

# Medical Abortion: Action Needed to Ensure Compliance with Medicaid Drug Rebate Program

GAO-25-107911 [Accessible Version]

Q&amp;A

Report to Congressional Requesters

August 26, 2025

## Why This Matters

Outpatient prescription drug coverage is an optional benefit under Medicaid, a joint federal-state program that finances health care for certain low-income and medically needy individuals. Medicaid programs that choose to cover prescription drugs generally must cover all Food and Drug Administration (FDA) approved drugs for their medically accepted indications when those drugs are made by a manufacturer that participates in the Medicaid Drug Rebate Program (MDRP). The MDRP provides significant discounts to Medicaid programs in the form of rebates for certain outpatient prescription drugs.

Mifepristone is approved by the FDA, in a regimen with the prescription drug misoprostol, for the medical termination of an intrauterine pregnancy, known as a medical abortion. In September 2000, FDA approved Mifeprex—the brand name drug for mifepristone 200 mg—for medical abortions. In April 2019, FDA approved a generic equivalent, referred to as Mifepristone Tablets, 200 mg, for the same purpose. Both drugs are approved for medical abortion through 70 days gestation. While not approved for any other indications, both drugs have been used for “off-label” purposes to treat other conditions, such as uterine fibroids. Danco Laboratories and GenBioPro are the exclusive manufacturers of Mifeprex and Mifepristone Tablets, 200 mg, respectively, and both participate in the MDRP.

Within the Department of Health and Human Services (HHS) the Centers for Medicare & Medicaid Services (CMS) is responsible for monitoring Medicaid programs’ compliance with federal requirements, including those related to the MDRP. In 2019, we reported that CMS was unaware that some state Medicaid programs did not cover Mifeprex as statutorily required.

We were asked to update our findings on Medicaid programs’ coverage of mifepristone. This report examines Medicaid programs’ coverage of Mifeprex and Mifepristone Tablets, 200 mg, and identifies programs that claimed a Medicaid rebate for them in the last 5 years.

## Key Takeaways

- All 50 states, the District of Columbia, and Puerto Rico have opted to cover prescription drugs and participate in the MDRP. Thus, they are required to cover Mifeprex and Mifepristone Tablets, 200 mg for beneficiaries when prescribed for medical abortion in circumstances eligible for federal funding. This includes when the pregnancy is the result of rape or incest, or the life of the pregnant woman is endangered unless an abortion is performed.

- Officials from 35 of the 49 Medicaid programs who responded to our questions told us their programs covered Mifeprex and Mifepristone Tablets, 200 mg for medical abortion in at least certain circumstances, as of December 31, 2024. According to program officials from the remaining 14 states,
  - four programs covered these drugs, but not for medical abortion;
  - one program covered these drugs, but did not specify the medical indication for which they were covered; and
  - nine programs did not cover these drugs for any medical indication.
- In 2019, we recommended CMS take action to ensure states' compliance with MDRP requirements to cover Mifeprex. As of August 2025, CMS had not implemented this recommendation and was not aware that some programs did not cover Mifeprex as required. CMS was also not aware of coverage gaps related to Mifepristone Tablets, 200 mg.
- We reiterate the importance of CMS implementing our 2019 recommendation regarding coverage of Mifeprex, and we recommend that CMS determine the extent of Medicaid programs' compliance with federal requirements regarding coverage of Mifepristone Tablets, 200 mg, and take action to ensure compliance.

### **Are state Medicaid programs required to cover Mifeprex and Mifepristone Tablets, 200 mg?**

Medicaid programs that opt to cover prescription drugs—which all 50 states, the District of Columbia, and Puerto Rico do—are generally required to cover Mifeprex and Mifepristone Tablets, 200 mg.<sup>1</sup> Federal law does not require Medicaid programs to cover prescription drugs. However, Medicaid programs that opt to do so must cover all FDA-approved outpatient drugs for medically accepted indications of any manufacturer participating in the MDRP, except as outlined in federal law.<sup>2</sup> In return, participating manufacturers agree to rebate a specified portion of the price for each covered drug to the states, and states share this rebate with the federal government.<sup>3</sup>

According to CMS officials, Danco Laboratories and GenBioPro, the exclusive manufacturers of Mifeprex and Mifepristone Tablets, 200 mg, respectively, both participate in the MDRP. CMS issued a letter in March 2001 informing states of Danco Laboratories' participation in the MDRP for Mifeprex.<sup>4</sup> CMS officials told us they informed states that GenBioPro's Mifepristone Tablets, 200 mg was added to the MDRP in August 2019 through the MDRP database, which is updated quarterly to include drugs that were added to the program.

