



# Federal Rebate Calculation for Medications to Treat Opioid Use Disorder in State Medicaid Programs

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This brief describes our approach to estimating the basic and inflationary federal rebates for medications to treat opioid use disorder and overdose (MOUDs) in state Medicaid programs. We use quarterly Medicaid State Drug Utilization Data (SDUD) from 2010 to 2018 to compute these estimates by National Drug Code (NDC) for three categories of MOUDs: (1) buprenorphine or buprenorphine/naloxone FDA approved for opioid use disorder (OUD) treatment, including buprenorphine monoproducts and buprenorphine-naloxone combination products; (2) naltrexone FDA approved for indications including OUD; and (3) naloxone FDA approved to reverse opioid overdose. We developed this methodology as part of a larger project, Tracking Medicaid-Covered Prescriptions to Treat Opioid Use Disorder.<sup>1</sup> Below, we provide an overview of our methods and findings, which we discuss in depth later in the report.

## Methods Overview

- This analysis primarily relies on SDUD to estimate the federal Medicaid rebate. SDUD are available in aggregate by 11-digit NDC code, state, quarter, and utilization type (fee-for-service or managed care). As such, we compute the rebate per unit by drug and quarter and then apply the rebate to quarterly state spending by drug and by utilization type, because claims-level data are not available and this is the smallest unit of data available.

- To compute both basic and inflationary federal rebates, we first estimate average manufacturer price (AMP) from data sources shown in previous research to closely approximate AMP, which differs for brand-name and generic drugs. To calculate AMP for most brand-name NDCs, we use Medicaid SDUD. To calculate AMP for most generic NDCs, we use weighted-AMP data from the Affordable Care Act Federal Upper Limits (FUL) data or National Average Drug Acquisition Cost (NADAC) data, the latter of which come from a national survey of retail pharmacies conducted for Medicaid programs (CMS 2013). For remaining NDCs without matches in FUL or NADAC data, we use Medicaid SDUD as AMP. We use average sales price (ASP), as reported by Medicare, as AMP for brand-name and generic “5i” drugs, which are inhaled, infused, instilled, implanted, or injected. When using SDUD to estimate AMP, we use the total amount spent by Medicaid and non-Medicaid entities.
- We calculate the basic federal Medicaid rebate for brand-name and generic drugs for all quarters within our study period, 2010 to 2018. For brand-name drugs, this rebate is whichever is greater: (1) 23.1 percent of AMP or (2) estimated AMP minus a best-price estimate. For generic drugs, the rebate is 13 percent of estimated AMP.
- We calculate the inflationary federal Medicaid rebate for all study quarters for brand-name drugs. For generic drugs, we only calculate this rebate starting in 2017, when the inflationary rebate for generic drugs took effect under the Bipartisan Budget Act of 2015 (MACPAC 2018a). For each drug in each quarter, we compute the inflationary federal Medicaid rebate as the baseline AMP multiplied by an inflation rate derived from the consumer price index in the baseline quarter. For example, to compute the inflationary rebate for a drug in the first quarter of 2018, we compute the inflation rate using the consumer price index from the baseline quarter to the first quarter of 2018, which is multiplied by the AMP in the baseline quarter. For brand-name drugs, we define the baseline AMP as the average AMP from the first three quarters with prescription counts over five after the drug first appears in SDUD in 1993. For generic drugs, we define the baseline AMP as the AMP in the first quarter with a prescription count over five in which the drug first appears in SDUD, beginning in the third quarter of 2014, following the Centers for Medicare & Medicaid Services (CMS) regulation. This calculation results in the inflation-adjusted allowable growth from the baseline AMP. If the current AMP is below this amount, the inflationary rebate is zero. However, if the current AMP exceeds the inflation-adjusted allowable growth, the inflationary rebate is computed as  $AMP - (baseline\ AMP \times inflation\ factor)$ .

- To calculate the total federal rebate, we add the basic and inflationary rebates and cap the total rebate at the quarterly AMP, per the 2010 federal rebate cap.

## Findings Overview

- We calculate each NDC's rebate per unit at the national level, combined across utilization types and package sizes, following CMS's calculation of the national-level rebate for 415 brand-name and 986 generic unsuppressed, nonzero quarters with prescription counts over five during our study period (MACPAC 2018a). From 2010 to 2018, all brand-name drug quarters and 362 generic drug quarters (37 percent of generic quarters with any rebate calculation) were eligible for the inflationary rebate. Seventy-two percent of brand-name quarters and 25 percent of eligible generic quarters had nonzero inflationary rebate values.
- When the final rebate, including both the national-level basic and inflationary rebates, exceeds quarterly AMP, it is reduced to quarterly AMP, per the 2010 federal cap limiting a drug's rebate to AMP. Five percent of total brand-name quarters and 1 percent of total generic quarters had a final rebate exceeding quarterly AMP, meaning the final rebates equaled quarterly AMP.
- We apply the national-level NDC rebate per unit for each quarter to state spending per NDC, quarter, and utilization type. We subtract the rebate per quarter based on the number of units reimbursed in that quarter. The estimated basic and inflationary rebates for these MOUDs substantially reduced net Medicaid spending (defined as the Medicaid pharmacy reimbursement reported in SDUD minus the estimated basic and inflationary rebates):
  - » The basic rebate for generic drugs is generally smaller than 13 percent of SDUD spending because estimated AMP from FUL and NADAC data is generally less than SDUD spending per unit. Conversely, the basic rebate for brand-name drugs is generally greater than 23.1 percent of SDUD spending per unit, because SDUD are usually used as the estimated AMP for brand-name drugs, and the inflationary rebate has a positive value for most quarters.
  - » As shown in table 1, across all study years, the estimated basic and inflationary rebates reduced the net Medicaid spending for MOUDs reported in SDUD by 34 percent for buprenorphine products (39 percent for brand-name and 6 percent for generic), 50 percent for naltrexone (54 percent for brand-name and 7 percent for generic), and 56 percent for naloxone (60 percent for brand-name and 21 percent for generic).

- » In 2018, spending was 22 percent lower for buprenorphine (26 percent for brand-name and 6 percent for generic), 50 percent lower for naltrexone (52 percent for brand-name and 8 percent for generic), and 46 percent lower for naloxone (46 percent for brand-name and 32 percent for generic) in the Medicaid SDUD (table 1).
- The computed final rebate is greater than the Medicaid amount spent for 8 percent of state quarters for brand-name NDCs and 4 percent of state quarters for generic NDCs. Thus, Medicaid gained from the rebates on MOUDs for these NDC quarters.

