

**Congress of the United States**  
Washington, DC 20515

March 22, 2018

The Honorable Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Administrator Verma:

As leaders of the committees with Congressional jurisdiction over the Medicaid program, we write to request additional information regarding the Centers for Medicare and Medicaid Services' (CMS's) oversight of the Medicaid drug rebate program. We are troubled that misclassifications of prescription drugs for purposes of the Medicaid drug rebate may have resulted in federal and state Medicaid expenditures for certain drugs that were higher than would otherwise be warranted.

Under current law, prescription drug manufacturers are required to enter into rebate agreements with the Secretary of the Department of Health and Human Services (HHS) and pay quarterly rebates to the States. As part of those rebate agreements, manufacturers must provide CMS with drug classification data that indicates whether any given drug is (1) an innovator, i.e., a single-source product or an innovator multiple-source product, or (2) a non-innovator multiple-source product. Drug manufacturers must report this drug classification data in the Drug Data Reporting for Medicaid System (reporting system).<sup>1</sup> Accurate classification of prescription drugs is critical, as federal law determines the Medicaid rebate amount based on a drug's classification.<sup>2</sup>

A report issued last month by the Office of the Inspector General for the U.S. Department of Health and Human Services (HHS-OIG) examined CMS's oversight of manufacturer-reported classifications for drugs in the Medicaid rebate program and found several areas of needed improvement.<sup>3</sup> This report, which was initiated at the request of our committees, is the first in a series of three reports OIG is conducting to examine CMS's oversight and operation of the Medicaid drug rebate program.

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<sup>1</sup> See CMS website, available at: <https://www.medicare.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>

<sup>2</sup> Section 1927(c) of the Social Security Act.

<sup>3</sup> Department of Health and Human Services Office of Inspector General, *Potential Misclassifications Reported by Drug Manufacturers May Have Led to \$1 Billion in Lost Medicaid Rebates*, December 2017, available online: <https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf>

Specifically, the report compared manufacturer-reported classifications for drugs in the Medicaid rebate program to drug information in the Food and Drug Administration's (FDA's) files and estimated the rebate amounts that Medicaid may have lost from 2012 to 2016 for the top 10 potentially-misclassified drugs with the highest total reimbursement in 2016. The report's general findings are problematic. OIG detailed that for the period reviewed, Medicaid may have lost \$1.3 billion in base and inflation-adjusted rebates for just these 10 drugs. Even more troubling, CMS does not track misclassification errors, so it is unclear what steps CMS has taken to address these errors. Moreover, OIG reported that CMS does not have explicit legislative authority to correct misclassification errors.

We are deeply concerned about these potentially longstanding weaknesses in the agency's oversight of the accuracy of drug classifications for purposes of the Medicaid drug rebate program.<sup>4</sup> Further steps appear to be needed to protect taxpayer dollars and strengthen the Medicaid program.

Based on the troubling findings of this report and previous conversations with the agency about oversight in this area, we respectfully request a response to the following questions outlined below.

1. Prior to the summer of 2016, what was CMS's process for tracking drugs that might be misclassified for purposes of the Medicaid drug rebate program? Was each drug classification reviewed? If so, how often? If so, how were staffing resources or contracting mechanisms allocated for such purposes, i.e., how many full-time equivalents (FTEs) were used (and in what capacity) to review the classification accuracy and completeness of drug manufacturers' submitted data?
2. The OIG report found that drug manufacturers may have owed an additional \$1.3 billion in rebates from 2012 to 2016 for the top 10 potentially-misclassified drugs with the highest total reimbursement in 2016. These top 10 drugs accounted for 68 percent of Medicaid reimbursement for potentially-misclassified drugs in 2016.
  - a. Of these top 10 potentially misclassified drugs, which drugs were actually misclassified and how did CMS determine that?
  - b. Of these top 10 drugs, what types of drugs are these drugs? (i.e., analgesics, antidepressants, oncology treatment or HIV drugs, antidiabetic drugs, antihyperlipidemic drugs, etc.)
  - c. Will CMS publicly commit to a timeframe by which the agency will address OIG's findings, i.e., review the drugs OIG identified as potentially misclassified and take appropriate action, and improve CMS's procedures for overseeing Medicaid drug classifications, including developing CMS's new Medicaid Drug Program system to better identify and reduce inconsistent data submissions?

