



How the Federal Government Can Help States Address Rising Prescription Drug Costs

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Introduction

States today struggle to fund health services for all their programs, including Medicaid, state employees, prisons, state university systems, and others. The rising cost of prescription drugs is a key factor in this struggle -- an estimated 25 percent of state budgets go to fund Medicaid, and state spending on Medicaid drugs alone [increased 25 percent in 2014 and 14 percent in 2015](#).

States operate in highly constrained budget environments, which require new and creative approaches to manage rapidly rising health care spending. State Medicaid programs are controlled by a variety of market forces and decades-old federal rules that today limit what states can do to curb rising prescription costs.

With the support of The Commonwealth Fund, the National Academy for State Health Policy (NASHP) convened state and federal health care policymakers to discuss how current rules governing Medicaid programs hinder state efforts to rein in rising prescription drug costs.

This off-the-record discussion provided valuable insights and recommendations for the federal government to revamp regulations and empower states to address prescription drug spending.

Recommendation: The federal government can:

- Perform audits to ensure manufacturers' "best price" drug calculations are accurate;
- Give states the same bargaining scope and clout that federal programs now wield;
- Determine extent to which manufacturer price concessions to pharmacy benefit managers are reflected in manufacturer Medicaid "best price" calculations. Allow states to realign their drug formularies to reduce costs;
- Facilitate state use of value-based purchasing to promote the highest-value, most cost-effective drugs to cover;
- Give states extra time to determine if "fast-tracked" drugs produce their promised results before covering them;
- Allow states to contract with specialty pharmacies or create pharmacy networks to reduce costs; and
- Consider creating a joint federal-state Medicaid Technical Advisory Group to address complex Medicaid drug coverage and rebate issues.

Background

In the late 1980s, there was growing concern that state Medicaid programs could not negotiate the prescription price concessions that other payers were getting. In response, in 1990 Congress enacted policies to make sure state Medicaid programs received significant discounts off the average commercial market drug price (called the Average Manufacturer Price or AMP). Congress also stipulated that manufacturers must give Medicaid programs the "best price" – the lowest price in the commercial market. Under these rules, state Medicaid programs generally get rebates equal to 23.1 percent of the AMP or the "best price," whichever is lower. In exchange, state Medicaid programs must cover all of a manufacturer's drugs, with few exceptions. States cannot oper-

ate a “closed” formulary where not all drugs, but rather the most effective and cost-effective drugs are covered. The law also provides an additional rebate, linked to the Consumer Price Index, so states can capture the costs of manufacturer price increases. The law was expanded to provide states with rebates on drugs dispensed to managed care organization enrollees.

There are also supplemental rebates states can negotiate directly with manufacturers to the extent that manufacturers feel compelled to negotiate when state procurement rules make this possible. State rebate amounts are confidential so states cannot share information about the results of these negotiations with each other. As a result, states are left negotiating in the dark, unaware of what price concessions other states have achieved. However, the Centers for Medicare & Medicaid (CMS) has access to this information because each agreement must be reviewed by the agency.

In order to create an incentive for manufacturers to negotiate, states can remove a drug from their Medicaid “preferred drug lists” (PDL) and condition placement on the PDL on the receipt of a supplemental rebate. States have differing ability to do this based on the size of their Medicaid programs, their state procurement rules, and because states are legally required to cover all drugs – so drugs that are not on the PDL are still effectively covered.

Drugs not on the PDL have effectively been put on prior authorization, which means the doctor has to specifically request the drug for the patient and specify the medical need. States can also try to control costs through typical drug benefit management tools, such as step therapy (requiring the less costly version of a drug to be prescribed first.) However, prior authorization and step therapy are of limited use in boosting states’ bargaining power because, as mentioned earlier, Medicaid programs cannot deny coverage of any drug – no matter how high its price – if its maker participates in the state’s rebate program. Additionally, states risk having providers withdraw from their Medicaid programs if administrative burdens such as more pre-authorization paperwork are used to control the use of high-cost medications.

Current Roadblocks to Effective State Price Controls

As new drugs come to market with increasingly high prices, and the price of older drugs rise without warning or apparent cause, states have an acute need for more effective tools to manage their Medicaid drug spending while balancing the needs of their beneficiaries. Rebates provide drug cost relief after drugs are dispensed and paid for, but rebates that come months after-the-fact do not help Medicaid agencies address budget problems that arise when drug prices rise substantially or new, very costly drugs hit the market. All rebates occur after-the-fact and the rebates generally are channeled into a state’s treasury – leaving Medicaid agencies ill-equipped to pay for sudden drug price increases during a budget year. The urgency for more leverage over drug spending is heightened by the U.S. Food and Drug Administration’s (FDA) rapid approval of new and costly drugs, which is expected to continue under the 21st Century Cures Act.

