February 10, 2025

Stephanie Carlton
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Draft CY 2026 Part D Redesign Program Instructions
Submitted electronically to: PartDRedesignPI@cms.hhs.gov

Dear Acting Administrator Carlton,

On behalf of the Alliance for Safe Biologic Medicines ("ASBM"), we appreciate the opportunity to comment on the Draft CY 2026 Part D Redesign Program Instructions ("Program Instructions").

Founded in 2010, the Alliance for Safe Biologic Medicines (ASBM) is a diverse group of stakeholders including physicians, pharmacists, patients, researchers, and manufacturers on biologic and biosimilar medicines, working together to advance patient-centered health policy in the U.S. and worldwide. It is ASBM's position that patients should have access to innovative medicines, and that biosimilars are an important tool to expand access by creating cost savings through market competition. ASBM's Executive Director, Michael Reilly served as Associate Deputy Secretary in the U.S. Department of Health and Human Services and worked on the development and implementation of the Part D prescription drug benefit during his six years in the Secretary's Office.

In the Program Instructions, CMS has solicited input on the overall program redesign, as well as two alternative regulatory approaches that would include maintenance changes of generic drugs, interchangeable biological products, and biosimilar biological products other than interchangeable biological products in the immediate substitution of generic drugs and interchangeable biological products that qualify as corresponding drugs as successor regulations to § 423.120(b)(5)(iv).

Under the first alternative approach, CMS proposes to "permit Part D plan sponsors to remove a selected drug that is a reference product and replace it with an interchangeable biological product as an immediate substitution." Further, CMS proposes to continue to permit removal of a selected brand name drug and replace it with a generic drug as an immediate substitution. Next, under the second alternative approach, CMS proposes "…to include maintenance changes of generic drugs and interchangeable biological products…and also include maintenance changes of biosimilar biological products other than interchangeable biological products."

As described further below, ASBM holds the following position:

- ASBM does not support the CMS proposal of allowing immediate substitutions and maintenance changes of generic drugs and interchangeable biological products

- ASBM does not support permitting maintenance changes of non-interchangeable biosimilar biological products

I. Background: ASBM's Long-Term Concerns with the Inflation Reduction Act's Price Controls and Their Effect on Medicare Part D Beneficiary Health and Access to Innovative Medicines

When examining and evaluating a potential redesign of Medicare Part D relating to the Inflation Reduction Act, it is important to understand that the prescription drug benefit was designed following two decades of experience seeing similar government price-setting schemes fail to control Medicare costs for services and healthcare provider rates.

To avoid this happening with the new prescription drug benefit, the Department created a new model. Contrary to what many believe, under Part D, drug price negotiations do occur. However, they are conducted by pharmacy benefit managers (PBMs), and the law specifically forbade government interference in price-setting or formulary selection.

As its designers intended, this approach has been incredibly successful in controlling costs: the Congressional Budget Office projected drug spending between 2004-2013 to be $770 billion; yet actual expenses were 45% lower- at $421 billion. While Part D has been hugely successful in lowering costs, these savings are not always being passed on to the beneficiaries by the PBMs. Unsurprisingly, there is a broad bipartisan effort underway in Congress to rectify this and provide relief for patients without modifying Part D in a manner which will jeopardize its success or beneficiary health.

It has a 90% approval rating among beneficiaries[i], premiums have held steady around $32/month since 2006, and it holds the distinction of being the only major federal program to ever come in under budget.

