

# Medicaid Payment for Outpatient Prescription Drugs

Medicaid prescription drug spending increased 24.6 percent in 2014, reaching its highest rate of growth since 1986, and slowed to 13.6 percent in 2015 according to the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS). The faster growth in 2014 was primarily due to increased spending for hepatitis C drugs while a higher amount of rebates helped temper the spending growth in 2015 (Martin et al. 2016).

In order to understand actions that would address this growth in spending, it is helpful to understand how Medicaid pays for prescription drugs and the Medicaid rebates that drug manufacturers pay to states. This issue brief outlines how states and managed care organizations pay pharmacies and describes the role manufacturer rebates play in Medicaid. Additionally, the brief highlights the different payment and rebate policies associated with the 340B drug pricing program. Other factors affecting spending such as decisions about coverage of specific drugs and use of benefit management strategies are not discussed here.

Because Medicaid drug payment and rebate policy includes many technical terms and acronyms, a glossary of these terms and acronyms is provided at the end of the brief.

## Overview

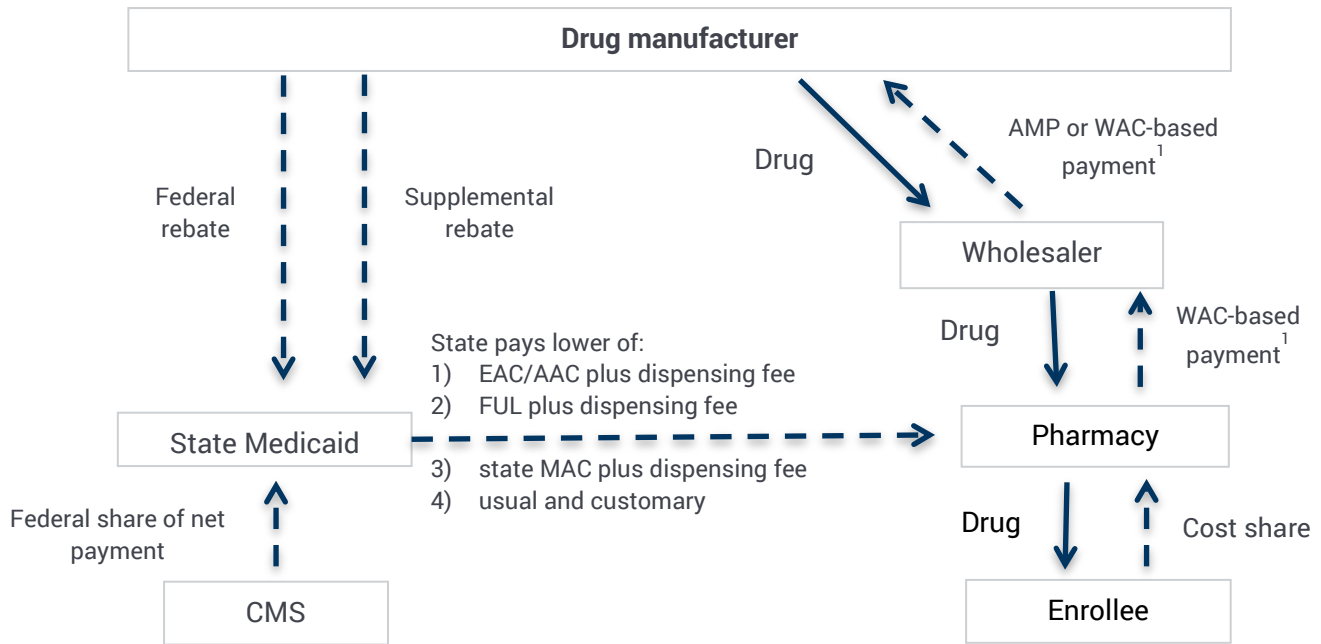
Outpatient prescription drug coverage is an optional benefit that all state Medicaid programs have elected to provide (§1905(a)(12) of the Social Security Act (the Act)). Outpatient prescription drugs are typically those that may be obtained only by prescription and dispensed by pharmacies. They do not include drugs administered directly by a physician or other provider or those provided and billed as part of other services such as an inpatient hospital or nursing facility stay. Medicaid programs may also cover drugs sold without a prescription, commonly referred to as over-the-counter drugs, when prescribed by a physician or other authorized prescriber.

The amount Medicaid spends for a particular outpatient prescription drug reflects two components—the initial payment to the pharmacy and the rebates Medicaid receives from manufacturers. States set pharmacy payment policy within broad federal guidelines and requirements. Additionally, a drug manufacturer must enter into a statutorily defined rebate agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) in order for its products to be covered by Medicaid (§1927 of the Social Security Act).<sup>1</sup>



Payment for Medicaid drugs involves several actors including the state Medicaid agency, pharmacies, drug manufacturers, beneficiaries, and CMS (Figure 1). As shown in Figure 1, the total Medicaid payment may be determined based on lesser of several payment formulas. The rebates the state receives from manufacturers are conducted through a separate process and do not involve the pharmacy. Each of these payment and rebate components is described in greater detail throughout the issue brief.

