Department of Health and Human Services
Office of Inspector General
Office of Audit Services

August 2026 | OAS-24-02-004

CMS Oversight Did Not Prevent Medicare Part D Sponsors From Making $587.7 Million in Ineligible Payments to Pharmacies for Drugs Available Over the Counter but Labeled as Prescription-Only

REPORT HIGHLIGHTS

August 2026 | OAS-24-02-004

CMS Oversight Did Not Prevent Medicare Part D Sponsors From Making $587.7 Million in Ineligible Payments to Pharmacies for Drugs Available Over the Counter but Labeled as Prescription-Only

Why OIG Did This Audit

- CMS contracts with Medicare Advantage organizations and private prescription drug plans (collectively referred to as "sponsors" in this report) to offer Part D managed care benefits to eligible Medicare enrollees. Medicare Part D does not cover products that may be purchased without a prescription (e.g., over-the-counter [OTC] drugs).
- In 2022, a drug manufacturer agreed to pay $7.9 million for causing the submission of false claims to Medicare Part D sponsors by continuing to sell three generic drugs under obsolete prescription-only (Rx-only) labeling after the brand-name drugs were switched to OTC. We conducted this nationwide audit to determine whether CMS oversight of Medicare Part D sponsors ensured compliance with Federal requirements for preventing payment for OTC drugs sold under obsolete Rx-only labeling.

What OIG Found

CMS oversight of Medicare Part D sponsors did not prevent payments to pharmacies for some OTC drugs sold under obsolete Rx-only labeling.

- Part D sponsors made payments for five drugs associated with obsolete Rx-only labeling more than 1 year after the brand-name drugs were switched to OTC use. For calendar years (CYs) 2021 through 2023, Part D sponsors made $587.7 million in ineligible payments associated with the five drugs.
- The ineligible payments occurred because CMS: (1) updated its Part D Formulary Reference File using obsolete FDA data on Rx-only drugs and (2) did not set a timeframe for Part D sponsors to reject payments for OTC drugs sold under obsolete Rx-only labeling.
- Before we issued our draft report, FDA issued a policy in December 2025 requiring generic drug manufacturers to update their labeling "at the earliest time possible and within 6 months" after FDA approves an associated brand-name drug's switch from Rx-only to OTC use.

What OIG Recommends

We recommend that CMS issue guidance on timeframes for Part D sponsors to reject payments for OTC drugs sold under obsolete Rx-only labeling after an Rx-to-OTC switch. This step could have helped to prevent $587.7 million in ineligible payments for CYs 2021 through 2023.

CMS concurred with our recommendation.

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INTRODUCTION

WHY WE DID THIS AUDIT

The Centers for Medicare & Medicaid Services (CMS) contracts with Medicare Advantage organizations and private prescription drug plans (collectively referred to as "sponsors" in this report) to offer Part D managed care benefits to eligible Medicare enrollees. Part D sponsors must submit to CMS valid prescription drug event (PDE) data for each drug provided to a Medicare enrollee.[1] Medicare Part D does not cover products that may be purchased without a prescription (e.g., over-the-counter [OTC] drugs).[2]

In September 2022, a drug manufacturer agreed to pay $7.9 million to resolve allegations that it caused the submission of false claims to Medicare Part D sponsors for three generic drugs that were no longer eligible for Medicare coverage.[3] According to the Department of Justice, this drug manufacturer caused the false claims to be submitted by continuing to sell the generic drugs under obsolete prescription-only (Rx-only) labeling after the Food and Drug Administration (FDA) approved the brand-name drugs' switch to OTC.[4] Even though this drug manufacturer continued to sell its generic drugs under obsolete Rx-only labeling, Part D sponsors should have removed these generic drugs from their formularies because the drugs no longer met Part D drug coverage requirements.[5]

We conducted this nationwide audit of Medicare Part D PDE data to identify payments for OTC drugs sold under obsolete Rx-only labeling.

OBJECTIVE

Our objective was to determine whether CMS oversight of Medicare Part D sponsors ensured compliance with Federal requirements for preventing payment for OTC drugs sold under obsolete Rx-only labeling.

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[1] 42 CFR § 423.329(b)(3).

