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The Centers for Medicare & Medicaid Services (CMS) calendar year 2023 rule proposing changes to payment policies under the Physician Fee Schedule (PFS) and Medicare Part B (the Proposed Rule) will officially be published in the Federal Register on July 29, 2022. This blog post highlights changes to the PFS that may be of most interest to pharmaceutical manufacturers. Comments to the Proposed Rule must be submitted no later than September 27, 2022.
An advance copy of the Proposed Rule can be found here.

Provisions of most interest to pharmaceutical manufacturers contained in the Proposed Rule include:

- The requirement that manufacturers of certain single-dose container or single-use package drugs provide refunds with respect to discarded amounts;
- Medicare Part B payment for preventive vaccine administration services; and
- Revised coding for wound care management products.

Refund Requirements for Discarded Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) amended section 1847A of the Social Security Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund is for discarded drugs that exceed a 10 percent threshold. The refund amount is calculated as the total Average Sales Price-based reimbursement for the drug divided by the units in the package times the units of discarded drug above the designated threshold. A refundable single-dose container or single-use package drug does not include: (i) a radiopharmaceutical or imaging agent, (ii) certain drugs requiring filtration, (iii) drugs that are not separately reimbursable, and (iv) certain new drugs, which will not be subjected to the refund requirement for the first six full quarters following the first date of sale for any such drug (with the exclusion to end beginning with the date of service after the last day of the sixth full sales quarter). In 2023, CMS would invoice manufacturers for the rebate due in the third quarter of 2023 for first quarter utilization. Annually thereafter, CMS would invoice manufacturers in the third quarter of each year for the second, third, and fourth quarters of the prior year plus the first quarter of the current year. Refund amounts would be due by December 31st of each year. The Proposed Rule also includes a proposed dispute resolution process and a civil monetary penalty of 25 percent of the amount that the manufacturer would have paid for late or incomplete refund payments.

Medicare Part B Payment for Preventive Vaccines

The Proposed Rule seeks to permanently codify into law the regulatory changes contained in the interim final rule with comment (IFC) period titled, ‘Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency,’ which appeared in the November 6, 2020 Federal Register, having to do with payment for vaccine administration services. The IFC included the COVID-19 and its administration as a service payable under Medicare Part B. Notably per the Proposed Rule, “CMS will maintain the current payment rate of $40 per dose for the administration of the COVID-19 vaccines through the end of the calendar year in which the March 27, 2020 EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products ends. Effective January 1 of the year following the year in which the EUA declaration ends, the payment rate for COVID-19 vaccine administration will be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines.”
Specifically, the Proposed Rule will permanently adopt the following regulatory changes from the IFC:

- § 410.152 (l)(1), which includes adding the COVID-19 vaccine to the list of vaccines for which Medicare Part B pays 100 percent of the Medicare payment amount.
- § 410.160 (b)(2), which includes the COVID-19 vaccine in the list of vaccines that are not subject to the Part B annual deductible and do not count toward meeting that deductible.
- § 414.701, which includes the COVID-19 vaccine in the list of statutorily covered drugs.
- § 414.707 (a)(2)(iii), which includes the COVID-19 vaccine in the list of vaccines with a payment limit calculated using 95 percent of AWP.

Revised Payment for Wound Care Products

The Proposed Rule also proposes to cease separately reimbursing for synthetic and non-synthetic substitute skin products—re-termed wound care products—and to bundle the reimbursement for such products in the evaluation and management payment (i.e., include wound care products as supplies in the bundled reimbursement for office visits). The change would be effective January 1, 2024.

CMS would operationalize this change through A codes. CMS proposes that “assignment of A codes to all wound care management products that are not drugs or biological products would continue with respect to products for which a HCPCS Level II code is requested for the first time, as well as for wound care management products [which] were previously assigned a Q code.” However, manufacturers of certain wound care management products will need to submit additional information to CMS in order to obtain an A code for the product.

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