

Chapter 1:

Next Steps in Improving Medicaid Prescription Drug Policy

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Recommendations

- 1.1 Congress should amend Section 1927(d)(1)(B) of the Social Security Act to allow states to exclude or otherwise restrict coverage of a covered outpatient drug for 180 days after a new drug or new formulation of a drug has been approved by the Food and Drug Administration and entered the market.
- 1.2 Congress should amend Section 1927(c)(2)(D) of the Social Security Act to remove the cap on Medicaid drug rebates.

Key Points

- State and federal policymakers continue to look for ways to control prescription drug spending, which is expected to experience one of the largest growth rates among health care goods and services over the next decade with the anticipated growth of new high-cost treatments.
- Under the Medicaid Drug Rebate Program, a state is generally required to cover all of a participating manufacturer's products as soon as they have been approved by the Food and Drug Administration and have entered the market. Medicare Part D and exchange plans have up to 180 days after a new drug enters the market to make a coverage determination.
- States must follow a prescribed process to publish and implement formal coverage criteria. Generally, states use pharmacy and therapeutics committees to examine the clinical evidence and make recommendations on the extent of coverage of a new drug.
- Medicaid pharmacy and medical directors say current law does not provide sufficient time to assess the effectiveness of a drug or determine appropriate coverage and prior authorization criteria, especially when the drug under review is a first-in-class or novel, complex treatment.
- Creating a formal grace period would align Medicaid's time frame with that of other payers and provide more time for the lengthy process of establishing appropriate coverage criteria. Giving states time to review the literature regarding safety, efficacy, and clinical outcomes helps prevent potential drug-related harm and would not likely create undue access restrictions.
- Currently, the Medicaid drug rebate for a particular drug is capped at 100 percent of the drug's average manufacturer price. This rebate cap limits the effectiveness of the inflationary rebate and restricts the dollar amount of rebates that Medicaid can receive.
- Removing the rebate cap would allow the inflationary rebate to achieve its full effect and create substantial savings for Medicaid, relieving some fiscal pressure on states by allowing them to maintain the same level of drug coverage at a lower cost.

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In fiscal year (FY) 2017, Medicaid spent approximately \$64.0 billion on outpatient prescription drugs and collected \$34.9 billion in rebates, resulting in net drug spending of \$29.1 billion, or about 5.1 percent of total Medicaid benefit spending that year. While gross drug spending (i.e., before rebates) has been rising since FY 2014, net spending has slowed. In FY 2017, gross spending increased 5.2 percent while net spending actually decreased by 1.7 percent due to an increase in the amount of rebates collected (MACPAC 2019).

Even so, controlling prescription drug spending remains a focus for policymakers because prescription drugs are expected to experience one of the largest growth rates in average annual spending among major health care goods and services over the next 10 years, due in part to the anticipated growth of new high-cost treatments (Sisko et al. 2019). In fact, increased spending on brand drugs has offset much of the savings states gained by using more generic drugs. While brand drugs' share of total claims has decreased since FY 2014, their share of spending increased; average spending for a brand drug increased by 40 percent (MACPAC 2019).

The use of high-cost specialty drugs is contributing to the increased spending on brand drugs (Express Scripts 2018, Magellan 2017).¹ From 2010 to 2015, net spending on specialty drugs in Medicaid almost doubled, growing from \$4.8 billion to \$9.9 billion (CBO 2019). This trend is expected to continue.² Projections show specialty drug spending for all payers growing faster than spending for traditional drugs, with specialty drugs representing 50 percent of total pharmacy spending in the next few years (IQVIA 2018, Magellan 2017).

State Medicaid officials have expressed concern about the fiscal pressures that will be created by

the use of new specialty drugs. State officials have also stated that Medicaid's statutory requirement to cover new drugs as soon as they enter the market is challenging, particularly when these are first-in-class drugs or are novel, complex treatments (Williams 2017). Pharmacy and medical directors say that they do not have sufficient time to assess the effectiveness of a drug or determine coverage and prior authorization criteria that align with the drug's labeling and medically accepted indications. When assessing a drug, some states enact prior authorization criteria that are so restrictive that beneficiaries essentially do not have access to that product.