**Figure 1. Medicaid Fee for Service Drug Payment and Rebate Flow**



**Notes:** AMP is average manufacturer price. WAC is wholesale acquisition cost. EAC is estimated acquisition cost. AAC is actual acquisition cost. FUL is federal upper limit. MAC is maximum allowable cost. Dotted line represents the flow of payment. Solid line represents the flow of the drug product.

<sup>1</sup> Payment may include prompt pay, volume, and other discounts.

## Payment to Pharmacies under Fee for Service

Once a Medicaid enrollee receives a prescription from a clinician, he or she typically goes to a retail pharmacy to get it filled. The pharmacy dispenses the drug and submits a claim to the state Medicaid agency.

The Medicaid agency pays the pharmacy for two components: 1) an amount to cover the estimated cost of the drug, known as the **ingredient cost**, and 2) an amount to cover the pharmacist's overhead and services to fill the prescription, known as the **dispensing fee**. The state has flexibility within federal regulations in setting these payment amounts (§1902(a)(30)(A) of the Act and 42 CFR 447). State policy may also require that the pharmacy collect a nominal copayment from the enrollee (§§1916(a)(3) and 1916A(c)(2) of the Act).



## Ingredient cost

The ingredient cost component of the payment recognizes the pharmacy's cost of acquiring a drug from a drug wholesaler or manufacturer. Historically, the ingredient cost component was based on the state's best estimate of the price generally and currently paid by providers, also known as estimated acquisition cost (EAC). However, under new federal rules issued in February 2016, actual acquisition cost (AAC) will now be used as the basis for establishing ingredient cost (CMS 2016a).

**Benchmark pricing.** Historically, most states have relied on published compendia of drug prices to provide a benchmark for setting the ingredient cost. These benchmark prices include average wholesale price (AWP), a list price given by a wholesaler to a retail pharmacy. Another benchmark is the wholesale acquisition cost (WAC), a list price given by a drug manufacturer to a direct purchaser such as a wholesaler. WAC is less than AWP as AWP includes costs added on after wholesale distribution.

Most states base the ingredient cost on a flat discount off of AWP (e.g., AWP minus 15 percent) or a markup on WAC (e.g., WAC plus 5 percent). Some states use a uniform ingredient cost formula, while others have established different ingredient cost formulas for brand versus generic drugs, or different types of pharmacies (e.g., chain pharmacies, independent pharmacies, specialty pharmacies) (CMS 2016b).

**Alternatives to benchmark pricing.** Recent research and legal challenges have focused on the extent to which these published benchmarks reflect an accurate estimate of pharmacies' actual acquisition costs, particularly AWP (OIG 2011a). Numerous HHS Office of the Inspector General (OIG) reports have noted that, in many cases, these published prices are substantially higher than prices paid in actual sales transactions (OIG 2011b, 2005). Additionally, some publishers of pricing data and drug wholesalers settled lawsuits alleging that they had marked up the published prices on several brand name drugs (Community Catalyst 2009). After the settlement, one of the major publishers of pricing data stated that it would cease publishing AWP (OIG 2011b).

Due to these challenges, some states switched to alternative pricing methodologies, including payment based on AAC (CMS 2016b). States using this method perform a periodic, random sample of pharmacies participating in Medicaid to collect actual paid invoices that are then used to calculate an average AAC for each drug. If an AAC cannot be obtained for a particular drug, then these states typically rely on WAC as a benchmark for payment.

In 2012, CMS began the National Average Drug Acquisition Cost (NADAC) survey, which collects retail pharmacies' invoices, to estimate a national AAC for each drug.<sup>2</sup> A few states have switched to using NADAC as a benchmark for determining an appropriate ingredient cost payment.<sup>3</sup>

**CMS final rule.** As mentioned previously, CMS released a final rule on Medicaid drug payment in February 2016 that changes the basis for the ingredient cost payment from EAC to AAC and requires that a state's payment methodology be in accordance with the definition of AAC (42 CFR 447.518(a)(2)). States have some flexibility in how they establish an AAC, including a state survey of retail pharmacy providers, the NADAC survey, or AMP-based pricing. States have four quarters from the April 1, 2016 final rule



implementation date to submit a state plan amendment to reflect a payment methodology based on AAC (CMS 2016a).<sup>4</sup> As of September 2016, 10 states had switched to an AAC-based methodology (CMS 2016b).

## Dispensing fee

In addition to ingredient cost, states pay a professional dispensing fee to cover the pharmacies' costs associated with ensuring that possession of the appropriate drug is transferred to a Medicaid beneficiary. In most states, the dispensing fee is between \$2 and \$6 per prescription. Some states vary the dispensing fee based on type of pharmacy, prescription volume, or type of drug. For example, they may pay a higher dispensing fee for a generic versus a brand drug (CMS 2016b).

