

March 3, 2017

Cynthia G. Tudor, Ph.D.
Acting Director, Center for Medicare

Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director, Parts C & D Actuarial Group
Office of the Actuary

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

Re: Advance Summary of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter

Dear Acting Director Tudor and Director Lazio:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide comments in response to the notice titled “*Advance Summary of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter*” released on February 1, 2017. AMCP offers comments on the following sections of the notice:

- A. Biosimilars
- B. Tiering Exceptions
- C. Star Ratings & Display Measures
- D. Follow-Up from 2017 Final Call Letter

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.

A. Biosimilars

Reduced Coinsurance for Applicable Beneficiaries in the Coverage Gap

CMS Proposal

CMS proposes that the beneficiary coinsurance under basic prescription drug coverage be reduced to 44% for non-applicable (generic medications and biosimilars) covered Part D drugs purchased during the coverage gap phase of the Part D benefit. After having applied the 50% manufacturer discount, the beneficiary coinsurance under basic prescription drug coverage would be reduced to 35% for applicable (brand medications and biologics) covered Part D drugs purchased during the coverage gap phase of the Part D benefit in 2018.

AMCP Recommendations

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 and accepting 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 Medicare Part D, 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 donut hole. AMCP is concerned that classifying biosimilars as non-applicable 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. While AMCP understands that classification of biosimilars as a non-applicable drug is based on statute, CMS should continue 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.

B. Tiering Exceptions

Approval of Tiering Exception Requests

CMS Proposal

Chapter 18, §30.2.1.4 states that, “When a tiering exception is approved, the plan sponsor must provide coverage for the drug in the higher cost-sharing tier at the cost-sharing level that applies to the drug in the applicable lower cost-sharing tier.” CMS proposes to clarify that, in situations where the requested drug has alternatives in multiple lower tiers and the plan sponsor has approved the request for a tiering exception, the plan must apply the cost-sharing for the lowest applicable cost-sharing tier that contains alternatives for the requested drug because, consistent with the manual provision, the lowest cost-sharing tier is the “applicable lower cost-sharing tier.”

AMCP Recommendations

AMCP is concerned that CMS’ proposed clarification and interpretation of “applicable lower cost-sharing tier” 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 proposed clarification for approval of tiering exception requests and maintain the current status quo which supports the development and use of evidence-based formularies.

C. Star Ratings & Display Measures

Medication Reconciliation Post Discharge (MRP)

CMS Proposal

CMS proposes to move the MRP measure from the display page to the 2018 Star Ratings. The measure would be weighted 1 for the 2018 Star Ratings and be increased to a weighting of 3 beginning in 2019.

AMCP Recommendations

AMCP appreciates the role of the MRP measure is assisting to improve a beneficiary's overall health status, but is concerned that the proposed increase in weighting from 1 to 3 may be too aggressive as it does not align with the traditional increase in weighting of 1 to 1.5 that CMS has historically used. Therefore, AMCP recommends that CMS reconsider the increase in weighting and consider an increase from 1 to 1.5 to align with how CMS traditionally increases measure weights in subsequent years.

Opioid Overutilization Measures

CMS Proposal

CMS proposes several revisions to opioid measures for the 2017 Patient Safety Reports as well as the development and implementation of several additional opioid measures for 2019 and beyond.

AMCP Recommendations

AMCP cautions CMS to proceed with discretion in the development and implementation of opioid measures. AMCP is concerned that there may be too many opioid measures that will be implemented within a short timeframe and may compete against one another. In addition, AMCP encourages CMS to consider state requirements for morphine equivalent dose (MED) limitations and other requirements related to opioid overutilization to allow for alignment and to minimize confusion and disruption for plans, providers, and patients. Finally, while AMCP understands CMS' rationale for generating the Patient Safety Reports quarterly instead of monthly moving forward to reduce variability due to data lags, AMCP encourages CMS to examine the impact and unintended consequences of less frequent reporting on smaller to mid-size plans.

D. Follow-Up from 2017 Final Call Letter

Part D Reporting Requirements for MTM

CMS Comments in 2017 Final Call Letter

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 Systematized Nomenclature of Medicine - Clinical Terms (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."

AMCP Follow-Up

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](#). 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.

Point of Sale Pilot

CMS Comments in 2017 Final Call Letter

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; testing the use of "smart edits" where information is or could be made available in real-time to allow certain claims to favorably auto-adjudicate at the POS; and further exploring how certain rejected claims may be targeted for proactive outreach in concert with existing rejected claim review and MTM requirements.

AMCP Seeks Follow-Up

AMCP is disappointed that further information on the POS pilot and possible strategies to increase the adoption of eRx and ePA were not included in the 2018 Draft Call Letter. As AMCP stated in comments to CMS on the 2017 Draft Call Letter, AMCP supports the adoption of the ePA standard approved by the National Council of Prescription Drug Programs (NCPDP) to improve efficiencies in the prior authorization process and improve patient outcomes. AMCP recommends that CMS support the adoption of the NCPDP ePA standard to help reduce POS rejections and improve the Medicare Part D member experience.

E. 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.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell", with a long horizontal line extending from the end of the signature.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer