Chapter 1:

Improving Operations of the Medicaid Drug Rebate Program

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Recommendations

1.1 To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.

1.2 Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities could include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data.

Key Points

- State and federal policymakers are looking for ways to control prescription drug spending, which is expected to grow faster than other health care goods and services over the next 10 years.
- This report focuses on specific improvements to the existing Medicaid Drug Rebate Program. Future work will focus on the merits of broader structural changes to Medicaid policy.
- Under the Medicaid Drug Rebate Program, drug manufacturers must enter into a Medicaid national drug rebate agreement. In exchange for the rebates, state Medicaid programs must generally cover all of a participating manufacturer's drugs.
- Medicaid drug rebates are defined in statute and calculated based on average manufacturer price (AMP). There are different rebate formulas for brand and generic drugs; brand drugs receive a larger rebate.
- The law requires a manufacturer to average the price of its authorized generic with the brand drug in calculating its brand drug's AMP. This requirement creates a loophole in which a manufacturer could sell its authorized generic at a low price to a corporate subsidiary to lower its brand drug's AMP, thus lowering the manufacturer's rebate obligation. Recommendation 1.1 is meant to close this loophole.
- Under the rebate program, manufacturers are responsible for classifying their products as brand or generic drugs. Other than terminating a manufacturer's rebate agreement, which could have negative repercussions on beneficiary access, the Secretary has limited statutory authority to address a misclassification.
- Recommendation 1.2 reflects the Commission's view that the Secretary needs additional enforcement powers to address misclassifications of drugs. The clear authority to impose financial penalties would give the Secretary an enforcement mechanism while protecting beneficiary access to prescription medications.

CHAPTER 1: Improving Operations of the Medicaid Drug Rebate Program

High rates of spending growth for prescription drugs over the past few years have been of great concern to state and federal Medicaid officials. Medicaid prescription drug spending increased 24.6 percent in 2014, reaching its highest rate of growth since 1986. This high rate of growth was primarily due to increased spending for hepatitis C drugs and enrollment growth associated with the expansion of Medicaid under the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) (Martin et al. 2016). The rate of drug spending growth slowed to 13.6 percent in 2015 and to 5.5 percent in 2016 (Hartman et al. 2017). Spending growth in 2015 was tempered by an increase in drug rebates compared to the prior year, and slower enrollment growth and a decline in spending for hepatitis C drugs further reduced drug spending growth in 2016 (Hartman et al. 2017, Martin et al. 2016). Even with the recent slowing of spending growth, controlling prescription drug spending remains a focus for policymakers because prescription drugs are expected to experience the fastest average annual spending growth among major health care goods and services over the next 10 years due to the anticipated growth of high-cost specialty drugs (Cuckler et al. 2018). As policymakers attempt to rein in expenditures, however, they must also consider how such efforts would affect Medicaid beneficiaries' access to therapies that extend lives and improve health and functional status.

Many factors can affect spending for Medicaid outpatient drugs. Total Medicaid drug spending reflects the number of prescriptions filled and the amount paid per prescription. Average drug spending per person reflects the enrollment mix (the mix of conditions being treated and the distribution of drugs across different therapeutic classes), the volume and intensity of services (the average number of drugs taken per person and the mix of brand and generic drugs), and the net prices paid for those services (i.e., the price paid to the pharmacy to purchase and dispense the drug minus any manufacturer rebates).

Efforts to control Medicaid spending on prescription drugs can focus on reducing the net price per unit, reducing utilization, or changing the mix of drugs used; these strategies can be pursued alone or in combination. Not all of these factors are within the control of program administrators, providers, or patients. Medicaid, like other payers, is affected by how manufacturers establish the market price of drugs as well as by their decisions about when and under what circumstances to bring their drugs to market. Additionally, while most payers seek to obtain rebates from drug manufacturers and control the use and mix of drugs, Medicaid is limited in its ability to use these cost control strategies. Reductions in Medicaid drug spending have been achieved by states and the federal government primarily through the Medicaid Drug Rebate Program. Under this program, Medicaid receives larger rebates than most other payers, including rebates based on the best price received by other payers. But Medicaid cannot make use of the full range of utilization management tools available to other payers, such as restricted formularies, tiered formularies, and cost sharing, to manage the utilization and mix of drugs.

MACPAC's inquiry into the rising costs of prescription drugs has focused on two separate but related issues: identifying specific improvements to the existing rebate program, which is the focus of this chapter, and developing ideas that might form the basis of more far-reaching recommendations in future reports. In the course of our inquiry, we have reached out to Medicaid directors, pharmacy benefit managers, managed care plans, federal agencies, and others. We plan to extend this conversation into the year ahead to learn whether additional policy levers may be needed—and if so, what form they should take—to help manage prescription drug spending while also ensuring that Medicaid

beneficiaries can continue to benefit from advances in scientific research.

This chapter presents the Commission's recommendations on the way the Medicaid Drug Rebate Program treats authorized generics and on gaps in the current oversight regime. Specifically:

- To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.
- Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities could include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data.

The chapter begins by describing current Medicaid prescription drug policy and the rebates established under the Medicaid Drug Rebate Program. It continues by detailing specific concerns regarding the pricing of authorized generic drugs and federal oversight of the program. It then presents the rationale for the Commission's recommendations for steps that Congress should take to mitigate these issues. The chapter concludes by outlining the Commission's plans for future work in this area, including examining Medicaid's existing ability to manage drug utilization and spending, exploring whether Medicaid could benefit from additional tools available to other payers, and monitoring the development of strategies for managing spending on specialty drugs, such as value-based purchasing arrangements.