Differences in dispensing fees may also reflect states' approaches to paying for the ingredient cost. States that pay based on an AAC methodology generally have the highest dispensing fees. This is because benchmark prices are typically higher than the pharmacy's true acquisition cost, so many pharmacies use the spread between the ingredient cost payment under an AWP or WAC-based methodology and actual drug cost to subsidize their dispensing costs or profit (Schondelmeyer and Wrobel, 2004). States that have moved to an AAC-based payment have increased the dispensing fee because AAC eliminates much of the margin that has been used to subsidize dispensing costs. The thought is that each component under the AAC methodology should more accurately reflect the pharmacy's actual acquisition and dispensing costs and reduce the need for cross-subsidization.

Any assessment of the adequacy of a state's payment for an outpatient prescription drug must take into account the combined amount of the ingredient cost and dispensing fee. Lower payment on one of the components may be compensated through higher payment on the other. Federal regulations require that any time a state proposes a change to either the ingredient cost or dispensing fee components, the state consider both the ingredient cost and dispensing fee together and ensure that the total reimbursement to the pharmacy is consistent with federal payment requirements (§1902(a)(30)(A) of the Act) (CMS 2016a).

## Beneficiary cost sharing

In 40 states and the District of Columbia, some beneficiaries also pay nominal copayments for outpatient prescriptions (CMS 2011).<sup>5</sup> These typically range from 50 cents to \$3 per prescription and may vary by brand and generic drug or preferred versus non-preferred status. Federal regulations allow for copayments of up to \$4 for preferred drugs and \$8 for non-preferred drugs for individuals with incomes under 150 percent of federal poverty limit (FPL). For individuals with incomes over 150 percent FPL, cost sharing may be up to 20 percent of the cost of the drug for non-preferred drugs (CMS 2013). The amount of the beneficiary's copayment is subtracted from the state's payment to the pharmacy.

Prior to the Deficit Reduction Act of 2005 (DRA, P.L. 109-171), a beneficiary could not be denied services due to an inability to pay the copayment. Now states are allowed to make cost sharing enforceable by permitting providers to withhold providing care or services if the copayment is not received. Most states have not adopted this provision, however (Smith et al. 2011).



## Payment Limits under Fee for Service

To ensure that Medicaid is a prudent purchaser of drugs, federal and state policies have instituted upper limits on payment for multiple source drugs—drugs that have a generic equivalent available. Because prices for the same product may vary widely when it is available from multiple sources, these limits help ensure that Medicaid pays a reasonable market price for these products. Additionally, there is a payment limit applied to all drugs to ensure that Medicaid does not pay more than the price generally available to the public.

There are three limits to fee-for-service (FFS) payments that states typically consider in order to determine the final payment to the pharmacy. States compare payment under their standard ingredient cost plus dispensing fee formula to the Medicaid federal upper limit (FUL), state maximum allowable cost (MAC), and usual and customary charges to ensure that they do not pay above these limits. Overall, states typically pay the lowest of:

- EAC or AAC plus dispensing fee;
- FUL plus dispensing fee;
- MAC plus dispensing fee; or
- pharmacy's usual and customary charge.

Each of these three limits is described below.

### Federal upper limit

The Medicaid federal upper limit (FUL) caps the federal financial contribution toward state expenditures for these products. CMS establishes a FUL price for innovator multiple source drugs (i.e., brand drug still sold by the original manufacturer or authorized producer after generic equivalents are available) and non-innovator multiple source drugs (i.e., generic) for which the Food and Drug Administration (FDA) has rated three or more products therapeutically and pharmaceutically equivalent (§1927(e)(4) of the Act).<sup>6</sup>

Under current law, the FUL amount is set as no less than 175 percent of the utilization-weighted average of the most recently reported monthly average manufacturer price (AMP) for equivalent multiple source drug products, also referred to as a FUL group, purchased by retail community pharmacies (§§ 2503(a)(1)(A) and 2503(a)(1)(B) of ACA). AMP is defined as the average price paid to the manufacturer for the drug in the US by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer (§1927(k)(1) of the Act).

In the February 2016 final rule, CMS established that the FUL would be calculated at 175 percent of AMP. However, if the FUL calculated at 175 percent of AMP is less than the average AAC for retail community pharmacies as determined by the most current national survey of such costs (i.e., NADAC survey), then the FUL will be increased so that it equals the average AAC from the national survey (42 CFR 447.514). CMS has calculated and published the AMP-based FUL files, which are effective as of April 1, 2016.



FUL is an aggregate limit. That means a state may pay above or below the statutorily defined price for a drug as long as the state's total payment for all drugs subject to the FUL requirement does not exceed the amounts that would be spent by applying the FUL price to each drug, plus a reasonable dispensing fee (42 CFR 447.514). Federal matching funds are not available for payment that exceeds the aggregate FUL amount.