Since the passage of the Inflation Reduction Act in 2022, ASBM has raised numerous concerns with the Act's inappropriate and harmful modification of the Medicare Part D prescription drug benefit. For example, in our April 2023 comments on the IRA's implementation, we noted the likelihood that introducing price controls could potentially undermine U.S. innovation, limiting U.S. patients' access to new drugs in the long-term as we have seen in Europe:

[i] *https://www.usatoday.com/story/onpolitics/2012/10/03/poll-medicare-prescription-drug-program-popular/1609995/*

In European countries and Canada, government-negotiated drug pricing (i.e., price controls) have negatively impacted patients by undermining innovation and limiting patient access:

- In the 1970s, European companies developed most new drugs; however, since the implementation of price controls in Europe, 60% of new drugs are currently developed in the US, compared to 13% in Switzerland, 8% in the United Kingdom (UK), and 6% in Germany and France.[ii]
- Of cancer medicines launched globally between 2011 and 2019, more than 96% are available to US patients, while only 65% are available in other developed nations such as Australia, Japan, and the UK.[iii] Furthermore, cancer death rates per 100,000 are 1.6 to 1.8 times higher in Europe than those in the US.[iv]
- Of new cancer medications, 90% are available to US patients within the first year of launch, whereas less than half of these are available to cancer patients in Germany, the UK, France, and Canada.[v]

Current US policy contributes to the availability of more life-saving medicines, earlier access to new drug launches, and fewer cancer-related deaths.

In April 2023, ASBM conducted a webinar featuring several former senior federal health officials who worked closely on the design and implementation of Medicare Part D, with the goal of sharing these concerns with the public; this webinar was the subject of a subsequent whitepaper[vi]. ASBM would like to take this opportunity to reiterate to CMS that the proposed Part D redesign will advance a policy (i.e., IRA's Maximum Fair Prices (MFPs) provisions) that will be harmful to American patients in the long term (through reduced access to innovative medicines and worse health outcomes). In addition, the proposed program redesign will harm Medicare beneficiaries and jeopardize their health in a number of ways in the short term, which we will outline below.

II. Response to Draft CY 2026 Part D Redesign Program Instructions: Section 90. Successor Regulation Exception to the Formulary Inclusion Requirement for Selected Drugs

CMS's proposal concerning the designation of a successor regulation that incorporates interchangeable biosimilars, maintenance changes, and non-interchangeable biosimilars into the Part D formulary poses significant legal and policy concerns. ASBM believes this proposal, along with the two alternatives suggested by CMS, do not align with statutory requirements and

[ii] "Europe negotiates a poor vaccine rollout"; Forbes, April 2021
[iii] IQVIA Analytics, FDA, EMA, PMDA, and TGA data. New active substances approved by at least one of these regulatory agencies and first launched in any country from January 1, 2011 to December 31, 2019; June 2020.
[iv] Democrat plan on drug costs will stifle innovation", San Antonio Express-News, May 12, 2021

[v] IQVIA Analytics, FDA, EMA, PMDA, TGA, &w3 Health Canada data, April 2021.
[vi] https://gabionline.net/conferences/asbm-gabi-2023-webinar-on-medicare-drug-price-negotiations

could introduce significant complexities and confusions in the implementation of MFPs in Part D.

The IRA mandates that covered Part D drugs which have an MFP imposed, must be included in all Part D formularies, with the sole exception allowing for the removal of such drugs from the formulary under specific circumstances as outlined in 42 CFR 423.120(b)(5)(iv) (or its successor regulation). Historically, this regulation has strictly pertained to the immediate substitution of brand-name drugs with their generic equivalents that are therapeutically equivalent—having neither been available at the time the original formulary was submitted for CMS approval due to their unavailability in the market.

However, the current CMS proposed redesign and its alternatives seek to extend this exception in ways that exceed the original regulatory framework by suggesting the inclusion of interchangeable and non-interchangeable biosimilars. These suggestions do not only stretch the boundaries of the IRA's stipulations but misinterpret the scope of permissible regulatory changes by proposing maintenance changes that deviate significantly from the established norms of immediate, clinically equivalent substitutions.

The term "successor," as commonly understood, refers to regulations that follow the substantive precedent of their predecessors. Therefore, proposing a successor that substantively alters the nature of formulary substitutions constitutes a departure from the traditional interpretation and application. Such a regulatory expansion is neither indicated by the statutory text nor supported by precedent, which traditionally confines "successor" to contextually similar replacements, not substantive expansions or deviations.