In terms of controlling spending, states have benefited from the statutory rebates under the Medicaid Drug Rebate Program, but a statutory cap restricts the amount of rebates Medicaid can receive. Currently, rebates are capped at 100 percent of a drug's average manufacturer price (AMP). This cap on rebates can limit the effectiveness of Medicaid's inflationary rebate in discouraging large price increases over time. Recently, a large number of drugs have reached the rebate cap, suggesting that lifting the cap could produce substantial savings to Medicaid and exert additional downward pressure on price increases.

This chapter presents the Commission's recommendations on authorizing a drug coverage grace period and removing the cap on Medicaid rebates. Specifically:

- Congress should amend Section 1927(d)(1)(B) of the Social Security Act to allow states to exclude or otherwise restrict coverage of a covered outpatient drug for 180 days after a new drug or new formulation of a drug has been approved by the Food and Drug Administration and entered the market.
- Congress should amend Section 1927(c)(2)(D) of the Social Security Act to remove the cap on Medicaid drug rebates.

The chapter begins with an overview of the Medicaid Drug Rebate Program. It continues by

detailing Medicaid's drug coverage requirements, the challenges states face in meeting these requirements, and how these coverage requirements compare to those imposed on other federal payers. It then discusses the cap on Medicaid rebates and how the cap limits the amount of rebates Medicaid receives and the effectiveness of the inflationary rebate in discouraging steep price hikes. The chapter 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, which includes examining Medicaid's existing ability to manage drug utilization and spending, exploring whether certain types and classes of drugs merit special consideration within the Medicaid program, and monitoring the development of new financing or payment strategies to manage spending on specialty drugs.

Medicaid Drug Rebate Program

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 Social Security Act (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 states may limit the use of some drugs through preferred drug lists (PDLs), prior authorization, and quantity limits.⁴

Statutory rebates

Medicaid drug rebates are calculated based on 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).⁵

The rebate formula for single source and innovator multiple source drugs (i.e., brand-name drugs) differs from the formula for non-innovator multiple source drugs (i.e., generic drugs).⁶ 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.

The rebate amount for covered outpatient drugs has two components: a basic rebate amount and an additional inflationary component. For most brand drugs, the basic rebate amount is either equal to 23.1 percent of AMP or AMP minus best price, whichever is greater.⁷ 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 generic drugs, the basic rebate amount is calculated as 13 percent of AMP with no best price provision.

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. 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 is designed to limit the increase in the net price of any drug to the rate of inflation. The total rebate amount (the sum of the basic and inflationary components) cannot exceed 100 percent of AMP (§ 1927(c)(2)(D) of the Act).

Supplemental rebates

As of December 2018, almost all states (46 states and the District of Columbia) were receiving supplemental rebates on top of the mandated federal rebates (CMS 2018).¹⁰ A state will negotiate with manufacturers to obtain supplemental rebates, which manufacturers provide to ensure that their products are placed on the state's PDL. Preferred drugs typically face fewer utilization management requirements (e.g., prior authorization) than therapeutically equivalent drugs that are not on the list, 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 2018).

Coverage of Drugs

Under the Medicaid Drug Rebate Program, a drug meets the definition of a covered outpatient drug if its manufacturer has a rebate agreement in place with the Secretary and the drug has been approved by the Food and Drug Administration (FDA) (§ 1927(k) of the Act). This means that a state is generally required to cover all of a participating manufacturer's products as soon as they have been approved by the FDA and enter the market—that is, when they are available for sale by the manufacturer in the state.¹¹ Although a state can use prior authorization, clinical criteria, or other utilization management tools to manage the use of a particular drug, the effect of these limitations “should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments” (CMS 2015).

The statutory requirement to cover new drugs upon market entry means that a state must quickly determine under what circumstances coverage is supported by the FDA label. For drugs within therapeutic classes for which extensive evidence is available and well known to state Medicaid officials and health care providers (e.g., statins), this requirement may be relatively easy to meet.

But for novel drugs or first-in-class therapies, state officials and providers may not know in advance what uses will be supported by its label or if there are additional clinical guidelines that should be followed in prescribing the drug. Additionally, some novel therapies are approved based on surrogate endpoints, a situation in which evidence about drug safety and efficacy is limited.¹² Due to the difficulty of evaluating a drug's safety, efficacy, and effectiveness immediately upon its entry into the market, most states require prior authorization for drugs they have not yet reviewed. If these prior authorization requirements are neither clearly defined nor publicly available, beneficiaries may not have a guaranteed path to coverage for the new therapy.

