One Percent of Drugs With Medicaid Reimbursement Were Not FDA-Approved

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Deputy Inspector General

One Percent of Drugs With Medicaid Reimbursement Were Not FDA-Approved

What OIG Found
Ninety-six percent of drugs with Medicaid reimbursement in 2016 were approved by the Food and Drug Administration (FDA) for safety and effectiveness. However, Medicaid reimbursed for a small percentage of drugs (1 percent, or 267 drugs) that were not FDA-approved. For the remaining drugs, we were unable to determine an FDA approval status.

Exhibit: Nearly all drugs with Medicaid reimbursement were FDA-approved

- FDA-approved
- Not FDA-approved
- Unable to determine
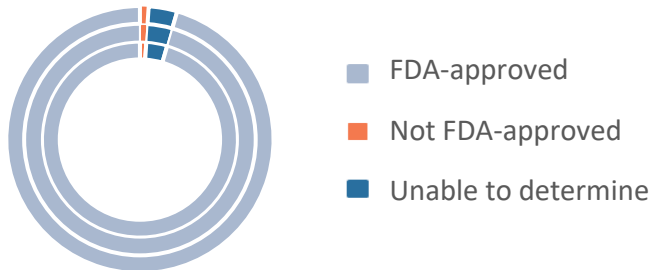
Source: OIG analysis of Medicaid and FDA data, 2016.

In the time since our previous report, FDA has implemented our recommendation to improve the completeness and accuracy of its drug directory to ensure the directory's integrity for the Centers for Medicare & Medicaid Services (CMS) and all other stakeholders. These improvements have strengthened CMS's ability to verify the FDA approval status of drugs in the Medicaid Drug Rebate Program. Since 2014, CMS also has implemented additional oversight activities to verify the FDA approval status of drugs. However, these improvements may not have prevented potentially inappropriate Medicaid reimbursement for a small number of drugs that were not FDA-approved.

What OIG Recommends
We recommend that CMS (1) work with States to recoup any potentially inappropriate Federal reimbursement for drugs that CMS determines were not FDA-approved and did not meet the criteria for an exception; (2) continue to improve its reporting system to prevent inappropriate reimbursement for drugs that are not FDA-approved, and (3) work with States to ensure that they prevent inappropriate reimbursement for drugs that are not FDA-approved and do not meet the criteria for an exception. CMS concurred with all three recommendations.

Full report can be found at http://oig.hhs.gov/oei/reports/oei-03-17-00120.asp

Why OIG Did This Review
Previous Office of Inspector General (OIG) work found that Medicaid may have paid for drugs in 2008 that were not FDA-approved as safe and effective. To qualify for Federal payments under Medicaid, drugs must be FDA-approved unless they meet the criteria for an exception—for example, prescription prenatal vitamins or drugs that are prescribed during times of drug shortages.

Congress asked OIG to examine CMS's oversight of the Medicaid Drug Rebate Program and the extent to which CMS relies on FDA's drug classifications.

How OIG Did This Review
We obtained utilization data for drugs with Medicaid reimbursement in 2016. We used the FDA marketing categories to determine whether drugs were FDA-approved. We calculated the number and percentage of (1) drugs that were FDA-approved, (2) drugs that were not FDA-approved, and (3) drugs for which we were unable to determine the FDA approval status. We also determined the amounts that Medicaid reimbursed for each of these groups of drugs in 2016. Finally, we reviewed CMS's policies and procedures for evaluating the FDA approval status of drugs in the Medicaid Drug Rebate Program.

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BACKGROUND

Objectives

1. To determine whether drugs with Medicaid reimbursement in 2016 were approved by the Food and Drug Administration (FDA).

2. To review the policies and procedures that the Centers for Medicare & Medicaid Services (CMS) has in place to review the FDA approval status of drugs covered under the Medicaid Drug Rebate Program.

A prior Office of Inspector General (OIG) report found that Medicaid may have inappropriately reimbursed for drugs in 2008 that were not FDA-approved.[1] Generally, drugs must be FDA-approved to qualify for Federal reimbursement under Medicaid; however, there are some exceptions to this requirement.[2] FDA is responsible for ensuring that drugs marketed in the U.S. are safe and effective for human use. Drugs that are not FDA-approved may pose public health concerns as they may not meet modern standards for safety, effectiveness, quality, and labeling.[3] However, some drugs—mostly older products—continue to be marketed illegally in the United States without the required FDA approval.[4]

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[1] In our prior report, we used FDA application numbers as indicators of drugs' FDA approval status. We found that 62 percent of drugs with Medicaid reimbursement in 2008 had an approved application number. Of the remaining 38 percent, 12 percent did not have an approved application number, and 26 percent were not listed in the FDA directory that we reviewed. OIG, *FDA's Approval Status of Drugs Paid for by Medicaid*, OEI-03-08-00500, November 2010.

[2] Medicaid provides exceptions for covering unapproved drugs on the basis of (1) drug shortages; (2) a drug's being commercially used or sold (or identical, similar, or related to a drug that was commercially sold) prior to the implementation of current approval requirements and that is not considered a new drug, or (3) a compelling justification for a drug's medical need. In addition, States must cover prescription prenatal vitamins and fluoride preparations, regardless of their FDA approval status. However, individual States may choose to exclude or restrict coverage for other prescription vitamins and mineral products. Sections 1927(d)(2)(F) and 1927(k)(2)(A) of the Social Security Act (the Act) and CMS, *Drug Product Data Web File Structure*. Accessed at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxx-7-recordspecificationanddefinitionsproductfile.pdf on July 10, 2018.

[3] FDA, *Unapproved Prescription Drugs: Drugs Marketed in the United States That Do Not Have Required FDA Approval*. Accessed at https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/selectedenforcementactionsonunapproveddrugs/default.htm on May 15, 2018.

[4] Ibid.

In September 2016, Congress requested that OIG examine CMS's oversight of the Medicaid Drug Rebate Program.[5] In response to the request, this study reviews Medicaid reimbursement for drugs in 2016 to determine whether Medicaid may have inappropriately reimbursed for drugs that were not FDA-approved.

FDA Approval of Drugs

FDA is responsible for evaluating drugs for patient safety. Before receiving FDA approval for marketing, pharmaceutical manufacturers must test a drug to discover how it works and prove that it is safe and effective for its intended use. Manufacturers then submit an application for FDA to review. If FDA decides that a drug's health benefits outweigh its known risks, the agency will approve a drug for sale in the U.S.[6]

FDA directories. Drug manufacturers are generally required to provide FDA with a list of all the drugs that they manufacture, repackage, or relabel for commercial distribution.[7] Manufacturers must update their drug product lists at least twice per year, and may also provide updates to FDA when changes occur.[8] FDA maintains this information in two directories—the NDC Directory and the NDC Structured Product Labeling Data Elements File—that include drugs' names, national drug codes (NDCs),[9] and manufacturers.[10]

The FDA directories include manufacturer-reported information about drugs with an assigned NDC. These directories currently include a field—the "marketing category"—that indicates the application type under which FDA approved the drug.[11] However, when we reviewed FDA's NDC Directory for our previous evaluation, it did not include specific information about each drug's approval status. Therefore, in our prior

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[5] The Medicaid Drug Rebate Program was established under Section 1927 of the Act.

[6] FDA, *Development & Approval Process (Drugs)*. Accessed at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm on July 10, 2018.

[7] 21 CFR § 207.41.

[8] 21 CFR § 207.57.

[9] NDCs are 11-digit identifiers that indicate the manufacturer, product, and package size of each drug product.

[10] According to CMS, there are a small number of products (fewer than a dozen) that are not listed in the FDA directories, but are Medicaid Drug Rebate Program-eligible drugs. CMS has a manual override process to accept those products into the Medicaid rebate drug product file. In addition, in the case of certain multilayer packaged products, only the outermost package and the dispensable inner layer package are listed in FDA's NDC Directory. Therefore, the inner layer of a multilayer package that is not dispensable may not always be listed separately in the NDC Directory. FDA, *NDC Package File Definitions*. Accessed at https://www.fda.gov/Drugs/InformationOnDrugs/ucm254528.htm on October 15, 2018.

[11] If a drug is not FDA-approved, its marketing category will identify it as unapproved.

work, we were unable to determine the FDA approval status for 38 percent of drugs with Medicaid reimbursement in 2008.

Because in our previous evaluation we were unable to determine the FDA approval status for 38 percent of drugs with Medicaid reimbursement, we recommended that FDA improve the completeness and accuracy of its NDC Directory. FDA implemented our recommendation, which included several quality control and enforcement activities to improve the completeness and accuracy of the NDC directory to ensure its integrity for CMS and all other stakeholders.

