

U.S. Department of Health and Human Services
Office of Inspector General



CMS Should Pursue Strategies To Increase the Number of At-Risk Beneficiaries Acquiring Naloxone Through Medicaid

Suzanne Murrin

Deputy Inspector General for Evaluation and Inspections
September 2020, OEI-BL-18-00360





Why **OIG** Did This Review

On average, 130 people in the United States die every day from an opioid overdose. The drug naloxone plays a critical role in saving the lives of those who abuse or misuse opioids—one review of emergency data found that when given naloxone, 94 percent of people survived their overdose. In April 2018, the U.S. Surgeon General issued an advisory stating that increasing the availability and targeted distribution of naloxone is a critical component of efforts to reduce deaths from opioid-related overdoses. Similarly, Federal and State agencies have undertaken numerous efforts to increase access to naloxone for those in need. However, it is widely acknowledged that more needs to be done. Medicaid covers almost 40 percent of nonelderly adults with opioid use disorder, underscoring the key role that the program can play in providing access to naloxone.

How **OIG** Did This Review

We used State-reported Medicaid data to determine how total utilization for naloxone changed in the program between 2014 and 2018. Using manufacturer-reported sales data, we determined the proportion of all naloxone distributed in the United States that was paid for under Medicaid each year between 2014 and 2018. We used data on Medicaid drug spending to examine how statutory rebates—paid by manufacturers to States—affected Medicaid payments for naloxone during this period.

CMS Should Pursue Strategies To Increase the Number of At-Risk Beneficiaries Acquiring Naloxone Through Medicaid

Key Takeaway

Despite a significant increase in naloxone utilization under Medicaid, the program accounted for only a small proportion of all naloxone distributed in the United States in 2018. Especially concerning, some States severely affected by the opioid crisis are paying for relatively little naloxone under Medicaid.

What **OIG** Found

Access to naloxone for Medicaid beneficiaries has expanded significantly, with the program paying for 21 times more doses in 2018 than in 2014. Despite this growth, Medicaid paid for only 5 percent of all naloxone distributed in the United States in 2018. This figure is especially concerning given that (1) Medicaid covers almost 40 percent of nonelderly adults with opioid use disorder (OUD) and (2) some States with extremely high overdose mortality rates paid for relatively little naloxone under Medicaid.

Because of statutory rebates that manufacturers pay to Medicaid, the program has been able to recoup a large percentage of its spending on naloxone. For example, in 2018, Medicaid achieved a significant discount off the list price for Narcan (the only version of naloxone currently covered under Medicaid that can be appropriately administered in emergency situations by those with minimal to no training). Narcan accounted for 9 out of 10 naloxone doses paid for under the program that year. In fact, Medicaid's net cost for Narcan in 2018 was less than the substantially discounted price that

Narcan's manufacturer offered to public health organizations for this "community use" version of naloxone.

What **OIG** Recommends and How the Agency Responded

The Centers for Medicare & Medicaid Services (CMS) and State Medicaid agencies can be encouraged by their progress to date in increasing access to naloxone while also continuing to look for ways to further expand naloxone availability under Medicaid. Such efforts have recently become even more crucial as States struggle with surges in drug overdose deaths during the coronavirus pandemic. Because the high cost of naloxone is often cited as a primary barrier to increased access, Medicaid's ability to achieve significant discounts for the drug increases the importance of helping more beneficiaries obtain the drug through the program.

We recommend that CMS pursue strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone through Medicaid. Potential strategies include the following: (1) educating Medicaid beneficiaries and Medicaid-eligible patients about the availability of naloxone under Medicaid; (2) encouraging and supporting State efforts to allow family members and friends of Medicaid beneficiaries to obtain community-use versions of naloxone on their behalf through Medicaid; and (3) encouraging and supporting State efforts that require providers to co-prescribe naloxone to Medicaid beneficiaries when they prescribe high doses of prescription opioids. CMS did not explicitly concur with our recommendation but stated that it is already pursuing multiple strategies to increase the number of at-risk beneficiaries acquiring naloxone through Medicaid and will continue to do so.

TABLE OF CONTENTS

BACKGROUND	1
Methodology	3
FINDINGS	6
Despite paying for rapidly increasing amounts of naloxone each year, Medicaid still accounted for only 5 percent of the doses distributed in the United States in 2018	6
Some States experiencing high overdose mortality rates paid for a comparatively small amount of naloxone through Medicaid	7
Because of statutory rebates, Medicaid was able to obtain significant discounts for naloxone	9
RECOMMENDATION	10
Pursue strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone through Medicaid	10
AGENCY COMMENTS AND OIG RESPONSE	12
DETAILED METHODOLOGY	13
APPENDICES	18
A. Medicaid Drug Rebate Calculation	18
B. Total Doses Paid for Under Medicaid, by Formulation	20
C. Drug Overdose Deaths and Distribution of Naloxone Paid for Under Medicaid in 2018, by State	21
D. Agency Comments	23
ACKNOWLEDGMENTS AND CONTACT	25
ABOUT THE OFFICE OF INSPECTOR GENERAL	26
ENDNOTES	27

BACKGROUND

Objectives

1. Determine how total utilization of naloxone under Medicaid changed between 2014 and 2018.
 2. Determine the proportion of all naloxone distributed in the United States that was paid for under Medicaid each year between 2014 and 2018.
 3. Examine how statutory rebates affected Medicaid payments for naloxone.
-

On average, 130 people in the United States die every day from an opioid overdose.¹ The drug naloxone plays a critical role in saving the lives of those who abuse or misuse opioids, with one review of emergency data finding that, when given naloxone, 94 percent of people survived their overdose.² In April 2018, the U.S. Surgeon General issued an advisory stating that increasing the availability and targeted distribution of naloxone is a critical component of efforts to reduce opioid-related overdose deaths.³ Similarly, Federal and State agencies have undertaken numerous efforts to increase access to naloxone for those in need. In this report, we examine utilization and cost of naloxone in Medicaid, a program that covers nearly 40 percent of nonelderly adults with opioid use disorder (OUD).⁴

Naloxone

Naloxone was first approved by the Food and Drug Administration (FDA) in 1971 to reverse opioid overdoses. The drug does this by blocking the effects of opioids on the brain and restoring normal breathing within minutes of administration.

For decades, naloxone was available only in formulations that required intravenous or intramuscular injection, and thus was primarily intended for use by health care professionals and trained first responders. (Hereinafter, we refer to these formulations as “professional use” versions.) In 2014, the first “community-use” version of naloxone, Evzio, reached the market. Evzio is an autoinjector that provides spoken instructions and visual guidance during administration. The following year, FDA fast-tracked approval of a nasal spray formulation of naloxone under the brand name Narcan. Evzio and Narcan can be appropriately administered in emergency situations by those with minimal to no training, such as bystanders with no medical skills. However, both community-use products are more expensive than professional-use versions of naloxone, raising concerns about the financial impact of purchasing community-use versions.⁵

Federal and State Efforts To Increase Access to Naloxone

In response to the opioid crisis, Federal and State agencies have implemented numerous policies to improve the distribution of naloxone to those in need. For example, 47 States are making it easier to distribute naloxone directly to residents—including to Medicaid beneficiaries—by allowing pharmacists to dispense naloxone prescribed independently or by collaborative practice agreements, standing orders,⁶ or other predetermined protocols.⁷ A number of States are also requiring providers to co-prescribe naloxone when they prescribe certain opioids.⁸ The Centers for Medicare & Medicaid Services (CMS) and State Medicaid agencies have also taken specific steps to make naloxone more accessible to Medicaid beneficiaries—a population that is (as previously stated) particularly vulnerable to OUD. For example, all State Medicaid agencies have removed prior-authorization requirements for naloxone prescriptions,⁹ and a few have allowed friends and family of Medicaid enrollees with addiction issues to obtain prescriptions for naloxone on the enrollee's behalf.¹⁰ In January 2016, CMS encouraged States to place naloxone on preferred drug lists to increase access,^{11, 12} and as of 2018, 43 State Medicaid programs had done so for at least one formulation.¹³ CMS has also proposed requiring States to implement safety edits that would identify Medicaid beneficiaries who could be at high risk for an opioid overdose and for whom the co-prescribing or co-dispensing of naloxone should therefore be considered.¹⁴

