Georgetown University
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CENTER FOR CHILDREN
AND FAMILIES

How Medicaid and CHIP Shield Children from the Rising Costs of Prescription Drugs

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Third in a series of briefs on the future of children's health care coverage

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ABOUT THIS SERIES

This issue brief is the third in a series of papers from Georgetown University Center for Children and Families on the future of children's health coverage. Other briefs in the series include:

The Future of Children's Coverage: Children in the Marketplace
Focuses on ways to improve marketplace coverage and the associated financial assistance for children.

Fulfilling the Promise of Children's Dental Coverage
Focuses on pediatric dental coverage and ways to improve children's oral health.

KEY FINDINGS

- Nearly a quarter of U.S. children use at least one prescription drug a month, most commonly treating such conditions as asthma, attention deficit hyperactivity disorder, and infections. Medicaid guarantees that most enrolled children who need drugs receive them without any financial barriers.
- Drug costs are projected to rise faster than overall health costs, which themselves are projected to continue rising faster than general inflation. Although Medicaid children are generally protected, cost increases place fiscal pressure on the state and federal governments that pay for the drugs.
- Preferred drug lists and prior authorization can help states secure price discounts, but an effective process for exceptions and appeals is necessary to ensure access.
- Price discounts achieved through Medicaid's drug rebate program have saved states and the federal government billions of dollars in purchasing prescription drugs, but that program does not address all sources of high drug prices. The Medicaid rebate program should be extended to the Children's Health Insurance Program.

Prescription drugs are critical to maintaining good health for many children, whether for chronic conditions, such as asthma or attention deficit hyperactivity disorder (ADHD), or acute ailments such as ear infections. For a smaller set of children, more serious conditions such as cancer or HIV/AIDS require more extensive care that typically includes costly drug treatments. Medicaid and the Children's Health Insurance Program (CHIP) offer critical support for low-income children in any of these circumstances by protecting them from rising drug costs. Most children enrolled in Medicaid are totally protected from incurring costs to get the drugs they need, and the remaining children with Medicaid or CHIP coverage have minimal out-of-pocket drug costs.

The Example of EpiPen

A notable example is EpiPen, a drug used to treat severe allergic reactions, such as those triggered by certain foods. EpiPen, which delivers epinephrine through an injection device, made headlines recently when Mylan, its manufacturer, raised the list price of a two-pen package to $608. The new price was more than six times the price when Mylan acquired the product from Merck in 2007. An estimated 3.5 million prescriptions were written for EpiPens in 2014,[1] and Medicaid covered about one of every five of these prescriptions.[2]

The good news for children with Medicaid coverage is that they were shielded from these price increases. Most families with Medicaid coverage can fill their EpiPen prescriptions free of charge, without a copayment. Others with higher incomes and health coverage through CHIP may face a nominal copayment—in most states no more than $5. But they are also protected from the increases in EpiPen's price because the copay is fixed. By contrast, some families with commercial health insurance may have cost sharing in the form of coinsurance and thus pay more every time the price increases. Furthermore, families with large deductibles in their health plan or without insurance at all may have to pay full cost of $608 for their EpiPens. Medicaid or CHIP coverage is thus a critical protection for the children enrolled in these programs. Yet the cost of EpiPens and other drugs should be addressed for all children, including those who do not benefit from the protections available from Medicaid and CHIP.

Protection from drug costs is an important feature of Medicaid. Still, some children enrolled in Medicaid and CHIP may face challenges getting the medication they need because of prior authorization requirements and other controls that states or managed-care organizations (MCOs) establish.

Some Basic Facts: Insurance Coverage and Drug Use for Low-Income Children

In 2015, 95 percent of all children had health insurance coverage, and 36 percent had coverage through public programs, primarily Medicaid (37 million) and the Children's Health Insurance Program, or CHIP (9 million).[3] Most other children were covered privately either through employer-sponsored insurance or individual coverage, such as plans purchased through the marketplaces created by the Affordable Care Act.