**TABLE 1**

**Unadjusted and Rebate-Adjusted Medicaid Spending and Rebate as a Share of Spending for MOUDs, 2010–18 and 2018**

	Unadjusted Medicaid spending (millions of dollars)	Rebate-adjusted Medicaid spending (millions of dollars)	Rebate as a share of unadjusted Medicaid spending (%)
<b>2010–18</b>			
<i>Buprenorphine</i>	5,188	3,433	34
Brand-name	4,373	2,665	39
Generic	815	769	6
<i>Naloxone</i>	71	31	56
Brand-name	64	25	60
Generic	7	6	21
<i>Naltrexone</i>	806	400	50
Brand-name	749	346	54
Generic	58	54	7
<b>2018</b>			
<i>Buprenorphine</i>	1,034	804	22
Brand-name	838	618	26
Generic	197	185	6
<i>Naloxone</i>	27	15	46
Brand-name	26	14	46
Generic	1	1	38
<i>Naltrexone</i>	268	134	50
Brand-name	259	125	52
Generic	9	8	8

**Source:** Urban Institute analysis of Medicaid State Drug Utilization Data, 2020; see “Tracking Medicaid-Covered Prescriptions to Treat Opioid Use Disorder,” Urban Institute, March 3, 2020, <https://www.urban.org/policy-centers/health-policy-center/projects/tracking-medications-to-treat-opioid-use-disorder>.

**Note:** MOUDs = medications to treat opioid use disorder.

## Background

Medicaid program spending for outpatient prescription drugs has several components: (1) an initial payment to a pharmacy or other outpatient provider that includes the drug cost and a dispensing fee; (2) mandated federal rebates Medicaid receives from manufacturers, which include basic and inflationary rebates related to the drug cost; and (3) supplemental rebates, which are negotiated by nearly all state Medicaid programs or multistate coalitions (MACPAC 2019b). Mandated and supplementary rebates substantially reduce Medicaid programs' spending on outpatient prescription drugs; in 2017, gross drug spending totaling \$64.0 billion was associated with federal and supplementary rebates totaling \$34.9 billion (MACPAC 2019b). Researchers estimate that Medicaid receives rebates of about 61 percent of the retail price for brand-name drugs, whereas Medicare Part D and private insurance plans receive rebates of about 31 and 16 percent of the retail price (Roehrig 2018).

We base our methodology for estimating federally mandated basic and inflationary rebates in Medicaid programs for outpatient prescription drugs on previous work by Sean Dickson, which used SDUD and other sources to estimate the federal Medicaid rebates and cap (Dickson 2019), and conversations with experts including Anna Anderson-Cook, Richard Frank, Andrea Noda, and Edwin Park. This methodology excludes computations of state supplemental rebates because no data source provides the necessary NDC-level information. In addition, our rebate calculations do not subtract dispensing fees from spending, because state-specific dispensing fee data are unavailable for all study years and by pharmacy and provider types. Additionally, we use both ingredient costs and dispensing fees in pricing analysis because, according to MACPAC (2018a), any analysis of state payments for outpatient prescription drugs must consider both of these elements, because a "lower payment on one of the components may be compensated through higher payment on the other."

## Study Data

For this analysis, we use Medicaid SDUD records of drug prescriptions filled and dispensed in outpatient settings, including pharmacies and any setting where a Medicaid-covered outpatient drug is billed as an outpatient drug and processed as a Medicaid outpatient drug claim (e.g., a physician's office) from the first quarter of 2010 through the fourth quarter of 2018. Records are from both fee-for-service (FFS) and managed care organizations. SDUD are available in aggregate by 11-digit NDC code (where the last two digits represent package size),<sup>2</sup> state, quarter, and utilization type (FFS or managed care). For example, SDUD provide the total number of prescriptions and units reimbursed and total Medicaid and non-Medicaid spending for a particular 11-digit NDC in a state and in a quarter for a utilization type, but it does not show spending amounts for individual prescriptions of that NDC.

In this study sample, we calculate the Medicaid rebates for each nine-digit NDC per quarter, combined for FFS and managed care organizations and across drugs' package sizes, at the national level. Our study sample contains 36 brand-name and 77 generic nine-digit NDCs. To compute national spending by NDC by quarter, we sum spending, units, and prescriptions for prescriptions filled and

dispensed across all states, utilization types, and package sizes. We sum 21,154 brand-name and 55,597 generic state SDUD quarters with prescription counts over five to the national level by NDC and quarter, resulting in 415 brand-name and 986 generic quarters of data. We calculate the rebate for all years of data in our study sample for brand-name and generic NDCs for unsuppressed, nonzero observations with prescription counts over five, because we found that very small prescription counts were often associated with inconsistent price data.

Medicaid SDUD suppress data for NDC state quarters with fewer than 11 prescriptions, which affects pricing and rebate calculations because they require observations at the drug launch, when data are often suppressed. We submitted a data use agreement to purchase unsuppressed Medicaid SDUD from CMS for 2014 through 2018. Additionally, our colleague, Alex Gertner of the University of North Carolina at Chapel Hill, generously shared unsuppressed data from 1991 to 2013, which he obtained through a Freedom of Information Act request (Gertner 2019). In cases where publicly available Medicaid SDUD were suppressed, we used total spending, Medicaid spending, prescription counts, and unit counts from the unsuppressed files if the prescription counts were lower than 11. In cases where the data were suppressed in the public file but the corresponding entry in the unsuppressed file showed a prescription count greater than 11, we calculated the total spending, Medicaid spending, and units per prescription based on the unsuppressed data; imputed the number of prescriptions; and then calculated total spending, Medicaid spending, and units based on the number of imputed prescriptions.

We calculate rebates per unit, which is a single pill, tablet, film, implant (where the implant is billed as an outpatient drug), or kit when the drug comes in these forms. If the drug comes as a solution, a unit is one milliliter. We define a single unit for implant and kit drugs as follows: one vial of nasal spray for Narcan, one autoinjector for Evzio, one implant consisting of four pouches for Probuphine, and one kit for Vivitrol. Some of these drugs are seldom dispensed through a retail community pharmacy (e.g., implants and Vivitrol are administered in a provider's office) but are billed as an outpatient drug and are thus included in SDUD.

