DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 114**

For Participating Drug Manufacturers

Medicaid Drug Rebate Program (MDRP) Requirements and FDA Guidance on Importation of Certain Drugs under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FFDCA)

On September 24, 2020 the Food and Drug Administration (FDA) issued final guidance (#2020-449) titled "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act" addressing the importation of certain FDA-approved drugs that are also authorized for sale in a foreign country in which the drugs were originally intended to be marketed.

The FDA final guidance refers to these products as multi-market approved (MMA) products. For the purposes of the FDA final guidance, an MMA product is an FDA-approved prescription drug or FDA-licensed biological product, or a combination product approved in a new drug application (NDA) or biologics license application (BLA) that:

- Was originally manufactured outside the United States and authorized for marketing by another country's regulatory authority;
- Is the subject of a supplement to an approved NDA or a BLA described in section IV.A or B of the FDA final guidance;
- Is imported into the United States and is authorized by the manufacturer under section 801(d)(1)(B) of the FFDCA to be marketed in the United States;
- Meets the quality standards in the approved application for marketing in the United States;
- Continues to meet the quality standards for marketing in its originally intended market; and
- Differs from the FDA-approved drug or FDA-licensed biological product only with regard to the labeling statement described in section III.B of the FDA final guidance.

Given the FDA final guidance, we believe manufacturers may have questions regarding their obligations under the Medicaid drug rebate program (MDRP) with respect to MMA products. We have drafted the following Questions and Answers to assist manufacturers.

1. *Would the MMA products described in the FDA final guidance be considered covered outpatient drugs and, therefore, subject to the requirements set forth in section 1927 of the Social Security Act (the Act)?*

Yes. MMA products can meet the definition of covered outpatient drug as defined at section 1927(k)(2) of the Social Security Act (the Act) because they would be treated as prescribed drugs for purposes of section 1905(a)(12) of the Act, and are approved under section 505 of the Federal Food Drug and Cosmetic Act (FFDCA), or are biological products licensed under section 351 of the Public Health Service (PHS) Act. MMA products are FDA-approved drugs or FDA-licensed biological products that were manufactured outside of the United States and also authorized for sale in a foreign country in which the drugs were originally intended to be marketed.

The importation pathway described in the FDA final guidance provides a manufacturer an avenue to import an MMA product if, consistent with section 801(d)(1)(B) of the FFDCA, the drug is manufactured outside the United States, and the manufacturer has authorized the drug to be marketed in the United States, and caused the drug to be labeled to be marketed in the United States.

In order for a manufacturer to ensure payment under Medicaid is available for an MMA product, a manufacturer would have to have entered into and have in effect a Medicaid drug rebate agreement with the Secretary, which is a statutory requirement for Medicaid payment for a covered outpatient drug. The manufacturer would also be required to meet all applicable statutory and regulatory requirements set forth at section 1927 of the Act and 42 CFR Part 447, Subpart I, as well as the rebate agreement, including submitting the required drug product and pricing information for all of the manufacturer's covered outpatient drugs. The reporting of all covered outpatient drugs by the importing manufacturer would include the National Drug Codes (NDCs) for the MMA product(s) when the manufacturer sells the MMA product in the United States. (See 42 CFR 447.510 and Section II of the National Drug Rebate Agreement).

2. *How should a manufacturer calculate an average manufacturer price (AMP) for a MMA product? Which sales would need to be included?*

The Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 amended sections 1927(k)(1) and (k)(11) of the Act regarding the calculation of the AMP for a brand name drug when there is an authorized generic. These changes provide that in the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under the manufacturer's NDA approved under section 505(c) of the FFDCA, the AMP shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies. The Centers for Medicare & Medicaid Services (CMS) has generally applied the separate AMP calculation provision in the context of a brand name drug and an authorized generic, and recently released two guidance documents on this issue to further explain the situations in which separate AMPs would be calculated (See CMS Manufacturer Releases 111

and 112). However, we believe the separate AMP calculation could also apply in the context of the manufacturer's calculation of the AMP for the non-MMA product and the MMA product.

As noted above, an MMA product may satisfy the definition of a covered outpatient drug, and will be marketed in the United States under a supplement to the FDA-approved NDA or BLA. The MMA product will also likely have a labeler code and NDC that is different from the FDA-approved product that is not an MMA product. That is, the MMA product will be authorized for sale in the United States.

As described in the FDA final guidance, the MMA product is a drug that the manufacturer approves, allows, or otherwise permits to be sold under the manufacturer's NDA approved under section 505(c) of the FFDCA as referenced in section 1927(k)(1)(C) of the Act. Therefore, we view that when a manufacturer authorizes the sale of the MMA product in the United States consistent with the FDA final guidance, the situation is akin to that of a brand drug and an authorized generic product. In such a case, a manufacturer should treat the FDA-approved MMA product as a separate product that it is allowing to be sold under the manufacturer's NDA, and submit a separate AMP for the MMA product based on the sales from that MMA product only, and a separate AMP for the non-MMA product based on the sales of that product only.

More specifically, the manufacturer would calculate and report to the MDRP a separate AMP for the MMA product based on sales of that MMA product only that take place in the U.S. from the manufacturer to a wholesaler or retail community pharmacy (see section 1927(k)(1), and 42 CFR 447.504(a)-(c)). If the MMA drug is a 5i drug, the AMP would also include sales made to other providers when the drug is not generally dispensed through a retail community pharmacy (see section 1927(k)(1)(B)(i)(IV) of the Act and 42 CFR 447.504(d)).

As a reminder, the manufacturer must report the same baseline information for products produced and distributed under the same NDA. Therefore, the base date AMP for the non-MMA product should be the same base date AMP for the MMA product because both are produced and distributed under the same NDA (see CMS Manufacturer Release 26).

CMS issued a notice of proposed rulemaking (CMS 2842-P), which proposes policies addressing the recent statutory changes to sections 1927(k)(1) and (k)(11) and authorized generics, more specifically. (See also Manufacturer Releases 111 and 112, discussing the statutory changes and their application to brand name and authorized generic drugs.) We will consider whether additional guidance is necessary when this proposed rule is finalized.

3. *Should the manufacturer's best price, as defined at section 1927(c)(1)(C) of the Act and 42 CFR 447.505 take into account the sales of the MMA product by the manufacturer?*

Yes. Best price is defined at section 1927(c)(1)(C)(i) of the Act to mean, with respect to a single source drug or innovator multiple source drug of a manufacturer (*including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the FFDCA*), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.

Moreover, the statutory definition of best price at section 1927(c)(1)(C)(ii)(IV) expressly provides that in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a NDA approved under section 505(c) of the FFDCA, best price shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to best price eligible entities.

As discussed above, we believe that the MMA product/non-MMA product scenario should be viewed similarly to that of the brand drug and authorized generic drug scenario discussed in more depth in regulations and related releases. See 42 CFR 447.506, and CMS Manufacturer Releases 111 and 112. Therefore, the manufacturer's determination of best price shall be reflective of the lowest price available to any entity for any such drug sold under a manufacturer's NDA and also be inclusive of the lowest price for such authorized drug under 505(c), which means "best price" would include the prices of the MMA product that is available from the manufacturer when sold in the United States.

Sincerely,

/s/

Melissa Harris, Acting Director
Disabled and Elderly Health Programs Group