## State maximum allowable cost

Although not required by federal regulations, most states (43 states and District of Columbia as of September 2016) have also established maximum allowable cost (MAC) lists for multiple source drugs as a cost-saving measure (CMS 2016b). Similar to FUL, the state's MAC establishes the maximum amount that the state will pay for drugs included on the MAC list. There is some overlap between the drugs on the MAC and FUL lists; states generally include many more drug products on the MAC than are included on the FUL list. States have flexibility in establishing the MAC prices, and typically the established MAC price is less than the FUL price in cases where the two lists overlap.

## Usual and customary charge

For single source drugs (i.e., brand drug without generic equivalents) and drugs that are not subject to FUL or state MAC limits, current federal regulations limit payment, in the aggregate, to the lower of the AAC plus a professional dispensing fee or the provider's usual and customary charge to the public (42 CFR 447.512). An example of usual and customary charge is a pharmacy charging \$4 for commonly used generics.

## Payment under Managed Care

For beneficiaries enrolled in managed care, states may choose to carve in (include) or carve out (exclude) the outpatient prescription drug benefit from the services included in their managed care contracts. Under a carve-in approach, the state estimates the expected utilization and cost of drugs for the enrolled population and builds this estimate into the overall capitation rate paid to the plans. Under a carve-out approach, the state continues to pay for the outpatient prescription drug benefit on an FFS basis. Currently, most states have carved in most or all of the outpatient prescription drug benefit under a capitated managed care program; five states carve out the entire outpatient prescription drug benefit.<sup>7</sup>

Similar to payments under Medicaid fee for service, Medicaid managed care plans pay pharmacies for ingredient cost and dispensing fees. However, managed care plans are not required to pay for ingredient costs based on AAC but must make payments sufficient to ensure appropriate access for their enrollees (CMS 2016a). Additionally, plans may differ in how they pay. Plans typically contract with a pharmacy benefits manager that negotiates payment terms with individual pharmacy providers instead of having a general payment formula that applies to all. Plans may implement their own MAC lists for multiple-source drugs and negotiate rebates and other discounts with manufacturers.





## Medicaid Drug Rebates

Under the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508), Congress created the Medicaid Drug Rebate Program to ensure that Medicaid receives a net price that is consistent with the lowest or best price for which manufacturers sold the drug. Under the drug rebate program, a drug manufacturer must enter into a Medicaid drug rebate agreement with HHS in order for states to receive federal funding for use of these products (§1927(a)(1) of the Act).<sup>8</sup> In exchange for the rebates, state Medicaid programs must generally cover a participating manufacturer's drugs although they may limit the use of some drugs through preferred drug lists (PDLs), prior authorization, or quantity limits. States may exclude coverage for drugs used off-label—that is, the prescribed use is not for a FDA-approved indication.<sup>9</sup> Additionally, there are a few drugs or classes of drugs that states may not cover at all (§1927(d)(2) of the Act).<sup>10</sup>

Amounts collected under the federal rebate program are shared by the federal government and states based on the state's current federal medical assistance percentage (FMAP). The rebates collected by the state are reported as an offset to drug spending on the CMS-64 quarterly expense report used to determine the federal and state share of Medicaid spending.

The federal Medicaid rebate is based on a specific formula defined in statute and collected each quarter from manufacturers through a process that is separate from payments made by states to pharmacies (§1927(c) of the Act). This means that every state receives the same federal rebate amount for each unit of a particular drug regardless of how much they pay the pharmacy. As a result, the net unit price (initial payment to pharmacy minus the rebate) for a Medicaid drug will vary by state.

Medicaid drug rebates are calculated based on AMP. CMS calculates a unit rebate amount (URA) for each drug based on the established formula for that type of drug and provides this URA to each state. The state then multiplies the URA by the number of units that it paid for that drug during the rebate period and submits a rebate invoice to the drug manufacturer.<sup>11</sup> The state collects the rebate dollars from the manufacturer and reports the rebate amount as an offset to the drug expenditures on the CMS-64.

There are separate rebate formulas for single source and innovator multiple source drugs versus non-innovator multiple source and all other drugs.<sup>12</sup>

### Formula for brand name drugs

The rebate amount for brand drugs has two components: a basic rebate amount and an additional inflationary component. The basic rebate amount is calculated as the greater of (a) 23.1 percent of AMP or (b) AMP minus best price (Figure 2). Best price is statutorily defined as the lowest price available to any wholesaler, retailer, provider, or paying entity excluding certain governmental payers (§1927(c)(1)(C) of the Act).<sup>13</sup>

For blood clotting factor drugs and drugs approved by the FDA exclusively for pediatric indications, the ACA created a different rebate percentage. For these drugs, the minimum rebate percentage is 17.1 percent of AMP instead of 23.1 percent of AMP.