In cases where an NDC represents a single pill, tablet, or film, we expect to see more than one unit per prescription, because the units per prescription likely represent the days' supply prescribed. For example, NDC 2496-1212-01 represents a single film, or one unit, of Suboxone. In SDUD, this NDC's median unit per prescription is 17, likely because each prescription contains 17 films.

However, in many cases where NDCs do not represent a single unit, the reported units in SDUD appear to be reported inconsistently. For example, Suboxone has more than one package size, one of which, NDC 12496-1212-03, is a carton of 30 films. For this drug, the median units per prescription reported in SDUD is 22.5. There are two possible reasons why the median units per prescription is less than the number of units in a single carton: The first is a potential problem with reporting; if some prescribers correctly report a single carton of 30 films as having 30 units and others incorrectly report the carton as one unit, the aggregate SDUD would show fewer than 30 units per prescription. Second, prescribers may prescribe fewer units than what comes in a certain package size, causing variation when pharmacists record the prescription as the number of units prescribed. Because SDUD are

published as the aggregate of all prescriptions within NDC codes, states, quarters, and utilization types, we cannot distinguish the breakdown by these two explanations. However, if there is a separate NDC package size for individual pills, we assume there is a reporting problem when the units per prescription are lower than what the label indicates for cartons or bottles that contain multiple units, because the NDC for the individual units should be used in these cases.<sup>3</sup>

To create a consistent unit of measurement for each NDC, we therefore created an algorithm to replace SDUD units in some instances. To more reliably estimate units, we record the number of units per prescription as listed on each NDC package label. We then compute the expected units in that state, quarter, and utilization type by NDC code by multiplying the number of units per prescription by the number of prescriptions in that quarter. We replace the number of units with the expected units for quarters when (1) the drug was measured by unit, not milliliter; (2) the package label showed more than one unit per prescription; or (3) the number of SDUD units for the drug in the state, quarter, and utilization type was lower than the expected number of units. We use the expected units for 32.1 percent of all unsuppressed, nonzero state observations, including the implantable and injectable kits Probuphine and Vivitrol, for which we assume each prescription has one unit. For 181 Narcan observations, or 0.2 percent of all observations, where the reported units appeared in milliliters rather than vials, we divide the number of reported SDUD units by the milliliters per vial.

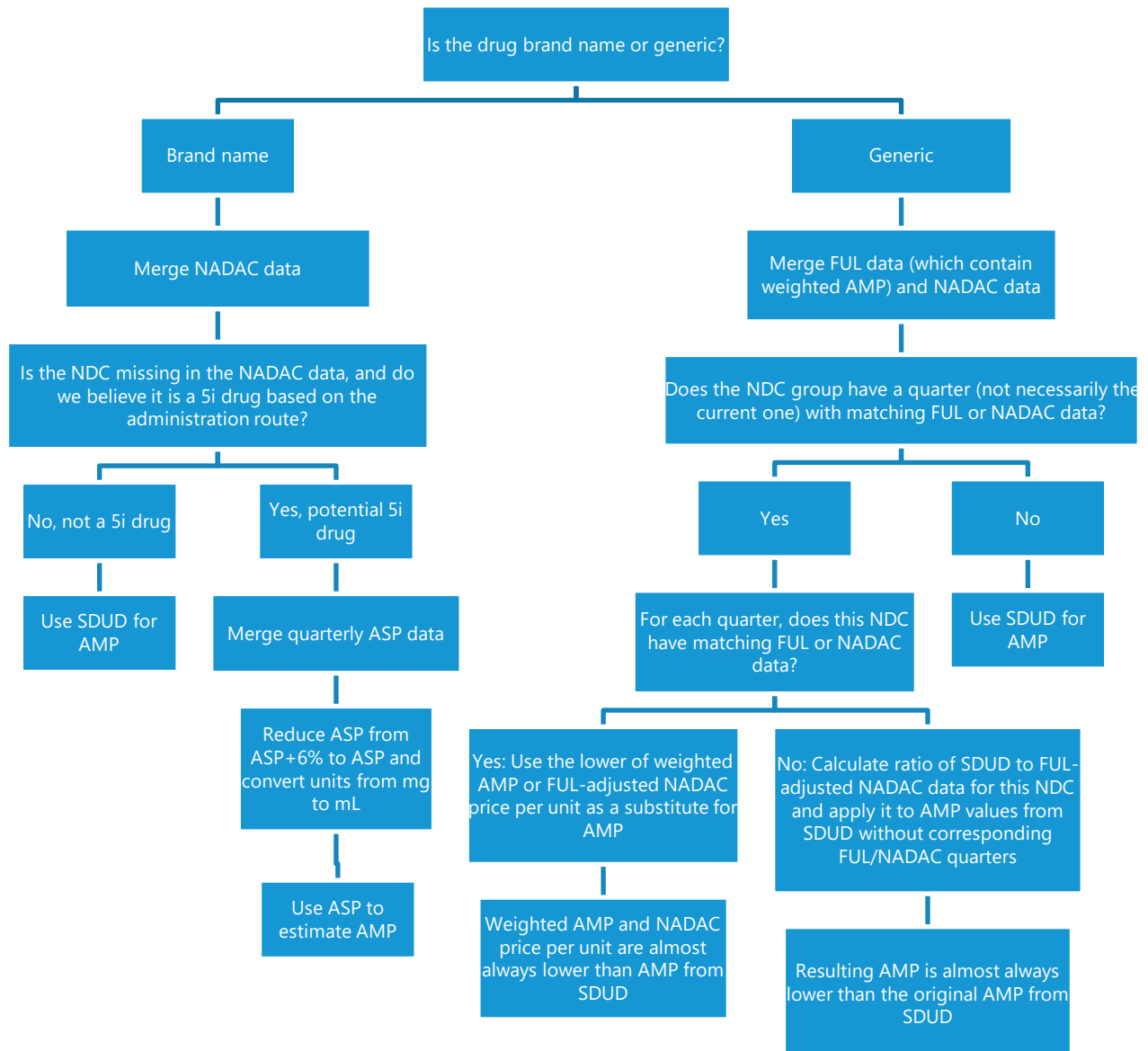
However, we use the SDUD-reported unit if (1) the drug was measured in milliliters, because the number of milliliters injected can vary by prescription; (2) the number of SDUD units for the drug in the state, quarter, and utilization type was equal to or higher than the expected number of units, because these appear to be prescriptions written for more than one package at once (i.e., SDUD unit is 60, representing one prescription for two bottles of 30 pills); (3) the package label listed one unit per prescription for reasons described above; or (4) the units measured in SDUD appeared to be for a different package than that listed on the package label (e.g., NDC 47335-0326-88 for generic naltrexone shows a package label of 100 tablets per bottle, but we see a median of 30 units in SDUD, which we believe to be a discrepancy). We use the reported units from SDUD for 67.9 percent of unsuppressed, nonzero state observations. Of these, we use the reported SDUD units for about a quarter of the observations because the drug was measured in milliliters.