Medicaid Drug Rebate Program

Coverage of outpatient prescription drugs 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 are dispensed by pharmacies. They do not include drugs provided and billed as part of other services such as inpatient hospital or nursing facility stays.[1]

The net price that Medicaid pays 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.[2] The rebates that Medicaid receives are substantial and result in Medicaid paying one of the lowest net prices of any payer (OIG 2015, GAO 2014). In fiscal year (FY) 2016, Medicaid spent approximately $60.8 billion on outpatient prescription drugs and collected $31.2 billion in rebates for net drug spending of $29.6 billion (MACPAC 2017). Net spending for outpatient prescription drugs accounted for about 5.4 percent of total Medicaid benefit spending.

The Medicaid Drug Rebate Program was created under the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) with the purpose of ensuring that Medicaid pays a net price that is consistent with the lowest or best price that manufacturers charge other payers for the drug. Under the program, a drug manufacturer must enter into a Medicaid national drug rebate agreement with the Secretary of the U.S. Department of Health and Human Services (the Secretary) in order for states to receive federal funding for using the manufacturer's products (§ 1927(a)(1) of the Act).[3] In exchange for the rebates, state Medicaid programs must generally cover all of a participating manufacturer's drugs when prescribed for a medically accepted indication, although the states

may limit the use of some drugs through preferred drug lists (PDLs), prior authorization, and quantity limits.[4]

Amounts collected under the federal rebate program are shared by the federal government and states based on each state's current federal medical assistance percentage (FMAP). The Centers for Medicare & Medicaid Services (CMS) calculates a unit rebate amount (URA) for each drug based on a specific formula defined in statute for that category of drug and provides this URA to each state. The state then multiplies the URA by the number of units of each drug purchased during the rebate period and submits a rebate invoice to the drug manufacturer.[5] The state collects the rebate dollars from the manufacturer and reports the total rebate amount as an offset to the drug expenditures on the CMS-64 quarterly expense report used to determine the federal and state share of Medicaid spending.

States collect the federal Medicaid rebate each quarter from manufacturers through a process that is separate from their payments 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 a pharmacy. Therefore, the net unit price (initial payment to pharmacy minus the rebate) for a Medicaid drug will vary by state because of differing pharmacy reimbursement calculations and other state-specific supplemental rebate arrangements.

Medicaid drug rebates are calculated based on average manufacturer price (AMP). AMP is defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer (§ 1927(k)(1) of the Act).[6]

There are separate rebate formulas for single source and innovator multiple source drugs (i.e., brand-name drugs) versus non-innovator multiple source drugs (i.e., generic drugs).[7] For purposes of simplicity, this chapter refers to single source and innovator multiple source drugs as brand drugs and refers to non-innovator multiple source drugs as generic drugs or generics.

Rebate formula for brand 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 23.1 percent of AMP or AMP minus best price (Table 1-1). 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).[8]

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

An additional rebate based on an inflationary component is added if the increase in a drug's AMP exceeds the increase in the Consumer Price Index for All Urban Consumers (CPI-U) over time (Table 1-1). 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.[9] This inflationary rebate limits the increase in the net price of any drug to the rate of inflation. The total rebate amount cannot exceed 100 percent of AMP (§ 1927(C)(2)(D) of the Act). The inflationary rebate has become an increasingly large portion of the overall brand drug rebate. A recent report by the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) 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 ACA established an alternative rebate formula for drugs that are considered to be line extensions of brand drugs that are in oral solid dosage form (e.g., an extended-release version).[10] The statutory language in the ACA contained what some have

characterized as a drafting error that reduced the rebates owed under the alternative rebate formula for line extension drugs (HHS 2016).[11] In February 2018, Congress passed the Bipartisan Budget Act of 2018 (BBA 2018, P.L. 115-123), which revised the line extension formula to increase rebates. For line extension drugs, the rebate per unit has been revised to be the greater of (a) the basic and inflationary rebate for the line extension drug, or (b) the basic rebate of the line extension drug plus the product of the AMP for the line extension drug and the highest additional inflationary rebate for any strength of the original drug (expressed as a percentage of the original drug's AMP). The revised calculation for line extension drugs will apply to rebate periods beginning October 1, 2018.

Rebate formula for generic drugs

The basic rebate amount for generic drugs is calculated as 13 percent of AMP. There is no best price provision (Table 1-1). The Bipartisan Budget Act of 2015 (P.L. 114-74) added the inflationary rebate to generic drugs, which went into effect in the quarter starting January 1, 2017 (CMS 2016a). This inflationary rebate is calculated in a similar manner to the inflationary rebate for brand drugs. For generic 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 generic 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 brand drug, and the baseline CPI-U is equal to the CPI-U for the last month of the baseline AMP quarter (CMS 2016a). Similar to brand drugs, the total rebate cannot exceed 100 percent of AMP.