[2] Section 1860D-2(e) of the Social Security Act, 42 CFR § 423.100 (defining Part D drug), and CMS, *Medicare Prescription Drug Benefit Manual*, chapter 6, sections 10.10 and 20.1.

[3] Department of Justice, "Pharmaceutical Company Akorn Agrees to Pay $7.9 Million For Allegedly Causing Medicare to Pay for Invalid Prescription Drugs," Sept. 15, 2022. Accessed on June 3, 2026.

[4] Under 21 CFR § 314.94(a)(8)(iv), a generic drug must generally have the same labeling as the related brand-name drug. When a brand-name drug switches from Rx-only to OTC labeling, the generic drug's Rx-only labeling becomes obsolete and is deemed to be misbranded under 21 U.S.C. § 353(b)(4).

[5] A Part D sponsor's formulary is the list of Part D drugs covered by that sponsor.

BACKGROUND

Medicare Part D Drug Coverage

Covered Part D drugs are defined in section 1860D-2(e) of the Social Security Act as drugs or biological products that may be dispensed only upon prescription. This definition does not include OTC products that may be purchased without a prescription.[6] Rx-only drugs require health practitioner supervision to be considered safe for use and may be dispensed only by prescription, while OTC drugs may be used without a prescriber's authorization.[7]

FDA Oversight of Prescription-to-Nonprescription Switches

FDA regulates the safety and effectiveness of Rx-only and OTC drugs sold in the United States. Rx-only drugs are marketed after FDA approves new drug applications (NDAs) for brand-name drugs and abbreviated new drug applications (ANDAs) for generic equivalents. FDA publishes *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book), which lists all approved NDAs and ANDAs, including the drug manufacturers (application holders).[8] FDA also maintains a National Drug Code (NDC) Directory that includes the application number and marketing start and end dates for each listed drug product and its associated 11-digit NDC.[9] To populate its NDC Directory, FDA relies on drug manufacturers to submit their drug listings and annually certify their accuracy.[10]

Rx-only drug manufacturers may seek FDA approval for a prescription-to-nonprescription (Rx-to-OTC) switch. FDA approves an Rx-to-OTC switch application if it determines that the previous Rx-only status is not necessary for the protection of the public health and that the drug is safe and effective for use in self-medication as directed in the manufacturer's proposed labeling. The manufacturer may choose a full or partial switch.[11, 12]

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[6] CMS, *Medicare Prescription Drug Benefit Manual*, chapter 6, section 10.10.

[7] Hassan Z. Sheikh, Congressional Research Service, *FDA Regulation of Over-the-Counter (OTC) Drugs: Overview and Issues for Congress* (CRS R46985), Dec. 10, 2021.

[8] FDA, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*. Accessed on June 3, 2026.

[9] FDA, "National Drug Code Directory." Accessed on June 3, 2026.

[10] 21 U.S.C. § 360(j)(1) and 21 CFR § 207.57(b)(2).

[11] FDA, "Prescription-to-Nonprescription (Rx-to-OTC) Switches." Accessed on June 3, 2026.

[12] Under a full switch, a drug is switched in its entirety to OTC marketing status for all of its approved conditions of use. Under a partial switch, a drug is approved for OTC use for certain conditions described in the new OTC labeling while remaining an Rx drug for other conditions.

To inform generic drug manufacturers and other parties of brand-name drug switches, FDA publishes an Rx-to-OTC switch list on its public internet site.[13] Following FDA approval of a brand-name drug's full Rx-to-OTC switch, manufacturers of generic equivalents are required to make their own Rx-to-OTC switches or cease marketing their generic equivalents; for partial switches, generics may remain Rx for the remaining prescription conditions of use.[14] According to FDA guidance issued in January 2024, generic drug manufacturers should routinely monitor FDA's internet site for information on changes in drug labeling and timely submit switch applications to FDA. Though FDA did not specify a timeframe for these manufacturers to submit their switch applications, it recommended that submissions be made at the earliest time possible.[15, 16] FDA may withdraw its approval of a generic drug and remove the associated NDCs from the NDC Directory if the generic drug labeling is no longer consistent with the brand-name drug labeling and FDA deems the drug to be misbranded.[17]

FDA Post-Switch Monitoring of Nonprescription Drugs

After a drug is switched from Rx-only to OTC, the drug manufacturer must contact FDA to delist the discontinued Rx-only NDC and list a new OTC NDC.[18] Each January, FDA identifies and inactivates drug listings that were neither updated during the previous calendar year (CY) nor certified within the annual registration renewal period. When generic drug manufacturers do not update their labeling after a brand-name drug's Rx-to-OTC switch, FDA may inactivate their drug listings as a last step after repeated notifications.[19] Because FDA did not have a timeframe to determine noncompliance with the Rx-to-OTC switch, FDA stated that it relied on complaints from other drug manufacturers to initiate its notification process.