## Methodology

To estimate the federal basic and inflationary rebates, we use the federal formula for each rebate with an estimate of AMP for each NDC. AMP is a critical input to both federal rebate computations but is a propriety value estimated by the manufacturer based on market data (manufacturer sales to retail community pharmacies and wholesalers) and is unavailable to researchers. And estimated AMP derived from the Medicaid SDUD only approximates true AMP in some cases. Below, we show how we compute AMP estimates for various brand-name and generic drugs (figure 1), the federal Medicaid basic and inflationary rebates (figures 2 and 3), and the federal Medicaid rebate cap.

FIGURE 1

**How We Estimate AMP for Federal Medicaid Rebate Calculations  
for Brand-Name and Generic Drugs in Medicaid SDUD**



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**Source:** Urban Institute analysis of Medicaid State Drug Utilization Data and other data sources, 2020.

**Notes:** AMP = average manufacturer price. SDUD = State Drug Utilization Data. NADAC = National Average Drug Acquisition Cost. FUL = Federal Upper Limits. NDC = National Drug Code. ASP = average sales price.



## Estimating AMP for Brand-Name Drugs

Previous studies have shown that Medicaid pharmacy reimbursements approximate AMP for brand-name drugs typically dispensed through retail community pharmacies, though AMP varies over time (e.g., month to month; Bruen and Young 2014). Additionally, AMP is the average price retail community pharmacies pay to manufacturers, and Medicaid pharmacy reimbursement is based on actual acquisition cost (Dickson 2019). Thus, we estimate AMP per unit of these drugs using Medicaid pharmacy reimbursement reported in SDUD by dividing the total amount spent, which includes Medicaid and non-Medicaid spending, by the number of units prescribed.<sup>4</sup> We compute this at the national level, combining FFS and managed care records and package sizes of the same NDC. We use the total amount spent reported in SDUD rather than the Medicaid amount spent because the federal Medicaid rebate from manufacturers depends on an AMP, which is most often based on the manufacturer's sales to retail community pharmacies and wholesalers, not on Medicaid's payments to pharmacies (MACPAC 2018a). When we aggregate data for the national AMP estimate, we exclude all records with five or fewer prescriptions (which excludes 33 percent of records for state quarters), because we believe the price per unit is unreliable for such small sample sizes. We also exclude managed care records for state quarters with nonzero unit counts but zero spending (which excludes 0.2 percent of managed care records for state quarters with prescription counts over five), because they likely reflect capitated payments where spending was not captured. We also exclude managed care records where the reported price per unit was at or below half the price per unit for the quarters before and after (which excludes 0.2 percent of records for state quarters with prescription counts over five), because these records were deemed unreliable and likely owe to capitated payments being included in the aggregate SDUD for specific quarters.

## Estimating AMP for Generic Drugs

For generic drugs, research shows that AMP is inconsistent with pharmacy prices (Levinson 2011). Therefore, we merge in weighted-AMP data from the FUL data, which better approximate AMP for generic drugs than do SDUD (Bruen and Young 2014). FUL data are collected and published by CMS to set limits on generic drug pricing in Medicaid and are available beginning in the second quarter of 2016. To estimate AMP for earlier data, we also merge in NADAC data, which are available beginning in the fourth quarter of 2013. We use NADAC price-per-unit data from the first week of each quarter as an approximation of AMP. In the few cases where the average AMP estimate in FUL or NADAC data varies across package sizes, we average the estimate across package sizes. Weighted AMP from the FUL data varies across package sizes for 1 percent of the FUL data, and NADAC price per unit varies across package sizes for 8 percent of the NADAC data.

For generic NDCs in SDUD that have matching quarterly records in both the FUL and NADAC data, we estimate AMP using the lower of (1) the weighted AMP from the FUL data or (2) the price-per-unit value from the NADAC data. We use whichever is lowest because CMS calculates the rebate using the lowest price for which manufacturers sold the drug (MACPAC 2018a).

However, when both FUL-weighted AMP and NADAC data are available for NDC quarters, the FUL-weighted AMP is always lower than the NADAC price. Because NADAC data are available beginning in the fourth quarter of 2013 but FUL data are not available until the second quarter of 2016, we observe an artificial drop in price between the first and second quarters of 2016, when we switch from using NADAC- to FUL-weighted AMP data. To smooth out this drop, we compute a FUL-weighted AMP-to-NADAC price ratio for the earliest four quarters in which both data are available. This price ratio has a mean of 0.46, a median of 0.42, and 10th and 90th percentile values of 0.30 and 0.73. We apply this ratio to quarters for which only NADAC data are available, adjusting NADAC values downwards. We call the FUL-weighted AMP and FUL-adjusted NADAC values the generic AMP.

For generic drug quarters before and after generic AMP data are available, we compute two estimates based on the earliest four quarters and latest four quarters in which generic AMP data are available. We compute early and late estimates of the ratio of SDUD to generic AMP for each NDC using the average SDUD-to-generic AMP ratio for the earliest and latest four quarters for which the drug has matching generic AMP records. We apply these ratios from the earliest and latest quarters to SDUD AMP estimates for quarters before and after generic AMP data are available. These ratios adjust SDUD AMP downward for nearly all quarters. For generic drugs that do not appear in the FUL or NADAC files, we use SDUD AMP data, because they are the only publicly available data.