While CMS asserts that Congress has provided the agency with flexibility to expand the scope of "successor" regulations within the Medicare Part D framework, the agency claims an overly broad authority to redefine what constitutes a "successor" regulation, which goes beyond the clear limits set by the statutory language. Moreover, the U.S. Supreme Court decision in *Loper Bright Enterprises v. Raimondo*[vii] emphasized that while Congress can delegate expansive regulatory powers to federal agencies, it must do so explicitly. In this case, the specific reference to a known regulation without indication that the term "successor" could include a broader scope of policy changes suggests that such delegation was not Congress's intent.

Further, this proposed expansion to include interchangeable and non-interchangeable biosimilars as part of the "successor" regulation significantly deviates from the established norms that have governed the immediate substitution of brand-name drugs with generics under Medicare Part D. This not only challenges the principle of statutory interpretation but also introduces substantial uncertainty into a program that depends on clarity and predictability for its success.

[vii] *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024)

III. Response to CMS Solicitation of Comment on Alternative Approaches

In the Program Instructions, CMS has solicited input on two regulatory approaches outlined in the draft program instructions, specifically concerning the immediate substitution of generic drugs and interchangeable biological products that qualify as corresponding drugs under sections § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor to § 423.120(b)(5)(iv). ASBM offers the below response in response to this solicitation.

a. Alternative Approach #1: ASBM does not support allowing immediate substitutions and maintenance changes of generic drugs and interchangeable biological products.

The first alternative approach would allow CMS to identify the successor regulation to also include maintenance changes for generic drugs and interchangeable biological products that are "corresponding drugs." Under § 423.120(e)(2)(i) of the successor regulation, CMS proposes to "permit Part D plan sponsors to remove a selected drug that is a reference product and replace it with an interchangeable biological product as an immediate substitution." Further, CMS proposes to continue to permit removal of a selected brand name drug and replace it with a generic drug as an immediate substitution. Stated differently, Part D plan sponsors would be permitted to remove a selected drug that is either a brand name drug or a reference product as a maintenance change within 90 days of adding a corresponding generic drug or interchangeable biological product to the same or lower cost-sharing tier.

While this approach aims to streamline drug substitutions, it inherently creates a "bait and switch" scenario for beneficiaries, as it permits changes to the formulary that can significantly alter patient care mid-year without adequate patient consent or notification. Such policy changes would undermine the stability of treatment for millions of Medicare beneficiaries, who rely on consistency to manage their health conditions effectively. It also strikes at the heart of the doctor-patient relationship, undermining public trust in the healthcare system.

Under the current system, beneficiaries select their Medicare Part D plans based on a set formulary, which lists the drugs covered for the plan year. Considering both efficacy and cost, this approach allows patients and their healthcare providers to make informed choices about drug plans that best meet their medical needs. The proposed Part D redesign, however, would allow for mid-year changes to the formulary. This would include the substitution of non-interchangeable biosimilars that have not undergone evaluation to ensure safety and efficacy are not negatively impacted when a patient is switched from the reference product.

Such changes could occur without the beneficiary's prior consent and potentially without adequate notification, forcing patients to switch to alternative medications that may not have been their physician's first choice. This disrupts treatment continuity and could lead to confusion, medication errors, or adverse reactions, particularly for patients with chronic conditions who rely on consistent and reliable medication management.

Physicians typically select medications based on a complex understanding of a patient's health history, current condition, and the specific benefits and risks of a particular medication. If Part D plan sponsors can alter the formulary mid-year, it places the sponsor's judgment over that of the physician, potentially forcing physicians to manage patients within the constraints of sudden formulary restrictions rather than medical necessity.

