine the impact of the protected classes.<sup>14</sup>

Requirements to include all or substantially all medications on a formulary in the protected classes also result in potential safety concerns, because plans have limited ability to use standard utilization management tools to

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<sup>10</sup> Report to Congress: Medicare and the Health Care Delivery System. *Revisit the protected classes*. June 2016; 189-191. <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>. Accessed April 21, 2017.

<sup>11</sup> *Ibid.*

<sup>12</sup> *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; 2035-2036. Available at <https://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf>. Accessed April 21, 2017.

<sup>13</sup> *Ibid.*

<sup>14</sup> Kipp RA, KoC. Potential Cost Impacts Resulting from CMS Guidance on ‘Special Protections for Six Protected Drug Classifications’ and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (PL 110-.275). <http://amcp.org/WorkArea/DownloadAsset.aspx?id=9279>. Accessed April 21, 2017.



discourage use of inappropriate medications. Furthermore, formulary placement determinations related to cost sharing also relate to the P&T committee's evaluation of the safety profile of medications. Often, newer medications with less reliable safety and efficacy data in comparison to other medications are placed on higher formulary tiers which require beneficiaries to pay additional costs and are designed to encourage use of safer medications. If a beneficiary requires a non-formulary covered medication, plans are required to have a formulary exceptions process in place to ensure the beneficiary can access the medication. Given these protections and CMS' formulary review process, continued restrictions on plan management of agents in these three classes are unnecessary. Beneficiaries may access necessary medications even if not covered under the formulary by using the exceptions process required by Medicare. For this reason, AMCP supports building on the recommendations made by CMS and MedPAC to remove the immunosuppressants and antidepressants from protected class status and then review clinical and real world evidence and examine commercial and Medicaid formularies to consider ways to manage other protected classes.

### ***CMS Should Consider Categorizing Biosimilars as Applicable Drugs under Medicare Part D***

The introduction of biosimilars in the United States marketplace has the potential to save the United States healthcare industry billions of dollars in annual expenditures, and encourages a competitive marketplace that could result in substantial savings to patients and public and private payers. AMCP remains concerned that biosimilars continue to be classified as non-applicable drugs under section 1860D-14A of the Social Security Act, which means they are not subject to the 50% manufacturer discount as required of manufacturers under the Affordable Care Act for applicable drugs during the coverage gap discount, known as the "donut hole." AMCP is concerned that classifying biosimilars as nonapplicable drugs may inhibit the uptake of biosimilars because this could result in biologics having lower cost sharing for patients during the donut hole. However, in many cases, the biosimilar would offer a lower cost alternative when patients are subject to greater cost sharing for products. AMCP encourages CMS to determine policy solutions to provide incentives in all phases of Medicare Part D payment policy to encourage the use of biosimilars and other more affordable alternative medications.

### ***CMS Should Reconsider Its Interpretation of "Applicable Lower Cost-Sharing Tier" to Support the Development and Use of Evidence-Based Formularies***

AMCP is concerned that CMS' clarification and interpretation of "applicable lower cost-sharing tier" in the 2018 Final Call Letter undermines the development of evidence-based formularies which enhance the quality of patient care by selecting the most appropriate medications for patients with the goals of reducing treatment failures, adverse drug events and hospitalizations and improving patient adherence and health outcomes. The formulary development process includes pharmacists working with other members of the health care team to evaluate the safety and clinical effectiveness of new medications through ongoing medication evidence reviews. This process helps to ensure that decisions regarding medication use are based on appropriateness of therapy and not price alone. Formularies are a means to encourage patients to use clinically proven medications, determined to be more appropriate for a population managed by a health plan, ACO or IDN, through reduced co-payment or coinsurance. Exceptions to the formulary are available to patients when a non-formulary medication is appropriate based on a patient's unique health circumstances.