States must follow a prescribed process to publish and implement formal coverage criteria. Statute requires that the PDL must be developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the governor of the state (§ 1927(d)(4)(A) of the Act). To fulfill this requirement, states typically use a pharmacy and therapeutics (P&T) committee to develop their PDLs and make recommendations on appropriate utilization protocols, such as prior authorization, for each drug (Box 1-1).

The process of P&T committee deliberations varies from state to state. For example, in a few states, P&T committees meet on a monthly basis, but in many others, P&T committees meet quarterly. P&T committee meetings are typically open to the public for comment and testimony, and states may require public notice and the publication of the meeting agenda a few weeks in advance of the meeting. If a drug is introduced after the agenda for the next scheduled P&T meeting is announced in states with quarterly meetings and public notice requirements, the committee must wait at least 90 days (until the next scheduled meeting) to review the drug. In some states, it can take two meetings (held quarterly) to finalize any recommendations for new drug classes. Some states allow members of the public to comment for a period of time after a committee meeting (e.g., 30 days) before the state can implement the committee's recommendations.

BOX 1-1. Pharmacy and Therapeutics Committees

States typically use a pharmacy and therapeutics (P&T) committee to make recommendations on coverage criteria and placement of drugs on the state's preferred drug list (PDL). There are no federal requirements for P&T committees. As such, the structure and operations of the committee—for instance, composition of members, frequency of meetings, opportunity for public comment, and conflict of interest policies—tend to vary by state.

The P&T committee examines the scientific literature (e.g., drug labeling, drug compendia, peer reviewed clinical literature, and professional association guidelines) for evidence that supports including a specific drug on the PDL based on the drug's safety, efficacy, and effectiveness relative to other drugs in its class. Price may also be considered once a drug's safety, efficacy, and effectiveness have been evaluated. For instance, inclusion on the PDL may be related to whether the state receives supplemental rebates from the drug's manufacturer. The P&T committee also makes recommendations on the appropriate utilization protocols, such as prior authorization or quantity limits for individual medications or for therapeutic categories.

The P&T committee may use a contractor, such as the state's pharmacy benefits manager or university, to assist in compiling and reviewing the evidence. Some states may use a drug utilization review board (§ 1927(g)(3) of the Act) instead of a P&T committee to fulfill some or all of these duties in developing the PDL and utilization management protocols.

If state policy is to restrict coverage of a new drug before it undergoes P&T committee review, the state might be, in effect, excluding coverage of that drug for an extended period of time, thus failing to meet its statutory obligation to cover the drug upon its entry into the market.

It typically takes from one to three months (although sometimes as long as six months to a year) for a state to evaluate a new drug and develop coverage criteria, depending on the resources available and the drug.¹³ It can be much faster to review a new drug or new formulation of a drug in an existing class than to review a novel drug or first-in-class treatment.

Other federal payers

In general, plans sold on health insurance exchanges and Medicare Part D plans have minimum requirements for drug coverage, but they are allowed to exclude coverage for some drugs.¹⁴ Exchange plans and Medicare Part D plans are required to use P&T committees to develop their

formularies, and they are allowed a period of time following a new drug's release into the market to evaluate it and make coverage decisions. Exchange plans are required to make a reasonable effort to review new drugs within 90 days of approval and make coverage determinations within 180 days (HHS 2015). Medicare Part D plans are similarly required to make a reasonable effort to review new drugs within 90 days and make coverage decisions within 180 days of a drug's release into the market. If a drug is in one of the six protected classes, Medicare Part D plans are required to conduct an expedited review and render a coverage decision 90 days after it comes on the market. At the end of the 90-day period, the drug must be added to the plan's formulary (CMS 2016a).

Cap on Medicaid Rebates

Under the Medicaid Drug Rebate Program, drug rebates are capped at 100 percent of a drug's

AMP (§ 1927(c)(2)(D) of the Act). A drug is likely to reach the rebate cap only if the price increases substantially over time and is thus subject to a large inflationary rebate.¹⁵ This rebate cap limits the inflationary rebate and restricts the dollar amount of rebates that Medicaid can receive. Recently, a number of drugs covered by Medicaid have reached the rebate cap: MACPAC analyses of Centers for Medicare & Medicaid Services (CMS) drug rebate data from the fourth quarter of 2015 show that about 18.5 percent of brand drugs (at the national drug code level) reached the rebate cap in that quarter and that Medicaid would have received an additional \$690 million in rebates if there were no caps on the rebates (MACPAC 2018a).

