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Office of Management and Budget (OMB)

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Centers for Medicare and Medicaid Services (CMS)

Date: June 25, 2026

Subject: Non-Substantive Change Request – Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800-806 (OMB No: 0938-0921; CMS-10110)

This memo requests approval of a non-substantive change to the approved information collection titled Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800-806 (OMB No: 0938-0921; CMS-10110).

BACKGROUND

In accordance with Section 1847A of the Social Security Act (the Act), Medicare Part B covered drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) of the drug or biological, beginning in Calendar Year (CY) 2005. The ASP data reporting requirements are specified in Section 1927 of the Act. Manufacturers that have a Medicaid Rebate Agreement are required to report ASP data of Part B drugs. Section 401 of Division CC of Title IV of the Consolidated Appropriations Act (CAA), 2021 amended section 1847A of the Social Security Act (the Act) to add new section 1847A(f)(2) of the Act, which requires manufacturers without a Medicaid drug rebate agreement to report average sales price (ASP) information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. The reported ASP data are used to establish the Medicare payment amounts.

OVERVIEW OF REQUESTED CHANGES

It recently came to our attention that we inadvertently submitted the wrong version of several documents that were approved by OMB on June 17, 2026. This June 25, 2026, submission proposes to correct that oversight by replacing those documents with the intended versions. As demonstrated below, all of the changes between what was approved by OMB on June 17, 2026, and our proposed uploads are non-substantive.

We are not proposing changes to our active burden estimates.

We are not proposing changes to our active collection of information requirements.

Instead, our proposed changes are limited to the following:

1. Bona Fide Service Fee Certification Form (Section 2)

We propose to correct one sentence in Submission Method and one box in Section 2 of the form. The revised sentence is missing the phrase, “the Submitter User Guide in Section 3.8...”. The complete sentence should read: “The instructions for submitting the certification are included in the Submitter User Guide in Section 3.8 and the Certifier User Guide in Section 3.4.”

In Section 2 we also propose to remove the box "Bona fide service fee amount (if the fee varies based on certain metrics, describe the metrics of the fee and how it is determined):"

A clean version of the correct Certification form is included in this non-substantive change request along with a Redline version of the corrected form and a Crosswalk of the changes.

2. Submitter User Guide

In the Submitter User Guide, we propose to correct the date and add Section 3.8 “Bona Fide Service Fee Certification.” The date should be “May 18, 2026” instead of “August 29, 2025.”

Section 3.8 instructs users on how to submit the Bona Fide Service Fee Certification form.

A clean version of the correct Submitter User Guide is included in this non-substantive change request along with a Redline version of the corrected form and a Crosswalk of the changes.

3. Certifier User Guide

In the Certifier User Guide, we propose to correct the date and revise Section 3.4 “Bona Fide Service Fee Certification.” The date should be “May 18, 2026” instead of “August 29, 2025.”

Section 3.4 revises certain language to align changes to the Bona Fide Service Fee Certification form.

A clean version of the correct Certifier User Guide is included in this non-substantive change request along with a Redline version of the corrected form and a Crosswalk of the changes.

4. Supporting Statement Part A

We propose revising Supporting Statement Part A by adding a note at the top of the document regarding this non-substantive change.

We also propose to revise Section 8 (Federal Register/Outside Consultation) with regard to our 30-day Federal Register notice.

A clean version of the correct Supporting Statement is included in this non-substantive change

request.