[13] FDA, "Prescription to Nonprescription Switch List." Accessed on June 3, 2026.

[14] 21 CFR § 314.94(a)(8)(iv).

[15] FDA, *Revising ANDA Labeling Following Revision of the RLD Labeling: Guidance for Industry*, January 2024. This final guidance revised an initial guidance issued in May 2000. Accessed on June 3, 2026.

[16] In December 2025, FDA issued a policy requiring generic drug manufacturers to update their labeling "at the earliest time possible and within 6 months" after FDA approves an associated brand-name drug's Rx-to-OTC switch. (FDA, *Manual of Policies and Procedures 5200.11: Prescription to Nonprescription Switches and Abbreviated New Drug Applications*. Accessed on June 3, 2026.)

[17] 21 U.S.C. § 353(b)(4) and 21 CFR § 314.150(b)(10).

[18] 21 U.S.C. § 360(j)(2), 21 CFR §§ 207.57(b)(2) and 207.35(b)(4).

[19] Before inactivating a drug listing, FDA notifies the drug manufacturer that an update is needed. FDA will reactivate an inactivated drug listing if the drug manufacturer submits a full and corrected listing. (Paul Loebach, "Drug Listing Inactivations: An Overview: Electronic Drug Registration and Listing Using CDER Direct" [workshop given Oct. 13, 2021]. Accessed on June 3, 2026.)

CMS Guidance on Prescription-to-Nonprescription Switches

CMS monitors Part D drugs for product-related changes, including Rx-to-OTC switches found on FDA's Rx-to-OTC switch list. After CMS identifies an Rx-to-OTC switch, CMS removes the associated OTC drug from its monthly Formulary Reference File (FRF), which lists drug products that Part D sponsors can include in their formularies.[20] CMS updates the FRF using FDA data (e.g., NDC Directory and Orange Book) and commercially available databases.[21]

A Part D sponsor that uses a formulary for its qualified prescription drug coverage must submit its formulary to CMS for approval.[22] When a drug on a Part D sponsor's formulary switches from Rx-only to OTC status, the drug manufacturer's inventory of Rx-only product available for purchase continues to satisfy the Part D drug definition. After the OTC product becomes available for purchase, CMS updates the FRF and directs sponsors to remove the Rx-only product from their formularies.[23]

CMS Process for Rejecting Nonprescription Drugs in Part D Data

CMS's Drug Data Processing System (DDPS) automatically checks the NDC for each PDE received from a Part D sponsor to determine payment eligibility. Specifically, DDPS accesses multiple FDA and commercially available databases to determine whether the associated drug is brand-name, generic, or OTC. For OTC drugs identified in one of the drug databases, an OTC category code is assigned to the NDC. If a Part D sponsor attempted to submit that OTC drug as a covered Part D drug instead of as a noncovered drug,[24] DDPS would reject the PDE. DDPS would also reject the PDE if the date of service falls outside the NDC's marketing start and end dates in the NDC Directory. However, CMS has no control over the accuracy or completeness of NDC data in FDA or commercially available databases.

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[20] Part D sponsors cannot cover OTC products under their basic prescription drug benefit or as a supplemental benefit but may provide them at no cost to enrollees out of their own administrative budget (CMS, *Medicare Prescription Drug Benefit Manual*, chapter 6, section 10.10). CMS guidance states that Part D sponsors are ultimately responsible for making coverage determinations and should not necessarily include or exclude a drug product from coverage based solely on the presence or absence of a drug code on the FRF.

[21] Tracey McCutcheon, Acting Director, Medicare Drug Benefit and C&D Data Group, CMS, "Formulary Reference File Frequently Asked Questions," memo to all Part D sponsors (Apr. 8, 2014). Accessed on June 3, 2026.