AMCP is concerned that the proposed clarification is inconsistent with 42 CFR §423.578 or section 30.2.1.4 of

Chapter 18 of Part D Prescription Drug Manual where there is no indication that a Part D plan sponsor must approve a tiering exception at the lowest available cost-sharing tier. Furthermore, 42 CFR §423.578 provides no prescriptive requirement for Part D plan sponsors to provide a drug at the lowest cost-sharing tier. Rather, this section requires that each Part D plan sponsor that provides Part D drug benefits through the use of a tiered formulary to “establish and maintain reasonable and complete exceptions procedures subject to CMS’ approval for this type of coverage determination.”

The exceptions process is a review process designed to determine whether a medication is appropriate for a specific patient. This process is necessary to maintain a formulary system that balances providing medications to beneficiaries at affordable prices. The current policy being elucidated by CMS would undermine the formulary process and could result in unnecessary costs for plans, beneficiaries, and the government by increasing administrative costs.

AMCP recommends that CMS carefully reconsider its clarification for approval of tiering exception requests and revert to the prior status quo which supports the development and use of evidence-based formularies.

#### **IV. Health Information Technology and Data Interoperability**

##### ***CMS Should Adopt the National Council of Prescription Drug Programs Standard for eRx and ePA***

In the 2017 Final Call Letter, CMS noted that it was further analyzing results from a point of sale (POS) pilot and exploring additional requirements related to electronic prescribing (eRx) and electronic prior authorization (ePA) to increase adoption of these technologies.

AMCP supports the adoption of the eRx standard approved by the National Council of Prescription Drug Programs (NCPDP) as electronic transmission of prescription information offers benefits over written prescriptions in terms of accuracy, storage capacity, accessibility, security and productivity. Benefits of electronic prescriptions include the reduction of errors because of misinterpretation of handwritten prescriptions, confusion between similar-sounding drug names during transmission of prescription orders, and order-entry errors. Electronic prescribing systems alert prescribers to potentially harmful drug interactions, patient drug allergies, and duplicate or overlapping drug therapy, enabling the prescriber to adjust the prescription before the pharmacy dispenses the drug. Electronic prescribing systems also allow prescribers to access the formulary for a patient’s prescription drug benefit, ensuring that they select a therapy for which the patient has coverage, in addition to any clinical edits that may be present. Specifically important for opioids, electronic prescribing allows prescription information to be securely transmitted directly to the dispensing pharmacy, reducing the possibility of fraudulent prescribing. Electronic prescribing prevents patients from photocopying, altering, or otherwise tampering with written prescriptions prior to presentation to the pharmacy. Therefore, AMCP encourages CMS to adopt the NCPDP eRx standard.

AMCP also supports the adoption of the ePA standard approved by NCPDP to improve efficiencies in the prior authorization process and improve patient outcomes. AMCP encourages CMS to adopt the NCPDP ePA standard to help reduce POS rejections and improve the Medicare Part D member experience.

## ***CMS Should Encourage the Adoption of SNOMED CT Codes for Clinical Documentation in the Medicare Part D Program***

In the 2017 Final Call Letter, CMS acknowledged the important work that AMCP's Medication Therapy Management Advisory Group was doing in collaboration with the Pharmacy Quality Alliance (PQA) and the Pharmacy Health Information Technology (PHIT) Collaborative to develop a framework to define drug therapy problems to allow for the shift towards outcomes-based measurements in Medicare Part D. CMS also foreshadowed that SNOMED CT codes may soon be required for MTM reporting by stating "sponsors should begin to develop the capacity to collect and report drug therapy problems using a standard framework and common terminology."