First responders and community health programs also play a critical role in providing naloxone to those in need. In many areas, law enforcement professionals, firefighters, emergency medical technicians, and paramedics carry naloxone, as they are often the first emergency personnel to respond to overdoses. In addition, community health programs throughout the country dispense naloxone to individuals at risk for an opioid overdose, as well as to the family and friends of such individuals. Although several manufacturers have established programs to offer naloxone at discounted prices for first responders and certain public health programs, numerous reports indicate that local governments are stretching their budgets to purchase this lifesaving drug.¹⁵ In response, the Department of Health and Human Services (HHS) has issued grants to States, local law enforcement, and first responders to assist in the purchase of naloxone and reduce the financial impact on communities.¹⁶

Medicaid

Medicaid is a joint Federal-State program providing health insurance for nearly 65 million low-income individuals across the United States.¹⁷ All State Medicaid agencies offer coverage for outpatient prescription drugs, including naloxone.

Medicaid Reimbursement for Prescription Drugs

Medicaid prescription drug benefits are offered under both fee-for-service (FFS) and managed care models.¹⁸ Under the FFS model, Medicaid State agencies reimburse pharmacies for covered outpatient drugs dispensed to beneficiaries, based on the

drug's actual acquisition cost (AAC) plus a professional dispensing fee.^{19, 20} States typically determine AAC using data obtained through pharmacy surveys (e.g., the National Average Drug Acquisition Cost files), although compendia-published benchmarks such as wholesale acquisition cost (WAC)—also referred to as the drug's "list price"—may be used as well.²¹

Under the Medicaid managed care model, States do not use a general payment formula to calculate reimbursement amounts. Rather, managed care organizations (MCOs)—or pharmacy benefit managers acting on their behalf—negotiate terms for prescription drug payment with individual pharmacies.²²

Medicaid Drug Rebate Program

The Omnibus Budget Reconciliation Act of 1990 created the Medicaid Drug Rebate Program (MDRP) to reduce State and Federal Medicaid expenditures for prescription drugs. For Federal financial participation to be available for covered outpatient drugs under Medicaid, manufacturers must enter into rebate agreements with the Secretary of HHS and pay quarterly rebates to State Medicaid agencies.²³ Statutorily mandated rebates enable Medicaid to recoup a substantial percentage of the billions that the program spends annually on prescription drugs. The formula to calculate the basic rebate depends primarily on whether the drug is brand-name or generic and is based on manufacturer-reported sales prices.²⁴ To protect Medicaid from significant price increases, drug manufacturers must pay additional rebates on drugs when certain reported prices have risen faster than inflation.²⁵

See Appendix A for a detailed description of the Medicaid drug rebate calculation.

Methodology

Scope

We examined spending and utilization data both for professional-use and community-use versions of naloxone. When examining the cost of naloxone, we limited our analysis to Narcan and Evzio—the two available "community use" versions of naloxone—because, as noted by the Surgeon General, "community use" versions of naloxone play a key role in reducing overdose deaths, and stakeholders have raised concerns about the cost of these two products. When analyzing the amount of naloxone paid for through Medicaid, we did not assess whether individual State policies may have led to variations in utilization among States.

Data Analysis

Surveying Naloxone Manufacturers. We surveyed the eight manufacturers who produced naloxone between 2014 and 2018. From each manufacturer, we requested data related to the total number of units of naloxone distributed (including all sales

and donations) in each quarter from 2014 through 2018. We also asked manufacturers whether they sold naloxone under a discount program to qualified purchasers such as public health organizations, and if so, to provide the quarterly discounted price per unit.

Calculating Medicaid Pre-Rebate Expenditures. To calculate Medicaid’s annual pre-rebate expenditures from 2014-2018, we summed total reimbursement amounts for naloxone products among all States using 2014-2018 Medicaid Drug Rebate System (MDR) data.

Calculating Medicaid Post-Rebate Expenditures. We subtracted total rebates claimed by States as reported in MDR from pre-rebate expenditures.

Summarizing Number of Naloxone Doses Paid for Under Medicaid. To ensure consistency when comparing utilization and cost across versions, we converted the number of units reimbursed to their equivalent number of doses (i.e., the quantity of naloxone the manufacturer recommends for overdose reversal) and then summed across all States to determine the national total. We also calculated how many doses of naloxone were paid nationally and by each State under Medicaid per 100,000 beneficiaries in 2018.

Identifying States with Potentially High Need for Naloxone. To identify States with a potentially high need for naloxone, we used 2018 CDC State-level drug overdose mortality data. We ranked the age-adjusted drug overdose mortality rates by State. We then identified the 10 States with the highest drug overdose mortality rates as having a particularly high need for naloxone availability.

Examining Cost per Dose. We calculated how much each dose of naloxone cost Medicaid on average after rebates in 2016 through 2018. As noted in the scope, we limited this portion of the analysis to Evzio and Narcan.

Determining Proportion of Naloxone Paid for Under Medicaid. Using data collected from our survey of manufacturers, we determined the total number of doses of naloxone distributed in the United States (through all channels and to all payers) during each year from 2014 through 2018. We divided the total number of doses paid for under Medicaid each year by the total number of doses distributed in the United States to determine the proportion of naloxone paid under Medicaid.

See the Detailed Methodology section for more information.

Limitations

We did not review drug compendia, drug manufacturer survey data, and manufacturer survey responses for accuracy. The naloxone utilization data from MDR reflects only units paid for by Medicaid. Therefore, we could not determine (1) whether all of these paid units were actually dispensed (i.e., whether beneficiaries picked up their naloxone prescriptions at the pharmacy) or (2) if Medicaid beneficiaries obtained naloxone through sources other than Medicaid, e.g., if the

naloxone was paid for out-of-pocket or distributed through public health programs funded by Federal grants, States, and local communities. Some State Medicaid agencies may not reimburse emergency medical services for naloxone separately; rather, they may provide a single bundled payment for all services and medications administered at the time of an overdose. MDR data does not include utilization, spending, and rebate information about naloxone that was part of a bundled service.

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.