Medicaid Reimbursement for Drugs

All 50 States and the District of Columbia (States) offer prescription drug coverage as part of their Medicaid benefit packages. States reimburse for drugs dispensed to Medicaid enrollees. Medicaid reimbursement for prescription drugs totaled $60.5 billion in 2016.

Oversight of Drugs in the Medicaid Drug Rebate Program

To qualify for Federal reimbursement under Medicaid, drugs must be FDA-approved for safety and effectiveness, with certain exceptions.[12] In addition, manufacturers must provide CMS with information about their drugs in the Medicaid Drug Rebate Program, including the "covered outpatient drug status," pricing information, and drug categories.[13] CMS's "covered outpatient drug status" field reflects each drug's FDA marketing category. CMS maintains information about covered drugs in the Medicaid rebate drug product file (Medicaid drug product file).

According to CMS, it conducts quarterly reviews of all drugs in the Medicaid Drug Rebate Program. CMS also stated that it reviews drugs that are new to the Medicaid Drug Rebate Program as soon as they are reported by manufacturers. As part of these reviews, CMS compares each drug's manufacturer-reported covered outpatient drug status to its FDA approval status. States also may independently track the approval status of drugs for which their respective Medicaid programs reimburse.

However, it is ultimately the drug manufacturers' responsibility to ensure that they accurately report drug information to the Medicaid Drug Rebate Program. When information provided by drug manufacturers is incorrect or missing, Medicaid might reimburse inappropriately.

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[12] 42 CFR § 447.502.

[13] 42 CFR § 447.510 and CMS, *National Drug Rebate Agreement*. Accessed at https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/national-drug-rebate-agreement/index.html on November 15, 2017.

Methodology

Data Collection

Medicaid drug data. We obtained Medicaid drug reimbursement and utilization data, which is publicly available on Medicaid.gov, to identify NDCs, i.e., drugs, with Medicaid reimbursement in 2016.[14]   We also obtained the 2016 quarterly Medicaid drug product files from Medicaid.gov.

FDA data. We downloaded the FDA directories from FDA's website. We used the marketing categories in these files to determine each drug's FDA approval status.

CMS procedures. We requested information from CMS about its procedures for reviewing the FDA approval status of drugs in the Medicaid Drug Rebate Program.

Data Analysis

Approval status of Medicaid drugs. Medicaid reimbursed for 30,848 NDCs, i.e., drugs, in 2016. We used the 2016 Medicaid drug product file to identify each drug's covered outpatient drug status, including whether an unapproved drug had a Medicaid exception for coverage.[15]   We identified and removed drugs that were (1) classified as over-the-counter in the 2016 Medicaid drug product file or the FDA directories; (2) listed as a prescription prenatal vitamin or fluoride preparation,[16] or unapproved with an exception for coverage in the

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[14] The Medicaid drug reimbursement and utilization data were extracted from CMS's State Drug Utilization Data file. We determined reimbursement amounts using data from the "Medicaid Amount Reimbursed" field, which represents both Federal and State reimbursement. We did not include amounts from the "Non-Medicaid Amount Reimbursed" field, as these amounts are not eligible for Federal matching funds.

[15] We included in our analysis drugs with covered outpatient drug status codes of 01, 02, 03, 04, 05, 06 and 08, and we excluded drugs with covered outpatient drug status codes of 07, 09, 10, 11, 12, and 13. CMS, *Drug Product Data Web File Structure and Definitions*. Accessed at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxx-7-recordspecificationanddefinitionsproductfile.pdf on July 10, 2018.

[16] States must cover prescription prenatal vitamins and fluoride preparations, regardless of their FDA approval status. However, individual States may choose to exclude or restrict coverage for other prescription vitamins and mineral products. Prescription vitamin and mineral products that are not prenatal vitamins or fluoride preparations are included in covered outpatient status code 08. We included drugs with this covered outpatient status code in our analysis because it is not possible to determine—using the data—which drugs each State chose to cover, and we wanted to alert CMS to all potential areas of vulnerability. Section 1927(d)(2)(F) of the Act.

Medicaid drug product file;[17] or (3) listed as dietary supplements in the FDA directories.

For the remaining 26,975 drugs with Medicaid reimbursement in 2016, we reviewed the FDA marketing categories to determine whether the drugs were FDA-approved.

We were unable to determine the FDA approval status for drugs that were:

- missing from the FDA directories;

- listed as approved for export only;

- listed as devices or medical foods;[18] or

- listed as both approved and unapproved across FDA directories.

