Academy of Managed Care Pharmacy®

November 20, 2017

Amy Bassano, Acting Director
Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Centers for Medicare & Medicaid Services: Innovation Center New Direction

Dear Acting Director Bassano:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services (HHS), the Centers for Medicare and Medicaid Services (CMS), and the Center for Medicare and Medicaid Innovation (CMMI) for the opportunity to provide comments in response to the request for information (RFI) titled "*Centers for Medicare & Medicaid Services: Innovation Center New Direction*" released on September 20, 2017. AMCP commends HHS, CMS, and CMMI for seeking feedback on how the Medicare and Medicaid programs can be transformed through innovation to best meet the individual health 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.

In April 2017, AMCP submitted comments in response to CMS' RFI contained within 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's comments focused on areas where CMS could make improvements to the Medicare Part D and Medicare Advantage programs through regulatory, subregulatory, policy, practice and procedural changes, including in potential demonstration models. AMCP was pleased that CMS considered some of these issues in the proposed rule*," Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program"* (42 CFR Parts 405, 417, 422, 423, and 498) (proposed rule). AMCP's recommendations included in the proposed rule are:
- Inclusion of medication therapy management (MTM) as a quality improvement activity (QIA) for incorporation into medical loss ratio (MLR).

- Inclusion of certain fraud, waste and abuse prevention programs as a QIA for incorporation into MLR.
- Inclusion of biosimilars as applicable drugs under Medicare Part D program to encourage the use of these lower cost alternatives.
- Implementation of the drug management program provisions under the "*Comprehensive Addiction and Recovery Act of 2016*" (CARA).
- Adoption of the National Council of Prescription Drug Programs (NCPDP) SCRIPT standard for electronic prescribing. However, AMCP seeks CMS to incorporate use of the NCPDP electronic prior authorization standard as a mandatory component of electronic prescribing.
- Evaluation of the Star Ratings program to determine the effectiveness of the existing program and whether changes are necessary.

AMCP will provide specific comments in these areas to CMS in response to the proposed rule. However, if these changes are not incorporated into a final rule, AMCP encourages CMMI to consider demonstration models to test some of these provisions for future consideration in rulemaking.

In response to CMMI's RFI to make improvements to the Medicare and Medicaid programs, AMCP offers comments in the following areas where demonstration programs may improve quality and value.

I. Medication Therapy Management (MTM)
II. Quality
III. Formulary Design and Utilization Management
IV. Expansion of Value Based Contracting (VBC) for Medicare and Medicaid
V. Expansion of Biosimilar Use in the United States
VI. Health Information Technology and Data Interoperability
VII. Opioid Management
VIII. Fraud, Waste, and Abuse

I.   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.

Publish Best Practices from Enhanced MTM Demonstration Model and Consider Expansion of the Enhanced MTM Demonstration Model to Medicare Advantage Plans, Medicaid, and to Reduce Opioid Misuse and Abuse

As CMMI evaluates the findings from the enhanced MTM (eMTM) demonstration program for Medicare Part D plans, it should publish best practices identified. It should work with the participants in the eMTM model and other stakeholders in conducting this evaluation.

CMMI should also consider expanding the demonstration program to Medicare Advantage Plans and offer state Medicaid programs the ability to use the eMTM model. CMMI may also consider MTM demonstration models that coordinate interventions to curb opioid misuse and abuse and increase access to medication assisted therapy. AMCP recommends that any MTM demonstration should incorporate pharmacists' interventions in recognition of their expertise in medication management as members of the health care team.

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.[1] 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. AMCP has also engaged in an initiative to examine ways to modernize and test alternative formats for the CMR and will share information with CMS and CMMI.

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 CMMI and CMS to work with NCQA to consider alternative records to satisfy this measure, including pharmacy records

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[1] AMCP Comments Re: CMS-10396 Medication Therapy Management Program Improvements. Available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=22164. Accessed November 19, 2017.

and MTM encounter data/vendor platforms, while the industry continues to move towards interoperability.