## Estimating AMP for 5i Drugs

Outpatient inhalation, infusion, instilled, implanted, or injectable drugs, or 5i drugs, are seldom dispensed through a retail community pharmacy (e.g., extended-release injectable naltrexone is administered monthly in a provider's office). For 5i drugs where more than 30 percent of sales are not to retail community pharmacies, the federal government uses different methodologies to compute AMP for the federal rebate calculation than they would use for non-5i drugs.<sup>5</sup>

To estimate AMP for 5i drugs, we first identify 5i drugs based on dosage and administration route, as published in the US Food and Drug Administration NDC Directory. We classify drugs as potentially 5i if they fall in the following categories: implant, injection, injection (solution), solution, kit, and vial from a kit. We then corroborate 5i status if the drug is not included in the NADAC data. We flag potential 5i NDCs without matching data in the NADAC as suspected 5i drugs. We thus determine that 7 of the 36 brand-name NDCs and 11 of the 77 generic NDCs in the study sample are potential 5i drugs based on their administration routes and lack of matching NADAC records (table 2). For these drugs, we merge in quarterly ASP data from CMS, which reports 106 percent of ASP; convert price per unit of milligrams to milliliters<sup>6</sup>; and account for the two-quarter lag in data. The ASP varies across package sizes for 1 percent of the ASP data; in these cases, we use the average of the ASP across the different package sizes.

TABLE 2

**Sources Used to Estimate AMP for Federal Medicaid Rebate Computations for Brand-Name and Generic Drugs in Medicaid SDUD, 2010–18**

	Brand-Name Drugs		Generic Drugs	
	Number of NDCs	Share of NDCs (%)	Number of NDCs	Share of NDCs (%)
Unique NDCs (combined across package sizes)	36	100	77	100
Potential 5i drugs (based on dosage form and NADAC data)	7	19	11	14
	Brand-Name Drugs		Generic Drugs	
	Number of quarters	Share of quarters (%)	Number of quarters	Share of quarters (%)
AMP source for unsuppressed national quarters	415		986	
SDUD	352	85	94	10
ASP	63	15	30	3
Weighted AMP from FUL data	—		270	27
Adjusted NADAC	—		273	28
FUL-to-NADAC ratio applied to earlier SDUD quarter	—		295	30
FUL-to-NADAC ratio applied to later SDUD quarter	—		24	2

**Source:** Urban Institute analysis of Medicaid State Drug Utilization Data and other data sources, 2020.

**Notes:** SDUD = State Drug Utilization Data. NDC = National Drug Code. NADAC = National Average Drug Acquisition Cost. AMP = average manufacturer price. FUL = Federal Upper Limits. For cells with a dash, no data were available. Our analysis combines NDCs across package sizes, meaning we aggregate the 11-digit NDC codes to the 9-digit NDC level.

Only 9 of the 17 NDCs flagged as potential 5i drugs have corresponding ASP data, and we believe they are 5i drugs because they are injected and implanted. They are NDCs 00641-6132, 17478-0041, 17478-0042, and 67457-0599 (generic naloxone injections); NDCs 12496-0100 and 12496-0300 (Sublocade, an injection with two different dosages); NDC 58284-0100 (Probuphine, an implant); and NDCs 63459-0300 and 65757-0300 (Vivitrol, an injection). We use ASP data to estimate AMP for these drugs because ASP should always be within 5 percent of AMP and is therefore a better AMP approximation than SDUD.

SDUD may not provide a reasonable estimate of AMP for 5i drugs, but if the drug is reimbursed under Medicare Part B and has a record in the ASP data, we can use a CMS formula to compare and replace the estimated AMP from SDUD with the ASP reported by Medicare. According to CMS, AMP should be substituted for ASP when computing federal rebates if a drug's ASP exceeds the AMP by 5 percent in the previous two quarters or three of the previous four quarters. The ASP file indicates whether the AMP was substituted for ASP. Though none of the 5i drugs that contain ASP data in our sample meet this criterion, we use ASP data to estimate AMP for these drugs. We have complete ASP data for all but one of the 5i drugs, NDC 63459-0300 (Vivitrol). For that drug, we compute the ratio of ASP to SDUD AMP for the four latest quarters with ASP data and apply the ratio to SDUD AMP in later quarters. For suspected 5i drugs without matching ASP data, such as NDC 65757-0302 (Vivitrol), we use SDUD to estimate their AMP, which are the best data publicly available. However, the SDUD estimate of AMP for this NDC is highly variable and may not be reliable.

## Computing the Basic Manufacturer's Rebate

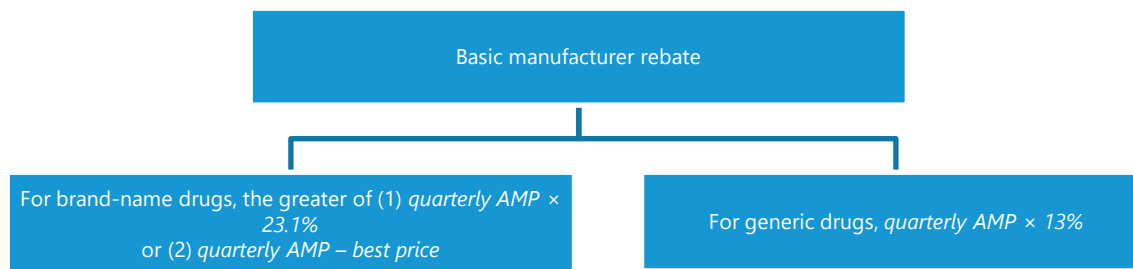
We calculate the national-level rebate per unit for all quarters in our sample for brand-name and generic drugs for unsuppressed quarters with prescription counts over five.

We calculate the basic rebate for brand-name drugs as the greater of (1) 23.1 percent of estimated AMP (as derived from various data sources) or (2) estimated AMP minus a best-price estimate, where best price equals the lowest price available to any private purchaser and includes discounts and rebates. For generic drugs, we calculate the rebate as 13 percent of estimated AMP (figure 2).

For brand-name drugs, we estimate best prices using prices from the Federal Supply Schedule (FSS), published by the US Department of Veterans Affairs. The US Department of Veterans Affairs negotiates prices with manufacturers based on the prices manufacturers charge their most favored commercial customer, and the prices from these contracts are published in the FSS for eligible federal government agencies (CBO 2005). US Department of Veterans Affairs staff advised us that prices listed in the FSS for our drugs of interest reflect prices for the package listed; as such, we divided the price by the number of units in each package to determine the price per unit. We aggregated the FSS prices per unit across NDCs of different package sizes, finding that 1 percent of prices differed within package size.

