



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



DEC 06 2016

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

Dear Mr. Chairman:

I am writing in response to your letter dated September 20, 2016, requesting that the Department of Health and Human Services (HHS), Office of Inspector General (OIG), examine Centers for Medicare & Medicaid Services' (CMS) oversight of the Medicaid Drug Rebate Program. HHS OIG shares the concerns expressed in your letter regarding CMS's oversight of the Medicaid Drug Rebate Program to ensure the correct classification of drugs, including EpiPen[®], and address the potential consequences to State Medicaid programs and beneficiaries.

HHS OIG has prior work examining the Medicaid Drug Rebate Program. After discussions with your staff, we agreed to build upon this prior work by completing three new reviews on data accuracy and validity as well as CMS oversight and management of the Medicaid Drug Rebate Program. These three reviews are as follows:

- Medicaid Drug Classification Data. We will examine the accuracy of CMS's Medicaid drug rebate classification data. We also will review the tools and processes CMS has in place to ensure that manufacturers are in compliance with Medicaid Drug Rebate Program requirements.
- Medicaid Payments for FDA-Approved Drugs. We will review the Food and Drug Administration's (FDA) approval status of drugs paid for by Medicaid. We will also determine what operations CMS undertakes to review the FDA approval status of drugs, and how CMS prevents inappropriate payments for unapproved drugs in the Medicaid program.
- Reasonable Assumptions Made by Manufacturers Reporting Data for the Rebate Program. We will review manufacturers' reasonable assumptions when calculating drug prices used for the Medicaid Drug Rebate Program and will interview CMS staff regarding the agency's oversight of reasonable assumption submissions.

We will keep you and your staff apprised of the status of these reviews. An identical letter is being sent to Chairman Upton of the House Energy and Commerce Committee, who, along with 14 other Committee Members, wrote to us with similar concerns.

If you have any questions, please do not hesitate to contact me, or your staff may contact Christopher Seagle, Director of External Affairs, at (202) 260-7006 or by email at Christopher.Seagle@oig.hhs.gov.

Sincerely,

A handwritten signature in black ink that reads "Daniel R. Levinson". The signature is written in a cursive style with a large initial 'D'.

Daniel R. Levinson
Inspector General

cc:

The Honorable Orrin Hatch
The Honorable Mike Crapo
The Honorable Pat Roberts
The Honorable Michael B. Enzi
The Honorable John Cornyn
The Honorable John Thune
The Honorable Richard Burr
The Honorable Johnny Isakson
The Honorable Rob Portman
The Honorable Patrick J. Toomey
The Honorable Dan Coats
The Honorable Dean Heller
The Honorable Tim Scott