DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

JAN 18 2017

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Thank you for your letter regarding the misclassification of EpiPen by Mylan, Inc., for purposes of the Medicaid Drug Rebate Program (MDRP). In your letter, you pose a number of questions relating to the announcement by Mylan on October 7, 2016, that it had agreed to a handshake settlement with the U.S. Department of Justice and other governmental agencies to resolve allegations that it had incorrectly classified EpiPen as a generic drug rather than a brand-name drug and, as a result, had underpaid rebates to Medicaid.

As you may recall, in response to a letter of November 1, 2016, regarding the Senate Committee on the Judiciary's planned hearing on November 30 to discuss Mylan N.V.'s EpiPen product, the Department of Justice advised the Committee by letter on November 14, 2016 with regard to the anticipated focus of the hearing, that it has not agreed to any settlement with any potential party. It remains the case that there is no settlement with any potential party. We otherwise have no comment on any pending matter that the government may have involving Mylan or EpiPen beyond the discussion below, and we continue to refer all questions to the Department of Justice. However, we seek to provide as much information to the Committee as is possible, and at this time I do want to take this opportunity to address your concerns about the administration of the MDRP by the Centers for Medicare & Medicaid Services (CMS).

The MDRP was created by the Omnibus Budget Reconciliation Act of 1990 and has been operational since 1991. The program reflects Congress's belief that state Medicaid programs should have the capacity to leverage the large volume of drugs they purchase on behalf of low-income beneficiaries in order to obtain price concessions from pharmaceutical manufacturers. State Medicaid programs that elect to cover prescription drugs, as all states do, must cover the Food and Drug Administration (FDA)-approved drugs (for medically accepted indications) of manufacturers that elect to participate in the rebate program by entering into a rebate agreement with the Secretary on behalf of the states. In exchange for coverage of their drugs, participating manufacturers agree to give price discounts in the form of rebates to the states. The federal government shares in both the cost of the drugs purchased and the rebates paid.

Rebate amounts are set by Congress by statute and vary depending on the classification of a drug. The basic rebate amount for brand name and authorized generic drugs is 23.1 percent of

average manufacturer price (AMP); for generic drugs, the basic rebate is 13 percent of AMP. In the case of brand name and authorized generic drugs, if the difference between the AMP and a manufacturer's "best price" (the lowest price the manufacturer gives to non-governmental purchasers), is greater than 23.1 percent of AMP, the rebate is that difference. To discourage manufacturers from raising the prices of their brand name and authorized generic drugs too rapidly, an additional rebate is owed if the AMP of the drug increases faster than general inflation. This additional rebate has applied to brand-name drugs since the inception of the MDRP in 1990 and will begin to apply to generic drugs for the quarter beginning on January 1, 2017. Drugs that have been on the market longer, and have increased their prices faster than the rate of inflation, pay higher rebates.

Currently, more than 600 drug manufacturers participate in the MDRP. Based on 3Q2016 product data reported to CMS, approximately 23,385 drugs are subject to rebates, of which 2,789 drugs are reported as brand name ("single source") drugs, 3,293 drugs are reported as brand name drugs with therapeutic equivalents or authorized generic ("innovator multiple source") drugs, and 17,303 drugs are reported as generic ("noninnovator multiple source") drugs. Over the past 25 years, the MDRP has brought in $244.7 billion in rebates. In FY 2016, the latest year for which we have reliable data, manufacturers paid $37.1 billion in rebates and offsets. Of the $37.1 billion in FY 2016 recoveries, $26.7 billion is the federal share, reflecting a return on investment for the federal government of $1,500 received for every $1 invested.

Before I outline our operational steps and processes for enforcement, I want to make clear that manufacturers that do not comply with classification requirements are in clear violation of the law. No amount of legal obfuscation disguises the fact that these companies are defaulting on their obligations. Under the MDRP authorizing statute, it is the responsibility of the manufacturer to properly report the classification of its drugs and the required pricing data (AMP, best price, customary prompt pay discounts, and nominal prices), and to pay the proper rebate amounts. CMS has provided subregulatory guidance and, more recently, regulatory guidance on these issues, described in more detail below. But CMS's authority to act if a manufacturer improperly classifies a drug is limited. If it comes to CMS's attention that the manufacturer's drug categorization is incorrect for rebate purposes, CMS notifies the manufacturer and attempts to reach an agreement. This occurs as a regular component of the oversight of the program. The statute does not expressly provide the Secretary with the authority to compel a manufacturer that has incorrectly reported a drug as, say, a non-innovator multiple source drug, to change that classification to a single source or innovator multiple source drug, or to issue civil monetary penalties in such a case.