For several reasons, our best-price estimate is an underestimate. First, FSS prices, the prices eligible federal agencies pay, have been found to be around 10 percent lower than actual best price, which is the lowest price available to any private purchaser (CBO 2005). Second, FSS prices cannot increase faster than inflation over five years, but actual best price can. This also means we may see an artificial, sudden increase in the FSS price after five years that does not represent an actual increase in best price. Third, manufacturers must provide an even further discounted price to the four largest federal purchasers of pharmaceuticals, the Big Four: the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard. The Big Four price is based off the federal ceiling price, which is based off 76 percent of the previous year's nonfederal AMP, which is the average price the wholesalers pay manufacturers for drugs distributed to nonfederal purchasers (including discounts or price reductions but excluding rebates paid by manufacturers; CBO 2005). About one-third of brand-name drugs in the FSS lists a separate price for Big Four purchasers and another price for all other federal purchasers. The other two-thirds of brand-name drugs have only one price listed in the FSS, which cannot exceed the price offered to the Big Four. FSS prices are known to be lower than best price, and a large portion of the listed FSS prices actually reflect Big Four prices, which are known to be even lower than FSS prices (CBO 2005); taken together, we likely underestimate best price and therefore overstate the best-price provision.

**FIGURE 2**  
**Basic Rebate Computation**



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**Source:** Urban Institute analysis of Medicaid State Drug Utilization Data and other data sources, 2020.

**Note:** AMP = average manufacturer price.

## Computing the Manufacturer's Inflationary Rebate

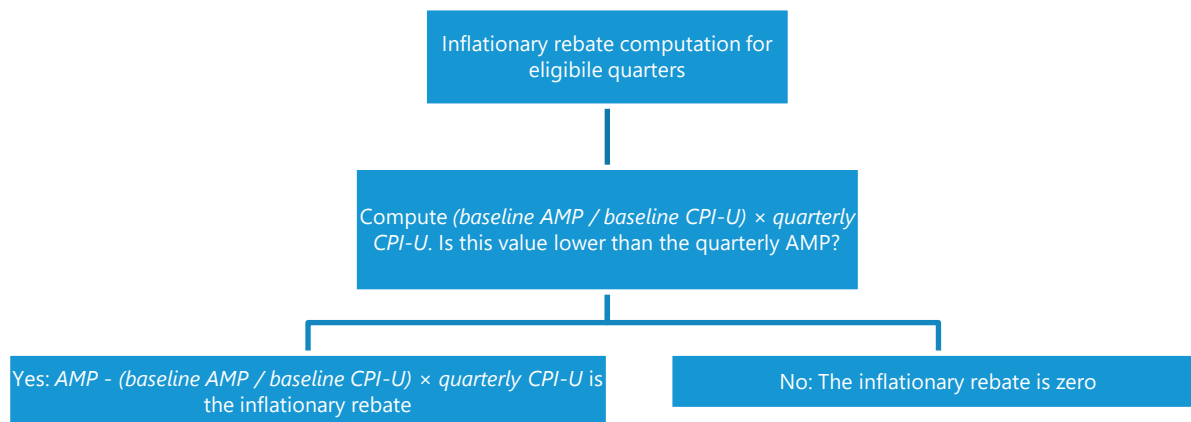
To compute the inflationary rebate at the national level, we multiply the baseline AMP by an inflation factor representing growth from the baseline quarter to the present quarter using the consumer price index for all urban consumers (CPI-U). In other words, we compute  $(\text{baseline AMP}) \times (\text{quarterly CPI-U} / \text{baseline CPI-U})$ . To minimize data validity problems related to small sample sizes, we identify the baseline quarter as the first nonmissing, nonzero quarter in which the drug appears with a prescription count over 10 in SDUD. If no quarters have a prescription count over 10, we use the first quarter in which the drug appears in SDUD, regardless of the prescription count. For generic drugs, we identify the baseline quarter by following these criteria beginning in the third quarter of 2014, the earliest baseline quarter for all generic drugs according to CMS (MACPAC 2018a).

For brand-name drugs, we calculate baseline AMP using an average of the first three quarters in which the NDC appears in SDUD. This evens out variations in AMP due to a potential lag in reported spending (but not units), which would otherwise result in an artificially low AMP. Additionally, we expect brand-name drug prices to remain fairly constant in the first quarters after the drug's launch. For generic drugs, we calculate baseline AMP as the AMP in the baseline quarter, because generic drug prices often drop significantly following their first 180 days on the market if other generics also enter the market (MACPAC 2018b).

We compare the computed amount of allowable growth from the baseline AMP due to inflation with the quarterly AMP. If the quarterly AMP is greater than the computed allowable growth, we subtract the computed allowable growth from the quarterly AMP to determine the inflationary rebate. If the quarterly AMP is less than or equal to the computed allowable growth, the inflationary rebate is set to zero (figure 3).

For brand-name drugs, all quarters are eligible for the inflationary rebate, and for generic drugs, 2017 quarters and onward are eligible, following CMS policy (MACPAC 2018a). For the study sample, we estimate the inflationary rebate takes effect, meaning it is greater than 0, for 74 percent of quarters for brand-name NDCs and 16 percent of eligible quarters for generic NDCs.

**FIGURE 3**  
**Inflationary Rebate Computation**



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**Source:** Urban Institute analysis of Medicaid State Drug Utilization Data and other data sources, 2020.

**Notes:** AMP = average manufacturer price. CPI-U = consumer price index for all urban consumers.

## Combined Federal Manufacturer's Rebates

We calculate the final federal rebate per unit at the national level as the sum of the basic and inflationary rebates, with the final rebate reduced to quarterly AMP if it exceeds quarterly AMP. Thus, for brand-name drugs, AMP can grow as high as 433 percent above allowable growth due to inflation (i.e.,  $1 / 0.231$ , because the basic federal rebate for brand-name drugs is 23.1 percent); for generic drugs, AMP can grow as high as 769 percent above allowable growth due to inflation (i.e.,  $1 / 0.13$ , because the basic federal rebate for generic drugs is 13 percent). For 5 percent and 1 percent of quarters for brand-name and generic drugs the final rebate is reduced to the quarterly AMP (table 3).

Table 4 shows examples of each computation discussed.