We calculated the number and percentage of the following: drugs for which the FDA approval status was approved, drugs for which the FDA approval status was not approved, and drugs for which we were unable to determine the FDA approval status in 2016. See Appendix A for our analysis determinations of drugs by FDA approval status.

We then used Medicaid utilization data to calculate Medicaid reimbursement for each of the three groups of drugs—FDA-approved drugs, drugs that were not FDA-approved, and drugs whose status we were unable to determine. We compared drugs using the 11-digit NDCs that manufacturers provided to CMS and FDA; therefore, each group of drugs could include different package sizes of the same drug product.

CMS Processes. We reviewed and summarized CMS information regarding its procedures for ensuring that Medicaid reimburses appropriately for drugs that are FDA-approved.

Limitations

We did not verify the completeness or accuracy of data from the Medicaid drug product file, Medicaid utilization data, or the FDA

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[17] Medicaid provides exceptions for covering unapproved drugs on the basis of (1) drug shortages; (2) a drug's being commercially used or sold (or identical, similar, or related to a drug that was commercially sold) prior to the implementation of current approval requirements and that is not considered a new drug, or (3) a compelling justification for a drug's medical need. Section 1927(k)(2)(A) of the Act and CMS, *Drug Product Data Web File Structure and Definitions*. Accessed at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxx-7-recordspecificationanddefinitionsproductfile.pdf on July 10, 2018.

[18] Manufacturers reported to FDA that the marketing categories for these drugs were "device" or "medical food," and manual searches identified most of them as solutions, tablets, or gels. Therefore, we were unable to determine whether the marketing categories in the FDA directories were correct.

directories.[19] We used the 2016 Medicaid drug product file and FDA directories to identify and remove over-the-counter drugs. However, if a drug was neither included in the 2016 Medicaid drug product file nor listed with FDA, we were unable to identify it as over-the-counter. Because not all drugs we reviewed were included in the 2016 Medicaid drug product files, we could not determine the covered outpatient drug status for these drugs in 2016.[20] However, all of the drugs in our analysis had Medicaid reimbursement data in the 2016 State Drug Utilization Data file.

We were unable to determine the FDA approval status of drugs that were not listed in FDA directories. FDA directories can be updated daily, and therefore drug listings are subject to change throughout the year. We downloaded the FDA directories in the first quarter of 2017.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

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[19] According to CMS, it is possible that States may not have claimed Federal reimbursement for the total drug reimbursement amount listed in the "Medicaid Amount Reimbursed" field in CMS's 2016 State Drug Utilization Data file. States report actual payment data for prescription drugs to the Medicaid Budget and Expenditure System. However, we could not use this system to identify reimbursement for individual drugs because this system does not include NDC-level data.

[20] States report utilization of drugs to CMS whether or not they appear in the Medicaid drug product file. A drug may not be listed in the Medicaid drug product file for a number of reasons, including that the manufacturer did not report it to CMS.

FINDINGS

One percent of drugs with Medicaid reimbursement in 2016 were not FDA-approved

Ninety-six percent of drugs with Medicaid reimbursement in 2016 were FDA-approved for safety and effectiveness. However, Medicaid reimbursed for a small percentage of drugs (1 percent, or 267 drugs) that were not FDA-approved, as shown in in Exhibit 1. Medicaid reimbursement for these 267 drugs totaled $34 million in 2016.[21] According to data in the 2016 Medicaid drug product file, these drugs did not have Medicaid exceptions for coverage. It is possible that reimbursement for some of these 267 drugs may not have been appropriate.

Exhibit 1: Nearly all drugs with Medicaid reimbursement were FDA-approved[1]