[22] 42 CFR § 423.120(b)(2)(iv).

[23] CMS, *Medicare Prescription Drug Benefit Manual*, chapter 6, section 10.10.

[24] CMS, *Medicare Prescription Drug Benefit Manual*, chapter 7, section 60.2.

HOW WE CONDUCTED THIS AUDIT

Our audit covered all payments made by Medicare Part D sponsors for prescriptions filled during CYs 2021 through 2023 (audit period) for Rx-only drugs that had switched to OTC, including brand-name and generic drugs.[25] Specifically, we analyzed Medicare Part D PDE data to identify payments for certain OTC drugs sold as Rx-only drugs more than 1 year after the brand-name drugs became available for purchase as OTC drugs.[26]

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A describes our audit scope and methodology.

FINDING

CMS oversight of Medicare Part D sponsors did not ensure compliance with Federal requirements for preventing payments to pharmacies for some OTC drugs sold under obsolete Rx-only labeling. Part D sponsors made payments for 5 drugs listed under 35 NDCs associated with obsolete Rx-only labeling more than 1 year after the brand-name drugs became available for purchase as OTC drugs. These ineligible payments for OTC drugs occurred because CMS: (1) updated its FRF using FDA data that contained NDCs associated with obsolete Rx-only labeling and (2) did not set a timeframe for Part D sponsors to reject payments for OTC drugs sold under obsolete Rx-only labeling. As a result, for CYs 2021 through 2023, Part D sponsors made $587.7 million in payments for 16.8 million PDEs associated with five of the six drugs that switched from Rx-only to OTC during CYs 2020 through 2022.[27] Payments for these drugs are detailed in the table on the next page.

[25] Our audit period was determined based on the most recent data available at the time we began the audit.

[26] To account for existing inventories of Rx-only labeled drugs available for purchase after each Rx-to-OTC switch, we applied a 1-year grace period for drug manufacturers to switch their labeling of generic equivalents to OTC or sell their remaining inventories of Rx-only labeled drugs. Therefore, we identified payments that ranged from CYs 2021 through 2023 for the drugs that switched from Rx-only to OTC during CYs 2020 through 2022.

[27] Part D payments for the five OTC drugs totaled $184 million for 2021, $194.54 million for 2022, and $209.14 million for 2023. We are not recommending recovery because these payments by Part D sponsors complied with CMS's FRF and guidance on existing inventories of Rx-only labeled drugs after a brand-name drug's Rx-to-OTC switch. The sixth drug had no improper payments.

Table: Part D Payments for Five OTC Drugs During CYs 2021 Through 2023

Prescription Brand Name/Active Ingredient (Generic Equivalent)	Brand-Name Rx-to-OTC Switch Date	Part D PDEs	Ineligible Payments	Associated NDCs
Voltaren (diclofenac sodium)	2/14/2020	15,870,464	$562,073,487	12
Pataday (olopatadine hydrochloride)	2/14/2020	885,950	25,506,367	16
Astepro (azelastine hydrochloride)	6/17/2021	2,414	95,703	5
Lastacaft (alcaftadine)	12/10/2021	13	3,413	1
Sklice (ivermectin)	10/27/2020	6	1,469	1
Total		**16,758,847**	**$587,680,439**	**35**

PART D SPONSORS MADE INELIGIBLE PAYMENTS FOR NONPRESCRIPTION DRUGS

Part D sponsors made payments for five drugs associated with obsolete Rx-only labeling more than 1 year after the brand-name drugs were switched to OTC use. For example, Part D sponsors made $562.1 million in payments for almost 16 million PDEs associated with generic equivalents of Voltaren (a topical drug used to treat arthritis pain) more than 1 year after the brand-name drug became available for purchase as an OTC drug. The sponsors made payments for 12 different NDCs associated with generic equivalents of the drug.

The ineligible payments for the five drugs occurred because, in part, CMS relied on FDA data (e.g., the NDC Directory) to identify Rx-to-OTC switches.[28] However, if a brand-name Rx-only drug switched to OTC in the NDC Directory but its generic equivalents did not update their own labeling (i.e., the drugs remained listed as Rx-only drugs), the NDC Directory continued to report the generic equivalents under their Rx-only labeling and NDCs.[29] Therefore, the FDA data on which CMS relied contained some NDCs associated with obsolete Rx-only labeling that were not updated.

