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March 6, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8016
Attention: CMS-2020-0003

Re: Advanced Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II

Dear Administrator Verma:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to its new Draft Guidance, *"Advanced Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II"* published on February 5, 2020. We appreciate the opportunity to leverage our members' expertise in offering feedback on this guidance. AMCP offers comments on the Potential New Measure Concepts, particularly those focused on Generic Utilization.

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 healthcare 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.

Updates for Part C and D Star Ratings – Potential New Measure Concepts: Generic Utilization

CMS Proposal
CMS states that it plans to develop measures to assess generic and biosimilar utilization in the Part D program. While the generic dispensing and generic substitution rate across Part D are 82% and 91% respectively, the agency views the remaining branded prescription fills as a significant opportunity to reduce Medicare expenditures and lower beneficiary out-of-pocket

costs. CMS seeks comments on three potential measure concepts: Generic Substitution Rate, Generic Therapeutic-Alternative Opportunity Rate, and Biosimilar Utilization Rate.

AMCP Response

AMCP supports and encourages the use of generic drugs as safe, cost-effective alternatives to the equivalent brand-name products. AMCP is generally supportive of measure concepts that would encourage increased utilization of low-cost generic drugs and provide plan enrollees with additional information with which to make plan purchasing decisions, but we urge CMS to move forward with the development of these measure concepts with caution. CMS states that the existing percentage of branded prescription fills in the Part D program represent a significant opportunity to reduce beneficiary out-of-pocket costs as well as to lower Medicare program expenditures. While drug prices have been shown to decrease with the introduction of a generic competitor, the Food and Drug Administration's (FDA's) own research shows that it is only with additional generic competition entering the market that prices are significantly lowered from the branded drug.[1] Providing this information to enrollees as they make decisions about their Part D plan options may be helpful for their purchasing decisions but may not automatically correlate with decreased costs. CMS should continue to work with partner federal agencies, including the Federal Trade Commission, to promote a competitive landscape to increase generic market entry.

AMCP encourages CMS to ensure that any added measure concepts involving generic utilization do not interfere with plan flexibility to determine the most appropriate formulary placement of drugs covered by the plan benefit package. AMCP supports the use of a well-designed, evidence-based formulary to assist in effectively managing a patient's total medical care regimen and believes that a formulary enhances the quality of care received by plan enrollees through encouraging the use of those prescription medications demonstrated to be the safest and most effective and which produce positive patient outcomes. Formularies should be developed and maintained by a Pharmacy & Therapeutics (P&T) Committee, reviewed and updated regularly, with a decision-making process centered on a drug's safety, efficacy, and effectiveness. We urge CMS to use caution in the development of any generic utilization measure to ensure that plans and their P&T Committees maintain the flexibility to determine the most appropriate tier placement for drugs within their benefit design, including the ability to include both branded and generic drugs on the same non-preferred drug tier.

We recommend that CMS establish an open, collaborative, and transparent process that includes the participation of varied stakeholders if the agency does move forward with the development of generic utilization measures. Stakeholders from across the pharmacy, plan, and consumer industries should be included and AMCP encourages CMS to engage an external measure developer such as the Pharmacy Quality Alliance (PQA). CMS should provide for an additional comment period on any measures developed before they are implemented in the Part D program, with ample time provided to plans to evaluate the use of these measures in the Part D population and to understand the measure specifications and weighting.

[1] Generic Competition and Drug Prices.

With respect to the potential Generic Substitution Rate measure concept, AMCP recommends that a generic drug be defined by the measure developer as a drug approved by the FDA with an Abbreviated New Drug Application (ANDA). Including only drugs approved through an ANDA would exclude authorized generics, products launched by brand manufacturers "to preserve their profits following the onset of generic competition" which discourage generic competition by significantly decreasing the revenues of first-filer generic manufacturers. The threat of offering an authorized generic is often deployed as a tactic by brand manufacturers during patent litigation, regularly resulting in delayed market entry of generic competition ("pay-for-delay").[2] Additionally, the FDA does not define authorized generics as generic drugs, stating that the term describes "an approved brand name drug that is marketed without the brand name on its label" and which is exactly the same drug as the branded product.[3] As such, authorized generics do not serve as generic competition and therefore should not be included in any potential measure concept designed to increased generic drug utilization.

Conclusion

AMCP appreciates the opportunity to comment on CMS-2020-0003: *Advanced Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II*. We are committed to be being a valuable resource to CMS on improving access to prescription drugs at lower costs and reducing costs in the health care system. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer

[2] Authorized Generic Drugs: Short-Term Effects and Long-Term Impact. A Report of the Federal Trade Commission
[3] FDA List of Authorized Generic Drugs.