January 16, 2018

The Honorable Seema Verma
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via http://www.regulations.gov

RE: 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, and the PACE Program Proposed Rule (CMS-4182-P)

Dear Administrator Verma:

The Association for Accessible Medicines (AAM) appreciates the opportunity to provide input on the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit, and the PACE Program proposed rule (CMS-4182-P). As manufacturers of nine out of every 10 prescription medicines dispensed in the United States, AAM members form an integral, and powerful, part of the healthcare system. Generic drugs have saved patients and the U.S. health care system $1.67 trillion in the last decade, generating $253 billion in savings in 2016 alone. Medicare savings amounted to $77 billion ($1,883 per enrollee) and Medicaid savings of $37.9 billion ($512 per enrollee).[1]

AAM is pleased with several of the proposals included in the rule, which we believe will help to strengthen the Part D prescription drug benefit for patients, and help make the benefit itself sustainable for the future. Specifically, we would like to provide comment on the following issues:

Part D Plan Sponsors Should Have Access to Formulary Management Tools that Speed Generic Substitution, Including for Biosimilar Products

AAM is pleased to see that the Centers for Medicare and Medicaid Services (CMS) is considering altering Part D program rules to allow plan sponsors the ability to better manage formularies to speed generic substitution. CMS is proposing to allow plan sponsors to immediately change cost-sharing or coverage levels for single-source products

[1] Association for Accessible Medicines. 2017 Generic Drug Access and Savings in the U.S. Report (https://accessiblemeds.org/resources/blog/2017-generic-drug-access-and-savings-us-report).

once a generic therapeutic substitute is available. This is common practice in the commercial sector[2], and likewise will reduce costs for patients and the federal government if adopted by the agency. If there is a clinical reason that the patient needs to continue to take the innovator product, plans have mechanisms in place for the patient to continue to receive the drug.

Currently, plan sponsors can immediately add a generic alternative to formulary once it is available, but must give beneficiaries 60-days' notice prior to changing the cost-sharing levels, or coverage policies surrounding, the single-source drug, and could make no changes at all between the close of the open enrollment period and March 1st of the plan year.[3] While many beneficiaries are likely to begin filling prescriptions with generic alternatives once they are available (either because of state generic substitution laws or because of price sensitivity), it is also likely that some beneficiaries were continuing to fill prescriptions for an innovator product after a generic alternative was available. This increases costs not only for the beneficiary, but also for the Medicare program.

CMS' proposal to eliminate the 60-days' notice requirement and allow plans to make a change between the end of open enrollment and March 1st of the plan year is a common-sense solution that, if finalized, will reduce costs for beneficiaries and the government without sacrificing clinical outcomes. The agency can take this proposal even further to include formulary changes in response to the approval of new biosimilars.

To this point, CMS has considered formulary changes to cost-sharing or coverage of reference biologics after the introduction of a biosimilar to be "non-maintenance" changes that require CMS review and approval.[4] While plan sponsors may immediately add biosimilars to the drug formulary, they may not change the cost-sharing or coverage of the reference biologic without CMS review and approval and the appropriate notice to beneficiaries.

Therefore, we also suggest that CMS consider a formulary change that encourage the use of biosimilars to be considered a "maintenance" change, similar to how current review requirements surrounding the launch of a generic alternative for small molecule drugs are considered maintenance changes. This would allow plans to approach formulary management of biosimilars and reference biologics in the same manner as small molecule drugs, encourage the adoption of biosimilar therapies, and reduce costs for patients and the Medicare program.

By allowing plans to update formularies more rapidly when a biosimilar has been approved, CMS can better support patient access to lower cost alternatives. Because biosimilars are approved as highly similar to their

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[2] *See, e.g.* Custom Drug List 2018, Blue Cross Blue Shield Michigan available at https://www.bcbsm.com/content/dam/public/Consumer/Documents/help/documents-forms/pharmacy/custom-drug-list-formulary.pdf, detailing that as new generics come to market they are placed on Tier 1 on the formulary and the brand is then moved to a higher cost sharing.

[3] CMS Prescription Drug Benefit Manual: Chapter 6- Part D Drugs and Formulary Requirements, Section 30. Accessible at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf

[4] March 30, 2015. CMS Guidance to Part D Sponsors, "Part D Requirements for Biosimilar Follow-On Biological Products." Accessible at http://media.wix.com/ugd/633570_5bc61629b1d0436494f7984ffbbfe1d8.pdf

reference products, plans can rely on the FDA's approval for certain routine changes. Additionally, earlier inclusion on the formulary would expedite savings for both patients and the program by giving patients access to lower cost options. More extensive use of biosimilars will also encourage investment in the development of additional therapies.

