Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REPORT TO CONGRESS ON THE REPORTED IMPACT OF DISCARDED DRUG REFUNDS ON BIOSIMILAR BIOLOGICAL PRODUCTS

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Report to Congress on the Reported Impact of Discarded-Drug Refunds on Biosimilar Biological Products

Why OIG Did This Audit

The Infrastructure Investment and Jobs Act amended section 1847 of the Social Security Act (the Act). The Act requires manufacturers of certain single-dose container or single-use package drugs payable under Part B of the Medicare program to provide refunds for discarded amounts of such drugs.

The Act also requires OIG, after consultation with the Centers for Medicare & Medicaid Services (CMS) and the Food & Drug Administration (FDA), to submit to certain Congressional committees, not later than 3 years after the date of enactment, a report on any impact the discarded-drug refund is reported to have or may have on the licensure, market entry, market retention, or marketing of biosimilar biological products (biosimilars).

Our objective was to determine what impact requiring refunds from manufacturers of certain single-dose products payable under Medicare Part B is reported to have on the licensure, market entry, market retention, or marketing of biosimilars.

How OIG Did This Audit

We consulted with CMS, FDA, selected biosimilar drug manufacturers, and a relevant trade association to determine what effect(s), if any, this Act has had or may have on the licensure, market entry, market retention, or marketing of biosimilars, and how it may affect availability of biosimilars under Medicare Part B.

What OIG Found

On the basis of our consultation with CMS, FDA, selected manufacturers of biosimilars, and a relevant trade association, we concluded that currently there is no known or expected impact on the licensure, market entry, market retention, or marketing of biosimilars as a result of legislation requiring refunds from manufacturers of certain single-dose container or single-use package drugs payable under Medicare Part B.

What OIG Recommends

This report contains no recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

The Infrastructure Investment and Jobs Act[1] amended section 1847A of the Social Security Act (the Act).[2] The Act requires manufacturers of certain single-dose container or single-use package drugs payable under Part B of the Medicare program to provide refunds for discarded amounts of such drugs.[3]

The Act also requires the Office of Inspector General (OIG), after consultation with the Centers for Medicare & Medicaid Services (CMS) and the Food & Drug Administration (FDA), to submit to certain Congressional committees, not later than 3 years after the date of enactment, a report on any impact the discarded-drug refund is reported to have on the licensure, market entry, market retention, or marketing of biosimilar biological products (biosimilars).[4, 5]

OBJECTIVE

Our objective was to determine what impact requiring refunds from manufacturers of certain single-dose products payable under Medicare Part B is reported to have on the licensure, market entry, market retention, or marketing of biosimilars.

BACKGROUND

Medicare Program

Title XVIII of the Act established the Medicare program, which provides health insurance coverage for people aged 65 and over, people with disabilities, and people with end-stage renal disease. CMS administers the Medicare program. Part B of the Medicare program provides supplementary insurance for medical and other health services, including drugs typically administered in a doctor's office or in a hospital outpatient setting.

[1] P.L. No. 117-58 § 90004, enacted Nov. 15, 2021.

[2] Federal regulation 42 CFR § 414.940 was added by 87 Fed. Reg. 69404 (Nov. 18, 2022), effective Jan. 1, 2023, and amended by 88 Fed. Reg. 15918 (Mar. 15, 2023) to implement P.L. No. 117-58 § 90004.

[3] Section 1847A(h) of the Act and 42 U.S.C. § 1395w-3a(h) (as added by P.L. No. 117-58 § 90004).

[4] As required by section 1847A(h)(9) of the Act, OIG will submit the report to the Senate Committee on Finance and the House of Representatives' Committee on Energy and Commerce and the Committee on Ways and Means.

[5] Section 1847A(h)(9) of the Act, 42 U.S.C. § 1395w-3a(h)(9) (as added by P.L. No. 117-58 § 90004).

Food & Drug Administration

FDA, an agency within the Department of Health and Human Services, is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, vaccines and other biological products, and medical devices. Among other things, FDA reviews, approves, and regulates prescription drugs, including biological products.

Discarded-Drug Reporting and Refund Requirements

Since January 2017, CMS has required health care providers to use the JW modifier to identify the portion of a drug from a single-dose vial that is discarded and eligible for payment under the "discarded drug policy."[6] Under this CMS policy, health care providers receive payment for the total amount of a drug indicated on the vial or package label of a single-dose product, including that which is discarded.[7] However, for each quarter beginning on January 1, 2023, the Act required manufacturers of certain single-dose products payable under Medicare Part B to provide refunds to CMS for the discarded amounts of these drugs.[8]

On a quarterly basis, for each refundable single-dose container or single-use package drug product, CMS will report to each manufacturer the refund amount for which it is liable.[9] The refund amount for a product is equal to the estimated amount, if any, by which the discarded drug charges exceed 10 percent of the total allowed charges of the drug for that quarter.[10]

Biosimilar Biological Products

Biological products are generally large, complex molecules that are made from living sources, such as yeast, bacteria, or animal cells. A biosimilar is like a generic drug in some ways because both are versions of medications already approved by FDA and may offer patients more affordable treatment options. A biosimilar is a biological product that is highly similar to, and

[6] 42 CFR § 424.32(a) and CMS Change Request 9603, Transmittal 3538 (dated June 9, 2016), revising Chapter 17, section 40, of the *Medicare Claims Processing Manual* to establish a consistent policy among all Medicare Administrative Contractor jurisdictions to require, effective January 1, 2017, use of the JW modifier for discarded drugs from single-use vials or packages that are separately payable under Part B. Available online at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3538CP.pdf. Accessed on Oct. 6, 2023.