Several drugs that have been on the market for decades have recently seen steep price hikes. For example, the price of Daraprim increased from \$13.50 per tablet to \$750 per tablet in 2015 and Eli Lilly and Novo Nordisk increased prices of insulin 450 percent above inflation over several years (Johnson 2016, Pollack 2015). Currently, Medicaid is largely insulated from these steep hikes by the inflationary rebate, which ensures that Medicaid programs receive a rebate equal to the amount that the price of the drug has increased over inflation. In other words, the Medicaid inflationary rebate ensures that net price increases for drugs purchased by Medicaid are limited to the rate of inflation. However, other payers and consumers, including those who are uninsured, are exposed to steep price increases.

Some policymakers have argued that the Medicaid inflationary rebate benefits other payers by penalizing steep price hikes. A manufacturer may choose to limit its price increases to avoid paying Medicaid a larger inflationary rebate. Once a drug hits the cap, however, the manufacturer can raise prices without being subject to a corresponding increase to its net rebate obligations to Medicaid. In other words, manufacturers would essentially receive no net revenue on Medicaid prescriptions (because the rebate would be equal to 100 percent of AMP), but they could increase the price even more to obtain greater revenues from other payers

without having to pay additional rebates on the Medicaid side.¹⁶ The Administration has recently expressed interest in removing the cap on Medicaid rebates as a way to discourage manufacturers from implementing steep price hikes (HHS 2018).

Commission Recommendations

In this chapter, the Commission recommends two changes to the Medicaid Drug Rebate Program. These should not be considered a package; that is, the adoption of one by Congress does not require the adoption of the other. The rationale and implications of these recommendations are described below.

Recommendation 1.1

Congress should amend Section 1927(d)(1)(B) of the Social Security Act to allow states to exclude or otherwise restrict coverage of a covered outpatient drug for 180 days after a new drug or new formulation of a drug has been approved by the Food and Drug Administration and entered the market.

Rationale

We recommend that Congress give states a set period of time to evaluate the clinical evidence for new drugs and determine appropriate coverage criteria for several reasons. First, providing states with this grace period has the potential to improve beneficiary safety. As discussed, the FDA approves drugs as safe and effective for the treatment of certain diseases in certain individuals. For other individuals, the same drug may present an unacceptable level of risk. Professional societies may also develop prescribing guidelines regarding appropriate dosing, potential drug interactions, and the need for additional clinical monitoring. Without time to evaluate the approved label indications and review the clinical literature, states risk either covering inappropriate uses of the drug or enacting utilization management protocols that do not

adhere to clinical guidelines developed by the relevant medical and professional associations. This is particularly relevant when innovative drugs are approved on the basis of surrogate outcomes and when there is little evidence available on long-term effects of treatment at the time of approval. Giving states time to review the literature regarding safety, efficacy, and clinical outcomes and assess real-world outcomes (on the chance that new adverse events are discovered postapproval) will help prevent potential drug-related harm.

Second, states need sufficient time to complete the lengthy process of reviewing the scientific literature and establishing appropriate coverage criteria. States must use a committee to develop the PDL and to make recommendations on appropriate utilization protocols. A 180-day period would allow most states to maintain their existing procedural timelines for the P&T committee to review drugs and develop coverage decisions. In addition, this would align Medicaid's time frames with those of Medicare Part D and exchange plans.

Finally, a statutory grace period would not be a huge departure from current state practices that may already result in limited access for new drugs for some period of time. States generally require prior authorization on a new drug before it has been reviewed by the P&T committee and coverage criteria have been established. It may not be clear to the beneficiary and prescribing physician that the drug is available, particularly if prior authorization is done on a case-by-case basis or claims are routinely denied for drugs that have not yet been reviewed for the PDL. In fact, the requirements to get the drug may be so rigorous that the state is essentially not covering it.

Given these circumstances, a statutory grace period may primarily serve to codify a practice that is already taking place informally. In addition, it may have an added benefit for beneficiaries and providers by clarifying what state actions are permissible.