A rebate based on the inflationary component can be added should the increase in a drug's AMP exceed the increase in the Consumer Price Index for All Urban Consumers (CPI-U) over time (Figure 2). The inflationary component is equal to the amount that the drug's current quarter AMP exceeds its baseline AMP trended to the current period by the CPI-U.<sup>14</sup> The inflationary component has become an increasingly large portion of the overall brand drug rebate. A recent OIG report found that more than half (54 percent) of total brand drug rebates for a sample of brand drugs in 2012 was attributable to the inflationary component (OIG 2015). The rebate amount cannot exceed 100 percent of AMP (§2501(e) of ACA).

The ACA also established a new rebate formula for drugs that are considered to be line extensions of single source or innovator multiple source drugs that are in oral solid dosage form (for example, an extended-release version).<sup>15</sup> For line extension products, the rebate is the greater of (a) the basic and inflationary rebate for the line extension drug, or (b) the product of the AMP for the line extension drug, the highest additional inflationary rebate for any strength of the original drug (expressed as a percentage and applied to the line extension AMP), and the total number of units of the line extension drug.

## Formula for generic and all other drugs

The rebate amount for generic and all other drugs is calculated as 13 percent of AMP. There is no best price provision (Figure 2). The Bipartisan Budget Act of 2015 added the inflationary rebate to non-innovator multiple source drugs effective with the quarter starting January 1, 2017 (CMS 2016c). This inflationary rebate is calculated in a similar manner to the inflationary rebate for brand name drugs. For non-innovator multiple source drugs marketed on or before April 1, 2013, the baseline AMP is equal to the AMP for the third quarter of 2014 and the baseline CPI-U is the CPI-U for September 2014. For non-innovator multiple source drugs marketed after April 1, 2013, the baseline AMP is equal to the AMP for the fifth full calendar quarter after which the drug is marketed as a drug other than a single source or innovator multiple source drug and the baseline CPI-U is equal to the CPI-U for the last month of the baseline AMP quarter (CMS 2016c).

## Federal rebate offset

The ACA increased the minimum rebate percentage for brand drugs from 15.1 percent to 23.1 percent of AMP and increased the rebate percentage for generic and other drugs from 11 percent to 13 percent of AMP and changed the rebate calculation for line extension drugs ((§2501(a)-(b), (d) of ACA). In conjunction with these increases, the ACA required states to remit the amounts attributable to these increased rebates to the federal government—that is, CMS gets both the federal and non-federal share of this rebate increase (§2501(a)(2) of ACA). In a State Medicaid Director letter, CMS further clarified that the offset would only occur on rebate dollars above that which would have been collected under the old rebate formula before implementation of the ACA (CMS 2010).

For brand drugs, the offset will be anywhere from 0 to 8 percent of AMP, depending on where best price lies in relation to the old minimum rebate percentage of 15.1 percent and the ACA minimum rebate of 23.1 percent (Figure 2, line j). For example, if AMP minus best price were equal to 18.1 percent of AMP, then the offset would be 5 percent of AMP (the difference between 23.1 percent and 18.1 percent of AMP). Because





generic drugs do not have the best price provision, CMS will offset 2 percent of AMP (the difference between 13 percent and 11 percent of AMP) for all generic drugs.

**FIGURE 2.** Illustrative Example of Federal Rebate Calculation

	Drug A (brand)	Drug B (brand)	Drug C (brand)	Drug D (generic) <sup>1</sup>
a) Current AMP per unit	\$100.00	\$100.00	\$100.00	\$20.00
b) Best price per unit	\$88.00	\$80.00	\$70.00	–
<b>Basic rebate</b>				
c) Minimum rebate (23.1% of AMP for brand, 13% of AMP for generic)	\$23.10	\$23.10	\$23.10	\$2.60
d) AMP–best price	\$12.00	\$20.00	\$30.00	
e) Basic rebate is greater of c) and d)	\$23.10	\$23.10	\$30.00	\$2.60
<b>Inflationary rebate (for brand drugs)</b>				
f) Baseline AMP per unit	\$70.00	\$80.00	\$90.00	–
g) CPI-U trend factor from baseline to current period	1.20	1.20	1.20	–
h) Baseline AMP trended to current period = f) x g)	\$84.00	\$96.00	\$108.00	–
i) Inflationary rebate = a–h if h) less than a)	\$16.00	\$4.00	\$0.00	–
<b>j) ACA federal rebate offset</b>	\$8.00	\$3.10	\$0.00	\$0.40
<b>k) Total rebate = e) + i)</b>	\$39.10	\$27.10	\$30.00	\$2.60
l) State share = (k–j) x 50%	\$15.55	\$12.00	\$15.00	\$1.10
m) Federal share = (k–j) x 50% + j	\$23.55	\$15.10	\$15.00	\$1.50

**Note:** AMP is average manufacturer price. CPI-U is consumer price index for all urban consumers. This example uses a 50 percent federal match rate.