Federal offset of rebates

The ACA increased the minimum rebate percentage for brand drugs from 15.1 percent to 23.1 percent of AMP, increased the rebate percentage for generic drugs from 11 percent to 13 percent of AMP, and created an alternative rebate calculation for line extension drugs (§§ 2501(a)–2501(b) and 2501(d) of the ACA). The ACA requires states to remit the amounts attributable to these increased rebate percentages to the federal government—that is, CMS gets both the federal and non-federal shares of this rebate increase (§ 2501(a)(2) of the ACA). In a state Medicaid director letter, CMS further clarified that the offset would apply only to rebate dollars above those that would have been collected under the rebate formula in effect before implementation of the ACA (CMS 2010a).

For brand drugs, the offset is anywhere from 0 to 8 percent of AMP, depending on where the best price lies in relation to the old minimum rebate percentage of 15.1 percent and the ACA minimum rebate of 23.1 percent (Table 1-1, line (j)). For example, if AMP minus best price were equal to 20 percent of AMP, then the offset would be 3.1 percent of AMP (Table 1-1, line (j) for Drug B). Because generic drugs do not have the best price provision, CMS offsets 2 percent of AMP (the difference between 13 percent and 11 percent of AMP) for all generic drugs. For line extension drugs, the federal offset is the URA for the drug calculated using the formula established in the ACA and BBA 2018 minus the URA for the drug calculated using the formula in effect prior to the ACA; if the URA based on existing law is not greater than the URA based on prior law, then the offset does not apply.

Supplemental rebates

Most states (46 states and the District of Columbia, as of March 2018) have negotiated supplemental rebates with drug manufacturers on top of the federal rebates (CMS 2018a).[12] States negotiate with manufacturers to obtain supplemental rebates, usually with one or more manufacturers of drugs that the state has determined to be therapeutically equivalent. Manufacturers provide these supplemental rebates to ensure that their products get placed on a state's PDL. Preferred drugs typically face fewer utilization management requirements than their therapeutic equivalents

TABLE 1-1. Illustrative Example of Federal Outpatient Prescription Drug Rebate Calculations T 1-1

Calculation	Drug A (brand)	Drug B (brand)	Drug C (brand)	Drug D (generic)[1]
(a) Current AMP per unit	$100.00	$100.00	$100.00	$20.00
(b) Best price per unit	$88.00	$80.00	$70.00	N/A
Basic rebate				
(c) Minimum rebate • for brand drugs = *a* x 23.1% • for generic drugs = *a* x 13%	$23.10	$23.10	$23.10	$2.60
(d) AMP minus best price = *a* – *b*	$12.00	$20.00	$30.00	N/A
(e) Basic rebate is the greater of *c* or *d*	$23.10	$23.10	$30.00	$2.60
Inflationary rebate				
(f) Baseline AMP per unit	$70.00	$80.00	$90.00	$10.00
(g) CPI-U trend factor from baseline to current period	1.20	1.20	1.20	1.20
(h) Baseline AMP trended to current period = *f* x *g*	$84.00	$96.00	$108.00	$12.00
(i) Inflationary rebate = *a* – *h* if *h* is less than *a*	$16.00	$4.00	$0.00	$8.00
(j) ACA federal offset of rebate	$8.00	$3.10	$0.00	$0.40
(k) Total rebate = *e* + *i*	$39.10	$27.10	$30.00	$10.60
(l) State share = (*k* – *j*) x 50%	$15.55	$12.00	$15.00	$5.10
(m) Federal share = (*k* – *j*) x 50% + *j*	$23.55	$15.10	$15.00	$5.50

Notes: AMP is average manufacturer price. N/A is not applicable. CPI-U is Consumer Price Index for All Urban Consumers. This example uses a 50 percent federal match rate.

[1] The Bipartisan Budget Act of 2015 (P.L. 114-74) added the inflationary rebate to generic drugs beginning January 1, 2017.

(e.g., prior authorization), and this results in a shift in market share to the preferred drugs. Some states pursue supplemental rebate agreements on their own while others have joined multistate coalitions for negotiation purposes (CMS 2018a). The federal rebate offset does not apply to any supplemental rebates that states may receive above the increased federal rebate percentages (CMS 2010a).

Medicaid drug rebates under managed care

The ACA extended federal Medicaid drug rebates to prescriptions paid for by Medicaid managed care plans (§ 2501(c) of the ACA). Previously, the federal rebates were only available for drugs paid for by the state on a fee-for-service (FFS) basis. Rebates for these drugs are subject to the offset in non-federal share on the rebate amounts above and

beyond those that 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 from manufacturers for the entire Medicaid population. Similar to the state's ability to negotiate supplemental rebates, managed care plans can negotiate their own rebates with manufacturers.

Authorized Generics

An authorized generic drug is a version of a brand drug that the brand manufacturer itself produces and sells, or causes to be sold, at a lower price point than the brand drug (FTC 2011).[13] Under the Federal Food, Drug, and Cosmetic Act (P.L. 75-717), the first true generic to challenge a brand drug's patent is granted 180 days of generic exclusivity (§ 505 of the Food, Drug, and Cosmetic Act). However, this 180-day exclusivity period does not exclude the brand manufacturer from launching its own generic (FTC 2011, citing Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005)). During this time period, the average retail price of the true generic is about 86 percent of the brand drug's retail price without a competing authorized generic and 82 percent of the brand drug's retail price with a competing authorized generic (FTC 2011). Once the 180-day period expires and other generics enter the market, the generic price drops substantially (Kirchhoff et al. 2018).