- FDA-approved
- Not FDA-approved
- Unable to determine
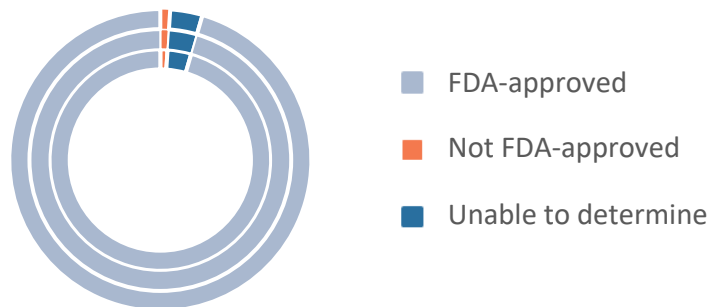
Source: OIG analysis of Medicaid and FDA data, 2016.
[1] We did not include drugs that, based on 2016 Medicaid and FDA data, were identified as over-the-counter drugs; drugs that were unapproved with an exception; prescription prenatal vitamins or fluoride preparations; or dietary supplements.
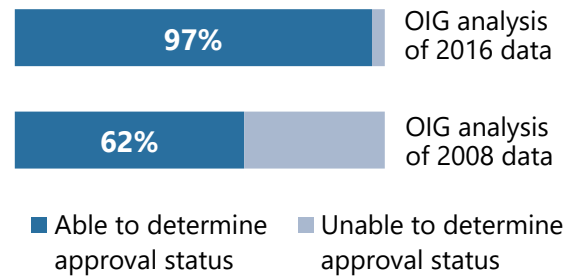
The ability to determine the FDA approval status of drugs has improved, making it easier for Medicaid to avoid inappropriate reimbursement for unapproved drugs

We were able to determine the FDA approval status for a greater percentage of drugs in 2016 than in 2008. Since our last review, FDA implemented our recommendation to improve the completeness and accuracy of its directory to ensure the directory's integrity for CMS and all other stakeholders. As a result, we were able to determine the FDA approval status—i.e., FDA-approved or not FDA-approved—for nearly all drugs (97 percent) with Medicaid reimbursement in 2016. In contrast,

[21] Of the 267 non-FDA-approved drugs, 125 were not listed in the Medicaid drug product file in 2016. Therefore, we were unable to determine whether any of these 125 drugs qualified for a coverage exception. Because manufacturers generally are required to report their drugs to CMS in order to qualify for coverage under Medicaid, these drugs may also have been ineligible for Medicaid reimbursement due to their coverage status.

we were able to determine the FDA approval status of only 62 percent of drugs with Medicaid reimbursement in 2008, as shown in Exhibit 2.[22]

97%	OIG analysis of 2016 data
62%	OIG analysis of 2008 data

■ Able to determine approval status   ■ Unable to determine approval status

Source: OIG analysis of Medicaid and FDA data, 2016.

However, Medicaid still reimbursed $30 million in 2016 for 936 drugs for which we were unable to determine an FDA approval status.[23] Specifically, Medicaid reimbursed $29 million for 913 drugs that were not listed in the FDA directories.[24] Of these 913 drugs, 869 (95 percent) may have been ineligible for Federal reimbursement because they also were not included in the Medicaid drug product file. Manufacturers generally are required to report all of their covered drugs in the Medicaid drug product file to qualify for Federal reimbursement under Medicaid.

For an additional 23 drugs, we were unable to determine whether the $1 million in Medicaid reimbursement was appropriate because the drugs were potentially miscategorized as devices or medical foods (19 drugs); there was conflicting data across FDA directories (1 drug); or the drugs were approved for export only (3 drugs).

Improvements in CMS's oversight may not have entirely prevented potentially inappropriate reimbursement for drugs that were not FDA-approved

Since 2014, CMS has made improvements in its oversight of Medicaid drug product data. CMS stated that it updated its Drug Data Reporting for Medicaid System (reporting system) to review drugs' FDA listing status.[25] In addition, CMS noted that it reviews drugs that are newly entered into the reporting system by manufacturers. As part of these

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[22] OIG, _FDA's Approval Status of Drugs Paid for by Medicaid_, OEI-03-08-00500, November 2010.

[23] The $30 million in reimbursement for the 936 drugs for which we were unable to determine an FDA approval status accounted for less than 1 percent of Medicaid reimbursement for all drugs in 2016.

[24] We conducted this analysis using 11-digit NDCs because manufacturers are required to report their drugs to CMS and FDA at this level. CMS verifies drugs' FDA approval status at the 9-digit NDC level. We conducted an additional analysis using the 9-digit NDCs after removing the 2 digits that represent the drugs' package sizes. The 913 11-digit NDCs that were not in the FDA directories were associated with 760 unique 9-digit NDCs. We found that 662 of the unique 9-digit NDCs were not included in the FDA directories or the Medicaid drug product file.

[25] The FDA listing status provides information about the application type under which a drug was approved.

reviews, CMS compares each drug's manufacturer-reported covered outpatient drug status to its FDA approval status.

Although CMS implemented a number of additional oversight activities in recent years, our findings demonstrate that improvements to CMS's reporting system may not have identified all drugs in need of additional review regarding their FDA approval status and appropriateness of payment.