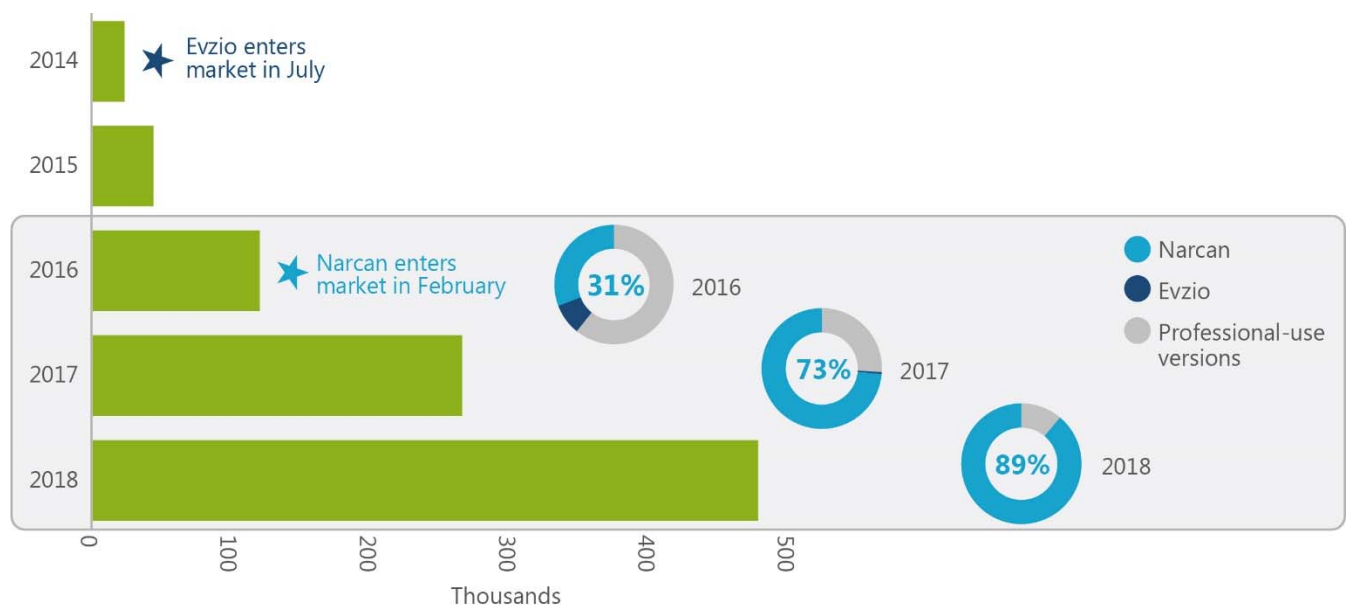
FINDINGS

Despite paying for rapidly increasing amounts of naloxone each year, Medicaid still accounted for only 5 percent of the doses distributed in the United States in 2018

Medicaid paid for 21 times more doses of naloxone in 2018 than in 2014

In 2014, Medicaid paid for roughly 23,000 doses of naloxone nationwide. By 2018 that figure had climbed to more than 477,000 doses—a 21-fold increase in just 5 years (Exhibit 1). Prior to the introduction of Narcan in February 2016, professional-use versions accounted for nearly all of the naloxone doses reimbursed under Medicaid.²⁶ However, once Narcan became available, Medicaid saw a pronounced shift to this community-use formulation that requires minimal or no training at all for appropriate use. By 2018, Narcan represented nearly 90 percent of naloxone doses reimbursed under Medicaid. Although Evzio was introduced in 2014 and is also intended for community use, it never comprised more than 12 percent of Medicaid utilization each year. Further, Evzio’s manufacturer terminated its rebate agreement in March 2017, meaning that in practice, Evzio is no longer covered by Medicaid.^{27, 28}

Exhibit 1: Medicaid utilization for naloxone grew by nearly half a million doses in just 5 years, driven primarily by increased use of Narcan.



Source: OIG analysis of 2014–2018 MDR data. See Appendix B for detailed information.

Relatively little of the naloxone distributed in 2018 was paid for by Medicaid, despite the program's serving a substantial percentage of individuals with opioid use disorder

Although Medicaid paid for substantially more naloxone each year, the overall proportion was still relatively small given that the program serves nearly 40 percent of all non-elderly adults in the United States who suffer from OUD. In total, manufacturers distributed 10.4 million doses of naloxone in 2018.²⁹ As previously noted, Medicaid paid for 477,000 doses of naloxone that same year, or just 4.6 percent of the total doses distributed (up from 0.5 percent in 2014). For Narcan specifically (i.e., by far the most common formulation paid under Medicaid in 2018), nearly 10 percent of all U.S. doses were paid for under Medicaid in 2018. It is important to note that this data does not necessarily mean that Medicaid beneficiaries in need of naloxone never acquired the drug. As previously stated, beneficiaries may have obtained naloxone through sources other than Medicaid, such as public health programs funded by Federal grants, States, and local communities.

Some States experiencing high overdose mortality rates paid for a comparatively small amount of naloxone through Medicaid

Nationally, Medicaid paid for 639 doses of naloxone per 100,000 beneficiaries in 2018. Among individual States this rate varied widely, ranging from a low of 68 doses per 100,000 beneficiaries to a high of 2,861 doses per 100,000 in that year. Especially concerning is that several States severely affected by the opioid crisis paid for comparatively few naloxone doses under Medicaid, sometimes by a substantial amount (Exhibit 2).³⁰

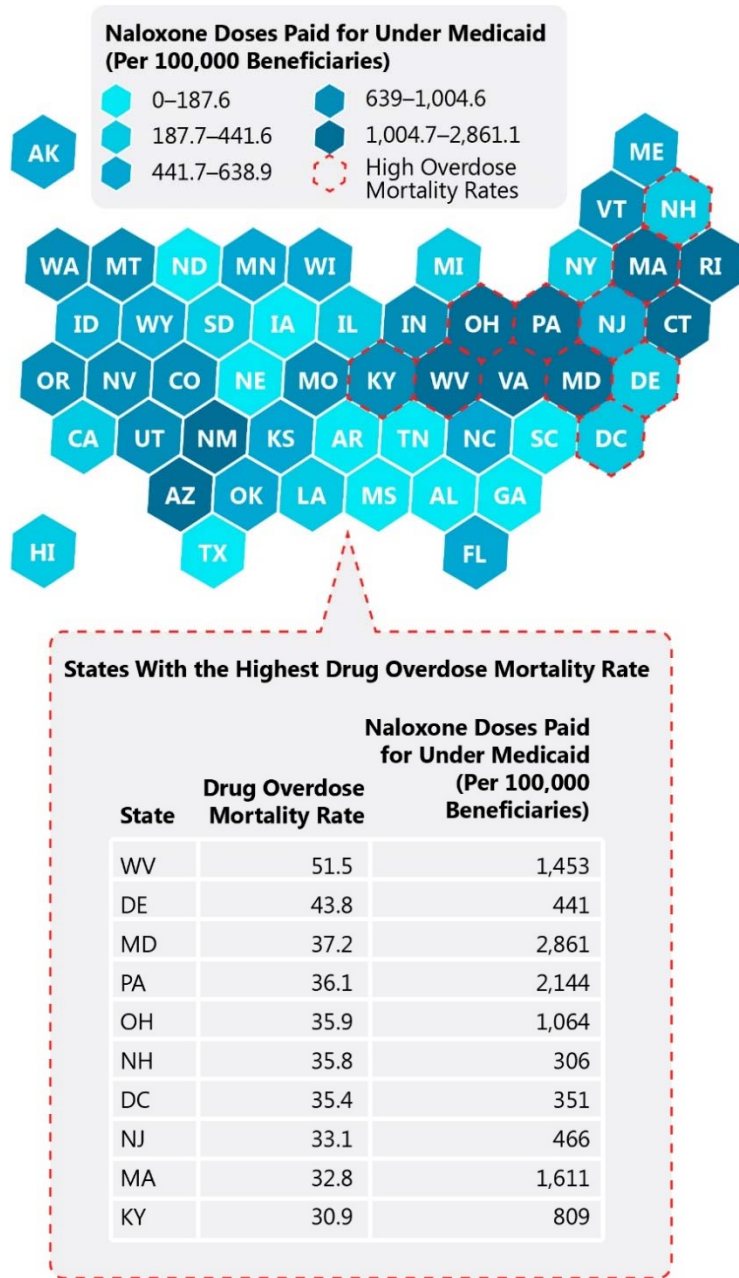
For example, both Delaware and New Hampshire experienced high drug overdose death rates but paid for relatively little naloxone under Medicaid. Delaware had the second highest drug overdose death rate in 2018, at 43.8 deaths per 100,000 residents (more than double the national rate). That same year, Delaware's Medicaid program paid for only 441 naloxone doses per 100,000 beneficiaries—31 percent less than the national Medicaid average. Similarly, New Hampshire's drug overdose mortality rate (35.8 per 100,000 residents) was also among the 10 highest in the nation in 2018; however, the State paid for just 306 doses of naloxone per 100,000 beneficiaries—less than half the national average.