It is important to note that although this recommendation provides states with the option to exclude or restrict coverage for up to 180 days,

it does not require them to do so. Nothing in this recommendation would prohibit a state from implementing its coverage policy earlier than the deadline. For new formulations of existing products or new drugs in an existing therapeutic class, states have shown that they can evaluate the product quickly and implement a coverage policy much faster than 180 days. Thus, CMS may wish to issue guidance that aligns the grace period with Medicare Part D standards and requires states to make a reasonable effort to review a new drug within 90 days (CMS 2016a). Nor would the recommendation prohibit a state from providing some level of coverage while it is developing its policies. The Commission expects states to have an exceptions process in place that allows beneficiaries in critical need to obtain early access to a medication.

The Commission makes this recommendation with the expectation that states will use the grace period to make informed coverage decisions based on clinical guidelines and not as a license to simply delay access to drugs. In implementing the grace period, it would be desirable for CMS to issue regulatory or subregulatory guidance to standardize the operations of P&T committees across states, to ensure that processes are fair and transparent to the beneficiary, and to ensure the time is used to formulate coverage policies that meet statutory requirements. For example, CMS could establish a minimum frequency for P&T committee meetings (e.g., quarterly), a period for public comment, and a requirement that coverage criteria be published at the end of the grace period. These requirements would reinforce the proper role and function of the P&T committee and provide a clear timeline to ensure appropriate beneficiary access to new drugs.

The Commission also sees the need for CMS to exercise its oversight role by actively monitoring state compliance with drug coverage requirements. Current CMS practice is largely reactive; when the agency becomes aware of compliance issues, it may contact state officials informally to attempt to resolve issues, but there can be a substantial time lag before it takes formal action.

The Medicaid experience with Sovaldi shows why more active monitoring of state coverage policies is needed. When Sovaldi was first introduced as a treatment for hepatitis C, some states were essentially denying coverage, either by not making formal coverage decisions or by instituting extremely restrictive prior authorization requirements. It took CMS nearly two years after Sovaldi's approval in December 2013 before it sent a letter reminding states of their coverage obligations (CMS 2015). It was May 2016 before a federal judge in the Western District of Washington issued a preliminary injunction that led the Washington State Medicaid program to loosen coverage restrictions and cover hepatitis C treatments more broadly.¹⁷

Implications

Federal spending. The Congressional Budget Office (CBO) estimates that this recommendation would produce modest savings, decreasing federal spending by less than \$25 million over 10 years compared to the current law baseline. The savings primarily result from delaying the start of the coverage period and shifting some spending to a later time period.

States. States have indicated that a grace period would help alleviate their administrative burden by providing sufficient time to determine appropriate prior authorization and coverage criteria for newly approved drugs.

Enrollees. A grace period has the potential to improve beneficiary safety by giving states time to develop appropriate prescribing guidelines that could reduce drug-related harm. A grace period also could affect beneficiary access to medications and result in delayed access to some drugs; however, current state practices may already result in limited access for new drugs. Beneficiary protections would be enhanced by issuance of new CMS guidance to ensure that P&T processes are fair and transparent and that CMS is actively monitoring state compliance with coverage requirements.

Drug manufacturers. This recommendation could delay the availability of a manufacturer's drug in the Medicaid market. Manufacturers may already be experiencing some delays in the coverage of their products based on current state practices, but we expect that manufacturers would prefer there not be a formal waiting period in which states are legally allowed to exclude coverage.

Recommendation 1.2

Congress should amend Section 1927(c)(2)(D) of the Social Security Act to remove the cap on Medicaid drug rebates.

Rationale

Removing the rebate cap would allow the inflationary rebate to achieve its full effect and lead to higher rebates on drugs with large price increases, which would reduce the net price for these products and create savings for Medicaid. These savings would relieve some fiscal pressure on states by allowing them to maintain the same level of drug coverage at a lower cost.

Removing the rebate cap would also reinforce the downward pressure that the Medicaid inflationary rebate already exerts on price increases. A drug manufacturer is likely to reach the rebate cap only if it increases its price substantially over time and therefore has to pay a large inflationary rebate. Removing the rebate cap could change the calculation for manufacturers considering a large increase in the market price of their products because there would be no limit on the Medicaid rebates and larger price increases would result in larger Medicaid rebate obligations for manufacturers. Manufacturers would have the incentive to lower list prices on current drugs as well as curtail price increases on future drugs.