Generic Tiering Exceptions

CMS also is proposing to base eligibility for tiering exception requests on the tier that contains the preferred alternative drug to the higher-cost requested drugs, rather than based on tier labels established by the plan. Part D plans are required by law to establish a structure through which beneficiaries may request an exception to the plan's tiered cost-sharing structure.[5] These exceptions allow beneficiaries to obtain drugs on a higher cost-sharing tier at the lower co-pay rate available on lower cost-sharing tiers.

Currently, these exceptions are granted when the non-preferred drug is deemed medically necessary by the prescriber. However, as the price of drugs has increased since the introduction of the Part D program, the complexity of formularies has grown as well. This has led to expanded tiers that in some cases include both brands and generics, and multiple tiers for generic drugs.[6]

This proposal would remove an existing loophole whereby plans could exclude generic tiers, including non-preferred generic tiers, from the tiering exception system. Under the proposed change, if a preferred alternative drug was on the plan's Tier 1 (Preferred Generic) and the requested drug was on the plan's Tier 2 (Non-Preferred Generic), the plan would need to evaluate the request, and if determined medically necessary, allow the beneficiary to access the requested drugs at the Tier 1 cost-sharing level. AAM supports this proposal because it would continue to encourage beneficiary use of lower-cost generic drugs.

Additional Transparency in Direct and Indirect Remuneration (DIR) Reporting Presents an Opportunity to More Directly Benefit Patients

As part of the proposed rule, CMS is issuing a request for information on the appropriate reporting of direct and indirect remuneration (DIR) by Part D plan sponsors. DIR frequently includes manufacturer rebates and pharmacy price concessions collected by plan sponsors and which cannot generally be applied at the point-of-sale (POS). Instead, plan sponsors report DIR annually to CMS, and are required to include a DIR estimate in their bids for upcoming plan years.

However, if rebates and price concessions are reported as DIR, that means that they are not included in the reported "negotiated price" for a prescription. The negotiated price is the foundation of the competitive Part D benefit. It is

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[5] CMS Prescription Drug Benefit Manual: Chapter 18 - Part D Enrollee Grievances, Coverage Determinations, and Appeals, Section 10.2. Accessible at https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Guidance.html

[6] CY 2017 Final Call Letter, Section III- Part D, Tier Labeling and Composition. Accessible at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf

the price off of which beneficiary cost-sharing, total drug costs, and out-of-pocket spending is calculated. When selecting a plan during open enrollment, beneficiaries evaluate both a plan's premium rates and the plan's negotiated prices for the drugs which they take. Negotiated prices are also used to determine a manufacturer's rebate liability while a beneficiary is in the coverage gap.

AAM supports CMS exploration of new and innovative ways to ensure patients benefit from the savings created by competition. Under current policy, plans and pharmacy benefit managers (PBMs) may see incentives to increase brand rebates rather than giving preferential treatment to a lower-cost generic. In these instances, DIR fees can be spread across the wider beneficiary pool, rather than shared directly with the patient. We believe that requiring patients to receive all discounts up front may reduce those incentives and allow the specific patient on the medication to recognize the savings created by competition.

While CMS is considering any changes, it is essential that the agency keeps in mind the fundamental differences between the branded marketplace and the generic marketplace and tailor reporting requirements appropriately. Most importantly, only rarely do generic manufacturers negotiate rebates with pharmacy benefit managers in the same manner as brand manufacturers.

Generic medicines are subject to a different set of economic incentives and arrangements –the result of multiple manufacturers marketing identical products and competing exclusively on price, in a commodity-style market. Because the products are virtually identical, the primary leverage manufacturers have is their ability to lower the price and provide the necessary volume. With over 200 generic manufacturers recognized by FDA, competition is fierce, and prices decline rapidly. The wholesalers, often in collaborative purchasing agreements with pharmacies across the country, then distribute generic medicines to various retail pharmacies. Generic manufacturers may have to compete even further by negotiating separate payments to pharmacies to stock their product.[7]

Generic drug reimbursement is also different. Rather than relying on per-transaction rebates, PBMs and insurers typically establish a "Maximum Allowable Cost" (MAC) list that sets a specific reimbursement rate for the product, regardless of the generic product cost to the pharmacy. These MAC lists create additional incentives for pharmacies to maximize their dispensing margins by finding the lowest cost source for generic products. The result is a business model that differs significantly from the brand business model. While brand companies typically market a small number of high margin products, many generic manufacturers market hundreds of products with varying levels of profitability or loss.[8]

As the agency continues to consider potential changes in policy in this area, AAM is happy to work with you to address any concerns that policy changes may have on generic drug access.