In addition, we identified 869 drugs with Medicaid reimbursement that were missing from both the Medicaid drug product file and the FDA directories in 2016. CMS's reporting system cannot determine an FDA approval status for drugs that are not listed in these files. Further, CMS would not be able to verify the Medicaid coverage status of these drugs during its quarterly reviews of FDA data.

CONCLUSION AND RECOMMENDATIONS

To qualify for Federal reimbursement under Medicaid, drugs must be FDA-approved, with some exceptions. We found that 96 percent of Medicaid-reimbursed drugs in 2016 were FDA-approved. However, Medicaid reimbursed $34 million in 2016 for a small percentage of drugs that were not FDA-approved. In addition, we were unable to determine the FDA approval status of 936 drugs for which Medicaid reimbursed $30 million in 2016.

Since our previous review of the FDA approval status of drugs with Medicaid reimbursement in 2008, FDA has improved the completeness and accuracy of its directories. These improvements have led to better coordination with CMS and strengthened CMS's ability to verify drugs' FDA approval status.

However, it is possible that CMS procedures may not have entirely prevented potentially inappropriate reimbursement for drugs that were not FDA-approved. As a result, continued improvements are needed to ensure that Medicaid does not inappropriately reimburse for drugs that are not FDA-approved.

Therefore, we recommend that CMS:

Work with States to recoup any potentially inappropriate Federal reimbursement for drugs that CMS determines were not FDA-approved and did not meet the criteria for an exception

Medicaid reimbursed $34 million in 2016 for 267 drugs that were not FDA-approved. In addition, Medicaid reimbursed $30 million for 936 drugs for which we were unable to determine the FDA approval status. We have provided CMS with the lists of these drugs, and we recommend that CMS review these drugs to determine whether the Medicaid drug product file should be updated to reflect the drugs' most recent FDA approval status.

In addition, CMS should review reimbursement for these drugs to determine whether reimbursement for any unapproved drugs was inappropriate. CMS should work with individual States to recoup any inappropriate reimbursement, and CMS should ensure that States repay the Federal Government for its share of any potentially inappropriate reimbursement for non-FDA-approved drugs that did not meet the Federal criteria for an exception.

Continue to improve its reporting system to prevent inappropriate reimbursement for drugs that are not FDA-approved

CMS should continue to improve its reporting system. CMS stated that it is working on a new system that will expand its ability to oversee data for all drugs in the Medicaid Drug Rebate Program. As CMS develops its new system, we recommend that CMS include system queries to review the FDA approval status of all drugs in the Medicaid Drug Rebate Program more often than quarterly.

If CMS identifies drugs that are not FDA-approved and do not qualify for any exceptions, or it cannot determine a drug's FDA approval status, CMS should flag these drugs in the Medicaid drug product file to identify drugs that may not be eligible for Federal reimbursement under Medicaid.

Work with States to ensure that they prevent inappropriate reimbursement for drugs that are not FDA-approved and do not meet the criteria for an exception

CMS should continue to reinforce the need for State oversight to prevent Federal reimbursement for drugs that are not FDA-approved when Federal exceptions do not apply. In addition to CMS correcting the Medicaid drug product file, CMS should continue to encourage States to independently track drugs' FDA approval status to avoid requesting Federal reimbursement for drugs that are not FDA-approved. CMS also should encourage States to—before they request Federal reimbursement—regularly check the Medicaid drug product file to ensure that drugs are listed in this file and appropriately covered by Medicaid. To accomplish this, CMS could issue guidance to States, e.g., in a State Medicaid Director letter.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with all three of our recommendations.

In response to our first recommendation, CMS stated that it will review OIG's findings to determine whether reimbursement for any unapproved drugs was inappropriate.

In its response to our second recommendation, CMS said that it continually examines its oversight of the Medicaid Drug Rebate Program and implements improvements. Specifically, CMS stated that it has implemented improvements to its reporting system to review all products on a quarterly basis and to review newly reported products in real time, and that its reporting system has flags to identify drugs' FDA marketing categories, including their approval status.

In response to our third recommendation, CMS stated that it will review OIG's findings to determine whether working with States to prevent inappropriate reimbursement is warranted.

In addition, CMS expressed concern with our analysis, noting that some of the drugs included in our analysis may be covered by Medicaid under a statutory exception even if they are not FDA-approved. We acknowledge these coverage exceptions throughout the report, and we removed from our analysis any drugs that we could determine met the exceptions criteria. However, as CMS acknowledges, indepth reviews are needed for some drugs to determine whether they qualify for a coverage exception or were reimbursed inappropriately.