CMS officials also confirmed that none of the MDRP's statutory exceptions that would permit a state to exclude drugs from coverage apply to Mifeprex or Mifepristone Tablets, 200 mg. Thus, all 52 state Medicaid programs participating in the MDRP are required to cover both drugs when prescribed for medical abortion in circumstances eligible for federal funding. Specifically, while federal law prohibits federal funding for abortions in most circumstances, state Medicaid programs are required to cover an abortion if a beneficiary's pregnancy is the result of rape or incest, or the life of the pregnant woman would be endangered unless an abortion is performed.<sup>5</sup>

State Medicaid programs may impose certain reasonable restrictions on their coverage of outpatient prescription drugs, including Mifeprex and Mifepristone Tablets, 200 mg, such as prior authorization processes.<sup>6</sup> However, according to CMS officials, such limitations may not categorically exclude prescription drugs from coverage or result in the denial or unreasonable restriction of access to



**Accessible Data for Figure 1: Medicaid Programs’ Coverage of Danco Laboratories’ Mifeprex and GenBioPro’s Mifepristone Tablets, 200 mg, as of December 31, 2024**

State coverage	Number of states	States
Covered both drugs for medical abortion.	35	AL, AZ, CA, CO, CT, DE, DC, IL, IN, KS, ME, MD, MA, MI, MN, MO, MT, NE, NV, NH, NY, NC, ND, OH, OR, PA, RI, SD, TN, UT, VA, VT, WV, WI, WY
Covered both drugs, but not for medical abortion.	4	AR, IA, KY, SC
Covered both drugs, but did not specify the medical indications that coverage would be provided.	1	HI
Did not cover either drug for any medical indications.	9	AK, FL, GA, ID, LA, MS, OK, TX, PR
Did not respond to GAO questions.	3	NJ, NM, WA

Source: GAO analysis of state responses (data); map resources (map). | GAO-25-107911

Notes: We collectively refer to the 50 states, the District of Columbia, and Puerto Rico as “states.” We sent written questions regarding coverage of Mifeprex and Mifepristone Tablets, 200 mg to officials in the 52 states that participated in the Medicaid Drug Rebate Program (MDRP) as of December 2024. Four U.S. territories—American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands—have Medicaid programs, but did not participate in the MDRP as of December 2024.

We did not independently verify states’ responses. We did not ask states to specify the circumstances under which they would cover the drugs for medical abortion. However, officials from 10 states noted their programs’ coverage was limited to certain circumstances, such as when the pregnancy is the result of rape or incest, or when the life of the pregnant woman would be endangered unless an abortion is performed.

According to officials from the Centers for Medicare & Medicaid Services, Medicaid managed care plans may voluntarily provide services that are in addition to Medicaid benefits—often called value-added services—which could include certain prescription drugs. See 42 C.F.R. § 438.3(e)(1) (2024). We did not ask officials in states that do not cover Mifeprex and Mifepristone Tablets, 200 mg to identify whether Medicaid managed care plans in their states voluntarily covered these drugs; however, an official in one state told us that at least one managed care plan in the state covered at least one of the drugs.

We did not ask state officials to specify the circumstances under which they would cover the drugs for medical abortion. However, officials from 10 of the 35 states that covered the drugs for medical abortion noted their programs’ coverage was limited to circumstances eligible for federal funding. Additionally, officials from three of these 10 states told us their programs further limited coverage to the circumstance of life endangerment of the pregnant woman.<sup>10</sup>

We also did not ask state officials to provide information on any restrictions, including prior authorization requirements, they may place on coverage of Mifeprex or Mifepristone Tablets, 200 mg. However, in responding to our questions, officials from four states provided additional information describing restrictions on abortions eligible for federal funding as a condition of Medicaid payment. Such restrictions included requiring documentation that the pregnancy was the result of one of the circumstances eligible for federal funding.