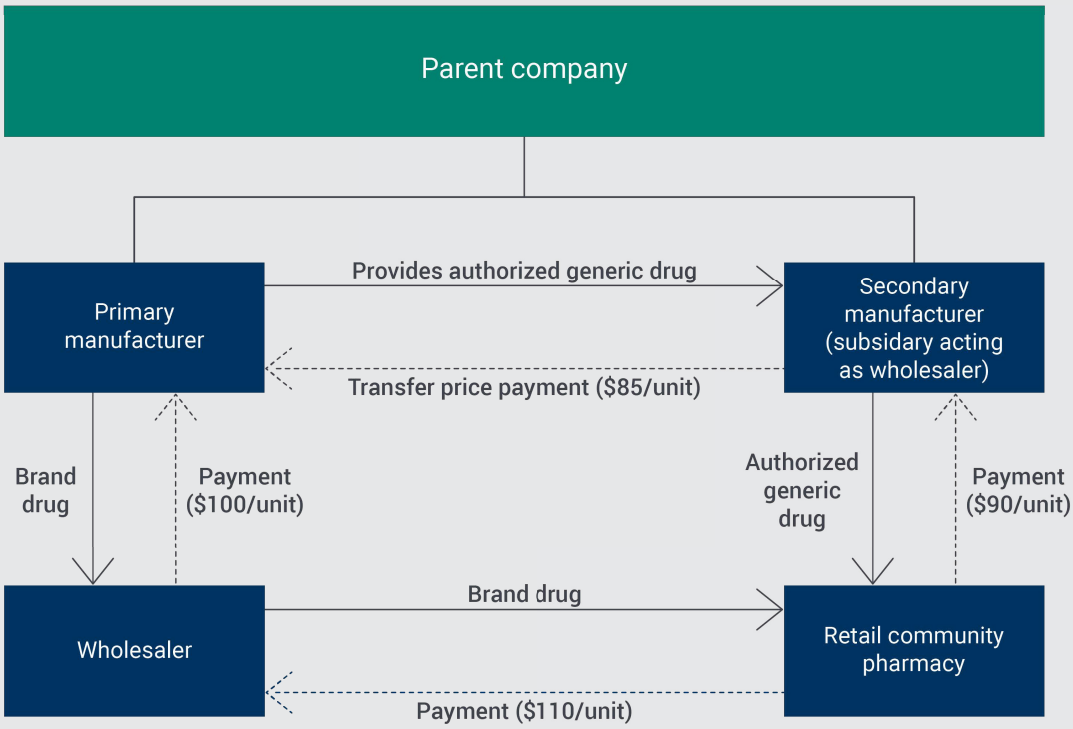
The presence of authorized generics in the market can affect the calculation of Medicaid drug rebates. The Medicaid statute generally directs manufacturers to calculate AMP based on sales to wholesalers and retail community pharmacies (§ 1927(k)(1) of the Act). The statute defines a wholesaler as any entity that engages in the wholesale distribution of drugs (§ 1927(k)(11) of the Act). The law requires manufacturers who produce an authorized generic of their brand drug and sell it to wholesalers or pharmacies to include those sales in calculating their brand drug's AMP (§ 1927(k)(1)(C) of the Act). This price, based on both a brand drug and its authorized generic, is frequently referred to as a blended AMP. The statute also directs manufacturers to include their authorized generic drug's best price in their calculation of best price for the brand product. This means that if a brand drug manufacturer—referred to in this scenario as the primary manufacturer—produces an authorized generic version of its brand drug and sells it to another manufacturer—referred to as the secondary manufacturer—for distribution, the secondary manufacturer might meet the definition of a wholesaler under the statute. If so, then the primary manufacturer would be required to include the price charged to the secondary manufacturer—known as the transfer price—when calculating the AMP of its brand drug. While many secondary manufacturers are independent of primary manufacturers, manufacturers are required to calculate blended AMPs if the primary manufacturer and the secondary manufacturer have a corporate relationship, that is, if one is a subsidiary of the other (Figure 1-1).

When there is a corporate relationship between primary and secondary manufacturers, the transfer price the primary manufacturer charges its related secondary manufacturer for the drug is generally lower than the price it charges other wholesalers (HDMA 2012). When a primary manufacturer averages in a lower transfer price when calculating its brand drug's blended AMP, it lowers the drug's AMP and thus reduces the rebate (OIG 2014).[14]

Oversight and Enforcement of the Medicaid Drug Rebate Program

Under the rebate program, manufacturers are responsible for providing CMS with the product and pricing information necessary to calculate rebates. The statute identifies certain data elements that are required, including AMP, customary prompt pay discounts, best price for brand drugs, and the number of units used to calculate AMP (§ 1927(b)

FIGURE 1-1. Authorized Generic Transactions Included in Blended Average Manufacturer Price



Note: AMP is average manufacturer price. A solid arrow represents the transfer of a product and a dotted arrow represents a financial transaction. In this illustrative example, the primary manufacturer would calculate a blended AMP for the brand and authorized generic drugs based on both the sales of the drug from the primary manufacturer to the wholesaler at $100 per unit and the sales from the primary manufacturer to the secondary manufacturer (a corporate subsidiary) at $85 per unit.