Our recommendation is that CMS conduct these indepth reviews of the drugs we identified as not FDA-approved to determine whether they qualified for an exception or were reimbursed inappropriately, and then take appropriate action. We encourage CMS to also include in its indepth reviews the drugs for which we were unable to determine an FDA approval status, due to the completeness or accuracy of the FDA directories. We acknowledge that this likely will require working with FDA, given that FDA—not CMS—is responsible for the data in those directories. This effort may lead to continued improvements to those FDA directories, as will sharing this report with FDA.

For the full text of CMS's comments, see Appendix B.

APPENDIX A: FDA Approval Status of Drugs With Medicaid Reimbursement

Exhibit 3 provides information about OIG's determinations for drugs with Medicaid reimbursement in 2016 based on their FDA approval status.

Exhibit 3: Finding Categories for Drugs with Medicaid Reimbursement in 2016

OIG's Analysis Determination	FDA Approval Status	Description of FDA Approval Status	Number of Drugs	Medicaid Reimbursement
FDA-approved	Abbreviated new drug application	Product that is approved for marketing as a generic drug	18,654[1]	$11,309,148,079
	Biologic license application	Product that is approved for marketing as a biologic, e.g., gene therapies and allergenics	629	$7,318,152,100
	New drug application (NDA)	Product that is approved for marketing as a new drug	5,384	$39,166,485,206
	NDA authorized generic	Product approved as a brand-name drug that is marketed without the brand-name label	1,105	$1,851,644,056
Not FDA-approved	Unapproved	Product that has not received FDA approval for marketing	267	$34,494,321
Unable to determine	Conflicting marketing categories across FDA directories	Product listed as approved in one FDA directory and unapproved in the other FDA directory	1	$4,644
	Exempt device	Medical device that does not require FDA clearance prior to marketing	8	$151,934
	Export only	Product that is only exported and not marketed in the United States	3	$3,348
	Medical food	Product consistent with the definition of medical food under section 5(b)(3) of the Orphan Drug Act	8	$610,158
	Missing from FDA directories	Product not listed in either FDA directory	913	$28,839,992
	Premarket notification (device)	Premarket submission to demonstrate that a device is at least as safe and effective as a legally marketed device	3	$11,117
		Total	**26,975**	**$59,709,544,956**

[1] One drug was listed with an abbreviated new drug application in one FDA directory, but listed with a new drug application in another FDA directory. We included this drug with those approved under abbreviated new drug applications.

Note: Because of rounding, numbers in columns may not sum to totals shown.

Source: FDA, *Data Standards Manual (monograph) Marketing Category*. Accessed at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManual monographs/ucm071826.htm on January 11, 2018; FDA, *Frequently Asked Questions about the FDA Drug Approval Process*. Accessed at https://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm279676.htm on October 8, 2017; FDA, *Learn if a Medical Device Has Been Cleared by FDA for Marketing*. Accessed at https://www.fda.gov/medicaldevices/resourcesforyou/consumers/ucm142523.htm on September 19, 2017; FDA, *Unapproved Prescription Drugs: Drugs Marketed in the United States that do not Have Required FDA Approval*. Accessed at

https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/selectedenforcementactionsonunapproveddrugs/default.htm on January 11, 2018; FDA, *FDA List of Authorized Generic Drugs*. Accessed at https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/ucm126389.htm on October 4, 2017; FDA, *FAQs about Medical Foods.* Accessed at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM500094.pdf on July 16, 2018; FDA, *Drugs@FDA Glossary of Terms*. Accessed at https://www.fda.gov/drugs/informationondrugs/ucm079436.htm on July 23, 2018; FDA, *Marketing Category*. Accessed at https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162528.htm on July 23, 2018.
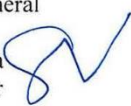
APPENDIX B: Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAR - 4 2019

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "One Percent of Drugs with Medicaid Reimbursement were Not FDA Approved" (OEI-03-17-00120)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is strongly committed to its oversight of the Medicaid Drug Rebate Program.

CMS appreciates the work OIG has done to review the Food and Drug Administration (FDA) approval status of covered outpatient drugs in the Medicaid Drug Rebate Program and notes OIG indicated at least 96 percent of drugs with Medicaid utilization in 2016 were appropriately reimbursed. CMS is committed to ensuring covered outpatient drugs are appropriately reimbursed and has made several improvements to the Medicaid Drug Rebate Program system to review all products on a quarterly basis and newly-reported products in real-time. CMS also has flags in its reporting system to identify FDA marketing status, including approval.