In contrast, West Virginia and Maryland also experienced high drug overdose death rates in 2018. However, unlike Delaware and New Hampshire, both States distributed relatively large amounts of naloxone under Medicaid that year. West Virginia had the highest drug overdose mortality rate in the United States in 2018—51.5 deaths per 100,000 residents (double the national average). The State also paid for more than double the national average amount of naloxone through Medicaid (1,453 doses per 100,000 beneficiaries) the same year. Similarly, Maryland ranked third highest in drug

overdose mortality rates in 2018, and its Medicaid program paid for more than 4 times (2,861 doses per 100,000 beneficiaries) the national average number of doses.

As previously stated, beneficiaries may have obtained naloxone through sources other than Medicaid, such as public health programs funded by Federal grants, States, and local communities.

Exhibit 2: States varied widely in their distribution of naloxone under Medicaid in 2018.



Source: OIG analysis of 2018 CDC and MDR data. See Appendix C for detailed information.

Note: Drug overdose mortality rates are age-adjusted. We did not examine whether Medicaid beneficiaries are acquiring naloxone through channels outside of Medicaid, such as through public health organizations.

Because of statutory rebates, Medicaid was able to obtain significant discounts for naloxone

Given the rapid rise in naloxone utilization in Medicaid, the program's overall spending for the drug increased dramatically from 2014 to 2018. However, this spending growth was tempered by statutorily mandated rebates—particularly for brand-name versions of naloxone (i.e., Narcan and Evzio). Between 2014 and 2018, Medicaid recouped between 6 percent and 84 percent of naloxone expenditures each year, with the sharp increase in 2016 stemming from increased use of the brand-name versions of naloxone (i.e., Narcan and Evzio) that are subject to higher rebates.

Rebates allowed Medicaid to pay substantially less than the list price—and slightly less than the heavily discounted price available to qualified public health organizations—for Narcan

As stated previously, Narcan accounted for nearly 9 out of every 10 doses of naloxone paid for under Medicaid in 2018. On average, rebates allowed Medicaid to pay significantly less than the list price for each dose of the nasal spray that year.³¹ In fact, Medicaid's net cost for the drug in 2018 was also less than the substantially discounted price offered to public health organizations by Narcan's manufacturer. According to more recent data, Narcan's pricing and net Medicaid cost remained relatively unchanged in 2019.

The substantial effect of Medicaid rebates on net costs was not solely limited to Narcan. During the period covered by our review, Evzio's list price was as much as 30 times greater than Narcan's. However, prior to Evzio's manufacturer's withdrawal from the Medicaid drug rebate program in early 2017, the program's net cost for Evzio was actually below that of Narcan.³² In part, Medicaid was able to achieve such massive rebates for Evzio because of the additional amounts owed under statute when a drug's price increases faster than inflation. Between 2015 and 2016, Evzio's manufacturer raised its average list price six-fold, triggering a substantial inflation-based rebate penalty.

RECOMMENDATION

Expanding affordable access to naloxone is crucial in fighting the opioid crisis and reducing overdose-related deaths. Medicaid—a program that serves almost 40 percent of American adults with OUD—continues to play a key role in achieving this goal. With the encouragement of CMS, States have implemented policies that make naloxone more readily accessible to Medicaid beneficiaries who struggle with OUD. For example, all States have removed prior-authorization requirements for naloxone, and most have placed naloxone on preferred drug lists.

Our findings show that although Medicaid has greatly increased the availability of naloxone to its beneficiaries, the program still paid for only 5 percent of all naloxone distributed in the United States in 2018. Especially concerning is that some States severely affected by the opioid crisis are reimbursing for relatively little naloxone under Medicaid.

In addition, because of statutory rebates, Medicaid obtains significant discounts for Narcan—a version of naloxone that can be appropriately administered by those with minimal to no training in emergency situations. These rebates help bring Medicaid's net cost for Narcan to an amount below even the highly discounted price offered by the manufacturer to public health organizations.

CMS and States can be encouraged by their progress towards increasing naloxone access to patients while also continuing to look for ways to further expand naloxone availability under Medicaid. Such efforts have recently become even more crucial as many States struggle with surges in drug overdose deaths during the coronavirus pandemic.³³ Given that the high cost of naloxone is often cited as a primary barrier to increased access, Medicaid's ability to achieve significant discounts for the drug only increases the importance of helping more beneficiaries obtain naloxone through the program.

Therefore, we recommend that CMS:

Pursue strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone through Medicaid

Because Medicaid covers a large share of individuals with OUD, undertaking efforts to increase beneficiaries' access to community-use naloxone such as Narcan could significantly reduce opioid overdose deaths. In its efforts to expand access to this critical drug, CMS should work with its Federal partners, such as the Substance Abuse and Mental Health Services Administration and the Office of National Drug Control

Policy, to collect and disseminate information from States about effective strategies for dispensing naloxone. This could be accomplished through several avenues, such through a Notice of Request for Information or Medicaid State Plan amendments. As part of this process, CMS and its Federal partners may wish to consider whether the following specific methods could increase naloxone dispensing through State Medicaid programs to beneficiaries in need:

- In conjunction with community public health organizations, educate Medicaid beneficiaries and Medicaid-eligible patients about the availability of naloxone under Medicaid;
- Encourage and support State efforts to allow family members and friends of Medicaid beneficiaries to obtain community-use versions of naloxone on their behalf through Medicaid;
- Encourage and support State efforts that require providers to co-prescribe naloxone to Medicaid beneficiaries when they prescribe high doses of prescription opioids.

AGENCY COMMENTS AND OIG RESPONSE

CMS did not explicitly concur with our recommendation but stated that the agency is already pursuing multiple strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone through Medicaid and will continue to do so. CMS anticipates that increased access will result from its recent proposal requiring States to implement safety edits that would identify at-risk Medicaid beneficiaries for whom the co-prescribing or co-dispensing of naloxone should be considered. Further, the agency explained that it will continue to work with its Federal and State partners where appropriate.

OIG appreciates the efforts CMS has taken to ensure that at-risk beneficiaries acquire community-use versions of naloxone through Medicaid. OIG continues to recommend that CMS build upon these efforts and further expand its strategies to increase beneficiaries' access to this lifesaving drug through Medicaid, particularly given our findings that some States severely affected by the opioid crisis are reimbursing for relatively little naloxone under Medicaid. We ask that CMS specify in its Final Management Decision how it is enhancing, or plans to enhance, these efforts.

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

DETAILED METHODOLOGY

Data Sources

Drug Products in the Medicaid Drug Rebate Program File. To identify national drug codes (NDCs) representing naloxone, we obtained all NDCs, associated product information (e.g., product names, package sizes, etc.), and Medicaid unit type data for 2014 through 2018 from CMS's Drug Products in the Medicaid Drug Rebate Program File. These files contain drugs that have been reported by drug manufacturers participating in the Medicaid Drug Rebate Program.

FDA NDC Directory. The FDA NDC Directory provides a current list of all drug products distributed in the United States. We obtained all NDCs and associated product information from the FDA NDC Directory on March 27, 2019 to identify NDCs representing naloxone.

