DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 00-00-00
Baltimore, Maryland 21244-1850

Division of Data Analysis and Market Based Pricing

Date: 11/29/2022

To: Drug Manufacturers & Repackagers

From: Maria Durham
Director

Subject: ASP Data for Drugs and Biologics Covered Under Medicare Part B

As part of our implementation of a new statutory requirement, CMS believes some manufacturers of drugs and biologicals payable under Medicare Part B have not reported required average sales price (ASP) data or may have only reported ASP data for a subset of their applicable product line. This can include repackagers. We request that you review your efforts in response to this new statutory requirement.

Section 1927(b)(3)(A)(iii)(I) of the Social Security Act (the Act) requires manufacturers with a Medicaid drug rebate agreement to report ASP data as specified in section 1847A of the Act. Section 401 of the Consolidated Appropriations Act (CAA), 2021 amended section 1847A of the Act to add new section 1847A(f)(2) of the Act, which requires manufacturers without a Medicaid drug rebate agreement to report 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. This is discussed in further detail in the Physician Fee Schedule 2022 Final Rule (86 FR 64996).

Such manufacturers were to first report ASP data to CMS for calendar quarters beginning on January 1, 2022. As stated in 42 CFR § 414.804, the "manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter." Therefore, manufacturers first reporting ASP data to CMS in accordance with provisions in section 1847A(f)(2) of the Act should have done so no later than April 30, 2022 (within 30 days of the close of the first quarter of 2022) for the July 2022 ASP Drug Pricing File. Manufacturers are required to continue to report each quarter thereafter.

We are writing to you today to ask that you review your efforts to meet this statutory obligation. This includes reviewing to ensure that all products are properly reported. We

believe that some companies may be reporting only a subset of their products for which ASP reporting is required, based on our review of current lists of products, including National Drug Codes, that we can identify from publicly available websites and public compendia.

Sections 1847A(d)(4)(B) and (C) of the Act apply civil money penalties (CMPs) for failure to report timely and accurate ASP data for manufacturers without Medicaid drug rebate agreements, consistent with the civil money penalties found at sections 1927(b)(3)(C)(i) and (ii) of the Act for manufacturers with Medicaid drug rebate agreements. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a CMP of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied.

Please visit https://portal.cms.gov to register for the ASP Data Collection System or login if you already have an account. The User Guide can be found in the links below as well as the data templates that must be used within the system. If you have any questions regarding the online portal system, please contact asphelpdesk@dcca.com. For additional information, please visit https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice or email Sec303ASPdata@cms.hhs.gov.

Thank you for your efforts in helping CMS to receive all appropriate information as we work to improve the sustainability of the Medicare Part B Trust Fund.

Maria Durham

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Director