### **What actions has CMS taken to ensure states’ compliance with Medicaid requirements related to coverage of Mifeprex and Mifepristone Tablets, 200 mg?**

CMS officials told us the agency has shared with states longstanding guidance on covering FDA-approved drugs under the MDRP. However, CMS has not taken other actions to ensure states’ compliance with MDRP requirements to cover Mifeprex and Mifepristone Tablets, 200 mg. Agency officials said they have not heard of any access issues related to these drugs and assumed that all states were covering them, as statutorily required.

As previously noted, however, officials from nine states told us their programs did not cover Mifeprex or Mifepristone Tablets, 200 mg for any medical indication, as of December 31, 2024. CMS officials told us they do not collect information on states’ prescription drug coverage and were unaware that these states did not cover the drugs. Four of the states were among the 14 states we identified in 2019 as not covering Mifeprex.<sup>11</sup> Mifepristone Tablets, 200 mg was not available

at the time of our 2019 report. In our 2019 report, we recommended CMS determine the extent to which states comply with MDRP requirements to cover Mifeprex, and take actions to ensure compliance, as appropriate. CMS agreed with our recommendation; however, as of August 2025, it had not been implemented.

Further, officials from an additional four states told us that as of December 31, 2024, their programs did not cover Mifeprex or Mifepristone Tablets, 200 mg when prescribed for medical abortion. CMS officials told us states must cover Mifeprex and Mifepristone Tablets, 200 mg for medical abortion in circumstances eligible for federal funding—specifically, when the beneficiary’s pregnancy is the result of rape or incest, or the life of the pregnant woman would be endangered unless an abortion is performed.

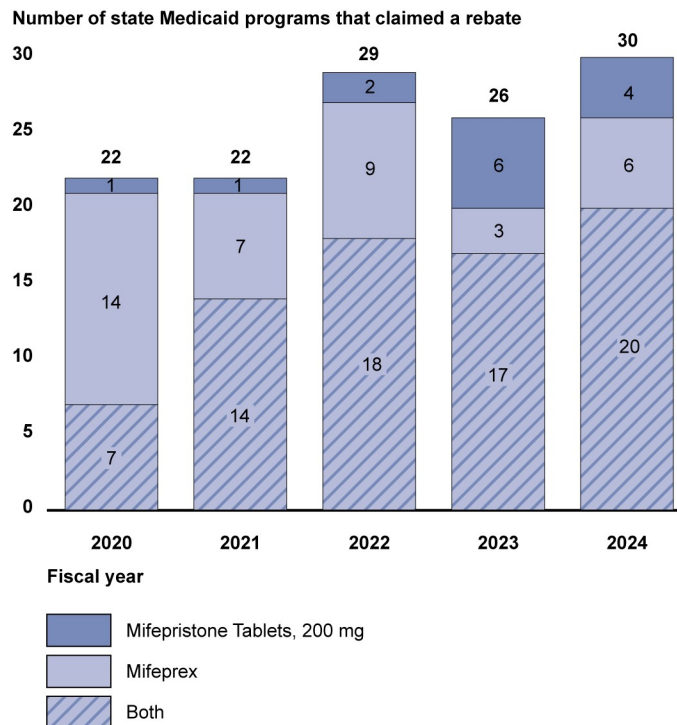
State officials’ responses to our questions indicated that some states may not be complying with MDRP coverage requirements for Mifeprex and Mifepristone Tablets, 200 mg. However, CMS has not determined the extent of states’ compliance with MDRP requirements for these drugs or taken actions to ensure states’ compliance, in part, because the agency has not implemented our 2019 recommendation, nor has it taken similar actions for Mifepristone Tablets, 200 mg. Without taking such actions, CMS cannot ensure that states comply with MDRP requirements. Additionally, Medicaid beneficiaries may not have access to Mifeprex and Mifepristone Tablets, 200 mg when prescribed for medical abortion in circumstances eligible for federal funding.