(3) of the Act). The terms of the rebate agreement specify other data that are used to identify and classify the drug, including whether the drug is a brand or generic, an authorized generic, or a line extension, as well as other information necessary to ensure that manufacturers have paid proper rebates (CMS 2018b). Manufacturers report and certify these product and pricing data via the Drug Data Reporting for Medicaid (DDR) system (OIG 2017).

Federal law provides a number of remedies in the event that a manufacturer does not comply with the reporting requirements, and several federal agencies share responsibility for enforcement. The Medicaid statute authorizes civil monetary penalties (CMPs) for manufacturers that fail to provide certain AMP and best price information on a timely basis and those that provide false information (§ 1927(b)(3)(B)–(C) of the Act).[15] The OIG is responsible for auditing manufacturer price information and issuing CMPs (§ 1927(b)(3) of the Act).[16] The Medicaid statute also authorizes the Secretary, acting through CMS, to terminate a manufacturer's participation in the rebate program for violating the terms of the rebate agreement or for other good cause (§ 1927(b)(4)(B)(i) of the Act). When a manufacturer is terminated, none of its drugs are eligible for federal financial participation ((§ 1903(i)(10) of the Act). CMS has stated that such a termination could have significant repercussions and potentially disrupt beneficiary access to drugs (OIG 2017). Manufacturers that report inaccurate data or pay inaccurate rebates may also be liable under the False Claims Act or other government claims, and the U.S. Department

of Justice (DOJ) is responsible for pursuing these remedies (CMS 2016b). Violations may come to the DOJ's attention either through the government's own investigation or through a qui tam action initiated by a private individual (CMS 2017a).

Aside from the above statutory authority, CMS can take administrative actions to address improperly categorized drugs; for instance, CMS issued subregulatory guidance in 2010 on the proper classification of drugs (CMS 2010b). This guidance was codified in 2016 by the covered outpatient drug final rule (CMS 2016c). The covered outpatient drug rule also specified a process for manufacturers to, in limited circumstances, appeal to CMS for approval to classify their drugs differently (CMS 2016c). Finally, the DDR system has been modified to prevent manufacturers from classifying drugs in a way that does not comply with the new regulatory requirements (OIG 2017). If CMS identifies what it believes to be a misclassification of a drug, it will contact the manufacturer to request an amended classification. However, CMS must rely on the manufacturer's willingness to change a drug's classification and has limited statutory authority in the event it disagrees with a manufacturer's classification (OIG 2017).

Commission Recommendations

In this report, the Commission makes two recommendations to improve the operations of the Medicaid Drug Rebate Program. These should not be considered a package of recommendations; that is, the adoption of one does not require the adoption of the other.

Recommendation 1.1

To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.

Rationale

This recommendation would close an apparent loophole in current law that allows drug manufacturers to reduce the AMP and, therefore, the rebate obligation on certain brand drugs.

Under current law, averaging the price of brand drugs and authorized generics to arrive at a blended AMP can substantially reduce a brand drug's AMP. In 2014, the OIG analyzed the AMP of three drugs and found that the unblended AMP was more than double the blended AMP for all three (OIG 2014). In some cases, the primary and secondary manufacturer may have a corporate relationship, which allows the primary manufacturer to offer the secondary manufacturer a transfer price that is lower than the price available to other wholesalers. By including the lower transfer price of an authorized generic version of a drug sold to a subsidiary company, a drug manufacturer can lower the drug's AMP and thus reduce its rebate obligation on the drug.

The loophole that allows manufacturers to blend AMPs in such a way as to lower the rebate for a brand drug stems from two discrete statutory changes. The Deficit Reduction Act of 2005 (P.L. 109-171) required manufacturers to apply the authorized generic's best price to the brand and to blend the AMP of authorized generics with brand drugs. Five years later, the ACA added a definition of wholesaler to the Medicaid statute that includes manufacturers engaged in wholesale distribution. Nothing in the legislative history suggests that Congress intended for manufacturers to be able to use low sales prices from an authorized generic to a related corporate entity to lower the rebate on the brand drug (Senate Finance 2009a, Senate Finance 2009b, Senate Finance 2005, U.S. House of Representatives 2005).

The Commission's recommendation is meant to close this apparently inadvertent loophole and ensure that a drug's AMP reflects the actual net

price available to wholesalers and pharmacies on the open market. Manufacturers would still calculate AMP and pay rebates on both brand and authorized generic drugs, but would no longer have an avenue to use complex internal sales structures to make the AMP of a brand drug appear lower than it is. The Commission notes that this recommendation is intended to address instances when a manufacturer uses the blended AMP requirement strategically to lower the AMP of the brand drug. Accordingly, Congress may be able to craft legislation to specifically target this behavior without removing the requirement that manufacturers blend the AMP of the brand and authorized generic drug when the secondary manufacturer qualifies as an independent wholesaler.

Implications

Federal spending. This recommendation is expected to reduce federal drug expenditures by increasing Medicaid drug rebates from manufacturers. The Congressional Budget Office (CBO) estimates that this recommendation would decrease federal spending by between $0 and $50 million in the first year and by less than $1 billion over five years compared to the current law baseline.

States. This recommendation is expected to result in increased drug rebates from manufacturers, and states will receive the non-federal share of the increase in rebate dollars.

Enrollees. This recommendation is unlikely to have any measurable effect on enrollees.