<sup>1</sup> This example does not show the inflationary rebate for generic drugs that went into effect January 1, 2017.

## Supplemental rebates

Most states (46 states and District of Columbia, as of September 2016) have negotiated supplemental rebates with drug manufacturers on top of the federal rebates (CMS 2016d).<sup>16</sup> States negotiate with manufacturers to obtain supplemental rebates for what they determine to be therapeutically equivalent drugs. Manufacturers provide these supplemental rebates to ensure that their products get placed on a



state's PDL. Drugs on the PDL are not subject to prior authorization, which results in a shift in market share to the preferred drugs. Some states pursue supplemental rebate agreements on their own while others have joined multi-state coalitions for negotiation purposes (CMS 2016d). The federal rebate offset does not apply to any supplemental rebates that states may receive above the increased federal rebate percentages (CMS 2010).

Supplemental rebates are often established around a guaranteed net price that the manufacturer will provide to the state. The supplemental rebate is calculated by subtracting the federal rebate and guaranteed price from a benchmark price such as WAC. Under this type of arrangement, supplemental rebates are inversely proportional to federal rebate amounts—that is, if federal rebates increase, the supplemental rebates would decrease by an equal amount. The OIG has found that many states had lower supplemental rebates for individual drugs than they would have been under pre-ACA rebate amounts due to the increase in federal rebates under the ACA (OIG 2014).

## Medicaid drug rebates under managed care

The ACA extended the federal Medicaid drug rebates to prescriptions paid for by Medicaid managed care plans (§2501(c) of ACA). Previously, the federal rebates were only available for drugs paid for by the state on an FFS basis. Rebates for these drugs are subject to the offset in non-federal share on the rebate amounts above and beyond that which would have been collected under the pre-ACA formulas.

Plans submit Medicaid drug utilization data to the state; the state then combines this information with FFS utilization and collects the rebates for the entire Medicaid population. Similar to the state supplemental rebates, managed care plans are allowed to negotiate their own rebates with manufacturers.

## Medicaid Drugs Provided by 340B Entities

As part of the federal Medicaid drug rebate agreement, drug manufacturers agree to provide substantial discounts to certain grantees of the Public Health Service, federally qualified health centers, and qualified hospitals, also known as covered entities, under Section 340B of the Public Health Service Act.

The 340B program creates a ceiling on the maximum price that manufacturers can charge covered entities. The ceiling price for a particular drug is calculated by subtracting the URA calculated under the Medicaid drug rebate formula from the AMP. The 340B ceiling price may be less than the net Medicaid price if the state generally pays a retail pharmacy more than AMP for the ingredient cost. The 340B discount is only available on drugs provided to patients of the covered entity. Covered entities may negotiate discounts with the manufacturers that are below the statutorily defined ceiling price.<sup>17</sup>

Drugs purchased under 340B pricing and dispensed to Medicaid enrollees are excluded from the prescription volume states submit for the Medicaid Drug Rebate Program. This exclusion prevents drug manufacturers from paying double rebates on drugs purchased through the 340B program.



Due to the requirement to keep 340B priced drugs separate from the Medicaid Drug Rebate Program, a qualified 340B entity has two options when billing for Medicaid enrollees (HRSA 2015):

- The first option is to purchase the drugs from the manufacturer under 340B prices and bill the Medicaid agency according to Medicaid billing guidelines. Often the Medicaid agency pays the 340B entity at its acquisition cost plus a dispensing fee. Some states have chosen to pay a higher dispensing fee to 340B entities than retail pharmacies. States exclude these prescriptions in their rebate submissions to the manufacturer.
- The second option is for the 340B entity to carve out Medicaid prescriptions from the 340B purchasing pool and purchase these drugs from the manufacturer through standard contracts. The 340B entity then bills Medicaid as a typical retail pharmacy and receives payment under the standard terms. The Medicaid agency includes these prescriptions in its rebate submission to the manufacturer.

The February 2016 final rule requires that the state's payment methodologies for 340B covered entities and contract pharmacies under contract with 340B entities are in accordance with the definition of AAC.



## Glossary

**Actual acquisition cost (AAC).** Defined in federal regulations (42 CFR 447.502) as a state Medicaid agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

**Average manufacturer price (AMP).** The average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. The calculation of AMP excludes the prices paid by certain payers (e.g., Department of Veterans' Affairs, Department of Defense, or Federal Supply Schedule) and providers (e.g., hospitals, long-term care facilities, mail order pharmacies, or managed care organizations) and certain discounts to wholesalers (e.g., prompt pay or bona fide service fees). In the February 2016 final Medicaid drug rule [CMS-2345-FC], CMS provides detailed technical guidance related to the calculation of AMP.

**Average wholesale price (AWP).** List price from a wholesaler to a pharmacy. AWP for drugs are reported by pharmaceutical manufacturers and published in commercial clearinghouses such as Redbook, Medi-Span, First DataBank, and Elsevier Gold Standard.