### **How many states claimed Medicaid rebates for Mifeprex or Mifepristone Tablets, 200 mg in the last 5 years?**

Our review of CMS’s Medicaid rebate data found that 37 of the 52 states that participate in the MDRP claimed a rebate from the manufacturers for Mifeprex, Mifepristone Tablets, 200 mg, or both drugs in at least one year between fiscal years 2020 and 2024.<sup>12</sup> During this 5-year period, the number of states that claimed a rebate for one or both drugs varied each year—ranging from 22 states in fiscal years 2020 and 2021, to 30 states in fiscal year 2024. (See fig. 2.) Additionally, the specific states that claimed a rebate for Mifeprex, Mifepristone Tablets, 200 mg, or both drugs varied each year.<sup>13</sup> (See app. I.)



**Figure 2: Number of States That Claimed a Medicaid Rebate for Danco Laboratories’ Mifeprex and GenBioPro’s Mifepristone Tablets, 200 mg, Fiscal Years 2020–2024**



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-25-107911.

**Accessible Data for Figure 2: Number of States That Claimed a Medicaid Rebate for Danco Laboratories’ Mifeprex and GenBioPro’s Mifepristone Tablets, 200 mg, Fiscal Years 2020–2024**

Category	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Both	7	14	18	17	20
Mifeprex	14	7	9	3	6
Mifepristone Tablets, 200 mg	1	1	2	6	4

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-25-107911.

Note: Data reflect rebates claimed through the Medicaid Drug Rebate Program by all 50 states, the District of Columbia, and Puerto Rico, which we collectively refer to as “states.” Rebate data for Puerto Rico were not available in fiscal years 2020 through 2022, because Puerto Rico began participating in the Medicaid Drug Rebate Program on January 1, 2023. The specific states that claimed a rebate for one or both drugs varied each fiscal year.

Among the 40 states whose officials told us their Medicaid programs covered Mifeprex and Mifepristone Tablets, 200 mg as of December 31, 2024, 27 claimed a rebate from the manufacturers for one or both drugs in fiscal year 2024. The remaining 13 states did not claim a rebate for either drug in fiscal year 2024.<sup>14</sup> CMS officials told us that states may still cover the drugs if no rebate was claimed. For example, states may not have claimed a rebate because they did not have any beneficiaries with a prescription for the drugs or the drugs may have been covered, but not eligible for a rebate for various reasons.<sup>15</sup> Of the nine states whose officials told us their programs did not cover Mifeprex or Mifepristone Tablets, 200 mg, eight states did not claim a rebate for either drug in 2024, and one state claimed a rebate for Mifepristone Tablets, 200 mg in 2024.

We also found that two of the three states that did not respond to our questions about their Medicaid programs’ coverage of Mifeprex and Mifepristone Tablets, 200 mg claimed a rebate for one or both drugs in fiscal year 2024. The third state did not claim a rebate for either drug in fiscal year 2024.<sup>16</sup> According to CMS officials, Medicaid rebate data indicate states were covering the drugs, because

they were claiming Medicaid rebates for them, but do not indicate whether the drugs were prescribed for medical abortion or for another purpose.

## Conclusions

CMS is responsible for ensuring states' compliance with MDRP requirements in states that opt to cover prescription drugs. However, due to gaps in CMS oversight, the agency was unaware that some states were not covering Mifeprex and Mifepristone Tablets, 200 mg when prescribed for medical abortion, as required. Implementing our 2019 recommendation related to coverage of Mifeprex and taking similar actions for Mifepristone Tablets, 200 mg would help CMS ensure states' compliance with federal MDRP requirements and Medicaid beneficiaries' access to these drugs when appropriate.

## Recommendation for Executive Action

The Administrator of CMS should determine the extent to which states comply with federal Medicaid requirements regarding coverage of GenBioPro's Mifepristone Tablets, 200 mg, and take actions, as appropriate, to ensure compliance. (Recommendation 1)

## Agency Comments

We provided a draft of this report to HHS for review and comment. In its written response, which is reproduced in appendix II, HHS noted that it is reviewing all applicable law, executive orders, and memoranda and will determine the best course of action moving forward. HHS also provided technical comments, which we incorporated, as appropriate.