Drug manufacturers. This recommendation would increase the amount of rebates that manufacturers pay on certain brand drugs that have an authorized generic available. Depending on how this recommendation is implemented, manufacturers may need to make changes to their reporting systems to accommodate the new requirements.

Plans and providers. This recommendation could increase some payments to providers by increasing the federal upper limit (FUL) for some drugs. If the FDA has rated at least three drugs as being therapeutically and pharmaceutically equivalent, aggregate state payments cannot exceed 175 percent of the weighted average AMP for such drugs.[17] If this recommendation results in increased AMPs, it is possible that some of the affected drugs will have an associated FUL that will increase.

Recommendation 1.2

Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities could include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data.

Rationale

This recommendation calls on Congress to provide the Secretary with the authority to impose appropriate intermediate financial sanctions on manufacturers to ensure that they accurately classify their drugs. Such intermediate sanctions might include the imposition of CMPs for misclassifications, the explicit authority for HHS to change the classification of a drug, or other sanctions that Congress considers appropriate.

Although misclassifications are rare, OIG reports suggest that they may have led to substantial losses in rebates (OIG 2017, 2009). The OIG found that prior to CMS clarification of the definition of an innovator drug and non-innovator drug in the 2016 covered outpatient drug final rule, manufacturers may have misclassified some drugs in the Medicaid Drug Rebate Program as brand or generic products. As a result, drug manufacturers may not have paid the appropriate amount of rebates. In its 2017 report, the OIG found that approximately 3 percent of drugs were potentially misclassified in 2016.[18] When the OIG analyzed the 10 potentially misclassified drugs with the total highest payments

in 2016, it estimated that manufacturers may have owed an additional $1.3 billion in rebates from 2012 to 2016.[19] In its response to the OIG report, CMS said it expects that the clarifications provided in the 2016 final rule and the changes made to the DDR will help identify and reduce these inconsistent data submissions going forward (OIG 2017).

It is not clear whether HHS has the authority to levy CMPs or other intermediate sanctions against manufacturers to compel them to correct inaccurate drug classification data. In its 2017 report, the OIG recommended that CMS pursue a means to compel manufacturers to correct inaccurate classification data. Further, the OIG stated that although it has been delegated the authority to levy CMPs in certain circumstances, it believes it lacks legal authority to levy penalties for the submission of inaccurate drug classification data (OIG 2017).

The statute provides HHS, acting through CMS, only one explicit enforcement mechanism to address instances of misclassification: terminating a manufacturer's participation in the rebate program for good cause (§ 1927(b)(4)(B)(i)). This is sometimes called the nuclear option because of its potentially disruptive effects on beneficiaries. The fact that CMS has never terminated a manufacturer that has misclassified a drug is an indication that this penalty is not a realistic option. Instead CMS relies on an informal process through which it engages with manufacturers and attempts to resolve what it considers improper classification. This system ultimately relies on manufacturers willingly changing a drug's classification, knowing that failure to do so may result in civil lawsuits and potential termination of its participation in the Medicaid program.

It is the Commission's view that while the current collaborative process is useful, the Secretary needs additional enforcement powers to address less serious instances of noncompliance—violations that do not justify terminating all of the manufacturer's products from the program but are nonetheless problematic. Given the lack of clear intermediate sanctions in statute and uncertainty as to whether CMPs can be levied against manufacturers for inaccurate drug classification data, it is the Commission's view that Congress should provide clear authority to HHS to level CMPs for inaccurate drug classification data. The Secretary can then delegate this authority to either CMS or OIG.

The Commission considered recommending that Congress give HHS the authority to suspend a misclassified drug but determined that the threat to beneficiary access outweighed the benefits of such a measure. Suspending a drug from the program carries with it the risk of harm to beneficiaries who rely on the drug, particularly if that drug is the primary course of treatment with few therapeutic alternatives. It is the Commission's view that authority to impose financial penalties would give HHS clear enforcement authority while protecting beneficiary access to the manufacturer's product, and is therefore the more appropriate remedy for misclassification of drugs. Likewise, providing HHS the authority to reclassify a drug would allow the Secretary to address the misclassification without limiting beneficiary access to the drug. The Commission notes that Congress also has the option of pairing the authority to reclassify a drug with the authority to apply the reclassification retroactively in the DDR, thereby allowing Medicaid to collect rebates from previous quarters during which a drug was misclassified.

The current informal approach that CMS takes to correct misclassifications is a constructive first step, and any intermediate enforcement authorities should supplement, not supplant, this approach. The Commission maintains that HHS should ensure that manufacturers are afforded due process to present evidence that their classification of a drug is correct, such as provided under the narrow exceptions process established under the 2016 covered outpatient drug rule, and that HHS should provide a robust appeals process and establish protections for beneficiary access as part of any intermediate enforcement authority. HHS should be mindful of how its enforcement actions may affect beneficiaries; for many, access to prescription drugs is critically important and there may be only one

drug that meets their needs. It is the Commission's view that any intermediate sanctions authorized by Congress be paired with appropriate protections to ensure that beneficiaries are not harmed by enforcement actions.

Implications

Federal spending. This recommendation could lead to increased rebates from a correction in a drug's classification or increased CMPs. However, the CBO has estimated that this recommendation will not affect federal Medicaid spending.