Nearly one in four children in the United States (23.5 percent), regardless of insurance status, used at least one prescription drug per month in 2009-2012.[4] About 4 percent used three or more drugs. In 2009, the most recent data publicly available, children with Medicaid coverage used an average of 0.5 prescriptions per benefit month—or 6 prescriptions a year. The cost to Medicaid was $31 per month.[5] These averages suggest that a majority of children do not take prescription drugs on a regular basis. Indeed, in 2014, only 14 percent of children covered by Medicaid or CHIP had a health issue for which they regularly took prescription medication for at least three months.[6] But many children do need drugs regularly for chronic health conditions, and many more need them when acute illnesses strike.

Most Common Types of Drugs Used by Children

Much of the prescription drug use by children (regardless of income) occurs for one of three health conditions (Table 1). For the youngest children, especially those under age 6, penicillin antibiotics are the most common.[7] These drugs address short-term needs, such as ear infections. Many antibiotics have modest costs even without insurance; for example, a prescription for amoxicillin might cost between $5 and $15. But the need arises with little warning. Insurance coverage means that cost need not be an impediment to obtaining treatment on a timely basis for these acute illnesses.

Table 1. Most Common Drug Classes for Children under 18 Years of Age (by the Percent of Population with at Least One Prescription in the Drug Class, 2009-2012)

Drug class	Percent of population with at least one prescription in drug class in past 30 days
Bronchodilators (asthma, breathing)	5.1
CNS Stimulants (ADHD)	3.5
Penicillins (bacterial infections)	3.3
Leukotriene modifiers (asthma, allergies)	2.0
Respiratory inhalant products (asthma and related disorders)	2.0
Antihistamines (allergies)	1.7

Source: Health, United States, 2015. DHHS/CDC/NCHS. 2016 (Hyattsville, MD), Table 80.

For children up to age 11, drugs in the bronchodilators class are the most used drugs. These drugs treat asthma and other breathing conditions. Unlike antibiotics, they are used for chronic conditions. As such, many are taken all year long and may be used over a lifetime. Asthma affects 8.5 percent of children and is more common for poor children (13 percent), boys (10 percent), black children (14 percent), and multi-race children (13 percent).[8] When asthma is not well managed, it leads to more emergency department visits, but also has consequences beyond health.

Half of school-age children with asthma missed at least one day of school, and more than half had at least some limitation in their daily activities as a result of their asthma. Asthma treatments include both controller medications that are taken daily to prevent problems and quick-relief (rescue) medications taken during an asthma attack. Some evidence suggests that poor adherence to controller medications can lead to emergency room visits.[9]

Among adolescents aged 12 to 19, central nervous system (CNS) stimulants are the most commonly prescribed drugs. These drugs also treat a chronic health condition—ADHD—and are likely to be used throughout the year. ADHD drugs were used by 7.5 percent of children aged 6 to 17 in 2011-2012 and more likely to be used by boys than girls and by non-Hispanic white children than either black or Hispanic children.[10]

Children on Medicaid or CHIP are more likely to take ADHD drugs than other children, in part because these conditions occur more often in lower-income families[11] and in part because Medicaid may be making it easier for children to be diagnosed and to obtain needed drugs. While issues around the use of ADHD drugs may mean that some children's use of these drugs may not be appropriate, more than half of children using drugs for emotional or behavioral difficulties had a parent report that the medication helped the child "a lot," more so for boys than for girls.[12] One study suggested that children with ADHD who were treated with medication outscored those who were not treated in both math and reading. Although the differences in scores are not large, they offer some evidence medication can help students with ADHD achieve higher grades.[13]