## How GAO Did This Study

To examine state Medicaid programs' coverage of Mifeprex and Mifepristone Tablets, 200 mg, we reviewed federal laws, regulations, and CMS guidance related to the MDRP and coverage of these drugs, including for the purpose of medical abortion, and interviewed agency officials. Additionally, we sent written questions to officials in the 52 states that participate in the MDRP regarding their Medicaid programs' coverage of the two drugs as of December 31, 2024. We received answers from officials from 49 states. We did not independently verify the accuracy of the responses to our questions, but did follow up with state officials to clarify inconsistencies or outliers we identified.

To identify which states claimed a Medicaid rebate for Mifeprex and Mifepristone Tablets, 200 mg in the last 5 years, we analyzed CMS rebate data for these drugs from fiscal years 2020 through 2024, the most recent 5-year period for which data were available at the time of our review. To assess the reliability of these data, we reviewed CMS documents, such as a data dictionary, and interviewed CMS officials. We determined that these data were reliable for the purpose of our analysis.

We conducted this performance audit from October 2024 to August 2025 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.

## List of Addressees

The Honorable Ron Wyden  
Ranking Member  
Committee on Finance

United States Senate  
The Honorable Elizabeth Warren  
United States Senate

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

## GAO Contact Information

For more information, contact: Michelle B. Rosenberg, Director, Health Care, [RosenbergM@gao.gov](mailto:RosenbergM@gao.gov).

Public Affairs: Sarah Kaczmarek, Managing Director, [Media@gao.gov](mailto:Media@gao.gov).

Congressional Relations: A. Nicole Clowers, Managing Director, [CongRel@gao.gov](mailto:CongRel@gao.gov).

**Staff Acknowledgments:** Susan Anthony (Assistant Director), Kristin Ekelund (Analyst in Charge), Erika Huber, Drew Long, Jeanne Murphy-Stone, Jennifer Rudisill, and Ethiene Salgado-Rodriguez.

Connect with GAO on [Facebook](#), [X](#), [LinkedIn](#), [Instagram](#), and [YouTube](#).  
Subscribe to our [Email Updates](#). Listen to our [Podcasts](#).

Visit GAO on the web at <https://www.gao.gov>.

This is a work of the U.S. government but may include copyrighted material. For details, see <https://www.gao.gov/copyright>.

## Appendix I: Medicaid Rebates for Danco Laboratories' Mifeprex or GenBioPro's Mifepristone Tablets, 200 mg

**Table 1: Medicaid Programs That Claimed a Medicaid Rebate for Danco Laboratories' Mifeprex or GenBioPro's Mifepristone Tablets, 200 mg, Fiscal Years (FY) 2020–2024**

State	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Alabama	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug
Alaska	did not claim a rebate for either drug	claimed a rebate for Mifepristone	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug
Arizona	did not claim a rebate for either drug	did not claim a rebate for either drug	claimed a rebate for Mifeprex	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for Mifeprex
Arkansas	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	claimed a rebate for Mifepristone
California	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone
Colorado	claimed a rebate for Mifeprex	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for Mifepristone	claimed a rebate for both Mifeprex and Mifepristone
Connecticut	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone
Delaware	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	claimed a rebate for Mifeprex
District of Columbia	did not claim a rebate for either drug	did not claim a rebate for either drug	claimed a rebate for Mifeprex	did not claim a rebate for either drug	claimed a rebate for Mifeprex
Florida	did not claim a rebate for either drug	did not claim a rebate for either drug	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for Mifeprex	claimed a rebate for Mifepristone





State	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
North Dakota	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	claimed a rebate for Mifepristone	claimed a rebate for Mifepristone
Ohio	claimed a rebate for Mifeprex	claimed a rebate for Mifeprex	claimed a rebate for Mifeprex	claimed a rebate for Mifeprex	claimed a rebate for Mifeprex
Oklahoma	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug
Oregon	claimed a rebate for Mifeprex	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone
Pennsylvania	claimed a rebate for Mifeprex	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone
Rhode Island	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug
South Carolina	did not claim a rebate for either drug	did not claim a rebate for either drug	claimed a rebate for Mifeprex	did not claim a rebate for either drug	did not claim a rebate for either drug
South Dakota	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug
Tennessee	claimed a rebate for Mifeprex	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug
Texas	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug
Utah	did not claim a rebate for either drug	claimed a rebate for Mifeprex	claimed a rebate for Mifeprex	claimed a rebate for Mifeprex	did not claim a rebate for either drug
Vermont	claimed a rebate for Mifeprex	claimed a rebate for Mifeprex	claimed a rebate for Mifeprex	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone
Virginia	claimed a rebate for Mifeprex	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone
Washington	claimed a rebate for Mifeprex	claimed a rebate for Mifeprex	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone	claimed a rebate for both Mifeprex and Mifepristone
West Virginia	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	claimed a rebate for Mifeprex
Wisconsin	did not claim a rebate for either drug	did not claim a rebate for either drug	claimed a rebate for Mifepristone	claimed a rebate for Mifepristone	claimed a rebate for both Mifeprex and Mifepristone
Wyoming	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug
Puerto Ricoa	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug	did not claim a rebate for either drug