Manufacturers strongly oppose changes to the rebate cap. As noted in its comments on the Administration's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, the Pharmaceutical Research and Manufacturers of America, a trade

group, referred to the proposal as a tax on drug manufacturers and said it would lead to further market distortions (e.g., cost shifting) (PhRMA 2018).¹⁸ Manufacturers may threaten to leave the Medicaid program or reduce research on drugs that disproportionately benefit Medicaid enrollees, such as treatments for cystic fibrosis. However, the Medicaid drug rebate agreement applies to all of a manufacturer's drugs, so a manufacturer cannot choose to withdraw only one or a select few of its products from the program. Although the possibility of such manufacturer retaliation cannot be dismissed, such actions would represent a considerable shift for drug manufacturers, likely requiring major changes to their business operations.

Removing the rebate cap would not address the issue of high launch prices. If the rebate cap were removed, manufacturers would have an incentive to launch their products at a higher price and, in so doing, avoid annual price increases that would outpace inflation and trigger the inflationary rebate. However, this strategy may not be an option for all drugs because drug launch prices are determined based on a variety of factors, including existing therapeutic competition, anticipated insurance coverage and formulary tier assignments, and anticipated provider prescription rates. Moreover, some economists believe that pharmaceutical manufacturers already launch their new drugs at the highest price they think the market will bear (Kaltenboeck and Bach 2018, Kesselheim et al. 2016).

In its deliberations on this issue, the Commission considered whether to remove the cap or to raise it to 125 percent of AMP, which would produce about half as much savings. The discussion of these options focused on the pressure each option would exert on manufacturers to limit price increases as well as any potential negative consequences. Although some Commissioners initially expressed optimism that raising the cap would provide an opportunity to evaluate the market response, all ultimately agreed that it would be difficult to evaluate the effect of the policy on drug prices in isolation. After weighing the two approaches, the Commissioners concluded that it would be preferable to place the greatest possible

amount of pressure on manufacturers to limit price increases, and so they recommended removing the cap completely.

Implications

Federal spending. Removing the rebate cap would increase the rebates Medicaid receives from manufacturers. The CBO estimates that this recommendation would decrease federal spending by \$15–\$20 billion over 10 years compared to the current law baseline. These savings would help offset the projected \$2–\$3 billion annual increases in Medicaid drug spending (OACT 2019).

States. State spending would decrease because states would receive the non-federal share of any increases in rebate amounts. Based on the average federal share of Medicaid rebates in recent years, this would amount to approximately \$7–\$10 billion in state savings across all states over 10 years. This change could affect supplemental rebate agreements; however, it is unlikely that states have supplemental rebate agreements on drugs that have reached the rebate cap as states are already receiving these drugs at essentially no cost.

Enrollees. This recommendation is unlikely to have a measureable effect on Medicaid beneficiaries.

Drug manufacturers. Manufacturers would be required to pay larger Medicaid rebates should they increase prices substantially faster than the rate of inflation. Manufacturers would need to take the potential for larger rebates into account as they establish their market prices.

Next Steps

Although implementation of these recommendations will provide states with additional time to make coverage decisions and generate savings for Medicaid by increasing rebates, states will still face a number of challenges in managing the prescription drug benefit. The Commission therefore plans further work in this area. For example, we are currently examining how Medicaid's

existing tools for managing drug utilization compare to Medicare Part D and commercial plans. Based on our initial findings, Medicaid tends to cover more drugs than Medicare or commercial plans, but also may place more restrictions on drugs. However, most formularies across all three payers include restrictions through prior authorization, step therapy, or quantity limits for the majority of the drugs in a class (MACPAC 2018b). We are continuing this analysis to determine how different coverage policies affect actual utilization of specific medications across payers.

The Commission has also heard that existing drug utilization management tools are ineffective 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 certain value-based arrangements or financing models (e.g., subscription-based models for curative treatments) could be used more broadly. A few states have just started implementing these value-based and alternative financing arrangements, so it will take some time before we can assess the effectiveness of these initiatives.

The Commission may also consider whether certain drugs or therapeutic classes that have unique characteristics (e.g., curative treatments, gene or cell therapy) should receive separate consideration apart from other covered outpatient drugs.