Drug Classes with the Most Spending on Behalf of Children

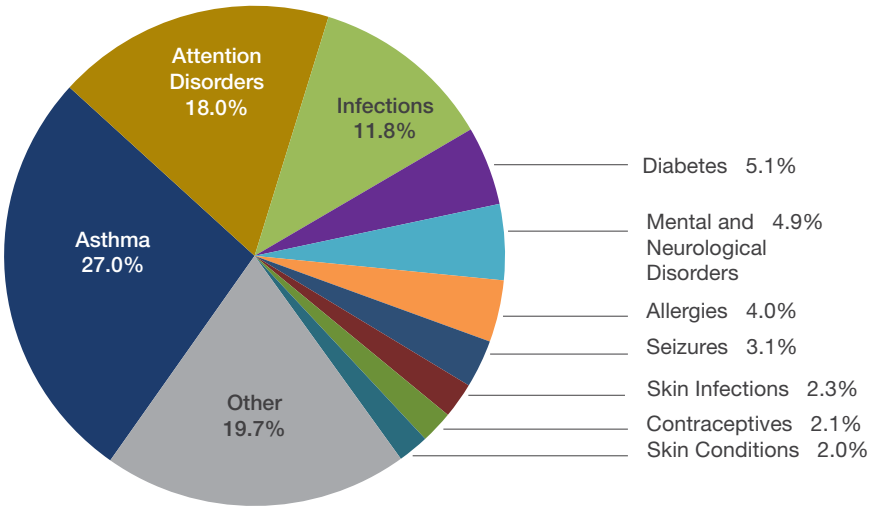
While the drugs used to treat infections, asthma, and ADHD are the most common drugs used by children, other drug classes generate considerable spending for Medicaid. Data for 2011 for Medicaid beneficiaries in managed-care plans managed by Express Scripts, one of the largest pharmacy benefit managers, highlight the drug classes with the most spending.[14] As shown in Figure 1, the top three classes by spending include the most commonly used drugs: anti-asthmatic drugs, drugs used to treat ADHD, and antibiotics used for infections. Other classes with high spending highlight health conditions for which the number of people may be lower but costs drive up total spending. Examples are drugs for diabetes and mental health conditions. The latter class includes both anti-psychotics (taken by those diagnosed with schizophrenia, bipolar disorder, or other related behavioral health conditions) and anti-depressants.

As described below, use of psychotropic drugs for behavioral health conditions may be inappropriate for some children, while other children may benefit. Although only about 5 percent of children use some type of psychotropic drug, the share is much higher for certain subgroups. One-third of children eligible for Medicaid based on disability use one of these drugs, and about one-fourth of children eligible for Medicaid based on child welfare assistance do so.[15] Many of these children used psychotropic drugs (more often antidepressants than anti-psychotic drugs) on a regular basis.

Other children have health conditions that require high-cost drugs. These conditions include HIV/AIDS, childhood cancers such as leukemia, and other uncommon health conditions. Although these drugs are taken by relatively few children, some of these conditions require treatment for an extended period or even for a lifetime. In many cases, drugs are quite expensive.[16] For example, enzyme replacement therapy for rare conditions such as Gaucher's disease, Pompe disease, and Maroteaux-Lamy syndrome typically cost in the range of $200,000 to $300,000 a year. For most of these children, drugs are critical to their survival.

Spinraza, a drug that received FDA approval in December 2016 for spinal muscular atrophy, illustrates the challenge faced by high-cost drugs.[17] The disease, characterized as the most common genetic cause of death for children, causes weakness and muscle wasting. But the drug's price of $750,000 for the first year's treatment and $375,000 for subsequent years has proved a challenge for Medicaid programs.[18]

Figure 1. Selected Drug Classes with the Most Spending for Medicaid Children and Adolescents, Ages 0-19



Source: Express Scripts, 2011 Drug Trend Report.

Protecting Children from High Drug Costs

Medicaid and CHIP provide covered children with a comprehensive health benefit package, which includes prescription drugs. CHIP covers about 9 million children, far fewer than Medicaid. States can choose to operate a free-standing CHIP program independent of Medicaid, enroll CHIP kids in their Medicaid programs, or use a combination of the two. States that enroll children in Medicaid provide those children the full benefits of the program. By contrast, those using a separate CHIP program do not provide the guarantee of a defined benefit, and they may offer a less comprehensive benefit and lack Medicaid's cost-sharing protections.[19]

Several elements of Medicaid and CHIP are vital for protecting children from drug costs. These include the coverage mandates established by Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit and limits on copayments and other out-of-pocket costs associated with drug benefits in Medicaid and CHIP.

Availability of Prescription Drugs as a Covered Medicaid Benefit

Critically for children, EPSDT requires that states provide all appropriate and medically necessary services needed to address a child's health conditions, even if the particular services are not included in the state's Medicaid plan.[20] Thus, even if a state were to restrict drug coverage for adults,[21] children should still be able to obtain any drugs their practitioners determine they need as the result of a screening and diagnosis. The screening and diagnosis functions under EPSDT also help to guarantee that health conditions needing drug treatments are identified on a timely basis. However, as discussed below, EPSDT protections do not insulate children from such utilization management controls as prior authorization.