● = claimed a rebate for both Mifeprex and Mifepristone Tablets, 200 mg in that fiscal year

● = claimed a rebate for Mifeprex in that fiscal year

● = claimed a rebate for Mifepristone Tablets, 200 mg in that fiscal year

— = did not claim a rebate for either drug in that fiscal year

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-25-107911

Note: Data reflect rebates claimed through the Medicaid Drug Rebate Program by all 50 states, the District of Columbia, and Puerto Rico, which we collectively refer to as “states.”

<sup>a</sup>Rebate data for Puerto Rico were not available in fiscal years 2020 through 2022, because Puerto Rico joined the Medicaid Drug Rebate Program on January 1, 2023.

## Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

August 4, 2025

Michelle B. Rosenberg  
Director  
Health Care  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Ms. Rosenberg:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"MEDICAL ABORTION: Action Needed to Ensure Compliance with Medical Drug Rebate Program"** (GAO-25-107911).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in cursive script, reading "Gary Andres", is positioned above the printed name.

Gary Andres  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH SERVICES ON  
THE GOVERNMENT ACCOUNTABILITY OFFICE DRAFT REPORT ENTITLED -  
MEDICAL ABORTION: ACTION NEEDED TO ENSURE COMPLIANCE WITH  
MEDICAL DRUG REBATE PROGRAM (GAO-25-107911)**

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report.

**GAO Recommendation**

The Administrator of CMS should determine the extent to which states comply with federal Medicaid requirements regarding coverage of GenBioPro's mifepristone 200 mg and take actions, as appropriate, to ensure compliance.

**HHS Response**

HHS is reviewing all applicable law, Executive Orders and Memoranda from the Office of Management and Budget, and will determine the best course of action moving forward.

## Accessible Text for Appendix II: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES  
OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

August 4, 2025

Michelle B. Rosenberg  
Director  
Health Care  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Ms. Rosenberg:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "**MEDICAL ABORTION: Action Needed to Ensure Compliance with Medical Drug Rebate Program**" (GAO-25-107911).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Gary Andres  
Assistant Secretary for Legislation

Attachment

### **GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE DRAFT REPORT ENTITLED - MEDICAL ABORTION: ACTION NEEDED TO ENSURE COMPLIANCE WITH MEDICAL DRUG REBATE PROGRAM (GAO-25-107911)**

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report.

#### **GAO Recommendation**

The Administrator of CMS should determine the extent to which states comply with federal Medicaid requirements regarding coverage of GenBioPro's mifepristone 200 mg and take actions, as appropriate, to ensure compliance.

#### **HHS Response**

HHS is reviewing all applicable law, Executive Orders and Memoranda from the Office of Management and Budget, and will determine the best course of action moving forward.

## Endnotes

1For purposes of this report, we refer to the 50 states, the District of Columbia, and Puerto Rico as “states.” In addition to Puerto Rico, four other U.S. territories—American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands—have Medicaid programs. As of December 2024, these four programs did not participate in the MDRP.

2See 42 U.S.C. § 1396r-8(d).

3HHS uses price data reported by participating manufacturers to calculate a unit rebate amount, which is based on a statutory formula. States multiply the units of each drug purchased by the unit rebate amount and invoice the manufacturers for that amount. Manufacturers then pay states the rebate amount, and states share the rebate amount with the federal government based on the states’ federal medical assistance percentage, which is the share of Medicaid spending in each state paid for by the federal government.