Drug Compendia. The IBM Micromedex Red Book database and First Databank (collectively referred to as the drug compendia) provide list prices and drug information for drugs approved by FDA. To identify NDCs representing naloxone, we obtained NDCs and associated pricing and product information for 2014 through 2018.

CDC Injury Center Data. We obtained NDCs and associated product data from CDC's 2018 Injury Center Data. CDC's data file contains information for opioids with morphine milligram equivalent conversion factors.

Medicaid MDR Data. States report to CMS the drug utilization and payments by NDC for covered outpatient drugs paid for by the State Medicaid agency. We obtained quarterly 2014–2018 data on Medicaid expenditures, rebates, and utilization for each naloxone NDC from CMS's nonpublic MDR system for all 50 States and the District of Columbia.³⁴

Medicaid Rebate Amounts. We obtained from CMS the Medicaid unit rebate amounts (URAs) for all NDCs associated with Narcan and Evzio in each quarter from 2014 through 2018.

Medicaid Budget and Expenditure System (MBES). We obtained monthly 2014 through 2018 counts of Medicaid enrollees for each State from CMS's MBES to calculate how many doses of naloxone were paid for under Medicaid per 100,000 beneficiaries (i.e., Medicaid per-capita doses).

CDC Drug Overdose Data. CDC's National Vital Statistics System collects information on births, deaths, and fetal deaths from U.S. States and jurisdictions. Age-adjusted drug overdose mortality rates are calculated based on the underlying cause-of-death codes from the International Classification of Diseases, Tenth Revision (ICD-10), that

detail drug poisoning.³⁵ In this report, we used mortality rates for all drug overdoses. Drug-specific overdose death information (e.g., death information that includes the type of drug that caused the overdose) is not routinely reported across all U.S. jurisdictions; therefore, using only the mortality rates specific to opioid overdoses would have underestimated the number of actual opioid overdose deaths. We obtained 2018 State-level age-adjusted mortality rates from CDC. We used these data as a measure to identify States with high indicators of opioid misuse and abuse.

Drug Manufacturer Contact Information. CMS's Drug Contact file contains contact information for each manufacturer participating in the Medicaid drug rebate program. We sent a survey to the legal contact listed in this file for every manufacturer associated with each naloxone NDC.

Drug Manufacturer Survey and Sales Data. We surveyed the eight manufacturers who produce naloxone products and received responses from each. We did not include repackagers (companies that repackage drugs into smaller quantities for sale to providers). We asked manufacturers whether they sell naloxone under a discount program to qualified purchasers, what types of entities are eligible for the discount price (i.e., public health price), and the quarterly discount price per unit for each NDC.

We also requested sales data from manufacturers. For each naloxone NDC, we asked how many units the manufacturer donated at no charge, sold to qualified purchasers at the discount program price, and sold outside of the discount program annually from 2014 to 2018.

Data Analysis

Selecting Naloxone NDCs. We obtained all NDCs representing products containing naloxone that were active at any point between 2014 and 2018 from CMS's Drug Products in the Medicaid Drug Rebate Program File, FDA NDC Directory, drug compendia files, and CDC Injury data. We then removed NDCs that represented combination medications containing naloxone (e.g., buprenorphine/naloxone) because these products are not used to treat opioid-related overdoses. In addition, we removed powder formulations of naloxone, as these versions would need to be reconstituted and therefore would not be widely used in settings relevant to our scope.

We identified 57 NDCs that represent naloxone products (excluding powder formulations) on the market at any point between 2014 and 2018.

Surveying Naloxone Manufacturers. We removed NDCs representing repackaged naloxone products and surveyed manufacturers regarding the remaining 31 NDCs. We asked manufacturers about what discount programs, if any, they offered to qualified purchasers for naloxone. We also requested discount program prices (i.e., public health prices) and sales data for our study period.

Categorizing NDCs by Formulation. Using quarterly Medicaid expenditure data from MDR, we determined that Medicaid paid for 28 of the 57 naloxone NDCs during the 5-year period. All 28 were produced by original manufacturers (i.e., none of the 26 repackaged NDCs had associated Medicaid utilization). We determined whether each of the NDCs with Medicaid expenditures represents Narcan, Evzio, or a professional-use version of naloxone. We referred to product labeling information to identify each drug's formulation.

Calculation of Medicaid Expenditures and Rebates Claimed. We calculated Medicaid expenditures and rebates for the 28 naloxone NDCs paid under Medicaid using the quarterly 2014 to 2018 MDR data.³⁶ To calculate how much Medicaid spent for naloxone before receiving rebates (i.e., pre-rebate spending), we summed total reimbursement amounts. To calculate total rebates owed by manufacturers for naloxone, we summed total rebates claimed by States. Finally, to calculate how much Medicaid spent for naloxone after receiving rebates (i.e., post-rebate spending), we subtracted total rebates from pre-rebate expenditures. We conducted these calculations for each year under review.

Correcting Utilization Data Anomalies. We identified anomalies in the MDR in which the data sometimes appeared to misrepresent the actual number of units reimbursed by certain States. This occurred primarily when States seemed to report data using an incorrect unit type (e.g., reporting the number of milliliters of Evzio reimbursed instead of the number of individual autoinjectors). In these instances, we manually corrected the data only for NDCs representing Narcan and Evzio because (1) these versions accounted for the most expenditures under Medicaid and (2) the relatively standard pricing for these versions made potentially incorrect data easier to identify.

Converting Units to Doses. In MDR, the number of units of a drug listed is generally based on the lowest dispensable amount of the drug (e.g., milliliter, tablet, etc.). Therefore, for naloxone, the number of units billed for a single dose (i.e., a single injection or nasal spray) varies depending on the specific formulation (e.g., a nasal spray of 0.1 mL versus an autoinjector of 0.4 mL). To ensure consistency when comparing utilization and cost across versions, we converted the number of units reimbursed for each NDC as reported in MDR to their equivalent number of doses. For example, if providers bill and Medicaid reimburses for a version of naloxone on a "per mL" basis, but a single dose of this version is 2 mL, we multiplied units by 0.5 to calculate doses. We converted units to doses for all naloxone NDCs.

Using data collected from the eight naloxone manufacturers, we converted units distributed to doses distributed for each naloxone NDC by identifying how many units are within a single dose of naloxone (i.e., the quantity of naloxone the manufacturer recommends that an individual administer for overdose reversal).

We also used manufacturer-reported data to convert quarterly public health prices for each Narcan and Evzio NDC to public health prices per dose. Similarly, the number of units on which WACs—i.e., manufacturer list prices—are based often differs from the number of units for which providers bill Medicaid for the same drug. To ensure

consistency when comparing the cost of naloxone under Medicaid to WACs, we used drug compendia data to convert quarterly WACs for each Narcan and Evzio NDC to WACs per dose by identifying how many units are within a single dose of naloxone.

Total Medicaid Utilization. To determine trends in naloxone utilization under Medicaid, for each year under review we summed the total doses reimbursed overall, by formulation, and by State.³⁷

Calculation of Medicaid Per Capita Utilization. To better compare State naloxone utilization rates, we calculated Medicaid doses per capita by State. We first summed the number of doses reimbursed under Medicaid in each State. We divided the result by the average number of Medicaid enrollees that year (i.e., calculated as an average of monthly Medicaid enrollments). Finally, we multiplied the result by 100,000 to calculate how many doses of naloxone were paid for under Medicaid in each State per 100,000 beneficiaries.