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,*[2] 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;
- 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.[3]

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.

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[2] 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 November 19, 2017.

[3] *Ibid* at 21.

Reevaluate the Burden Estimate for CMRs

CMS currently estimates the burden for completing a CMR as 40 minutes.[4] 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).

II.   Quality

Review Comments and Recommendations from CMS' 2019 Medicare Part D and Medicare Advantage Proposed Rule for Areas Where CMMI May Implement Demonstrations to Improve Star Ratings

CMMI should review the comments and recommendations from CMS proposed rule to identify areas where demonstration models could help improve the efficiency and effectiveness of the Star Ratings program.

Support the Shift towards Outcomes-Based Measurements in Medicare Part D and MA Plans

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 CMMI to consider initiatives that shift the support toward effective outcomes based measurements in Medicare and Medicaid... For example, most measurements used to assess quality in the Medicare Part D and MA programs 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

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[4] 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. Accessed November 19, 2017.

Part D and MA programs 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 provides the following recommendations for Medicare Part D and MA:

- 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.

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.

CMMI issued a RFI in December 2013 to consider integration of Medicare Part D into ACOs,[5] 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 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 Benefit Management: Medicare Part D and Medicare Part B

Implement Demonstration Projects to 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.[6] In its analysis, MedPAC indicated that it "generally supports

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[5] CMMI Request for Information. Evolution of ACO Initiatives at CMS. December 2013. http://innovation.cms.gov/Files/x/Pioneer-RFI.pdf. Accessed November 19, 2017.

[6] 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 November 19, 2017.

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. [7]

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.[8] 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.[9] This finding is consistent with findings from a 2008 report commissioned by AMCP to determine the impact of the protected classes.[10]

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 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.

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[7] *Ibid.*

[8] *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 November 19, 2017.

[9] *Ibid.*

[10] 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 November 19, 2017.

Consider Targeted Demonstration Projects Allowing for Formulary and Utilization Management in the Medicare Part B Program

Currently, Medicare Part B does not include provisions to allow for formulary or utilization management programs used by the Medicare Part D program and commercial insurers to manage medications. CMMI should work with stakeholders to develop health plan or PBM-established formularies and utilization management tools to manage Medicare Part B medications. AMCP recommends that this approach should initially be limited in scope to ensure patient health, safety and access to care.

AMCP supports the use of well-designed and evidence-based formularies that enhance the quality of pharmaceutical care while lowering medication costs. A drug formulary is a continually updated list of prescription medications that represents the current clinical judgment of providers who are experts in the diagnosis and treatment of disease. Formularies often contain additional prescribing and clinical information that assists health care professionals as they promote high quality, affordable care to patients. Generally, a formulary is developed and maintained by a P&T Committee, comprised of physicians, pharmacists, and other health care professionals, that meets regularly to review and evaluate the medical and clinical evidence from the literature, relevant patient utilization and experience, economic data, and provider recommendations to determine which drugs are the safest, most effective, and produce the best clinical outcomes. Since a formulary is a dynamic and continually revised document, the P&T Committee regularly evaluates the formulary and adjusts it to reflect the best medical practices, newly marketed medications, and new clinical and economic evidence that may have an impact on which drugs are included or excluded.

Furthermore, implementation of well-designed, evidence-based utilization management tools, such as prior authorization and step therapy, optimizes patient outcomes by ensuring patients receive the most appropriate medications while reducing waste, errors, adverse effects, and unnecessary prescription drug use and cost. Utilization management tools and requirements for coverage are based on clinical need, therapeutic rationale, and the desired outcome for the patient. Studies show that choice of the most appropriate drug results in fewer treatment failures, reduced hospitalizations, and better patient adherence to the treatment plan, fewer adverse side effects, and better overall outcomes. Such efficient and effective use of health care resources helps to keep overall medical costs down, improves the consumer's access to more affordable care, and provides the patient with an improved quality of life.