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[7] October 2017. Introduction to the Generic Drug Supply Chainand Key Considerations for Policymakers. Available at https://www.accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf
[8] *Id*.

CMS Should Reduce Cost Sharing for Biosimilars When Enrollees are in Catastrophic Coverage
AAM supports CMS' proposed treatment of biosimilars (or "follow-on biologics") for cost-sharing purposes in the catastrophic coverage portion of the Part D benefit. Current estimates suggest that during the first 10 years of biosimilar availability, consumers could save as much as $250 billion.[9] The biosimilars market in the United States is still nascent. As physicians and patients continue to adopt their use, manufacturers will invest in developing additional biosimilar products. This proposed change can continue to incentivize the use of biosimilars, which in turn will incentivize the development of new biosimilars in the future.

However, AAM and the Biosimilars Council believe legislation is required to equalize treatment of biosimilars and reference biologics in the Part D Coverage Gap Discount Program. Unless Congress classifies biosimilars as "applicable drugs" under the Coverage Gap Discount Program, it is unlikely that patient will ever see significant cost-savings in the program.

As it currently stands, biosimilar manufacturers are not eligible to provide the 50 percent discounts to the program offered by their reference product competitors for patients in between the initial coverage phase and catastrophic coverage. Because these discounts are counted toward a patient's "True Out-of-Pocket" (TrOOP), there is a strong incentive for plans to direct patients to more expensive products. Allowing this policy to continue unchanged will have significant effects on patient costs. In the immediate future, this will increase patient out-of-pocket costs by forcing them to use expensive brand products.[10]

Moreover, if biosimilars are subjected to an uneven competitive playing field, patients will continue to pay the high costs already associated with biologics. In the long run, this unequal playing field could significantly depress biosimilars investment and development. Because the Part D program represents such a large percentage of the overall market for some products, manufacturers may ultimately not pursue development of certain products, resulting in less competition and higher costs for patients and the program. However, categorizing biosimilars as applicable drugs within the program would save Part D over $1 billion in just the first 10 years according to a study conducted by the Moran Company for AAM's Biosimilars Council.[11] We expect those savings will grow as more products enter the market in the next decade.

AAM Supports CMS' Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)
AAM joins many other healthcare stakeholders in our concern regarding the abuse of prescription opioid products. While opioids do serve as an important therapeutic option for some patients, their abuse is a significant public

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[9] April 2013. Express Scripts: The $250 Billion Potential of Biosimilars. Available at http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars
[10] *See,* April 2016. Patient Out-of-Pocket Costs for Biosimilars in Medicare Part D, Avalere Health. Available at http://go.avalere.com/acton/attachment/12909/f-02c0/1/-/-/-/-/20160412_Patient%20OOP%20for%20Biosimilars%20in%20Part%20D.pdf
[11] October 2017. Biosimilar Inclusion in Manufacturer Coverage Gap Discount Program: Fiscal Implications, Moran Company. Available at https://accessiblemeds.org/sites/default/files/2017-11/AAM-Biosimilars-in-Coverage-Gap-10-05-2017.pdf

health threat. It is critical that policymakers take steps to reduce prescription drug abuse while maintaining appropriate patient access to needed treatment. Accordingly, AAM supports the continued implementation of the CARA Act, which allows Medicare Part D plan sponsors to use several utilization management tools that have proven effective in the commercial sector at reducing abuse of opioids.

AAM supports the use of "lock-in" programs, which restrict beneficiaries suspected of inappropriate opioid use to one prescriber, one pharmacy, or both. This solution allows the beneficiary to continue to access opioids as therapeutically appropriate, but requires those prescriptions to be coordinated through a single prescriber or pharmacy. The program as described requires patients and prescribers to be notified before a patient is enrolled, and allows the patient time to appeal the decision and select providers that are most convenient to the patient. Appropriate management of those taking opioids for extended periods of time is one way to combat abuse.

Again, we appreciate the opportunity to provide comments on this proposed rule. If you have questions, please do not hesitate to contact me at (202) 249-7100 or christine.simmon@accessiblemeds.org.

Sincerely,

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Executive Director, Biosimilars Council