We then divided States' Medicaid doses per 100,000 beneficiaries into quintiles to better compare States' distribution of naloxone doses paid for under Medicaid in 2018. To determine how many doses beneficiaries received on average over the years, we calculated the average number of naloxone doses paid for under Medicaid per 100,000 beneficiaries in the entire United States (i.e., nationwide rate) every year between 2014 and 2018.

Identifying States with High Indicators of Opioid Misuse and Abuse. To identify States with a potentially high need for naloxone, we used CDC State-level drug overdose mortality data. We ranked the age-adjusted drug overdose mortality rates by State. We then identified States with rates that were in the top 20 percent of the distribution (i.e., the 10 States with the highest drug overdose mortality rates) as having a particularly high need for increased naloxone availability.

Calculating Medicaid Cost Per Dose. To calculate Medicaid's nationwide post-rebate cost per dose, we divided total post-rebate spending by the number of doses paid for by the program that same year. We conducted this calculation for each year between 2016 and 2018. We limited this part of our analysis to only Narcan and Evzio because community-use formulations of naloxone are currently the most widely utilized versions of the drug.

Calculating WAC Per Dose. To calculate an annual WAC per dose for Narcan and Evzio, we first averaged the quarterly WACs per dose. Because there were multiple NDCs associated with Narcan and Evzio, we then calculated a volume-weighted WAC per dose for these products using manufacturer-reported sales data. We conducted this calculation for Narcan and Evzio each year between 2016 and 2018.

Calculating Public Health Price Per Dose. Because manufacturers offered discount prices for only one NDC associated with each product, we simply averaged the quarterly public health prices per dose to calculate a single annual public health price per dose for Narcan and Evzio each year between 2016 and 2018.

Determining the Proportion of Naloxone Paid for under Medicaid. Using data collected from the eight naloxone manufacturers, we calculated the total number of doses of naloxone distributed in the United States each year. We summed the number of doses for each NDC that were donated at no charge, sold at discount prices to public health organizations (if applicable), and sold outside of the manufacturer's public health program (to all payers, such as Federal and private payers). We divided the total doses reimbursed under Medicaid by the total doses distributed to calculate the percentage of naloxone doses paid for under Medicaid each year overall and by formulation.

APPENDIX A

Medicaid Drug Rebate Calculation

Under section 1927 of the Act, manufacturers are responsible for accurately calculating and paying rebates to the States. To assist States, CMS uses the pricing and drug category data reported by manufacturers to calculate by NDC a unit rebate amount (URA) every quarter for each covered outpatient drug included in the Medicaid drug rebate program. In general, the URA equals the sum of the basic rebate and the inflation-indexed rebate (if any).

Basic Rebate

Pursuant to section 1927(c) of the Act, the formula used to calculate the URA depends on the drug category reported by the manufacturer. The basic URA for a noninnovator multiple-source drug is 13 percent of the AMP. The basic URA for a single-source or innovator multiple-source drug is the greater of 23.1 percent of the AMP or the difference between the AMP and best price. In addition, for drugs approved exclusively for pediatric indications and certain blood-clotting factors, the basic rebate is the greater of 17.1 percent of AMP or the difference between the AMP and the best price.

Inflation-Indexed Rebate

If the AMP for a drug has risen faster than the Consumer Price Index-Urban (CPI-U), the drug's manufacturer must pay an additional rebate over and above the basic URA.³⁸ To determine whether a drug is subject to the increased rebate amount, CMS compares the reported AMP for a given quarter to its inflation-adjusted baseline AMP.

To adjust the baseline AMP for inflation, CMS first divides the baseline AMP by the baseline CPI-U (see Exhibit 3 for details). The result of that calculation is then multiplied by the quarterly CPI-U, which is the CPI-U for the month before the quarter being calculated. If the reported AMP is greater than this inflation-adjusted baseline AMP, the difference is added to the basic rebate when determining the URA. If the result (i.e., total rebate amount) is greater than the reported AMP, it is reduced to equal AMP.

Exhibit 3: Key variables used to calculate inflation-indexed rebates

Drug Category	Market Date	Baseline AMP	Baseline CPI-U
Single-Source or Innovator Multiple-Source	On or before October 1, 1990	3 rd -quarter 1990 AMP	CPI-U for September 1990
	After October 1, 1990	AMP for the first quarter after the drug's initial market date	CPI-U for the first month before the first quarter after the drug's initial market date
Noninnovator Multiple-Source	On or before April 1, 2013	3 rd -quarter 2014 AMP	CPI-U for September 2014
	After April 1, 2013	AMP for the 5 th full calendar quarter after the market date	CPI-U for the last month of the Baseline AMP quarter

Source: Sections 1927(c)(2) and 1927(c)(3) of the Act.

Total Rebate

CMS provides the URA for each NDC to State Medicaid agencies each quarter. To determine the total rebate due from manufacturers for each NDC, the URA is multiplied by the total number of units of the NDC reimbursed by the State during the quarter. This utilization figure should include all units for which Medicaid paid a portion of the claim, including Part B claims for beneficiaries who also have coverage under Medicare (i.e., dual eligibles) for which Medicaid covered any Part B coinsurance or deductible. To prevent subjecting drug manufacturers to duplicate discounts when claiming Medicaid rebates, States need to exclude claims for drugs purchased under the 340B Program when calculating the total rebates owed.³⁹

APPENDIX B

Total Doses Paid for Under Medicaid, by Formulation

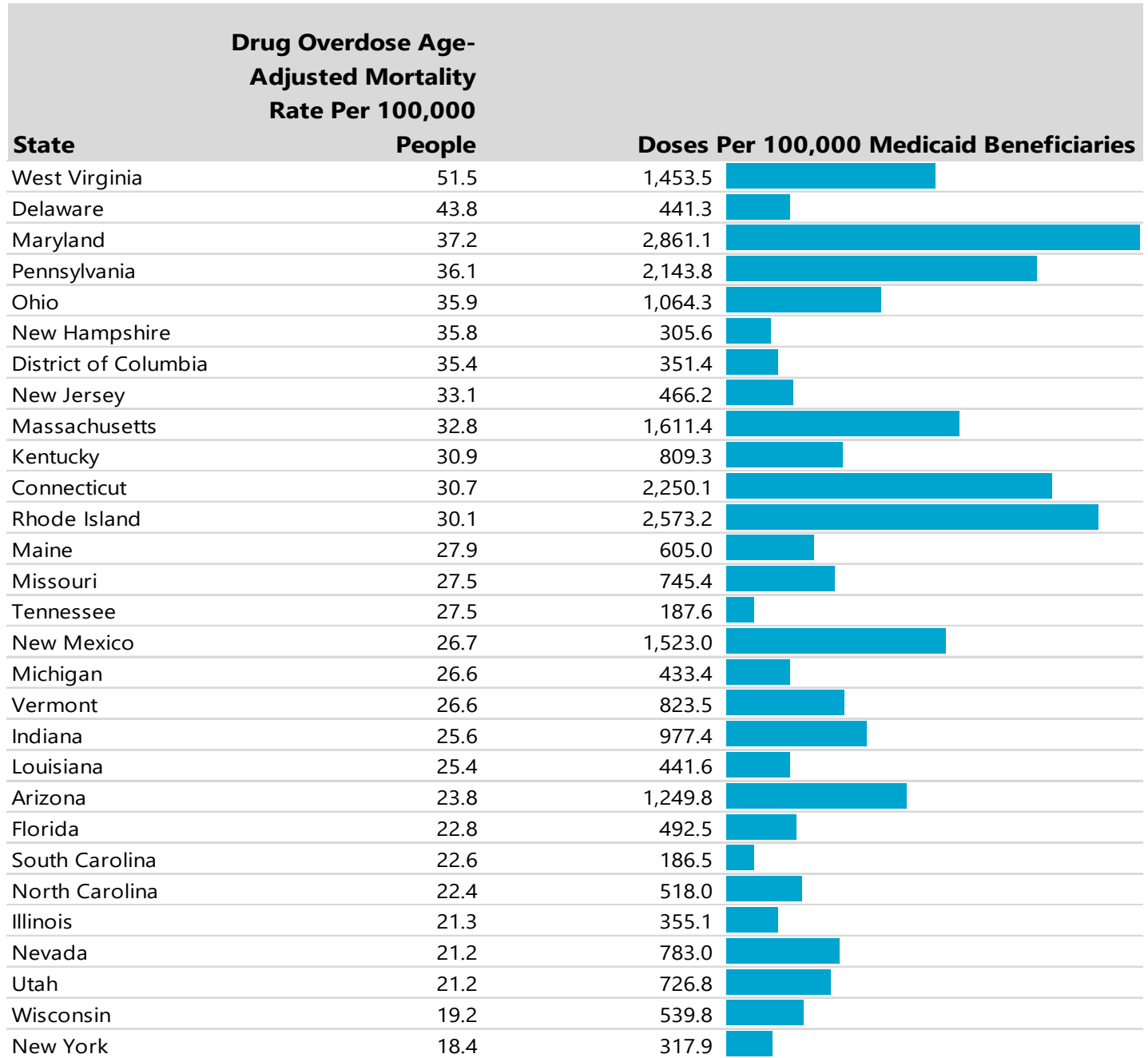
Formulation		2014	2015	2016	2017	2018
Community-Use Versions	Autoinjector (Evzio)	110	5,050	10,159	1,455	0
	Nasal Spray (Narcan)	0	0	36,876	194,835	424,381
	Community-Use Versions Total	110	5,050	47,036	196,289	424,381
Professional-Use Versions	Professional-Use Versions Total	22,638	38,557	72,799	68,839	53,026
Grand Total		22,748	43,606	119,834	265,128	477,407