[7] *Medicare Claims Processing Manual*, Chapter 17, section 40. This manual provision was revised on June 2, 2023, by Change Request 13056, Transmittal 12067 (effective Jan. 1, 2023). Available online at https://www.cms.gov/files/document/r12067cp.pdf. Accessed on Oct. 6, 2023. (There were no changes regarding the reporting of the JW modifier.)

[8] Section 1847A(h) of the Act.

[9] Section 1847A(h)(1) of the Act.

[10] Section 1847A(h)(3) of the Act.

has no clinically meaningful differences from, an existing FDA-approved biological product, referred to as a "reference product." Compared with reference products, biosimilars:

- are made with the same types of living sources;
- are administered to the patient in the same way; and
- have the same strength, dosage, potential treatment benefits, and potential side effects.[11]

As a result, the discarded drug amounts from a reference biological product will generally be similar to the corresponding biosimilar.

Medicare Part B covered 21 biosimilars during calendar year (CY) 2022. The table shows 2022 Medicare Part B drug expenditures.

Table: 2022 Medicare Part B Drug Expenditures

Biosimilar Spending CY 2022	$2,255,582,751
Reference Product Spending CY 2022	$1,869,214,619
Biological Product Spending CY 2022	$41,799,748,347
Total Part B Drug Spending CY 2022	$53,516,931,305
Percent Biological Product/Total Part B	78%
Percent Biosimilar/Total Part B	4%

HOW WE CONDUCTED THIS AUDIT

A few months after the refund requirement went into effect, we consulted with CMS, FDA, selected biosimilar drug manufacturers,[12] and a relevant trade association to determine what effect(s), if any, this Act has had or may have on the licensure, market entry, market retention, or marketing of biosimilars, and how it may affect availability of biosimilars under Medicare Part B. Due to the early timing of this audit, data was not yet available for analysis, therefore, our work was limited to just consultations.

The Appendix contains the details of our audit scope and methodology.

[11] FDA. Available online at Overview for Health Care Professionals. Accessed on July 27, 2023.

[12] Medicare Part B paid 10 manufacturers of biosimilars during our audit period. Of these 10, we were able to contact 8; one manufacturer had sold that portion of its business, and we were unable to contact one manufacturer. Of the 8 that we contacted, seven responded to us.

RESULTS OF AUDIT

On the basis of our consultation with CMS, FDA, selected manufacturers of biosimilars, and a relevant trade association, we concluded that currently there is no known or expected impact on the licensure, market entry, market retention, or marketing of biosimilars as a result of legislation requiring refunds from manufacturers of certain single-dose container or single-use package drugs payable under Medicare Part B.

During our meeting with CMS, we learned that while it does not have any data about what refunds might be owed for any biosimilars in the future, based on historical data, no biosimilars have met the refund amount. Furthermore, there has been no formal communication from manufacturers of biosimilars, including comments as part of the notice-and-comment rulemaking period, indicating that the refund requirement would affect the manufacturing of current or future biosimilars.

During our meeting with the FDA, we learned that it has not received communications from manufacturers who cited this legislation as affecting their current or future plans related to biosimilars.

Six of the seven biosimilar manufacturers that responded declined to comment. The manufacturer that did provide comments stated that its biosimilars "do not currently have any exposure to the discarded-drug refund requirement due to our products' zero-to-minimal drug wastage. Accordingly, [it] has not encountered any significant issues as it relates to the licensure, market entry, market retention, or marketing of our biosimilar products."

According to the relevant trade association we spoke to, it does not appear that the refund requirement will affect any current or planned biosimilars. Its data indicates that both current biosimilars and the biosimilars coming to the market will be under the refund amount.

This report contains no recommendations.

APPENDIX: AUDIT SCOPE AND METHODOLOGY

SCOPE

We obtained input from January through April 2023 from officials at CMS, FDA, seven manufacturers of biosimilars, and a relevant trade association to determine the reported impact that section 90004 of the Infrastructure Investment and Jobs Act (P.L. No. 117-58) has had or may have on the licensure, market entry, market retention, or marketing of biosimilars because of the requirement for manufacturers of certain single-dose container or single-use package drugs payable under Medicare Part B to provide refunds on discarded amounts of such drugs.

We performed our audit work from December 2022 through October 2023.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and comments submitted to CMS during the regulatory process;
- held discussions with CMS officials;
- held discussions with FDA officials;
- held discussions with officials at a relevant trade association;
- sent request-for-comment letters to officials at eight manufacturers[13] of biosimilars payable under Medicare Part B; and
- provided the results of our audit to CMS and FDA officials.

We provided CMS and FDA with a draft report on November 1, 2023, for review. CMS and FDA elected not to provide formal comments; however, FDA provided technical comments, which we addressed as appropriate.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[13] We sent letters to eight manufacturers and received responses from seven.