Since 2010, the Center for Medicaid and CHIP Services (CMCS) has taken a number of steps to improve the operations of the MDRP. In January of 2010, in response to a July 2009 OIG evaluation report on the accuracy of drug classifications, CMCS issued Manufacturer Release #80 informing manufacturers that there appeared to be incorrectly categorized drugs and requesting that manufacturers review the drug categories they reported to CMS for their MDRP drugs for accuracy. In November 2010, CMCS issued Manufacturer Release #82, which repeated the information provided in #80 and informed manufacturers about the process by which they can request a change to correct an improperly reported drug category.

The statute governing the MDRP does not require that manufacturers list their drugs with the FDA. In 2012, CMCS issued Manufacturer Release #84 to encourage manufacturers to list their drugs with the FDA for MDRP reporting purposes so that we can better verify whether the drug classifications meet the applicable statutory definitions. In 2013, we issued Manufacturer Release #87, which included a link to a list of drugs that were not listed with the FDA. That guidance strongly encouraged manufacturers to review the list to identify any National Drug Codes under their labeler codes that were not listed with FDA and to list them promptly. In July 2014, CMCS imposed stronger systems edits to ensure manufacturers confirm their FDA listing status; since that time, we have been able to better verify drug categorizations and follow-up with manufacturers that do not meet the statutory definition of a covered outpatient drug for purposes of the Medicaid rebate program.

In February 2012, we issued a proposed rule on Covered Outpatient Drugs, which clarified how manufacturers should treat drugs approved under new drug applications (NDAs) for purposes of the MDRP. We published the Covered Outpatient Drug Final Rule with comment (Final Rule) in February 2016. Among other things, the Final Rule clarifies many of the changes made to the MDRP by the Affordable Care Act and provides drug manufacturers with enhanced regulatory guidance to ensure proper calculation and reporting of drug product and pricing information. More specifically, it reiterates prior guidance concerning the regulatory definitions for "single source drug, "innovator multiple source drug," "noninnovator multiple source drug," and "AMP," among other definitions.

In October 2016, we began development of a new MDRP system that will update our existing information systems and enhance the agency's capacity to oversee the more than 23,000 drug classifications and rebates. Our existing systems are not able to accommodate significant changes required to improve the program, such as matching manufacturer-reported data to FDA data in order to verify the manufacturer submissions, receiving state drug utilization data via online submission, processing the rebate agreement electronically, or automating some of the current process for better data validations. The new system is scheduled to be completed and operational in approximately two years.

Finally, in November 2016 we published a proposed notice of rulemaking announcing changes to the Medicaid National Drug Rebate Agreement (NDRA), which clarifies the responsibilities of manufacturers participating in the MDRP and of CMS in administering it. We are proposing to update the NDRA to incorporate legislative and regulatory changes that have occurred since the agreement was published in the Federal Register on February 21, 1991. The proposed updates include modifications to the definitions section, the manufacturer's responsibilities section, the dispute resolution section, and the nonrenewal and termination section.

Additionally, under section 1927 of the Social Security Act, a drug that is produced or distributed under an NDA approved by the FDA for marketing is considered either a single source drug or an innovator multiple source drug, unless, as provided by in the Covered Outpatient Drug Final Rule, CMS determines that a narrow exception applies. In the case of new drugs that enter the MDRP and are marketed under an NDA, manufacturers must now report them in the Medicaid drug rebate system as either single source or innovator multiple source drugs, unless or until those manufacturers apply for the narrow exception and CMS confirms in

writing that the exception applies, in which case we will provide an override edit. These safeguards will help ensure that manufacturers are properly and consistently classifying drugs in the future.

CMS will continue to do as much as current authority allows to increase oversight of manufacturer compliance with MDRP requirements. Congress could strengthen this statutory authority, which would enable CMS to improve the integrity of the MDRP. The President's FY 2017 budget contains a number of proposals to this end, including allowing more regular audits and surveys of drug manufacturers where cost effective, requiring drugs to be electronically listed with FDA in order for them to be eligible for Medicaid coverage, and increasing penalties for fraudulent noncompliance on rebate agreements—particularly where drug manufacturers knowingly report false information under their drug rebate agreements. If Congress were to adopt these recommendations it would greatly assist CMS in holding companies accountable should they fail to comply with the legal requirements of the MDRP.

As we have previously stated, we believe EpiPen does not meet the definition of a noninnovator multiple source drug, but, in fact, meets the definition of a single source drug or branded drug. As a result, EpiPen has been misclassified and Mylan has underpaid rebates owed under the Medicaid Rebate Drug Program, including the additional rebate, which penalizes a manufacturer for increasing the price of its drug faster than inflation (as Mylan did with EpiPen).

Thank you for your continued interest in this matter as CMS administers this important program. Please contact the Office of Legislation at (202) 690-8220 should you have any further questions or concerns.

Sincerely,

Andrew M. Slavitt
Acting Administrator