In 2016, AMCP, PQA, and the PHIT Collaborative lead an industry-wide effort to develop a *Standardized Framework for Cross-Walking Medication Therapy Management (MTM) Services to SNOMED CT Codes*.<sup>15</sup> This framework includes definitions of pharmacist services and the SNOMED CT codes that are used to document them in electronic health records. The framework was formally presented to CMS in October 2016 and is now being used by organizations participating in the Enhanced MTM Model Test to report innovative practices using SNOMED CT codes. In 2017 and moving forward, AMCP will continue to work with stakeholders to review and update the standardized framework as evidence from the Enhanced MTM Model Test becomes available, as innovation in the delivery and documentation of MTM services continue, and as the practice of pharmacy continues to evolve. Furthermore, AMCP will continue to drive education, adoption, and implementation of the standardized framework.

AMCP encourages CMS to begin to consider broader adoption of SNOMED CT codes for clinical documentation in the Part D program. AMCP further encourages CMS to ensure appropriate advanced notice to Part D sponsors of any requirements to document using SNOMED CT codes to allow sponsors sufficient time to implement the necessary changes. In addition, AMCP urges CMS to consider the financial burden implementation of SNOMED CT codes will have on sponsors to make the necessary changes to their IT infrastructure and how CMS can help offset costs and provide incentive for this to occur.

## ***CMS Should Ensure Part D Sponsors Have Access to Part A and Part B Data to Best Care for Patients***

AMCP believes that PDP sponsors should have access to Medicare Part A and B claims data, upon request, to enable PDP sponsors to see services a beneficiary has received and to provide greater context for a beneficiary's medication regimen. AMCP also believes that visibility of PDP sponsors to Medicare Part A and B claims data will also aid in the shift towards outcomes-based measurements as highlighted above. Therefore, AMCP encourages CMS to develop a mechanism for PDP sponsors to gain access to Part A and B claims data. Furthermore, AMCP encourages CMS to also develop a mechanism to provide PDP sponsors access to information regarding beneficiary alignment with integrated care models, such as the ACO alignment records managed in CMS's Master Data Management (MDM) system.

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<sup>15</sup> Standardized Framework for Cross-Walking Medication Therapy Management (MTM) Services to SNOMED CT Codes. Available at [www.amcp.org/SNOMED](http://www.amcp.org/SNOMED). Accessed April 24, 2017.

## V. Opioid Management

### ***CMS Should Work Collaboratively With Other Federal Agencies to Address the Opioid Epidemic***

AMCP supports a holistic, comprehensive, and multi-stakeholder approach among health care providers and patients that is necessary to truly address the opioid epidemic.<sup>16</sup> AMCP encourages CMS to work collaboratively with other federal agencies, such as the Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Diseases Control and Prevention (CDC), and the Food and Drug Administration (FDA), providers, pharmacists, and patients to develop a holistic, comprehensive, and multi-stakeholder approach to address the opioid epidemic. In the spirit of collaboration, AMCP also encourages CMS to work collaboratively and communicate effectively with the patient's care team, including pharmacists and other health care providers who provide patient care and psychosocial services, to ensure a holistic and comprehensive approach to the patient's individualized treatment. Finally, AMCP encourages CMS, in collaboration with HHS and SAMHSA, to work with Congress to find a mechanism for expanding the definition of a qualified practitioner under section 303(g)(2) of the Controlled Substances Act to include additional providers, such as qualified nurse practitioners, physician assistants, and pharmacists. Enabling non-physician practitioners to prescribe buprenorphine, with the appropriate training and state licensure, is critical to expanding opioid abuse disorder treatment to a greater number of individuals throughout the nation.

### ***CMS Should Strive to Implement the Drug Management Program Provisions of CARA in a Timely Manner***

AMCP has long advocated for the ability of Medicare Part D sponsors to establish drug management programs for at-risk beneficiaries and was pleased that the Comprehensive Addiction and Recovery Act (CARA) included provisions to authorize such programs. AMCP submitted detailed comments<sup>17</sup> to CMS on how to implement these provisions for the Part D program and looks forward to continuing work with CMS on this area for implementation in the 2019 plan year.