**TABLE 3**  
**Summary of Rebate-Related Computations for Medicaid SDUD Prescriptions for Treating Opioid Use Disorder and Overdose, Quarterly Data from 2010 to 2018**

	Brand name		Generic	
	#	%	#	%
<b>Quarters with a rebate calculation</b>	<b>415</b>		<b>986</b>	
Basic rebate is 23.1% (brand-name) or 13% (generics) of AMP	214	52	986	100
Basic rebate is <i>AMP - best price (FSS)</i>	201	48	-	-
SDUD quarters eligible for the inflation/additional rebates (for generics, beginning 2017)	415	100	362	37
Inflation/additional rebate is 0	118	28	271	75
Inflation/additional rebate is greater than 0 (AMP has exceeded the allowable growth)	297	72	91	25

	Brand name		Generic	
	#	%	#	%
Total rebate is greater than the quarterly AMP and is reduced to AMP	20	5	8	1
<b>SDUD quarters for states</b>	<b>21,154</b>		<b>55,597</b>	
Quarters with a rebate calculation; SDUD quarters are unsuppressed and nonzero and have a national-level rebate	20,573	97	5,992	97
Rebate is greater than Medicaid amount spent	1,572	7	1,559	3

**Source:** Urban Institute analysis of Medicaid State Drug Utilization Data and other data sources, 2020.

**Notes:** SDUD = State Drug Utilization Data. AMP = average manufacturer price. An empty cell means the row does not apply to the column head. SDUD quarters are unsuppressed and nonzero and have prescription counts over five.

**TABLE 4**

**Federal Medicaid Rebate Calculation Examples, First Quarter of 2018**

Medicaid rebate calculation steps	NDC 12496-1208, Suboxone	NDC 50383-0287, generic buprenorphine/naloxone
(a) AMP: AMP estimate	\$6.97	\$1.43
(b) Baseline quarter: The first quarter in which the drug appears in SDUD with a prescription count over 10	2010 Q3	2016 Q1
(c) Baseline AMP: The average AMP for the first three quarters after the baseline quarter for brand-name drugs and the AMP for the baseline quarter for generic drugs	\$6.04	\$2.18
(d) Baseline CPI: CPI value for the baseline quarter	217.965	236.525
(e) Quarterly CPI: CPI value for the first quarter of 2018	246.524	246.524
(f) Best price: Estimated using the Federal Supply Schedule price; for brand-name drugs only	\$5.33	
<b>Basic rebate</b>		
(g) 23.1% of AMP for brand-name drugs and 13% of AMP for generic drugs; calculated as 23.1% or 13% of (a)	\$1.61	\$0.19
(h) AMP – best price, for brand-name drugs only; Equal to (a) – (f)	\$1.65	
(i) Basic rebate: The greater of (g) or (h)	\$1.65	\$0.19
<b>Inflationary rebate</b>		
(j) Inflation-adjusted allowable growth, calculated as <i>baseline AMP × (quarterly CPI / baseline CPI)</i>	\$6.84	\$2.27
(k) Inflationary rebate: If the quarterly AMP has exceeded the inflation-adjusted allowable growth, the inflationary rebate = <i>AMP – allowable growth due to inflation</i> , otherwise 0; in other words, if (a) > (j), (a) – (j), else 0	\$0.14	\$0.00
<b>Final rebate</b>		
(l) Total rebate: <i>basic rebate + inflationary rebate</i> , or (i) + (k)	\$1.79	\$0.19
(m) Final rebate: If the total rebate is greater than quarterly AMP, it is reduced to AMP, otherwise the rebate does not change	\$1.79	\$0.19

**Sources:** Urban Institute analysis of Medicaid State Drug Utilization Data and other data sources, 2020.

**Notes:** NDC = National Drug Code. Q = quarter. AMP = average manufacturer price. SDUD = State Drug Utilization Data. FUL = Federal Upper Limits. CPI = consumer price index. An empty cell means the row does not apply to the column head. For

Suboxone NDC 12496-1208, estimated AMP comes from SDUD; for generic buprenorphine/naloxone NDC 50383-0287, the estimated AMP is the weighted AMP from FUL.

## Applying the Rebate to State Spending

We apply the national-level rebate per unit to state data by 11-digit NDC, FFS or managed care group, and quarter. We calculate the quarterly rebate as the national-level rebate per unit multiplied by the number of units reimbursed in that quarter, using the edited number of units per 11-digit NDC based on package size. We subtract the quarterly rebate from the total Medicaid amount spent.

We do not subtract the rebate amount for managed care data where SDUD show zero Medicaid spending but a positive number of prescriptions, because these observations likely reflect capitated payment arrangements in managed care.<sup>7</sup> Subtracting the rebate would result in negative Medicaid spending for the suspected capitated payment observations. We do not subtract the rebate amount for 982 managed care state observations that likely reflect capitated payments.

We apply the national-level, per unit rebate to state data to mirror how states collect the federal Medicaid rebate from manufacturers (based off the rebate price per unit calculated by CMS; MACPAC 2018a). As such, the rebate received varies as a share of each state's spending.

## Limitations

Our estimation of the federal Medicaid rebates has several limitations. First, we know AMP for generic drugs is inconsistent with list prices (Levinson 2011). We use SDUD to estimate AMP for generic drugs when FUL or NADAC data are unavailable, even though the SDUD price may not be a reliable AMP estimate. However, the SDUD price is the best data available in these cases, and we believe it is better to compute the rebate this way than to not compute it at all.

Secondly, we do not account for blended AMP calculations. Until recently, when President Trump signed the Fair and Accurate Medicaid Pricing Act into law on September 27, 2019,<sup>8</sup> manufacturers took advantage of a loophole allowing them to include generic AMPs in their AMP calculation for brand-name products. This loophole AMP calculation, called blended AMPs, drove AMP estimates down significantly, because generic AMPs are often far lower than those of brand-name drugs, and subsequently lowered the rebates manufacturers paid Medicaid. Manufacturers could take advantage of this loophole when they produced a generic version of their brand-name drug or sold their generic drug to a secondary manufacturer with whom they have a corporate relationship for distribution (i.e., if one manufacturer is a subsidiary of the other; MACPAC 2018b). A report from the US Department of Health and Human Services Office of the Inspector General estimates that by closing this blended AMP loophole and excluding authorized generics from AMP calculation, the federal government could save \$20 million per year, which is likely a low estimate (OIG 2019). Because we exclude blended AMPs in our AMP estimates, we likely overstate the rebates Medicaid received for brand-name drugs.