The current state of the drug rebate program also creates challenges for Medicaid’s fellow state agencies, which may be limited in what drug discounts they can negotiate because of the Medicaid best price mandate. Manufacturers remain reluctant to provide rebates greater than 23.1 percent of the Medicaid AMP in negotiations with non-Medicaid state agencies because they could create a “best price” and would have to pay all Medicaid agencies nationwide that new negotiated best price. Meanwhile, federal programs (e.g., the US Department of Veterans Affairs and Medicare Part and D) are exempt from Medicaid’s best price, so those programs can negotiate deep drug discounts without manufacturers’ fearing the low price will trigger a national “best price” Medicaid rebate.

State officials who attended the NASHP meeting stressed that the Medicaid drug rebate program needs to be updated to keep pace with prescription drug market dynamics that were not envisioned when the law was first created. The program has been updated in small ways, for example additional state rebates on physician-administered drugs were required in 2006 and rebates to states for drugs paid for by Medicaid managed care organizations was mandated in 2010. However, the program requires deeper changes to enable states to better manage drug spending in the face of unprecedented price increases. According to state officials, these two key provisions in the federal Medicaid law particularly hinder state actions:

- Medicaid’s best-price requirements impede non-Medicaid state agencies from obtaining significant drug price concessions or significant performance-based contracts because manufacturers will not risk creating a new Medicaid “best price.”¹ As a result, the federal flat Medicaid rebate of 23.1 percent often becomes the ceiling for discounts that manufacturers give to any payer whose price concession is not exempted by federal law from figuring in the Medicaid “best price.”
- Medicaid agencies cannot use the same formulary tools as commercial payers to constrain drug spending. Currently, they cannot:
 - Limit coverage of drugs in specific therapeutic classes by excluding all but the most cost effective (i.e., operate a closed formulary);
 - Create or contract with specialty pharmacies for expensive drugs with complex treatment regimens; or
 - Establish if there is adequate clinical evidence about the effectiveness of breakthrough drugs before covering them.

There are approaches and rule changes that CMS should consider to lessen the pricing challenges states face under the current law. Below are 10 ways CMS could improve states’ ability to better control prescription drug costs.

Recommendations to Improve Pricing Transparency

Conduct audits to verify that a drug’s “best price” and Average Manufacturer Price (AMP) -- on which Medicaid drug discounts are based – are truly accurate to ensure states are getting the lowest price possible. Currently, little is done to verify manufacturers’ “best price” or AMP calculations. The US Health and Human Services Office of Inspector General (inspector general) should conduct regular random audits to verify the manufacturer calculations and reporting of these rebate benchmarks.

Work with state agencies to develop new approaches to address the impact of Medicaid “best price” on state public purchasing. CMS should help non-Medicaid state agencies develop strategies through demonstration waivers that would be exempt from the Medicaid “best price” requirements, similar to what federal drug-purchasing programs now enjoy.

Establish that non-Medicaid state agencies can use Medicaid drug rebate benefits to broaden state negotiations and drug purchasing. CMS should affirm that non-Medicaid state programs can leverage the Medicaid drug benefit to strengthen their negotiations with manufacturers by re-visiting its 2002 guidance to clarify that state initiatives do not harm the Medicaid program. Current guidance, for example, limits the extent that states can impose Medicaid prior authorization or supplemental rebate demands on manufacturers that do not negotiate satisfactory price concessions in other state government programs.

Examine pharmacy benefit manager (PBM) pricing impact on drug costs for states and consumers: The inspector general should require PBMs to disclose how much of manufacturers' discounts are passed on to their health plan clients, and should examine the extent to which any price concessions not "passed through" are included in manufacturer calculations of Medicaid "best price," which is the intent of current regulations.

CMS should help states share their negotiated supplemental rebate amounts with each other so all states know if they are optimizing the supplemental rebate negotiation: CMS should help states share supplemental rebate information -- without violating federal confidentiality rules -- so states have access to the full range of state discounts currently negotiated for different drug products or product classes.

Recommendations to Improve State Formulary Management Tools

Several states have expressed interest in operating the Medicaid drug benefit program more like commercial payers to effectively drive down their costs through intensive formulary management.