### ***CMS Should Continue to Provide Access to Medication Assisted Treatment for Medicare Beneficiaries***

To help address the opioid epidemic, AMCP supports the evidence-based use of medications used in the treatment of substance use disorder and encourages health plans to improve access to medication assisted treatment (MAT).<sup>18</sup> AMCP was pleased to see that in its 2017 Call Letter, CMS reinforced that Part D formulary and plan benefit designs that hinder access to MAT for opioid use disorder will not be approved.<sup>19</sup> AMCP encourages CMS to continue to support the coverage of MAT for Part D beneficiaries.

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<sup>16</sup> 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 April 24, 2017.

<sup>17</sup> AMCP Comments Re Medicare Program; Listening Session Regarding the Implementation of Certain Medicare Part D Provisions in the Comprehensive Addiction and Recovery Act of 2016 (CARA) - [CMS-4183-N]. Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=21663>. Accessed April 24, 2017.

<sup>18</sup> The Role of Managed Care Pharmacy in Improving Access to Naloxone: Findings from the AMCP Addiction Treatment Advisory Group. Available at: <http://www.jmcp.org/pb-assets/Outserts/The%20Role%20of%20Managed%20Care%20Pharmacy%20%20-%20Dec%202016.pdf>. Accessed April 24, 2017.

<sup>19</sup> Centers for Medicare & Medicaid Services. Announcement of calendar year (CY) 2017 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter. Available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvvtgSpecRateStats/Downloads/Announcement2017.pdf>. Accessed November 4, 2016

### ***CMS Should Advocate for the Modification of Federal Regulations Governing the Confidentiality of Drug and Alcohol Treatment and Prevention Records***

The modification of federal regulations governing the confidentiality of drug and alcohol treatment and prevention records, 42 CFR Part 2 (Part 2), is a priority for AMCP and AMCP is committed to aligning Part 2 with HIPAA to allow appropriate access to patient information that is essential for providing comprehensive patient care. Part 2 reform is particularly important as we work to address the nation's opioid crisis. The regulations are outdated and are not compatible with the way health care is delivered currently. Without access to a patient's complete medical record, including addiction records, providers and organizations are limited in their ability to care for those patients and may, for example, unknowingly prescribe, administer, or recommend an opioid to an individual being treated for addiction.

Pharmacists, as medication experts, are integral members of health care provider teams who evaluate whether a patient is at risk or who is currently misusing or abusing opioids and whether a patient could be an appropriate candidate for medication assisted therapy. Access to a patient's complete medical record is critical to patient treatment, safety, and recovery. Of equal concern for patient treatment, safety and recovery, is the multitude of unintended consequences of drug to drug interactions, adverse drug reactions, and even death. Opioids also interact negatively with other controlled substances or those not scheduled by the Drug Enforcement Administration. Pharmacists, working in collaboration with other members of the health care team, help to identify and resolve these issues potentially reducing overdose and death in many patients. However, medical interventions by pharmacists and other health care professionals cannot occur without access to full medical records.

Therefore, AMCP urges CMS to advocate for the modification of federal regulations governing the confidentiality of drug and alcohol treatment and prevention records.

### ***CMS Should Develop a Robust Education Strategy for Prescribers Related to Opioid Prescribing Guidelines***

AMCP encourages CMS to work collaboratively with the Centers for Disease Control and Prevention (CDC) to develop a robust education strategy for prescribers on the *CDC Guideline for Prescribing Opioids for Chronic Pain*.<sup>20</sup> 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.

### ***CMS Should Seek Legislative Changes to Allow Part D Sponsors Access to Prescription Drug Monitoring Program Data***

AMCP is concerned that current point of sale (POS) edits required of Part D sponsors are based only upon information available to the sponsor via available claims data available, and do not take into account patients who choose to pay cash for their prescriptions. While forty-nine states and the District of Columbia have Prescription Drug Monitoring Programs (PDMPs) that collect dispensing data for all opioid medications,

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<sup>20</sup> Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>

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.<sup>21</sup> 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. AMCP urges CMS to 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, AMCP urges CMS to address how opioids that are administered in physician offices will be accounted for because this information is also traditionally not available to plan sponsors.