As CMS indicated to OIG during the course of this audit, Section 1927 of the Social Security Act (the Act) allows for reimbursement of certain drugs not approved by FDA. Such excepted products may include prenatal vitamins, fluoride preparations, and alternative treatments available during a drug shortage. Because excepted products may be appropriately covered and paid for under the Medicaid Drug Rebate Program, CMS would expect that not all drugs that received Medicaid reimbursement would be FDA approved. As a result, the fact that a drug is not FDA approved does not necessarily mean that reimbursement for the product is inappropriate, as suggested by the OIG report.

As such, CMS continues to have concerns about OIG's analysis and application of its findings in this draft report. Based on OIG's findings and draft recommendations, CMS believes an in-depth review of OIG's findings is required to determine whether working with States to prevent and recoup inappropriate Medicaid reimbursement is warranted. As OIG notes, administering the Medicaid Drug Rebate Program requires reporting and coordination between drug manufacturers, the FDA, CMS, and State Medicaid programs. For its in-depth review, CMS will examine each aspect of the information reported from various stakeholders to determine the correct course of action.

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Specifically, CMS will review the list of drugs OIG provides to determine if the 267 Medicaid-reimbursed drugs (one percent of all drugs in the program) that were not FDA approved either had an exception or were otherwise appropriately reimbursed. There are a small number of drugs that are not able to be listed in the FDA directory, but are eligible drugs for reimbursement. It is also important to note that 125 of these 267 drugs were not in the CMS Medicaid drug product file; therefore, it is unclear how OIG determined these drugs did not have Medicaid exceptions that allowed for Medicaid reimbursement.[1] CMS maintains that OIG's findings continue to include prescription vitamins and minerals that may be appropriately covered regardless of their FDA approval status.

In addition, OIG found that 914 of the 936 drugs for which they were unable to determine an FDA-approval status are missing from, or have conflicting marketing categories across, FDA directories. CMS cannot fully address the completeness and accuracy of the FDA's directories.[2] Therefore, CMS will ensure FDA is aware of this draft report and its findings. Additionally, OIG's inability to determine a drug's FDA approval status does not indicate that the drug is necessarily unapproved or inappropriately reimbursed.

As OIG states in this draft report, improvements made by the FDA resulted in a dramatic increase in the ability to determine the FDA approval status of a product in the Medicaid Drug Rebate Program. Since OIG last examined this issue,[3] the percentage of drugs and products OIG was able to determine the FDA approval status for rose from 62 percent in 2008 to 97 percent in 2016.

OIG's recommendations and CMS's responses are below.

OIG Recommendation
Work with States to recoup any potentially inappropriate Federal reimbursement for drugs that CMS determines were not FDA approved and did not meet the exceptions criteria.

CMS Response
CMS concurs with this recommendation. As noted above, CMS continues to have concerns about OIG's analysis and application of its findings in this draft report. However, CMS will review OIG's findings to determine whether reimbursement for any unapproved drugs was inappropriate.

OIG Recommendation
Continue to improve its reporting system to prevent inappropriate reimbursement for drugs that are not FDA approved.

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[1] CMS clarifies that of the 267 drugs in this finding, OIG determined 142 (or 0.5 percent) of drugs that States report utilization and Medicaid reimbursement for were not FDA approved and did not meet an exception that allowed coverage despite its unapproved status.
[2] CMS notes that 76 percent of OIG's findings in this draft report are due to missing or conflicting information in the FDA directories.
[3] https://oig.hhs.gov/oei/reports/oei-03-08-00500.pdf

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CMS Response

CMS concurs with this recommendation. CMS continually examines its oversight of the Medicaid Drug Rebate Program and implements improvements. As stated above, CMS implemented improvements to the Medicaid Drug Rebate Program system to review all products on a quarterly basis and newly-reported products in real-time. CMS also has flags in its reporting system to identify FDA marketing status, including approval.

OIG Recommendation

Work with States to ensure they prevent inappropriate reimbursement for drugs that are not FDA approved and do not meet the exceptions criteria.

CMS Response

CMS concurs with this recommendation. As noted above, CMS continues to have concerns about OIG's analysis and application of its findings in this draft report. However, CMS will review OIG's findings to determine whether work with States to prevent inappropriate reimbursement is warranted.

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ACKNOWLEDGMENTS