Third, managed care plans often negotiate payments with individual pharmacy providers and can negotiate rebates and other discounts directly with manufacturers (MACPAC 2018a). Because of this, our AMP and rebate estimates may be less accurate for managed care estimates than for FFS estimates.

Fourth, we do not calculate a separate rebate for line extension drugs, which are new formulations of existing brand-name drugs. As part of the Affordable Care Act, and later amended by the Bipartisan Budget Act of 2018, line extension drugs are eligible for an inflationary rebate equal to the highest inflationary rebate amount for any form of the original brand-name drug.<sup>9</sup> This ensures that manufacturers cannot avoid paying a high inflationary rebate by selling a slightly modified version of their drug, which the US Food and Drug Administration views as a new product. Because we do not account for the alternative rebate these drugs are eligible for, we understate the rebate for line extension drugs.

Fifth, as detailed above, we rely on FSS prices to estimate best price, which likely underestimates best price and therefore overestimates the rebate.

Sixth, we do not account for pharmacy benefit managers (PBMs) in our spending estimates. State Medicaid agencies, both FFS and managed care, often rely on PBMs for services such as administrative support and negotiating supplemental rebates, and PBMs can negotiate prices with pharmacies for individual drugs. PBMs who negotiate prices on behalf of managed care organizations (MCOs) are not subject to the same pricing regulations as FFS organizations, and therefore PBM-negotiated payment rates to pharmacies are often proprietary and unknown to states. The amount MCOs pay PBMs is also seldom known to states. Because both payments from MCOs to PBMs and from PBMs to pharmacies are unknown, many states do not know the difference between the two, or the profit that PBMs keep. The difference between what MCOs pay PBMs and what PBMs pay to pharmacies is often called the “spread,” or the profit for PBMs (Dolan and Tian 2020).

PBMs have been found to be costly for states: A report found that PBMs cost Ohio \$225 million in 2018 through spread pricing in managed care, and Michigan found that PBMs had collected a spread of over 30 percent on generic drugs, overcharging the state \$64 million (Dolan and Tian 2020). Another study found that PBMs charged MassHealth MCOs more than the acquisition price for generic drugs for 95 percent of drugs in one quarter of 2018 (Dolan and Tian 2020). Another report found that rebates to PBMs in managed care likely account for most of the difference between drugs’ list and net prices, and that a \$1 increase in rebates, which they define as the difference between list and net prices, is associated with a \$1.17 increase in list prices (Sood et al. 2020). Because MCOs rely on PBMs to negotiate prices and over two-thirds of Medicaid gross spending was administered through managed care in 2017, rebates to PBMs are involved in most prescription drug claims reimbursed by Medicaid.

Because SDUD report spending to pharmacies, our estimates do not include the spread amount retained by PBMs. Therefore, we underestimate Medicaid spending on prescription drugs.

Seventh, we do not estimate managed care spending on drugs included in capitated payments. Because SDUD show zero Medicaid spending and a positive number of prescriptions reimbursed for state observations where capitated payments are used, we cannot estimate the spending amount in these cases. Therefore, our total spending estimates likely underestimate true spending.

## Notes

- <sup>1</sup> “Tracking Medicaid-Covered Prescriptions to Treat Opioid Use Disorder,” Urban Institute, March 3, 2020, <https://www.urban.org/policy-centers/health-policy-center/projects/tracking-medicaid-covered-prescriptions-treat-opioid-use-disorder>.
- <sup>2</sup> Though SDUD show 11-digit NDCs, we calculate rebates for NDCs after aggregating across package sizes. We therefore calculate rebates at the 9-digit NDC level, because the last two digits of an NDC represent package size.
- <sup>3</sup> IQVIA, formerly Quintiles and IMS Health, uses a standard unit of one tablet or capsule for solid-form drugs and one ampule or vial for injectable drugs. Units are calculated as the number of units sold divided by the standard unit factor, which is a single tablet, capsule, ampule, or vial, as defined by IMS HEALTH. We could not find information explaining the methodology used for units that appear inconsistent with the package size. See Duggan, Garthwaite, and Goyal (2014).
- <sup>4</sup> The total amount spent reflects the total amount reimbursed by Medicaid and non-Medicaid entities to pharmacies or other providers, including cost-sharing payments. The amount excludes the Medicaid rebate and includes dispensing fees.
- <sup>5</sup> Further, a letter from CMS to participating drug manufacturers states, “The calculation of AMP for 5i drugs that are not generally dispensed through a retail community pharmacy includes payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health management organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy.” See Centers for Medicare & Medicaid Services, notice to participating drug manufacturers, Medicaid drug rebate program, May 17, 2019, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-110.pdf>.
- <sup>6</sup> For the nine NDCs with matching ASP data, we converted prices from the units reported in the ASP data to the units reported in SDUD, most often converting milligrams (mg) to milliliters (mL). For the four generic naloxone injections, NDCs 00641-6132, 17478-0041, 17478-0042, and 67457-0599, we multiply the ASP price by 0.4, because ASP data show the price for 1 mg, whereas SDUD show the price for 0.4mg/mL. For the two Sublocade injections, NDCs 12496-0100 and 12496-0300, we divide the ASP price by the milliliters in the injections, 0.5 and 1.5, respectively, which results in prices closely aligned with SDUD prices. For these two injections, ASP data list the reported number of milligrams inconsistently, listing both over and under 100 mg. However, because the estimated prices closely align with SDUD estimates after dividing by the number of milliliters in each injection, we feel confident in our estimates. For the Probuphine NDC, 58284-0100, we use the price reported in ASP data, which is for 74.2 mg of buprenorphine, equivalent to the 80 mg buprenorphine Hcl reported in SDUD. Lastly, for the two Vivitrol NDCs, 63459-0300 and 65757-0300, we multiply the ASP price by 380, because the ASP price is reported for 1 mg, whereas the SDUD price is reported for one injection of 380 mg.
- <sup>7</sup> “State Drug Utilization Data (SDUD) FAQs,” Medicaid.gov, accessed March 2, 2020, <https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/state-drug-utilization-data-faq/index.html>.
- <sup>8</sup> Fair and Accurate Medicaid Pricing Act, H.R. 3276, 116th Cong. (2019).

- 9 “Unit Rebate Amount Calculation for Line Extension Single Source or Innovator Multiple Source Drugs,” Medicaid.gov, accessed February 11, 2020, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/s-or-i-line-extension-drugs/index.html>.

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