

Report in Brief

Date: February 2024

Report No. A-06-23-04003

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



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.

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

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.