States. States could receive the non-federal share of any changes in rebate amounts. The impact on states, however, will depend largely on whether the state has a supplemental rebate agreement in place for that drug. Based on the way many states calculate supplemental rebates, an increase in federal rebates could be offset by a reduction in the amount that states receive through state supplemental rebates.

Enrollees. This recommendation could affect beneficiary access depending on the enforcement authority provided by Congress. Some intermediate authorities, such as the authority to suspend misclassified drugs from participation, could disrupt beneficiary access while the drug's classification is under dispute. Accordingly, the Commission maintains that financial penalties are a more appropriate remedy, one that can address misclassifications without limiting access to necessary medications.

Drug manufacturers. This recommendation would affect drug manufacturers that might have misclassified one or more of their drugs. Drug manufacturers could see increased scrutiny of their drug classification decisions; they could be subject to additional enforcement actions and penalties from HHS; and they could ultimately be required to pay higher rebates for these previously misclassified drugs.

Plans and providers. This recommendation could affect providers if the payment to the pharmacy differs for brand and generic drugs. For example, some states have paid a different dispensing fee for brand versus generic drugs.

Line Extension Rebate

At its December 2017 meeting, the Commission highlighted what some consider to be a drafting error in the alternative rebate calculation for line extension drugs and discussed making a recommendation to address the matter. As part of that discussion, the Commission also expressed interest in making another recommendation to remove the federal offset and allow states to share in the line extension rebate. Subsequently, Congress passed the BBA 2018, which changed the line extension rebate calculation. The BBA 2018 maintains the federal offset on the line extension rebate, so the federal government receives the entire amount of the projected increase in rebate dollars; CBO scored this provision as saving $5.7 billion in federal spending over 10 years.

Given that Congress changed the line extension formula, the Commission discussed making a stand-alone recommendation to allow states to share in the line extension rebate at its March 2018 meeting. Although the Commission was initially interested in this recommendation as part of a package with the change to the rebate formula, the Commission decided that a stand-alone recommendation should not be made at this time and should instead be part of a larger discussion on how spending and savings should be shared between the federal government and the states.

Next Steps

This chapter is the Commission's first step in making recommendations on Medicaid drug coverage and spending. The recommendations in this chapter focus on discrete, technical changes to the Medicaid Drug Rebate Program that improve operations without changing its overall structure.

Although these changes will improve operations, states will still face a number of challenges in managing the prescription drug benefit that warrant further work in this area. Several states have expressed interest in obtaining additional flexibility to adopt widely used commercial tools to manage increasing drug costs, such as a closed formulary that excludes certain drugs.[20] The Commission plans to examine how Medicaid's existing tools for managing drug utilization compare to other payers and how the use of additional tools such as closed formularies could affect state Medicaid programs and beneficiaries. Such analysis might include, for example, whether closed formularies could yield additional savings to states and how they might affect beneficiary access to treatment.

The Commission has also heard that existing drug utilization management tools are less effective at containing costs associated with high-cost specialty drugs and that additional authorities and policy options might be necessary (Brown 2017). MACPAC is currently examining whether there are drug utilization management tools or other value-based contracts used by other payers that could benefit state Medicaid programs and will continue to monitor the development of these strategies for potential use within the Medicaid program.

Additionally, the Commission has heard from state officials who expressed concern with the requirement that states cover new outpatient drugs as soon as they are approved by the FDA and enter the market. These officials stated that it can be difficult to determine appropriate coverage of these drugs without states having sufficient time to assess the effectiveness of a drug or determine coverage and prior authorization criteria that aligns with the drug's labeling and medically accepted indications. This is particularly true if a drug has been approved through an accelerated pathway with limited evidence of clinical efficacy. The Commission will conduct further analysis of this issue and evaluate possible policy solutions, such as giving states time to develop appropriate coverage criteria by allowing them to exclude a newly approved drug from coverage for a specified period of time. Any policy option to delay coverage would need to be weighed against the potential effect on beneficiary access.

Endnotes

[1] A prescription drug provided and billed for as part of another service may be considered a covered outpatient drug if there is a direct reimbursement for the drug itself (e.g., physician-administered drugs).

[2] Information on how Medicaid pays pharmacies can be found in MACPAC's May 2018 issue brief, Medicaid Payment for Outpatient Prescription Drugs (MACPAC 2018a).

[3] 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 (P.L. 102-585) and a master agreement with the Secretary of Veterans Affairs as a condition for Medicaid coverage (§ 1927(a)(1) of the Act). 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.

[4] 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 that 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 (§ 1927(k)(6)).

[5] CMS calculates the URA to assist states in developing the rebate invoice, but the manufacturer remains liable for the correct calculation of the rebate.

[6] The covered outpatient drug final rule in 2016 included a separate definition of AMP for the so-called 5i drugs—inhalation, infusion, instilled, implanted, or injectable drugs. These drugs are not generally sold through the same distribution channels as non-5i drugs, so the AMP for 5i drugs includes sales of a type not included in AMP calculations of non-5i drugs.

[7] Generally, an innovator drug is a drug produced or

distributed under a new drug application approved by the U.S. Food and Drug Administration (FDA). Single source drugs are innovator drugs manufactured by only one company and innovator multiple source drugs are innovator drugs that have at least one generic equivalent available. Non-innovator multiple source drugs are multiple source drugs that are not innovator drugs—generally, these are drugs that have been approved under an abbreviated new drug application by the FDA.

[8] Best price excludes 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.