**Best price.** The lowest price available to any wholesaler, retailer, provider, or paying entity excluding certain governmental payers such as the Indian Health Service, Department of Veterans' Affairs, Department of Defense, Public Health Service (including 340B), Federal Supply Schedule and Medicare Part D plans.

**Brand name drug.** A drug that is produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA), covered by a patent, and marketed and sold under a proprietary, trademark-protected name. A brand name drug may be a single source drug or an innovator multiple source drug.

**Dispensing fee.** A professional dispensing fee is defined in federal regulations (42 CFR 447.502) as the professional fee that pays for costs in excess of the ingredient cost of an outpatient prescription drug each time a drug is dispensed. The dispensing fee covers the pharmacy's costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary, including but not limited to the time and services required by the pharmacist to dispense the prescription and overhead.

**Estimated acquisition cost (EAC).** Previously defined in federal regulations (42 CFR 447.502) as a state Medicaid agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers. The February 2016 final Medicaid drug rule [CMS-2345-FC] replaces estimated acquisition cost with actual acquisition cost.



**Federal upper limit (FUL).** Federal upper limit that caps the federal financial contribution toward state expenditures for certain multiple source drugs. A FUL price is established by CMS for innovator multiple source drugs and non-innovator multiple source drugs for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent. The ACA established the FUL amount as no less than 175 percent of the utilization-weighted average of the most recently reported monthly AMP for equivalent multiple source drug products (FUL group) purchased by retail community pharmacies. States can pay above or below the FUL amount for individual prescription drugs, as long as the aggregate expenditures for drugs with FULs do not exceed the amounts that would be spent by applying the FUL limit, plus a reasonable dispensing fee.

**Generic drug.** A drug that is distributed by multiple manufacturers and is rated therapeutically equivalent to a brand name drug by the FDA. Drug products evaluated as therapeutically equivalent can be expected to have equal effect and no difference when substituted for the brand name product.

**Innovator multiple source drug.** A multiple source drug that was originally marketed under an original new drug application approved by the FDA as a brand name drug. A brand name drug (i.e., single source drug) becomes an innovator multiple source drug as it loses its patent protection and generic equivalents become available.

**Line extension drug.** A single source or innovator multiple source drug that is an oral solid dosage form that has been approved by the FDA as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug, such as a new ester, a new salt or other non-covalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug. For example, an extended release version of an existing drug would be considered a line extension drug. The Comprehensive Addiction and Recovery Act of 2016 excluded abuse-deterrent formulations of prescription drugs from the definition of line extension drugs for Medicaid rebate purposes.

**Maximum allowable cost (MAC).** Payment limit on certain multiple source drugs and select other drugs set by state Medicaid agencies.

**Multiple source drug.** A drug that is distributed by multiple manufacturers who provide a therapeutically equivalent product having the same active ingredient(s), strength, and dosage form. For purposes of the Medicaid Drug Rebate Program, a multiple source drug means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent.

**Non-innovator multiple source drug.** A multiple source drug that is not originally marketed under an original new drug application (i.e. multiple source drug not distributed by the original manufacturer). Non-innovator multiple source drugs are frequently called generic drugs.

**Non-preferred drug.** Drugs that are not preferred drugs as defined in federal regulations (42 CFR 447.51).



**Over-the-counter drug.** A drug that may be obtained without a prescription.

**Outpatient prescription drug.** Drug obtained with a prescription and typically dispensed from a retail or other outpatient pharmacy. Outpatient prescription drugs do not include drugs provided as part of or incident to and in the same setting as inpatient and outpatient hospital services, hospice services, dental services, nursing facility and intermediate care facility services, and physician services (e.g., physician administered drugs).

**Preferred drug.** Defined in federal regulations (42 CFR 447.51) as drugs that the state has identified on a publicly available schedule as being determined by a pharmacy and therapeutics committee for clinical efficacy as the most cost effective drugs within each therapeutically equivalent or therapeutically similar class of drugs, or all drugs within such a class if the agency does not differentiate between preferred and non-preferred drugs.

**Single source drug.** A drug that is produced or distributed under an original new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application. Single source drugs are brand name drugs that are still under patent and are available only from the manufacturer(s) listed on the application.

**340B-covered entities.** Section 340B of the Public Health Service Act (created under Section 602 of the Veterans Health Care Act of 1992) requires pharmaceutical manufacturers participating in the Medicaid program to enter into a second agreement with the Secretary under which the manufacturer agrees to provide discounts on covered outpatient drugs purchased by specified government-supported facilities called covered entities. 340B- entities include certain high-volume disproportionate share hospitals, as well as specified grantees of the Public Health Service, including certain federally qualified health centers, state operated AIDS drug assistance programs (ADAPs), the Ryan White CARE Act Title I, Title II, and Title III programs, tuberculosis, black lung, family planning and sexually transmitted disease clinics, hemophilia treatment centers, public housing primary care clinics, homeless clinics, urban Indian clinics and Native Hawaiian health centers.

