



March X, 2020

VIA Electronic Filing: www.regulations.gov, CMS-2020-0003

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Administrator Verma:

Re: Advance 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

The Medicare Access for Patients Rx (MAPRx) Coalition appreciates this opportunity to raise concerns about the Medicare prescription drug benefit (Part D) and issues that have the potential to adversely affect beneficiary access to certain medications.

Our group, MAPRx, is a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. We appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with our official commentary in response to the Advance 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 released on February 5, 2020.

Over the past 15 years, MA has provided a critical avenue for beneficiaries to access prescription drugs. Its success in providing millions of Medicare beneficiaries with coverage for self-administered drugs is commendable. MAPRx supports CMS's efforts to reduce out-of-pocket expenses, but we are concerned the potential changes may lead CMS down the path of limiting beneficiary access to the complete spectrum of medication treatments. In particular, MAPRx would like to address the generic utilization measures in the Advance Notice – Part II:

Generic Utilization (Part D). CMS wants to continue to encourage generic and biosimilar utilization over branded products to reduce Medicare expenditures and lower out-of-pocket costs for beneficiaries. To assess generic and biosimilar utilization, CMS requests comments on three measure concepts: Generic Substitution Rate, Generic Therapeutic-Alternative Opportunity Rate, and Biosimilar Utilization Rate.

MAPRx appreciates the need to ensure efficient and responsible allocation of healthcare spending and respects CMS's efforts to increase the utilization of generic and biosimilar medications. We agree that generic utilization is appropriate in many circumstances and can help beneficiaries save on their out-of-pocket expenses. However, the proposed rule changes may have unintended consequences that can substantially impact a beneficiary's access to

medications that their providers feel are necessary and ultimately reduce their quality of care. Therefore, appropriate safeguards should be incorporated to protect patients for whom a generic alternative is not appropriate.

First, encouraging Part D sponsors to favor therapeutically equivalent generic alternatives (often referred to as A/B generics) over branded products is not appropriate for all patients. Generic alternatives are not required to contain the same inactive ingredients as their branded counterparts, which may make the generic version less effective or potentially dangerous for some patients. For example, a patient may have a different response to a generic medication compared to the branded medication (eg, levothyroxine), or a patient may be allergic to an inactive ingredient in a generic medication not included in the branded medication. MAPRx generally supports generic utilization as long as it is for A/B-rated generics and not for plans to select therapeutic alternatives within a broader class and provided there are mechanisms for patients to obtain the reference product should the generic-equivalent not be appropriate for them.

However, MAPRx is opposed to CMS taking the additional step to look at generic utilization of therapeutic alternatives that are not equivalent to the brand product. Implementing this measure may result in a significant barrier to patient access. Providers, and in turn patients, weigh several factors in making treatment decisions. There are already incentives (and barriers) in place that drive these decisions including cost-sharing differentials and utilization management.

MAPRx is concerned that measuring utilization of generic therapeutic alternatives in the class may motivate Part D plans to further restrict access, which is potentially harmful to patient health outcomes. Incentivizing the use of utilization management techniques by Part D sponsors will likely create additional barriers for patients to receive the appropriate medication. In addition, encouraging Part D plan sponsors to favor biosimilar medications presents a potentially serious risk to patient safety for those already stabilized on the reference product. One of the most significant concerns associated with biosimilar utilization is the risk of inducing immune-mediated adverse reactions. Favoring a biosimilar product will incentivize sponsors to switch patients using branded biologics, which could potentially increase the risk of serious adverse events.

Lastly, the currently proposed measures may disincentivize the use of new medications, many of which address an unmet need in care or are more efficacious than previously available treatment options. Incentivizing the use of utilization management techniques on branded medications will result in patients having to “step through” multiple medications, which will delay access to appropriate care. This approach may have the greatest impact on the most vulnerable populations, particularly patients with rare diseases who cannot afford such delays in care.

We believe Medicare beneficiaries should have access to the drugs that work best for them. We want to ensure that Part D policies are not made at the expense of access to medications, regardless of whether those medications are branded or generic. While generic and biosimilar products certainly have an important place in the American healthcare system, we urge CMS not to enact measures or policies that would unnecessarily inhibit beneficiaries’ access to branded medications. The most exciting and life-changing advances in pharmaceuticals are occurring in the branded-product arena, and we want to ensure beneficiaries continue to be able to participate in the incredible benefits of cutting-edge medicine. The undersigned members of the MAPRx Coalition appreciate your consideration of our concerns. For questions related to MAPRx or the above comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Sincerely,

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