In addition to covering prescription drugs, most states cover at least some over-the-counter (OTC) drugs.[22] These may include analgesics (e.g., aspirin, acetaminophen), antihistamines (e.g., loratadine), antimicrobials (e.g., bacitracin), gastrointestinal products (e.g., omeprazole, ranitidine), and vitamins. But coverage restrictions vary by state; for example, several states currently do not cover OTC proton pump inhibitors, such as omeprazole. And many states do not cover OTC emergency contraceptives. A child needing a drug from a class that is excluded should still receive that drug as a result of EPSDT requirements. Coverage of OTC drugs generally requires obtaining a prescription and may include other paperwork (such as prior authorization) or limits (such as generic products only).

Limits on Cost Sharing

A key for establishing effective access to drugs, particularly for those with limited resources, is eliminating or minimizing out-of-pocket costs so that they do not limit access. In most insurance programs, cost sharing—in the form of flat copayments or percentage coinsurance—are included to give the insured individual an incentive to reduce inappropriate use of drugs, such as the use of expensive brand-name drugs instead of equivalent generics or the use of drugs where the clinical benefit is uncertain. The theory is that the quality of health care might be improved and costs lowered, but a major 15-year study in the 1970s and 1980s found that asking individuals to share more costs reduced their use of both appropriate and inappropriate drugs and other services. Low-income individuals in particular were as likely to skip needed services as inappropriate ones. Children's use of outpatient care decreased as much as 30 percent, depending on how much families were required to pay.[23]

Prescription drug copayments, in particular, appear to achieve savings at least in part from people forgoing needed medications. Older studies on Medicaid drug benefits have shown that when faced with copays (even 50 cents to $3), people on limited incomes reduced use of both necessary and unnecessary drugs.[24] Two studies of children with asthma found that higher cost sharing was associated with reductions in medication use; one also found an association with higher rates of hospitalization with children aged 5 or older.[25]

A study of health coverage for one employer that implemented changes to its drug benefit found that copayment increases resulted in a significant decrease in the likelihood of using ADHD medications by children with ADHD.[26]

In addition, one study found that higher out-of-pocket health costs for the family as a whole (regardless of insurance status) had an adverse impact on access to care (including drugs) for children. Specifically, an increase in costs to the family was associated with a higher rate of unmet needs or delayed care due to out-of-pocket costs.[27] Insurance coverage for the family that reduces out-of-pocket costs thus helps reduce access barriers for children.

For conditions such as diabetes and asthma, decisions to skip a needed drug for any reason, including out-of-pocket costs, can have a dramatic effect on one's health. When the health consequences of these decisions lead to an emergency room visit or hospitalization, the state's cost will far exceed the savings from requiring copayments.[28]

Medicaid generally eliminates cost sharing as a barrier for children who need drugs. For most children on Medicaid, there is no cost sharing.[29] By law, children in families that are below 133 percent of the federal poverty level ($27,159 for a family of three in 2017) do not incur cost sharing for most of their drugs. In practice, only those at higher income levels, including those with CHIP coverage and those with insurance obtained in the private market, may face copays. But Medicaid and CHIP rules limit copays to nominal amounts in most situations.[30]

Managing Children's Prescription Drug Use

Use of prescription drugs for many children is a direct response to their health conditions. Monitoring of their care by their health care providers should ensure that they are using drugs appropriately. Two situations illustrate the interplay of utilization management with the medical needs of patients: behavioral health conditions and drugs with extraordinarily high costs.

As noted above, psychotropic drugs may be prescribed for children more frequently than necessary. Risks associated with the use of psychotropic drugs may include weight gain, metabolic disorders, and suicidal thinking; experts suggest that these drugs are best used as a component of a comprehensive treatment plan.[31] States often address these concerns by creating specific requirements when these drugs are prescribed. As of 2014, for example, 31 state Medicaid programs required prior authorization for children who are prescribed certain antipsychotic drugs.[32] Most state prior authorization requirements for antipsychotic drugs targeted children 7 years old or younger, but some applied the requirement more broadly.