Source: OIG analysis of 2014–2018 MDR data.

Note: Sum of rows may not equal totals due to rounding.

APPENDIX C

Drug Overdose Deaths and Distribution of Naloxone Paid for Under Medicaid in 2018, by State



Drug Overdose Age-Adjusted Mortality Rate Per 100,000		
State	People	Doses Per 100,000 Medicaid Beneficiaries
Oklahoma	18.4	561.0
Virginia	17.1	1,561.9
Colorado	16.8	705.7
Alabama	16.6	109.8
Arkansas	15.7	97.5
Washington	14.8	855.5
Alaska	14.6	638.9
Idaho	14.6	447.0
Hawaii	14.3	307.3
Georgia	13.2	112.0
California	12.8	228.6
Oregon	12.6	1,004.6
Kansas	12.4	455.7
Montana	12.2	758.1
Minnesota	11.5	606.0
Wyoming	11.1	500.7
Mississippi	10.8	68.2
Texas	10.4	119.3
North Dakota	10.2	166.3
Iowa	9.6	133.4
Nebraska	7.4	108.9
South Dakota	6.9	231.1

Source: OIG analysis of 2018 CDC drug overdose mortality data and 2018 MDR data.

APPENDIX D

Agency Comments




DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: September 11, 2020

TO: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections

FROM: Kimberly Brandt
Principal Deputy Administrator for Policy and Operations 

SUBJECT: Office of Inspector General (OIG) Draft Report: CMS Should Pursue Strategies To Increase the Number of At-Risk Beneficiaries Acquiring Naloxone Through Medicaid, OEI-BL-18-00360

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. Substance use disorders impact the lives of millions of Americans, including individuals enrolled in the Medicaid program. Of the approximately 53.5 million Medicaid beneficiaries with full or comprehensive benefits ages 12 and older who could be identified in the states included in a recent analysis, almost 4.1 million, or nearly 8 percent, were treated for a SUD in 2017.¹

Medicaid has already played a key role in expanding naloxone use covered under Medicaid by making naloxone affordable for low-income beneficiaries struggling with opioid use disorder. As OIG notes, access to naloxone for Medicaid beneficiaries has expanded significantly, with the program paying for 21 times more doses in 2018 than in 2014. For 2019, all states, including the District of Columbia, submitted a Medicaid Drug Utilization Review (DUR) Annual Survey encompassing federal fiscal year 2018 data. This DUR data indicates that naloxone is already available through state Medicaid programs without prior authorization in all 50 states. Furthermore, 47 states allow pharmacists to dispense naloxone prescribed independently or by collaborative practice agreements, standing orders, or other predetermined protocols where beneficiaries can obtain naloxone through state Medicaid plans. CMS has also issued guidance to states on improving access to naloxone. States may utilize grants and other financial sources to offer training in overdose prevention and response for providers and members of the community, including family members and friends of opioid users.

To further increase access to naloxone, CMS recently published a proposed rule on expanding access to naloxone for beneficiaries who are at risk of opioid overdose. The rule proposes requiring states to implement safety edits that would identify beneficiaries who could be at risk so that providers can consider co-prescribing naloxone. If finalized, CMS believes this rule will be a significant step towards increasing the number of Medicaid beneficiaries who receive naloxone through Medicaid.

OIG's recommendations and CMS' responses are below.

¹ Azar II, Alex. (October 24, 2019). *Report to Congress: T-MSIS Substance Use Disorder (SUD) Data Book, Treatment of SUD in Medicaid, 2017*. U.S. Department of Health and Human Services. <https://www.medicaid.gov/medicaid/data-and-systems/downloads/macbis/sud-data-book.pdf>

OIG Recommendation

CMS should pursue strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone through Medicaid.

CMS Response

CMS is already pursuing multiple strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone through Medicaid and will continue to do so. The recently published NPRM is a significant step that will increase beneficiary access, and we will continue to work with our federal and state partners where appropriate.

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

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Bahar Adili served as the team leader for this study, and Kara Robinson served as the lead analyst. Office of Evaluation and Inspections staff who provided support include Adam Freeman, Althea Hosein, Kevin Manley, and Christine Moritz.

We would also like to acknowledge the contributions of other Office of Inspector General staff, including Lauren McNulty and Jessica Swanstrom.

This report was prepared under the direction of Dave Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office; Heather Barton, Deputy Regional Inspector General; and Louise Schoggen, Assistant Regional Inspector General.

Contact

To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

ABOUT THE OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

ENDNOTES

¹ CDC, *America's Drug Overdose Epidemic: Data to Action*. Accessed at <https://www.cdc.gov/injury/features/prescription-drug-overdose/index.html> June 18, 2020.

² Weiner SG, Baker O, Bernson D, Schuur JD/Brigham and Women's Hospital, Boston, MA, "One-Year Mortality of Opioid Overdose Victims Who Received Naloxone by Emergency Medical Services." *Annals of Emergency Medicine* Volume 70, Issue 4, Supplement, October 2017.

³ Office of the Surgeon General. "U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose." Accessed at <https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html> on March 24, 2020.

⁴ Kaiser Family Foundation, "The Opioid Epidemic and Medicaid's Role in Facilitating Access to Treatment." Accessed at <https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicoids-role-in-facilitating-access-to-treatment/> on February 25, 2020.

⁵ United States Senate, *Combatting the Opioid Crisis: The Price Increase of an Opioid Overdose Reversal Drug and the Cost to the U.S. Health Care System*.

⁶ Standing orders take the place of an individual prescription.