Endnotes

¹ Magellan, a large national pharmacy benefits manager (PBM), reported that for its contracted Medicaid fee-for-service programs, net spending per claim (net of federal and supplemental rebates) decreased 5.1 percent for traditional drug classes but increased 20.5 percent for specialty drug classes from 2015 to 2016; the share of net spending attributed to specialty drugs increased by almost 5 percentage points during this period, from 31.8 percent to 36.5 percent (Magellan 2017). Express Scripts, another large national PBM, reported that specialty medications accounted for 42.3 percent of their total Medicaid drug

spending in 2017, increasing 7.4 percent in per-member, per-year spending compared to 2016 (Express Scripts 2018).

² About 80 percent of the drugs approved by the U.S. Food and Drug Administration (FDA) in 2017 could be classified as specialty drugs under most definitions (CBO 2019).

³ In addition to executing a Medicaid drug rebate agreement as a condition for Medicaid coverage of their products, 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 (§ 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) of the Act).

⁵ The covered outpatient drug rule finalized 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.

⁶ Generally, an innovator drug is a drug produced or distributed under a new drug application approved by the 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 by the FDA under an abbreviated new drug application.

⁷ For blood clotting factor drugs and drugs approved by the FDA exclusively for pediatric indications, the rebate percentage is 17.1 percent of AMP instead of 23.1 percent of AMP.

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. 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 2016b).

¹⁰ In accordance with Section 2501(c) of the Patient Protection and Affordable Care Act (P.L. 111-148, as amended), 20 states—Arizona, Arkansas, California, Delaware, Florida, Illinois, 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 2018).

¹¹ A drug manufacturer must have a signed Medicaid drug rebate agreement in place in order for its products to be covered by Medicaid. If a manufacturer does not have a rebate agreement with the Secretary, then a state does not have to cover that manufacturer's products until the rebate agreement is effective.

¹² The accelerated approval pathway allows the FDA to approve a drug based on whether the drug has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit (§ 506(c) of the Federal Food, Drug, and Cosmetic Act). A surrogate endpoint is a marker—a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit.

¹³ To learn more about how states develop clinical coverage criteria for new drugs, we sent a set of focused questions

to state Medicaid pharmacy directors and conducted informal interviews with four states and received written survey responses from five states. Some states said that they typically can review the clinical evidence and develop guidelines within a matter of weeks; one state said it takes six months. However, most states that responded said it normally takes two to three months, and one said that it takes six months to a year.

¹⁴ For Medicare Part D formularies, each drug category or class must include at least two drugs (regardless of the classification system utilized), and Part D plan formularies must include all or substantially all drugs for the following six protected classes: immunosuppressants (for prophylaxis of organ transplant rejection), antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics (CMS 2016a). Exchange plans must cover one drug in every United States Pharmacopeia category and class, or the same number of drugs in each category and class as the state benchmark plan (45 CFR 156.122(a)(1)).

¹⁵ A study by the Pew Charitable Trust estimated that brand drugs with price increases of more than 433 percent above inflation in 2017 would exceed the rebate cap when the basic rebate is 23.1 percent of AMP (Dickson 2019).

¹⁶ The 340B program would also get these drugs at essentially no cost. Additionally, some companies offer assistance to low-income and insured patients in the form of coupons and reduced prices.

¹⁷ *B.E. v. Teeter*, C16-227-JCC (W.D. Wash. 2016).

¹⁸ The full publication, *HHS blueprint to lower drug prices and reduce out-of-pocket costs*, is available at <https://www.regulations.gov/contentStreamer?documentId=CMS-2018-0075-0001&contentType=pdf>.

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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, fulfills 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 Medicaid prescription drug policy. 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 April 11, 2019.

Next Steps in Improving Medicaid Prescription Drug Policy

1.1 Congress should amend Section 1927(d)(1)(B) of the Social Security Act to allow states to exclude or otherwise restrict coverage of a covered outpatient drug for 180 days after a new drug or new formulation of a drug has been approved by the Food and Drug Administration and entered the market.

Yes:	Bella, Burwell, Carter, Davis, Douglas, George, Gordon, Gorton, Lampkin, Milligan, Retchin, Scanlon, Szilagyi, Thompson, Weil, Weno	16	Yes
		1	Not present

Not present: Cerise

1.2 Congress should amend Section 1927(c)(2)(D) of the Social Security Act to remove the cap on Medicaid drug rebates.

Yes:	Bella, Burwell, Carter, Davis, Douglas, George, Gordon, Gorton, Lampkin, Milligan, Retchin, Scanlon, Szilagyi, Thompson, Weil, Weno	16	Yes
		1	Not present

Not present: Cerise