Also, when a drug on a Part D sponsor's formulary switches from Rx-only to OTC status, CMS allows drug manufacturers to sell their existing inventories of the Rx-only labeled product under Part D.[30] However, CMS did not set a timeframe for Part D sponsors to begin rejecting payments for inventories with obsolete Rx-only labeling. Some generic drug manufacturers continued producing and selling OTC drugs as Rx-only inventories under NDCs associated with obsolete Rx-only labeling. For example, even though Voltaren became available for purchase as

[28] Tracey McCutcheon, Acting Director, Medicare Drug Benefit and C&D Data Group, CMS, "Formulary Reference File Frequently Asked Questions," memo to all Part D sponsors (Apr. 8, 2014). Accessed on June 3, 2026.

[29] We also noted that FDA did not set a timeframe for generic drug manufacturers to update their labeling after manufacturers of the related brand-name drugs switched their labeling to OTC.

[30] CMS, *Medicare Prescription Drug Benefit Manual*, chapter 6, section 10.10.

an OTC drug on February 14, 2020, eight of its generic equivalents continued to be sold as Rx-only drugs during CY 2023.

As a result, for CYs 2021 through 2023, Part D sponsors made $587.7 million in payments to pharmacies for 16.8 million PDEs associated with five of the six drugs that switched from Rx-only to OTC during CYs 2020 through 2022.

During our fieldwork, we provided the results of our analysis to CMS and FDA. Before we issued our draft report, FDA issued a policy on generic drugs related to a brand-name drug's full Rx-to-OTC switch. According to the policy, effective December 8, 2025, generic drug manufacturers should update their labeling "at the earliest time possible and within 6 months" after FDA approves an associated brand-name drug's full Rx-to-OTC switch. Also, FDA will notify these manufacturers that their generic drugs can no longer be marketed under misbranded Rx-only labeling.[31, 32] Therefore, we are not making a recommendation related to FDA data on NDCs associated with obsolete Rx-only labeling.

RECOMMENDATION

We recommend that CMS issue guidance on timeframes for Part D sponsors to reject payments for OTC drugs sold under obsolete Rx-only labeling after an Rx-to-OTC switch. This step could have helped to prevent $587.7 million in ineligible payments to pharmacies for CYs 2021 through 2023.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendation and indicated that it will issue guidance to Part D sponsors that is consistent with the updated FDA policy. CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix B.

[31] FDA, *Manual of Policies and Procedures 5200.11: Prescription to Nonprescription Switches and Abbreviated New Drug Applications*. Accessed on June 3, 2026.

[32] FDA wrote that though the new policy does not apply to partial prescription-to-nonprescription switches, generic drug manufacturers should update their labeling as early as possible and within 6 months after FDA approves a brand-name drug's partial switch.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered all payments made by Medicare Part D sponsors for prescriptions filled during CYs 2021 through 2023 (audit period) for Rx-only drugs that had switched to OTC, including brand-name and generic drugs. Specifically, we analyzed the Medicare Part D PDE data to identify payments for certain OTC drugs that were sold as Rx-only drugs more than 1 year after the brand-name drugs became available for purchase as OTC drugs.[33]

We did not assess CMS's or FDA's overall internal control structure. We limited our review of CMS's and FDA's internal controls to those applicable to our audit objective. Specifically, we reviewed CMS's policies and procedures for preventing Medicare Part D payments for OTC drugs and FDA's policies and procedures for the Rx-to-OTC switch of a brand-name drug and its generic equivalents.

We conducted our audit from October 2024 through June 2026.

METHODOLOGY

We took the following steps to accomplish our objective:

- Reviewed applicable Federal laws, regulations, and guidance
- Met with CMS officials to gain an understanding of CMS's internal controls for preventing Part D payments for OTC drugs
- Met with FDA officials to gain an understanding of FDA's internal controls for approval and oversight processes related to Rx-to-OTC switches of brand-name drugs and their generic equivalents
- Obtained and reviewed the FDA Rx-to-OTC switch list and identified for audit the six brand-name drugs associated with eight approved NDAs that switched from Rx-only to OTC status during CYs 2020 through 2022[34]

[33] To account for existing inventories of Rx-only labeled drugs available for purchase after each Rx-to-OTC switch, we applied a 1-year grace period for drug manufacturers to switch their labeling of generic equivalents to OTC or sell their remaining inventories of Rx-only labeled drugs. Therefore, we identified payments that ranged from CYs 2021 through 2023 for the drugs that switched from Rx-only to OTC during CYs 2020 through 2022.