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<sup>4</sup> OIG, Accuracy of Drug Categorizations for Medicaid Rebates (OEI-03-08-00300), July 2009.

3. To date, CMS has disclosed relatively few details regarding the “narrow exception” process by which drug manufacturers may request to continue to classify a drug approved under a New Drug Application as a non-innovator drug as permitted under the 2016 Covered Outpatient Drugs Final Rule. From conversations with CMS program staff, we have learned the agency received applications for an exception from more than 30 manufacturers covering more than 500 national drug codes, and granted four approvals total during 2016 and 2017. Please explain in detail the processes, procedures, and policies the agency is using to operate this exceptions process. Specifically, please detail:
  - a. What criteria is the agency using to evaluate requests by drug manufacturers for exceptions? Will the agency make such criteria publicly available?
  - b. Please provide a breakout of the number of requests, number of manufacturers, number of national drug codes received, as well as the number of approvals made, related to drug manufacturers’ application for the exceptions process.
  - c. For the applications that have been adjudicated, how long did it take CMS to review and make a determination? With many applications still pending, how long does CMS estimate it will take until such reviews are complete?
4. Potential misclassifications identified in the OIG report were associated with 54 different manufacturers in 2016. However, just four manufacturers were responsible for over one-half (54 percent) of the potential misclassifications. Have any of these four manufacturers previously been subject to any administrative or legal punitive, compliance, or other enforcement action from this Administration or prior administrations?
5. The OIG report recommended CMS should follow-up with manufacturers associated with potentially-misclassified drugs identified in the report to determine whether current classifications are correct. CMS concurred with this recommendation and in the agency’s response to the OIG report it said, “CMS will begin review of the potentially misclassified drugs identified in the report once CMS receives the list of identified National Drug Codes from the OIG.”
  - a. Please provide a workplan and specific timeframe for CMS to initiate and complete its review upon receipt of the NDCs.
  - b. How many of these manufacturers applied—and how many were granted—a “narrow exception” request to continue to classify a drug approved under a New Drug Application as a non-innovator drug as permitted under the 2016 Covered Outpatient Drugs Final Rule?
6. The OIG report recommended CMS should improve its Drug Data Reporting for Medicaid System to minimize inconsistent data submissions and track potential classification errors for follow-up. CMS concurred with this recommendation and said the agency is in the process of developing a new Medicaid Drug Program system that will

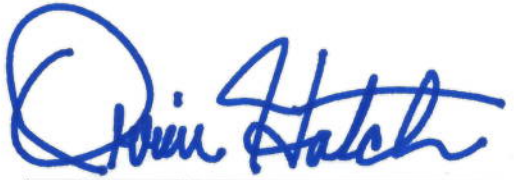
“help to identify and reduce inconsistencies in data submissions...”