Further, physician concerns with the U.S. Food and Drug Administration ("FDA") and Congressional proposals would weaken interchangeable biosimilar standards and make proposed Part D redesign more problematic for patient treatment stability. Proposed changes to the Part D program, while troubling on their own, will be made significantly more challenging to Medicare beneficiaries should CMS implement the regulatory and legislative changes related to interchangeable biosimilar standards.

While the FDA currently has discretion on what type of data a biosimilar's sponsor must submit to earn an interchangeability designation and has not required them in most cases[viii], the FDA has found clinical switching studies to be warranted in certain cases. Yet, recent FDA Draft Guidance for Industry[ix] has proposed to weaken the approval standards for interchangeable biosimilars, de-emphasizing the role of switching studies in biosimilar approval.

In addition, the "Biosimilar Red Tape Elimination Act" (S. 2305, 118th Congress) was introduced in the previous two Congresses. This bill would deem all biosimilars interchangeable, without the additional evaluation of post-switch safety and efficacy currently required. Some drafts of the bill would have banned the FDA from considering the switching studies when appropriate. Other versions imposed such stringent conditions on the use of switching studies — such as requiring the Secretary of Health and Human Services to provide private briefings to the U.S. Senate Committee on Health, Education, Labor and Pensions and the U.S. House of Representative Energy and Commerce Health Subcommittee on a per-product basis to gain permission from the Committee Chairs and Ranking Members before the FDA could factor in a switching study as part of a biosimilar's data package — as to create a de facto ban.

U.S. physicians, unsurprisingly, are overwhelmingly opposed to weakening interchangeable biosimilar standards[x]:

- 88% of respondents agreed that biosimilar switching studies increase their confidence in the safety of moving their patients from an originator medicine to the biosimilar that has been studied and determined to be interchangeable with the originator.

[viii] https://insidehealthpolicy.com/daily-news/fda-drug-center-officials-defend-biosimilar-switching-policy-change

[ix] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-update

Field Code Changed

[x] US Physician Perspectives on Interchangeable Biosimilars, August 2024; www.tinyurl.com/USSurv2024

- Only 11% believe all biosimilars should be deemed interchangeable (i.e., substitutable by third parties under state law.

Nevertheless, efforts to weaken these data standards, and to inappropriately conflate interchangeable and non-interchangeable biosimilars, are likely to persist. If successful, even biosimilars now considered non-interchangeable will be considered interchangeable.

b. Alternative Approach #2: ASBM does not support permitting maintenance changes of biosimilar biological products non-interchangeable biological products.

The second alternative approach is also concerning. CMS proposes "…to include maintenance changes of generic drugs and interchangeable biological products…and also include maintenance changes of biosimilar biological products other than interchangeable biological products." Under this second alternative approach, "Part D plan sponsors would also be permitted to remove a selected drug that is a reference product as a maintenance change within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that reference product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements."

The substitution of non-interchangeable biosimilars (those without adequate evaluations of safety and efficacy following a switch-assurances that accompany interchangeable products) by third parties is highly controversial, banned in many advanced nations[xi], and strongly opposed by physicians worldwide. Allowing Part D plan sponsors to make maintenance changes without these safety and efficacy guarantees challenges the established standards that currently protect patient health, potentially jeopardizing the health of millions of Medicare beneficiaries being well-treated with their current biologic medicines (whether reference product or biosimilar).

There is evidence that physicians share concerns with ASBM regarding CMS's proposals in the realm of biosimilar substitution (non-interchangeable biosimilars). The proposed Part D redesign would permit plan sponsors to substitute biosimilars in place of their reference products. While the redesign refers only to the substitution of interchangeable biosimilars, it does propose changes that could affect how both interchangeable and non-interchangeable biosimilars are used within Medicare Part D plans. Under this approach, plan sponsors would be permitted to make mid-year formulary changes, which could involve adding and favoring biosimilars that are not deemed interchangeable.

While FDA-approved biosimilars are unquestionably as safe and effective as their reference products, they are indisputably not generics. Indeed, in its educational materials[xii] for biosimilars, the FDA identifies as a "foundational concept" that "biosimilars are not generics— and important differences exist between them." Policymakers in the U.S. and worldwide have

[xi] https://gabi-journal.net/policy-recommendations-for-a-sustainable-biosimilars-market-lessons-from-europe.html
[xii] https://www.fda.gov/media/154912/download

acknowledged the generic substitution paradigm (i.e., unrestrained third-party substitution) is not appropriate for biologics.

For example, the European Medicines Agency clarifies that while "biosimilars in the EU may be prescribed interchangeably…decisions about dispensing one medicine instead of another medicine without consulting the prescriber, such as automatic substitution at the pharmacy level, are not within the remit of EMA and are managed by individual member states.[xiii]" Automatic substitution of biosimilars by third parties at the pharmacy level is rare in Europe and banned in most advanced European countries[xiv]. In fact, both European and U.S. physicians can substitute any approved biosimilars when prescribing medication.

ASBM has surveyed US physicians extensively on the topic of biosimilar substitution, which will be impacted by the Program Instructions. Maintaining treatment stability when switching to biosimilars was found to be of critical importance.

While 92% of U.S. physicians[xv] surveyed are confident in the safety and efficacy of FDA-approved biosimilars, these surveys have also shown a consistent concern about third-party substitution of non-interchangeable biosimilars—that is, those approved without additional data ensuring that switching between the reference product and the biosimilar will not reduce safety and efficacy for the patient relative to a patient who remained on the originator. 69% believe only the physician and patient should determine which biologic to use, not a third-party such as a pharmacy, insurance company, or Medicare Part D plan sponsor.

The FDA's current interchangeability standards were found to significantly improve physician confidence that biosimilar switching can be done safely and appropriately, including third-party substitution. A 2021 survey of 401 physicians revealed that an interchangeable designation made the majority (58%) more comfortable with third-party substitution. A subsequent 2024 follow-up survey of 270 physicians[xvi] revealed that the FDA's current data standards are responsible for the confidence the designation engenders among U.S. physicians. Notably, 87% of respondents agreed that they are more comfortable switching a patient from an originator biologic to a biosimilar if that medicine has been **specifically evaluated for the impact of switching on safety and efficacy.**

IV. Summary: Draft CY2026 Part D redesign program instructions jeopardize patient health, undermine the doctor-physician relationship, and trust in the Medicare Part D benefit.

In summary, the Program Instructions pose a significant risk to the stability of treatments for millions of Medicare beneficiaries. As proposed, these instructions facilitate a bait-and-switch

[xiii] https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf
[xiv] https://gabi-journal.net/policy-recommendations-for-a-sustainable-biosimilars-market-lessons-from-europe.html

[xvi] https://safebiologics.org/wp-content/uploads/2024/09/ASBM-US-Physician-Survey-IC-Biosims.pdf

scenario by allowing potentially inappropriate mid-year formulary changes, including the substitution of non-interchangeable biosimilars that undermine the sanctity of the doctor-patient relationship. Moreover, U.S. physicians continue to express grave concerns about the dangers posed by third-party substitution of biosimilars not rigorously evaluated for safety and efficacy. Even the substitution of interchangeable biosimilars is now fraught with potential problems, as federal policymakers advance proposals that would weaken FDA interchangeability standards and dispense with or prohibit these necessary safety and efficacy evaluations in the future. removed.

In light of the above considerations, ASBM strongly advises CMS against finalizing the current proposal or adopting either of the suggested alternatives. Such changes would not only undermine the legislative intent of the IRA but also compromise the clarity and predictability essential to the successful administration of Medicare Part D. We urge CMS to adhere to the historical regulatory framework, focusing on maintaining consistency with the immediate substitution of generics as originally outlined without expanding the scope to include biosimilars in a manner that could disrupt patient care and lead to significant confusion among stakeholders.

Sincerely,

Michael S. Reilly

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