[34] The six brand-name drugs on the Rx-to-OTC switch list were associated with eight NDAs because one drug (Pataday, an eyedrop used to treat itchy and red eyes) was associated with three NDAs (different dosages).

- Obtained and reviewed the NDC Directory, other FDA data sources, and CMS FRFs effective during CYs 2020 through 2022, and identified the generic equivalents and Rx-only NDCs associated with the six brand-name drugs selected for audit

- Obtained from CMS's Integrated Data Repository the Medicare Part D PDE payments data for covered drug prescriptions filled during CYs 2021 through 2023 for Rx-only NDCs associated with the six brand-name drugs selected for audit and their generic equivalents

- Matched the Rx-only NDCs to PDE data and identified all Part D payments for OTC drugs that were sold as Rx-only drugs during CYs 2021 through 2023 more than 1 year after the OTC drugs' marketing start dates on the NDC Directory

- Discussed the results of our audit with CMS and FDA officials

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: July 20, 2026

TO: Megan Tinker
Chief of Staff

FROM: Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *CMS Oversight Did Not Prevent Medicare Part D Sponsors From Making $587.7 Million in Ineligible Payments to Pharmacies for Drugs Available Over the Counter but Labeled as Prescription-Only (OAS-24-02-004)*

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 committed to its oversight of Medicare Part D sponsors and takes seriously its stewardship of taxpayer dollars.

As stated in the *Medicare Prescription Drug Benefit Manual*, the definition of a covered drug under Part D does not include over-the-counter drugs (OTCs).[1] Therefore, Part D sponsors cannot cover OTCs under their basic prescription drug benefit or as a supplemental benefit under enhanced alternative coverage.

CMS routinely monitors Part D drugs for product related changes, including prescription-to-OTC (Rx-to-OTC) switches. However, CMS's monitoring relies on the Food and Drug Administration's (FDA's) oversight of Rx-to-OTC switches. Rx-only drug manufacturers must seek FDA approval for a prescription-to-OTC switch, and if FDA approves, FDA publishes this change on its Rx-to-OTC switch list on its public internet site. CMS's process for identifying generic drugs associated with a brand-name drug's Rx-to-OTC switch relies on FDA data, such as the FDA's Rx-to-OTC public switch list, National Drug Code (NDC) Directory, and Orange Book. In addition to FDA data, CMS uses the commercially available database, Medispan. If CMS identifies an Rx-to-OTC switch, CMS removes the product(s) relevant to the switch from its Formulary Reference File (FRF), which lists drug products that Part D sponsors can include in their formularies. CMS updates the FRF using FDA data. As OIG states in its report, the FDA previously did not include a timeframe for associated generic drug manufacturers to submit their applications for approval for an Rx-to-OTC switch. However, during the course of OIG's audit, the FDA issued a policy requiring generic drug manufacturers to update the labeling of affected products within six months after FDA approves a full Rx-to-OTC switch for the corresponding brand-name drug. CMS believes this updated policy will address a substantial portion of OIG's finding.

[1] Please see https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf

Finally, when an existing formulary product switches to an OTC status during the contract year, any existing inventory of the previous legend product (manufactured under the legend New Drug Application (NDA) and possessing the legend NDC number) will continue to satisfy the Part D drug definition. Given the potential for beneficiaries requiring conversion to other therapeutically equivalent legend products, CMS strongly recommends immediate notification of affected enrollees.

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

OIG Recommendation

CMS should issue guidance on timeframes for Part D sponsors to reject payments for OTC drugs sold under obsolete Rx-only labeling after an Rx-to-OTC switch. This step could have helped to prevent $587.7 million in ineligible payments to pharmacies for CYs 2021 through 2023.

CMS Response

CMS concurs with this recommendation and will issue guidance to Part D sponsors that is consistent with the updated FDA policy.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

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