IV. Support Initiatives to Encourage Value-Based Contracting (VBC) in Medicare and Medicaid

AMCP supports the use of VBC as a tool to ensure quality outcomes and lower costs in health care and in the Medicare and Medicaid programs. In June, 2017, AMCP held a multi-stakeholder Partnership Forum, "*Advancing Value-Based Contracting*" where representatives from health plans, integrated delivery systems, pharmacy benefit managers, data and analytics experts, and biopharmaceutical companies agreed on areas to strengthen and improve VBC, including:

- A definition of VBC for facilitating discussion with key policy makers, regulators and other stakeholders;
- Strategies for advancing development and utilization of performance benchmarks;

- Best practices in evaluating, implementing and monitoring VBCs; and
- Action plans to mitigate legal and regulatory barriers to VBCs.

AMCP encourages CMMI to adopt the definition of VBC adopted by participants as a starting point for any demonstrations. This definition is: A value-based contract is a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures."

CMMI should use the key recommendations from the Partnership Forum to create projects that focus on identifying appropriate outcomes to measure and determining how much value to assign them. AMCP will also be engaged with the participants of the Forum and other stakeholders in an initiative to identify best practices to implement, monitor, and evaluate VBC efforts. AMCP believes that areas of partnership exist with CMMI to achieve these objectives and looks forward to furthering the work in this area.

AMCP also believes that opportunities exist to work with CMMI and the Office of the Inspector General to find solutions to reduce regulatory barriers to implementing VBC, including revisions to the Anti-Kickback Statute and the best price requirement of the Medicaid Drug Rebate Program. CMMI could implement demonstration projects that waive some requirements and determine the impact to beneficiaries and the programs.

The [Proceedings of the VBC Partnership Forum](#) were published in the November 2017 edition of the *Journal of Managed Care and Specialty Pharmacy*.

V. Expansion of Biosimilar Use in the United States

In recent months, CMS has made efforts to expand the use of biosimilars in the United States, including a proposal to include biosimilars as applicable drugs under Medicare Part D and to change billing and coding of biosimilars under Medicare Part B. CMMI should evaluate the success of these initiatives by reviewing data and comments submitted to CMS to determine whether these efforts expand the use of biosimilars in the United States or whether changes are necessary. CMMI should work with stakeholders to identify opportunities for demonstrations to expand biosimilar adoption in the United States.

VI. Health Information Technology and Data Interoperability

Implement Programs to Encourage 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*.[11] This framework includes definitions of pharmacist services and the SNOMED CT codes that 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 eMTM 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 and CMMIT to begin to consider broader adoption of SNOMED CT codes for clinical documentation in the Part D program. As part of potential demonstration projects, AMCP urges consideration of 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.

VII. Opioid Management

Develop a Robust Education Strategy for Prescribers Related to Opioid Prescribing Guidelines

AMCP encourages CMS and CMMI 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*.[12] 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.

Support Demonstrations that Evaluate 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, including prescriptions paid for by insurance and cash, only five states provide PDMP access to Medicare plan sponsors and three states to

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[11] Standardized Framework for Cross-Walking Medication Therapy Management (MTM) Services to SNOMED CT Codes. Available at www.amcp.org/SNOMED. Accessed November 19, 2017.

[12] 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

commercial third-party payers.[13] 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 encourages CMMI and CMS to evaluate how the current limitations of the PDMP systems impact the ability of plans to effectively implement programs to curb opioid misuse and abuse.

VIII. 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.[14] 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

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[13] 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.

[14] 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 November 19, 2017.

attempt to recover the payments after the fact. As AMCP and other stakeholders seek a statutory change, CMMI should consider demonstration projects that seek to reduce fraud, waste, and abuse in Medicare Part D.

IX. Summary and Conclusion

AMCP appreciates your consideration of the ideas outlined above and looks forward to continuing work on these issues with CMMI. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-6200 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer