Greg Portner
Senior Vice President

Global Government Affairs & Policy
601 Thirteenth Street, NW
Suite 1100 North
Washington, DC 20005
Phone: 202.585.9649
Email: gportner@amgen.com
www.amgen.com

June 28, 2024

VIA ELECTRONIC DELIVERY

William N. Parham III
Director, Division of Regulations Development
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
Attention: Document Identifier/OMB Control Number: CMS-2024-0152
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Small Biotech Exception and Biosimilar Delay Information Collection Request (ICR) for Initial Price Applicability Year 2027 (CMS-10844)

Dear Mr. Parham:

Amgen Inc. (Amgen) appreciates the opportunity to submit comments on the Small Biotech Exception and Biosimilar Delay ICR for Initial Price Applicability Year (IPAY) 2027, issued by the Centers for Medicare & Medicaid Services (CMS) on May 3, 2024 (Biosimilar Delay ICR).[1]

Amgen is committed to using science and innovation to dramatically improve people's lives, improving access to drugs and biologics (collectively, "drugs," consistent with CMS's convention), and promoting high-quality care for patients. Amgen develops innovative medicines and biosimilar biological products. Thus, our interest is to ensure a robust market for both innovative and biosimilar biological products in the United States.

As such, we appreciate the opportunity to provide CMS with the below feedback on certain aspects of the Biosimilar Delay ICR, which are in line with our comments regarding the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act (SSA) for IPAY 2027 and Manufacturer Effectuation of the Maximum Fair Price

[1] Centers for Medicare & Medicaid Services (CMS), *Agency Information Collection Activities: Proposed Collection; Comment Request*, 89 Fed. Reg. 36,821 (May 3, 2024); CMS, *Small Biotech Exception and Biosimilar Delay, CMS-10844* (May 3, 2024), *available at* https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10844.

(MFP) in 2026 and 2027 (IPAY 2027 Draft Guidance). These comments are summarized as follows:

- CMS should add questions to the initial delay request form requesting any United States Patent and Trademark Office (USPTO) decision and/or an attestation confirming that no valid patent will be infringed once the biosimilar is launched.
- CMS should add additional questions pertaining to second year delay requests.

I. BACKGROUND

Section 1192(f) of the SSA establishes a "Special Rule" that permits CMS to delay selection of a reference biologic for price setting for up to two years under certain circumstances:

(1) The reference biologic that would be selected for price setting but for the requested delay must be an extended-monopoly drug.[2]

(2) A manufacturer that intends to market a biosimilar of the reference biologic must request the delay before what would otherwise be the reference biologic's selected drug publication date.[3]

(3) CMS must determine that there is a "high likelihood" that the biosimilar will be licensed and marketed within two years of what would otherwise be the reference biologic's selected drug publication date.[4]

(4) Certain disqualifying circumstances must not be present.[5]

If the high likelihood criterion is met, a first year of delay is granted. For a second year of delay, the biosimilar manufacturer must submit a second delay request before the selected drug publication date that follows what would otherwise have been the reference biologic's selected drug publication date.[6] As CMS did not grant any initial delay requests with respect to IPAY 2026, the Biosimilar Delay ICR is focused only on the information to be collected for initial delay requests with respect to IPAY 2027.[7]

[2] SSA § 1192(f)(1)(A).
[3] *Id.* § 1192(f)(1)(B)(i)(1).
[4] *Id.* § 1192(f)(1)(A).
[5] *Id.* § 1192(f)(2)(D).
[6] *Id.* § 1192(f)(1)(B)(i)(II).
[7] Biosimilar Delay ICR at 7.

II. RECOMMENDATIONS REGARDING THE BIOSIMILAR DELAY ICR

A. CMS Should Add Questions to the Initial Delay Request Form Requesting Any USPTO Decision and/or an Attestation Confirming That No Valid Patent Will be Infringed Once the Biosimilar is Launched

CMS has indicated that it intends to consider information that "clearly demonstrate[s] that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before February 1, 2027" as clear and convincing evidence in support of the "high likelihood" determination for a first year of delay.[8] CMS, however, has indicated that it intends to consider only court decisions in determining the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent. But USPTO decisions may similarly inform such a determination. As such, CMS should adopt a question that enables manufacturers to also submit this information. As noted in Section II(A), CMS has broad discretion to determine what information and documents constitute "clear and convincing evidence" and are necessary to support a high likelihood test determination. Given this discretion, *CMS should request and consider any USPTO decision that establishes the invalidity or unenforceability of any potentially applicable unexpired patent relating to the reference product*.

Alternatively, *CMS should permit a biosimilar manufacturer submitting an initial delay request to attest that, to the best of its knowledge, there are no valid patents that will be infringed once the biosimilar is launched*. Here, too, such information would "clearly demonstrate that patents related to the Reference Drug are unlikely to prevent the biosimilar from being marketed before February 1 of the IPAY,"[9] and thus should support the granting of a first year of delay.

As noted in our comment on the IPAY 2027 Draft Guidance, these additional options are needed given the statutory constraint on filing of a Biologics License Application (BLA) and the length of patent litigation and settlement negotiations.

B. CMS Should Add Additional Questions Pertaining to Second Year Delay Requests to the Biosimilar Delay ICR Form

In our comments on the IPAY 2027 Draft Guidance, Amgen recommends that CMS establish standards for granting second year delay requests so that biosimilar manufacturers can plan ahead for future delay requests. Accordingly, we ask that CMS add additional questions in anticipation of second year delay requests for future IPAY years that reflect the criteria below.

[8] IPAY 2027 Draft Guidance § 30.3.1.2.
[9] *Id*.

CMS should find that a biosimilar manufacturer that meets the following criteria has satisfied the statutory standard for a *second* year of delay:

a) If the BLA for the biosimilar was pending review during the first year of delay:

(i) The Food and Drug Administration (FDA) has since approved the BLA for the biosimilar; *or*

(ii) The first cycle of review remains ongoing, i.e., FDA's Biosimilar User Fee Act (BsUFA) date has not yet occurred; *or*

(iii) FDA has issued a complete response letter to the biosimilar manufacturer denying the BLA for the biosimilar, but, as of the time CMS is assessing eligibility for a second year of delay, the biosimilar manufacturer has resubmitted the BLA for the biosimilar; *or*

(iv) The biosimilar manufacturer's disclosures to investors or filings with Securities and Exchange Commission (SEC), such as Forms 10-K or 10-Q, indicate that it plans to market the biosimilar within the requisite time frame; *or*

(v) The manufacturing schedule for the biosimilar submitted to FDA indicates that commercial lots of the biosimilar are expected to be produced within the requisite time frame; *or*

(vi) Agreements filed with the Federal Trade Commission (FTC) or the Department of Justice (DOJ) do not bar the biosimilar manufacturer from marketing the biosimilar within the requisite time frame.

* * *

We appreciate CMS's consideration of these comments. Please do not hesitate to contact Yola Gawlik at ygawlik@amgen.com or (202) 320-1159 if you have any questions.

Sincerely,

Greg Portner
Senior Vice President
Global Government Affairs & Policy