**Unit rebate amount (URA).** The rebate amount calculated by CMS that a drug manufacturer must pay under the Medicaid Drug Rebate Program. The rebate amount is calculated on a unit basis for each drug at the National Drug Code level. The specific methodology used is determined by statute and depends on the drug's classification as a single source, innovator multiple source, non-innovator multiple source, a clotting factor drug, or an exclusively pediatric drug. CMS provides the URA to the states to assist the state in invoicing the manufacturer. The manufacturer remains liable for the correct calculation of the rebate amount.

**Wholesale acquisition cost (WAC).** Price paid by a wholesaler for a drug purchased from the wholesaler's supplier, typically the manufacturer of the drug. WAC amounts may not reflect all available discounts, such as prompt-pay (cash) discounts.





## Endnotes

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<sup>1</sup> Established under the Omnibus Budget Reconciliation Act of 1990 (OBRA '90, P.L. 101-508).

<sup>2</sup> CMS posts final NADAC pricing data on its website: <https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html>.

<sup>3</sup> Alaska, Delaware, Nevada, and North Carolina use NADAC as the pricing benchmark their AAC-based payment methodology (CMS 2016b).

<sup>4</sup> Effectively, states have until June 30, 2017 to submit a state plan amendment implementing the AAC-based methodology because states have until the last day of a quarter to maintain an effective date no earlier than the first date of that quarter.

<sup>5</sup> See CMS, *Medicaid prescription reimbursement information by state—quarter ending June 2017*. CMS no longer publishes cost-sharing information on the drug reimbursement information chart.

<sup>6</sup> FUL may not apply if there is a brand medically necessary override.

<sup>7</sup> Many states have carved out a subset of drugs such as behavioral health or HIV/AIDS drugs from the managed care program. Six states—Indiana, Missouri, Nebraska, Tennessee, and Wisconsin—carve out prescription drugs. As of April 1, 2016, Iowa includes pharmacy as part of the benefits covered under the managed care contract.

<sup>8</sup> In addition to a Medicaid drug rebate agreement, drug manufacturers must also enter into an agreement that meets the requirements of Section 340B of the Public Health Service Act and a master agreement with the Secretary of Veterans Affairs as a condition for Medicaid coverage. A drug not covered under a rebate agreement may be eligible for federal funding in limited circumstances if the State has determined that the drug is essential to the health of its beneficiaries.

<sup>9</sup> A medically accepted indication means any use for a covered outpatient drug that is approved under the Federal Food, Drug, and Cosmetic Act (P.L. 75-717) or the use of which is supported by one or more citations included or approved for inclusion in one of the following three compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, or the DRUGDEX Information System.

<sup>10</sup> The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted: drugs used for anorexia, weight loss, or weight gain; drugs used to promote fertility; drugs used for cosmetic purposes or hair growth; drugs used for symptomatic relief of cough and colds; prescription vitamins and mineral products except prenatal vitamins and fluoride preparations; nonprescription drugs except tobacco cessation products; drugs used for the treatment of sexual or erectile dysfunction unless the drug is used to treat a FDA-approved indication other than sexual or erectile dysfunction.

<sup>11</sup> While CMS calculates the URA to assist states in developing the rebate invoice, the manufacturer remains liable for the correct calculation of the rebate.

<sup>12</sup> Single source drugs are innovator drugs manufactured by only one company and innovator multiple source drugs are original innovator drugs that now have generic equivalents available. Over-the-counter drugs would receive the same rebate as non-innovator multiple source drugs.

<sup>13</sup> Best price excludes certain governmental payers such as the Indian Health Service, Veterans Affairs, Dept. of Defense, Public Health Service (including 340B), Federal Supply Schedule and Medicare Part D plans.

<sup>14</sup> The baseline AMP is the AMP during the quarter before the drug rebate program was started or, for new drugs, the first quarter after the drug's market date.



<sup>15</sup> The Comprehensive Addiction and Recovery Act of 2016 excluded abuse-deterrent formulations of prescription drugs from the definition of line extension drugs for Medicaid rebate purposes.

<sup>16</sup> In accordance with §2501(c) of the ACA, 12 states—Arizona, California, Delaware, Florida, Iowa, Kansas, Massachusetts, New Hampshire, New York, Oregon, Texas, and West Virginia—are expanding supplemental rebate collections to include drugs dispensed to beneficiaries who receive drugs through a managed care organization (CMS 2016d).

<sup>17</sup> The HHS Health Resources and Services Administration (HRSA) manages a prime vendor program (PVP) that 340B-covered entities can join voluntarily. The PVP will negotiate discounts below the 340B ceiling price on behalf of all participating entities. 340B entities may also negotiate sub-340B pricing with manufacturers on their own. <https://www.340bpvp.com/about-us/>.

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