- a. We request CMS provide a briefing for relevant bipartisan Committee staff within 30 days of the receipt of this letter detailing the current data systems used to receive, track, and administer drug manufacturers’ classifications, as well as planned changes to such systems (including the projected costs of such changes and timeframes for completion).
7. The OIG report recommended CMS should pursue a means to compel manufacturers to correct inaccurate classification data reported to the Medicaid rebate program. CMS concurred with this recommendation and noted the agency “will consider methods to improve the agency efforts to compel manufacturers to correct inaccurate drug classification data.”
  - a. Does CMS agree Congress needs to provide the agency/HHS with explicit legal authority to compel drug manufacturers to correct inaccurate classification data reported to the Medicaid rebate program?
  - b. Without explicit statutory authority, what authorities and processes does CMS find most useful to correct inaccurate classification data reported to the Medicaid rebate program?
8. With certain exceptions, generally, drugs must be approved by FDA for safety and effectiveness to qualify for Federal matching payments under the Medicaid program. According to the OIG report, Medicaid classifications for 95 percent of drugs in the Medicaid rebate program matched FDA data in 2016 and 3 percent had classifications that contradicted FDA data, i.e., they were potentially misclassified in 2016. The report notes that “1 percent of drugs had FDA marketing categories that did not directly correspond to a Medicaid classification” so the OIG was “unable to determine whether these drugs were classified appropriately” while “another 1 percent of drugs were missing from both FDA files.”
  - a. For the 1 percent of drugs that are not listed with FDA, how does CMS determine appropriateness of classification in these cases? How does CMS plan to address this lack of FDA listing in a manner that avoids legal or regulatory uncertainty?
9. OIG was unable to determine the financial effects (i.e. potential federal and state savings) for some drugs because manufacturers are required to report the “best price” only for their innovator products. As the report noted, “Base rebate amounts for innovator drugs are usually calculated as the difference between AMP and best price, or 23.1 percent of AMP, whichever is greater. All top 10 of the potentially-misclassified drugs with the highest total reimbursement were classified as non-innovator products, and manufacturer-reported best price information was not available for these drugs.” As a result, the OIG report estimated the base rebate amounts using only the 23.1 percent of AMP formula.

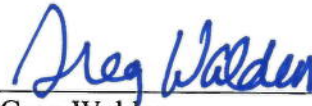
- a. Does the absence of a requirement that manufacturers report best price for their non-innovator products hamper CMS's oversight of the Medicaid drug rebate program?
10. Does CMS need broader authority or tools—either under Section 1927 of the Social Security Act, or elsewhere in federal law—to ensure better compliance with current law with respect to the Medicaid drug rebate program?

To help inform our committees' oversight and legislative considerations, we respectfully request a response to this letter no later than 30 days from its receipt.

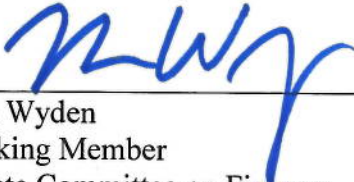
Sincerely,



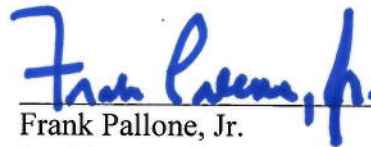
Orrin G. Hatch  
Chairman  
Senate Committee on Finance  
U.S. Senate



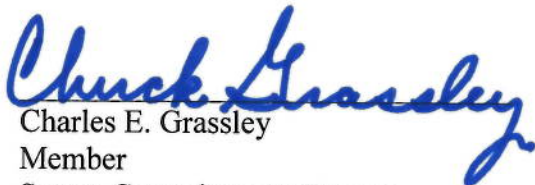
Greg Walden  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives



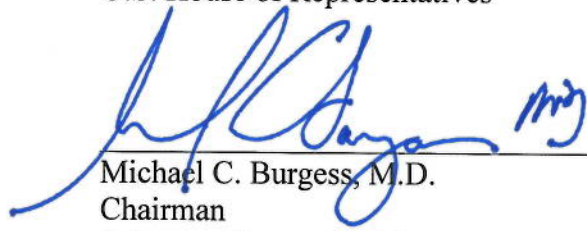
Ron Wyden  
Ranking Member  
Senate Committee on Finance  
U.S. Senate



Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
U.S. House of Representatives



Charles E. Grassley  
Member  
Senate Committee on Finance  
U.S. Senate

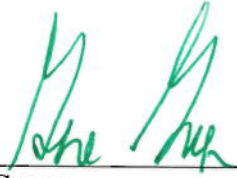


Michael C. Burgess, M.D.  
Chairman  
Subcommittee on Health  
U.S. House of Representatives



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Claire McCaskill  
Member  
Senate Committee on Finance  
U.S. Senate



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Gene Green  
Ranking Member  
Subcommittee on Health  
U.S. House of Representatives



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Gregg Harper  
Chairman  
Subcommittee on Oversight  
and Investigations



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Diana DeGette  
Ranking Member  
Subcommittee on Oversight  
and Investigations