States believe their Medicaid programs could, if given the right tools, negotiate net prices lower than a manufacturer's best price. Under current policy, Medicaid cannot use private sector tools, such as exclusive formulary placement through a closed formulary, to drive those price negotiations. But with strong formulary management ability, state Medicaid agencies could effectively negotiate for better drug costs.

For example, if Medicaid were able to select one or two drugs to cover in a therapeutic class (like one hepatitis C product or one PCSK9 cholesterol product), it could be an effective strategy to gain very significant price concessions, particularly for newer innovator drugs.

As described earlier, states do not find that the ability, available under current law, to create "preferred" and "non-preferred" drug lists to be an effective market-based negotiation tool to get significant supplemental rebates for several reasons.

The difference in the patient out-of-pocket cost between the two lists is minimal (unlike the significant differences in patient costs in commercial health plan formulary tiers). Some states do not use copays at all and other states are not interested in creating market leverage by seeking waivers of beneficiary copays to drive utilization like the private sector does.

Prior authorization associated with drugs on the non-preferred list is not always onerous – because states do not want to make things too problematic for Medicaid participating providers and patients, and because if the drug is ultimately medically necessary, it must be covered. Instead, many states would like more formulary design discretion to better manage big-ticket drugs, which would complement the current practice of numerous small supplemental rebates for many products and a prior authorization process that is not overly burdensome.

Give states more control over their drug formularies so they can better manage high-cost drugs and give them a streamlined authorization process that is not overly burdensome. The federal government should create a process to approve Medicaid selective contracting initiatives in consultation with states.

Support Medicaid value-based contracting by creating a national Medicaid pharmacy and therapeutics (P&T) committee: States need assistance getting value- and performance-based contracting off the ground because negotiating these contracts is challenging. HHS should create a national Medicaid P&T committee to identify standards for value-based drug contracting and create contract templates for states and other payers to use.

Allow states to delay coverage of any US Food and Drug Administration fast-tracked drug until there is more verifiable effectiveness data available: States want to make sure Medicaid funds are spent wisely on proven treatments. They want guidance and/or waiver authority to delay coverage of new, high-cost drugs licensed under an expedited review process until more authoritative drug effectiveness data is available.

Allow Medicaid agencies to create pharmacy networks to negotiate lower costs: States would like the option to create a statewide Medicaid pharmacy network and/or contract with specialty pharmacies for either their fee-for-service population, or to carve out some drugs from health plan contractor management and move to a statewide retail network or specialty pharmacy contractor.

Consider a joint federal-state Medicaid Technical Advisory Group (TAG) to address complex Medicaid drug coverage and rebate issues: This group could tackle the complex issues involved in controlling drug costs, re-evaluating the drug rebate program, and improving communication between states and CMS on pressing policy and operational issues that impact drug costs.

Conclusion

Critics of state efforts to better control state government drug spending contend that Medicaid already does better than commercial payers in achieving the lowest net cost for drugs—due to the Medicaid drug rebate law. With respect to the best price rebate, it is not clear that there is data to prove or disprove this point. However, the success of the commercial sector is not the metric by which states want to evaluate their pharmacy benefits. States need better control over spending than they have now—regardless of what the private sector is able to negotiate. States must balance their budgets and do not have the budgeting latitude that commercial payers have, and, states have a unique responsibility to consumers as the payers of care and they must balance consumer needs against budgetary realities.

States have limited capacity to raise premiums or shift costs to Medicaid beneficiaries to control spending, nor would they necessarily want to do so given the low incomes of the population. Therefore, states need stronger negotiating leverage to increase price reductions over what they can extract from the industry today. States need the tools to manage spending now in the absence of a national approach to prescription drug prices and these state initiatives can inform the national debate about what strategies work to lower prescription drug costs.

The issues of Medicaid best price and drug coverage rules may appear relatively insignificant in the context of federal and state policy writ large—or even in the context of drug pricing/drug cost policies. However, these issues are significant given that many other state-level drug cost containment policies are either not permitted or subject to uncertain litigation. Therefore, potential avenues for state action affecting Medicaid programs must be clarified to allow states to move forward with greater impact, certainty, and success. With such action, both state and federal budgets will benefit. In the absence of such action, states will be less able to meet the needs of Medicaid beneficiaries and others for whom they purchase coverage.

Endnotes

1. Medicaid/manufacture price negotiations are exempt from the best price rules. But negotiations by other state agencies are not exempt. For more detailed information, please see NASHP white paper on this topic - <https://nashp.org/wp-content/uploads/2018/02/White-paper-background-for-NASHP-Rx-Medicaid-discourse.pdf>

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