4See Department of Health and Human Services, Health Care Financing Administration, State Medicaid Director Letter #01-018 (Baltimore, Md.: Mar. 30, 2001). CMS was formerly called the Health Care Financing Administration.

5In annual appropriations acts, Congress prohibits HHS from funding abortions in most circumstances. This restriction is commonly referred to as the Hyde Amendment. The most recent restriction applies to all abortions except where the pregnancy is the result of rape or incest; or where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed. See Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 507, 138 Stat. 460, 703. States may, at their own expense, choose to cover abortion services, including these drugs, in additional circumstances beyond those outlined in federal law.

6Prior authorization is when coverage of a service, such as medical abortion, must be approved by the state Medicaid agency before the procedure is performed.

7Mifeprex and Mifepristone Tablets, 200 mg are subject to a risk evaluation and mitigation strategy (REMS), which is a drug safety program the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. Mifeprex and Mifepristone Tablets, 200 mg are covered under a single, shared system REMS program, which includes several requirements, such as that these drugs only be dispensed by certified pharmacies or by or under the supervision of certified prescribers. This program is intended to mitigate the risk of serious complications associated with these drugs when used for medical abortion.

8Officials from three states—New Jersey, New Mexico, and Washington—did not provide information in response to our written questions.

9According to CMS officials, Medicaid managed care plans may voluntarily provide services that are in addition to Medicaid benefits—often called value-added services—which could include certain prescription drugs. See 42 C.F.R. § 438.3(e)(1) (2024). We did not ask officials in these nine states to identify whether Medicaid managed care plans in their states voluntarily covered Mifeprex and Mifepristone Tablets, 200 mg; however, an official in one of these states told us that at least one managed care plan in the state covered at least one of the drugs.

10Our work was not designed to assess state compliance with this aspect of federal Medicaid law, as modified by the Hyde Amendment. However, these three states’ voluntary statements raise questions as to whether all states’ approaches are consistent with federal requirements. We have informed CMS of the variation we observed so that the agency may consider whether clarification of these requirements or other actions are necessary to ensure compliance.

11The four states are Florida, Idaho, Oklahoma, and Texas. The 14 states that we reported in 2019 that did not cover Mifeprex were Alabama, Arkansas, Colorado, District of Columbia, Florida, Idaho, Kentucky, Missouri, North Carolina, Oklahoma, Rhode Island, South Carolina, Texas, and Utah. We conducted our 2019 study prior to FDA’s approval of GenBioPro’s Mifepristone Tablets, 200 mg and Puerto Rico’s decision to join the MDRP. See GAO, Medicaid: CMS Action Needed to Ensure Compliance with Abortion Coverage Requirements, GAO-19-159 (Washington, D.C.: Jan. 4, 2019).

12Our review found that 34 states claimed a rebate from Danco Laboratories for Mifeprex from fiscal year 2020 through fiscal year 2024, which is more than double the 13 states we reported claiming a rebate for Mifeprex in our 2019 report. See GAO-19-159. Mifepristone Tablets, 200 mg was not available at the time of our prior report. In fiscal years 2020 through 2024, 27 states claimed a rebate from GenBioPro for Mifepristone Tablets, 200 mg. Rebate data for Puerto Rico were not available at the time of our prior report, because its program joined the Medicaid Drug Rebate Program on January 1, 2023.

13For example, a state that claimed a rebate for one or both drugs in fiscal year 2023 may not have claimed a rebate in fiscal year 2024.

14Four of these 13 states claimed a rebate in at least one year between fiscal years 2020 through 2023.

15According to CMS officials, rebate data are not a proxy for state coverage because they exclude certain circumstances under which states may cover Mifeprex and Mifepristone Tablets, 200 mg, such as when a state pays for the drugs with state funds, covers the drugs as part of a bundled payment, or claims a rebate or discount through another drug discount program. Officials also told us that the data do not include information on the intended use of drugs and, therefore, do not indicate whether a state claimed a rebate for Mifeprex and Mifepristone Tablets, 200 mg for medical abortion or for another purpose.

16In fiscal year 2024, New Mexico and Washington claimed a Medicaid rebate for one or both drugs; New Jersey did not claim a rebate for either drug.