⁷ CMS, *National Medicaid Fee-For-Service (FFS) 2018 Drug Utilization Review (DUR)*. Accessed at <https://www.medicaid.gov/medicaid/prescription-drugs/downloads/drug-utilization-review/2018-dur-ffs-summary-report.pdf> on July 10, 2020.

⁸ Association of State and Territorial Health Officials, *Increasing Number of States Require Naloxone to be Co-Prescribed with Opioids*. Accessed at <https://www.astho.org/StatePublicHealth/Increasing-Number-of-States-Require-Naloxone-Co-Prescribed-with-Opioids/08-15-19/> on May 21, 2020.

⁹ CMS, *National Medicaid Fee-For-Service (FFS) 2018 Drug Utilization Review (DUR)*. Accessed at <https://www.medicaid.gov/medicaid/prescription-drugs/downloads/drug-utilization-review/2018-dur-ffs-summary-report.pdf> on July 10, 2020.

¹⁰ For example, in Florida, a family member or friend obtaining a prescription for a Medicaid enrollee must present the enrollee's Medicaid identification number for the pharmacy to bill Medicaid. In this case, the Federal Government's share (Federal Medical Assistance Percentage) of payments would be available for this prescription as well. Kaiser Family Foundation, *Medicaid Behavioral Health Services: Naloxone Coverage Provided for Family Members or Friends Obtaining a Naloxone Prescription on Enrollee's Behalf*. Accessed at <https://www.kff.org/other/state-indicator/medicaid-behavioral-health-services-naloxone-coverage-provided-for-family-members-or-friends-obtaining-naloxone-prescription-on-enrollees-behalf/> on May 21, 2020.

¹¹ Medications are often designated as preferred or nonpreferred drugs by the State Medicaid agency or contracted managed care organization. In most cases, providers are permitted to prescribe preferred drugs without seeking prior authorization.

¹² CMS, *Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction*. Accessed at <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib-02-02-16.pdf> on March 19, 2020.

¹³ SAMHSA, *Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose*. Accessed at https://store.samhsa.gov/sites/default/files/d7/priv/medicaidfinancingmatreport_0.pdf on February 27, 2020.

¹⁴ 85 Fed. Reg. 37286-37322 (June 19, 2020).

¹⁵ For example, see Alison Kodjak, “First Responders Spending More On Overdose Reversal Drug,” *NPR*, August 8, 2017. See also Matt Stout, “State funds for overdose-reversing Narcan run dry, raising prices for municipalities,” *Boston Globe*, April 4, 2018.

¹⁶ The Comprehensive Addiction and Recovery Act (CARA) established a grant program to assist local governments in providing naloxone for first responders to administer during opioid overdose emergencies. Comprehensive Addiction and Recovery Act of 2016, P.L. No. 114-198. The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act recently expanded the grant program. SUPPORT for Patients and Communities Act, P.L. No. 115-271.

¹⁷ Medicaid enrollment for 2018. Kaiser Family Foundation, “Health Insurance Coverage of the Total Population.” Accessed at <https://www.kff.org/other/state-indicator/total-population/> on April 7, 2020.

¹⁸ MACPAC (the Medicaid and CHIP [Children's Health Insurance Program] Payment and Access Commission), *Provider Payment and Delivery Systems*. Accessed at <https://www.macpac.gov/medicaid-101/provider-payment-and-delivery-systems/> on February 27, 2020.

¹⁹ CMS, *Implementation of the Covered Outpatient Drug Final Regulation Provisions Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program*. Accessed at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd16001.pdf> on March 31, 2020.

²⁰ Actual acquisition cost (AAC) is the purchase price paid by a pharmacy net of all discounts and rebates to the price of the drug, not including the professional dispensing fee.

²¹ WAC is an estimate of the manufacturer's list price for a drug to wholesalers or other direct purchasers, not including discounts or rebates.

²² Kaiser Family Foundation. *Pricing and Payment for Medicaid Prescription Drugs*. Accessed at <https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/> on February 28, 2020.

²³ Sections 1927(a)(1) and (b)(1) of the Social Security Act (the Act).

²⁴ The basic rebate amount for a brand-name drug is set at either the difference between the quarterly average manufacturer price (AMP) and the best price or 23.1 percent of the AMP, whichever is higher. For generic drugs, the basic rebate amount is equivalent to the 13 percent of the AMP. Section 1927(c) of the Act.

²⁵ Sections 1927(c)(2) and 1927(c)(3) of the Act.

²⁶ Evzio entered the market in 2014, and its manufacturer, Kaleo, left the Medicaid drug rebate program in 2017.

²⁷ According to a U.S. Senate staff report, Kaleo's explanation for leaving the Medicaid drug rebate program was: “[M]any state Medicaid plans restrict patients to only one preferred product on their formularies. To help meet the needs of the community and ensure patients at risk for an opioid emergency have access to EVZIO, we are no longer participating in Medicaid.” See U.S. Senate, *Combatting the Opioid Crisis: The Price Increase of an Opioid Overdose Reversal Drug and the Cost to the U.S. Health Care System*, pp. 79-80.

²⁸ In the second quarter of 2017, Medicaid reimbursed providers in three States for Evzio even though Kaleo had exited the Medicaid drug rebate program in the first quarter of 2017.

²⁹ In 2018, 3 percent of doses were donated by manufacturers and one-third were sold at discounted prices to qualified public health entities, such as emergency personnel, community health programs, and colleges. The remainder were sold at nondiscount prices and paid for by other entities—such as private insurance, Medicare, and Medicaid—or directly by

consumers. One manufacturer reported to OIG only total units distributed for each of its naloxone products and did not report specifically how many of those doses were donated, sold at discount prices, and sold at nondiscount prices. Therefore, we may have underestimated these calculations.

³⁰ Medicaid beneficiaries may acquire naloxone through channels outside of Medicaid, such as through public health organizations.

³¹ OIG is unable to disclose prices for Narcan because drug pricing information is confidential.

³² OIG is unable to disclose prices for Evzio because drug pricing information is confidential.

³³ For example, see Brianna Ehley, "Pandemic unleashes a spike in overdose deaths," *Politico*, June 29, 2020.

³⁴ We obtained data directly from CMS's nonpublic MDR system. MDR contains fields that have been removed (e.g., data fields related to Medicaid drug rebates) and data that have been suppressed from the public to protect beneficiary privacy.

³⁵ CDC. *Drug Overdose Deaths in the United States, 1999-2018*. To identify drug overdose deaths, the National Center for Health Statistics uses ICD-10 underlying-cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14.

³⁶ MDR contains data summarizing Medicaid payments by State and payment arrangement (i.e., FFS or MCO). However, there are instances in which capitated payment arrangements between States and MCOs result in reimbursement amounts of \$0. Capitation payments are premiums paid by the State to the MCO to cover the cost of providing services. A payment is made regardless of whether a given beneficiary receives services for that month. Because we could not identify a reimbursement amount for the drug specifically in these instances, we removed these records. These accounted for 3 percent of records over the 5-year study period.

³⁷ Capitated payment arrangements are sometimes used by States to reimburse MCOs. In these cases, Medicaid provides a payment for a number of services, and reports paying \$0. Because we could not determine how much the State reimbursed for the naloxone NDC specifically, we removed the associated utilization from our analysis.

³⁸ Sections 1927(c)(2) and 1927(c)(3) of the Act.

³⁹ The 340B Drug Discount Program (340B Program) requires drug manufacturers to provide discounted outpatient drugs to certain eligible health care entities—known as covered entities—that serve the underinsured or uninsured. Covered entities include disproportionate share hospitals, which are hospitals that serve a disproportionately large number of low-income patients. Duplicate discounts under Medicaid are prohibited by law. 42 U.S.C. § 256b(a)(5)(A).