[9] The baseline AMP is the AMP during the quarter before the Medicaid Drug Rebate Program was started or, for new drugs, the first full quarter after the drug's market date.

[10] The Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198) excluded abuse-deterrent formulations of prescription drugs from the definition of line extension drugs for Medicaid rebate purposes.

[11] The discussion of the line extension rebate provision in the Chairman's mark for the America's Healthy Future Act of 2009, which was the precursor to the ACA that originally contained the line extension rebate, indicated the desire to treat new formulations of brand-name drugs as if they were the original product for purposes of calculating the additional inflationary rebate (Senate Finance 2009a). When a new version of an existing drug is introduced, the additional rebate obligation for that new drug would be calculated on the original drug's baseline AMP rather than on a new baseline. However, under the ACA, the alternative rebate, which is essentially the inflationary component of the original drug, gets compared to the standard rebate (basic rebate plus inflationary rebate) of the line extension drug. Because the alternative rebate calculation does not include the basic rebate, the inflationary increase of the original drug will need to be at least 23.1 percent (the minimum basic rebate amount) greater than the inflationary increase of the line extension drug to trigger the alternative rebate.

[12] In accordance with Section 2501(c) of the ACA, 18 states—Arizona, California, Delaware, Florida, Iowa, Kansas, Kentucky, Massachusetts, Minnesota, Nebraska, New Hampshire, New York, North Dakota, Oregon, Texas, Virginia, Washington, and West Virginia—are expanding supplemental rebate collections to include drugs dispensed to beneficiaries who receive drugs through a managed care organization (MCO). Minnesota limits its collection of supplemental rebates for MCO enrollees to direct-acting antivirals for the treatment of hepatitis C (CMS 2018a).

[13] Brand drug manufacturers introduce authorized generics for a variety of reasons: to discourage third-party manufacturers from introducing generic versions of the drug, to make it less profitable for a generic manufacturer to challenge a brand drug's patent, to siphon sales from the first generic drug during the 180-day exclusivity period, or to retain market share by competing with third-party manufacturers in the generic market (FTC 2011).

[14] These sales are also included in determining the best price and the federal upper limit (FUL) of the drug, which provides disincentives for manufacturers to lower the transfer price beyond a certain point.

[15] The penalty for false information is a maximum of $100,000 for every piece of false information. The language detailing the penalty for failure to provide timely information is unclear. It states that the amount of the penalty shall be increased by $10,000 for every day the information is late, but does not indicate a base penalty amount.

[16] Every quarter, CMS transmits a list to the OIG of manufacturers that have failed to report timely data for two out of the last four quarters (OIG 2009).

[17] There is an exception to the FUL for drugs for which the price listed in the National Average Drug Acquisition Cost (NADAC) survey is greater than 175 percent of AMP. In such cases, the FUL for these drugs is increased to be equal to the price listed in the NADAC.

[18] Drugs were identified at the 11-digit national drug code level.

[19] All 10 drugs were classified as non-innovator products (i.e., generic) in the Medicaid file but were approved under new drug applications by the FDA and therefore should likely have been classified as innovator (i.e., brand) drugs. Manufacturers would have paid a lower base rebate amount, and would not have paid the additional inflationary rebate, when applicable, for these drugs in the years 2012–2016 because the inflationary rebate on generic drugs did not

begin until 2017. Ninety percent of the $1.3 billion in rebates potentially lost by the misclassification was associated with only two drugs (OIG 2017).

[20] Two examples of states that have requested additional flexibility to manage increasing drug costs: Massachusetts has submitted a section 1115 demonstration waiver request that is still under CMS review (CMS 2017b). Arizona has submitted a letter to CMS expressing interest in additional flexibility in the coverage of drugs (AHCCCS 2017).

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Commission Vote on Recommendations

In its authorizing language in the Social Security Act (42 USC 1396), Congress requires MACPAC to review Medicaid and CHIP program policies and make recommendations related to those policies to Congress, the Secretary of the U.S. Department of Health and Human Services, and the states in its reports to Congress, which are due by March 15 and June 15 of each year. Each Commissioner must vote on each recommendation, and the votes for each recommendation must be published in the reports. The recommendations included in this report, and the corresponding voting record below, fulfill this mandate.

Per the Commission's policies regarding conflicts of interest, the Commission's conflict of interest committee convened prior to the vote to review and discuss whether any conflicts existed relevant to the recommendations on improving operations of the Medicaid Drug Rebate Program. It determined that, under the particularly, directly, predictably, and significantly standard that governs its deliberations, no Commissioner has an interest that presents a potential or actual conflict of interest.

The Commission voted on Recommendation 1.1 and Recommendation 1.2 on March 1, 2018.

Improving Operations of the Medicaid Drug Rebate Program

1.1 To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.

15	Yes
2	Not Present

Yes:	Burwell, Carter, Cerise, Cruz, Davis, Douglas, George, Gold, Gorton, Lampkin, Milligan, Retchin, Scanlon, Szilagyi, Thompson
Not Present:	Gordon, Weil

1.2 Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities could include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data.

15	Yes
2	Not Present

Yes:	Burwell, Carter, Cerise, Cruz, Davis, Douglas, George, Gold, Gorton, Lampkin, Milligan, Retchin, Scanlon, Szilagyi, Thompson
Not Present:	Gordon, Weil