## **VI. Fraud, Waste, and Abuse**

### ***CMS Should Address Fraud, Waste, and Abuse in Medicare Part D***

According to a 2014 Government Accountability Office (GAO) report, the federal government spent \$58 billion on Medicare Part D and an estimated \$1.9 billion of that total was improper prescription payments.<sup>22</sup> Section 6402 in the Patient Protection and Affordable Care Act, P.L. 111-148 (the "ACA") permits the Secretary of the Health and Human Services (HHS) to suspend payments pending an investigation of a credible allegation of fraud against providers of services or suppliers in Medicare Parts A and B, unless there is good cause not to suspend the payment. Federal and private-sector estimates of Medicare fraud range from 3-10% of total expenditures, amounting to between \$68 billion and \$226 billion annually. The substantial size of the dollars lost annually in fraud, waste and abuse in the entire Medicare Program has made Medicare fraud one of the federal government's top priorities.

Fraudulent activity within Medicare Part D can take many forms, including patients acquiring prescriptions under false pretenses, providers writing illegitimate prescriptions and the trafficking of counterfeit drugs. Medicare PDPs can and should play an important role in fighting fraud, waste and abuse under the Medicare prescription drug program.

With the passage in 2008 of the Medicare Improvements for Patients and Providers Act (MIPPA), Part D plan sponsors were required to begin paying all "clean" electronic claims within 14 days of receipt and all other "clean" claims within 30 days of receipt. This "prompt pay" regulation requires plans to pay claims rapidly, often before they can be adequately vetted by the plan sponsor's internal fraud control team. Plan sponsors have little recourse to delay payment, and while payments may be recovered in instances of fraud, this is often a difficult, if not impossible, task. AMCP supports amending current law to authorize the HHS Secretary, under the same authority under the ACA and used for Medicaid programs, to decrease improper prescription payments by authorizing the suspension of payments when a Medicare Part D sponsor reports a credible allegation of fraud relating to a pharmacy or other supplier. This solution would allow plans to combat suspected fraud before payments are made, instead of attempt to recover the payments after the fact.

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<sup>21</sup> 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

<sup>22</sup> Medicare Part D: Changes Needed to Improve CMS's Recovery Audit Program Operations and Contractor Oversight. Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, August 2015. <http://www.gao.gov/assets/680/671997.pdf> . Accessed April 24, 2017.

***CMS Should Attribute Investments in Fraud Prevention Activities as Expenses to Incurred Claims for Medical Loss Ratio Reporting Purposes***

AMCP strongly supports the inclusion of fraud prevention expenditures in incurred claims for MLR reporting purposes. AMCP believes that including fraud, waste, and abuse expenses in the MLR calculation, rather than treating them as administrative costs, would encourage health plans to field more robust fraud detection programs and avoid efforts to pare back those activities.

***The CMS Center for Program Integrity Should be Adequately Funded by Congress***

AMCP believes Congress should adequately fund the Center for Program Integrity, the anti-fraud division within CMS, through the annual appropriations process. This division is responsible for identifying and prosecuting suspected instances of fraud and is currently underfunded. With appropriate support, CMS can combat fraud, waste and abuse in the Medicare and Medicaid programs, saving taxpayers millions of dollars on an annual basis. Fraud, waste and abuse are unacceptable within any health care program, especially within health care programs that are financed through taxpayer dollars. In a time of diminishing financial resources, it is more important than ever that Medicare providers, including Part D plan sponsors, are effectively able to combat suspected fraud. AMCP recognizes the seriousness of this problem and is supportive of efforts that would reduce the instance of fraudulent activity.

**VII. Conclusion**

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](mailto:scantrell@amcp.org).

Sincerely,



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