Furthermore, the Centers for Medicare & Medicaid Services (CMS) requires states to report on programs that ensure appropriate use of psychotropic drugs by children; 41 states have specific programs.[33] CMS has also developed performance measures to assess the use of antipsychotic and ADHD drugs for children. Other state initiatives include prior authorization and peer review programs, requirements for informed consent from parents or legal guardians, feedback to clinicians on their prescribing practices, and broader educational efforts aimed at clinicians.[34]

Drugs with extraordinarily high price tags put budgetary pressure on Medicaid programs to limit use. The price of hepatitis C drugs, for instance, has focused attention on this challenge for states, many of which have set tight clinical guidelines, enforced by measures such as prior authorization, for which beneficiaries may receive the drugs. Although children are infected with hepatitis C much less often than adults, 0.4 percent of children age 12 to 19 are estimated to have this condition.[35] Similar pressures are confronting states for other costly drugs (such as the newly approved Spinraza for spinal muscular atrophy) prescribed for children now or in the future.

Factors Limiting Medicaid's Protection for Children from Drug Costs

Medicaid programs in many states place limits on their prescription drug benefits. Examples include an overall limit on the number of covered prescriptions per month, a limit on the number of brand drugs per month, and prior authorization restrictions that apply to certain drugs which are not on a preferred drug list (PDL) or which have safety considerations. Although children are mostly exempt from some measures such as monthly limits, others such as prior authorization often do apply.[36]

Although some states set limits on the numbers of prescriptions or those for brand drugs that can be filled each month, most states do not apply their limits to children. But in Mississippi, for example, the limit for children is lifted only if the doctor sends Medicaid a plan of care.[37]

States often impose prior authorization requirements where drug safety or health considerations are involved, as in the case of psychotropic drugs described above. But many states also use prior authorization in situations that are more driven by economics. A common example, described in more detail below, is the use of a PDL as a means to obtain discounts from manufacturers. In these situations, prior authorization is typically required for any drug that is not on the list.

Some states also apply step therapy requirements where a drug that is less expensive or one that is generally regarded as more effective must be tried before use of the alternative drug that may work better for the particular patient is authorized.

Prior authorization and step therapy may be effective in containing drug costs if they are well designed and based on clinical evidence.[38] Still, the need to obtain prior authorization creates an additional barrier when prescribers believe a drug that is not on the preferred list would work best for their patients. Federal law requires that a request for prior authorization have a response within 24 hours. It further requires that Medicaid beneficiaries can obtain a 72-hour emergency supply of a drug while awaiting prior authorization and the medication is needed without delay. The reality is that these emergency supplies are not always provided, often because pharmacists are unaware of the requirements.[39] The right to file appeals in these situations is designed as a protection for Medicaid beneficiaries. Some steps have been taken to ensure that beneficiaries know why a prescription was rejected and their rights around obtaining prior authorization. For example, a legal settlement in Florida in 2003 in Hernandez v. Meadows established requirements that included notices to beneficiaries about their rights.[40]

The Role of Medicaid Managed Care

Increasing numbers of Medicaid beneficiaries have been enrolled in managed-care organizations over the years. In 2013, two thirds of Medicaid children were in managed care.[41] In 2016, most states that rely on comprehensive managed care for their Medicaid programs (34 of 39 such states) had enrolled at least 75 percent of their Medicaid children in MCOs.[42] Overall, for adults and children, over half of drug spending (55 percent) was paid for by managed-care plans as of 2015, up from just 14 percent in 2011.[43]

Use of PDLs can become more complicated for coverage through Medicaid MCOs. Regulatory requirements issued by CMS in a final rule published in May 2016 and phased in over the next three years emphasize that Medicaid's statutory requirements flow through to MCOs. For example, a plan that maintains a formulary for drugs must ensure that off-formulary drugs are available under a prior authorization process, including a required timeline for prior authorization reviews and the availability of emergency supplies of a drug where appropriate.

In Florida's Medicaid managed-care pilot in 2007, HMO formularies included fewer commonly prescribed drugs on their PDLs than were on the official state list. This situation led in some cases to delayed access to needed drugs for patients.[44] As part of Florida's statewide expansion of Medicaid managed care, the state now requires all participating health plans to use a state-mandated formulary for the first year of a contract.[45] More recently, a survey of Florida's pediatricians found that prior authorization requirements imposed by Medicaid managed-care plans created both paperwork burdens and potential barriers to access for medications needed by children.[46]

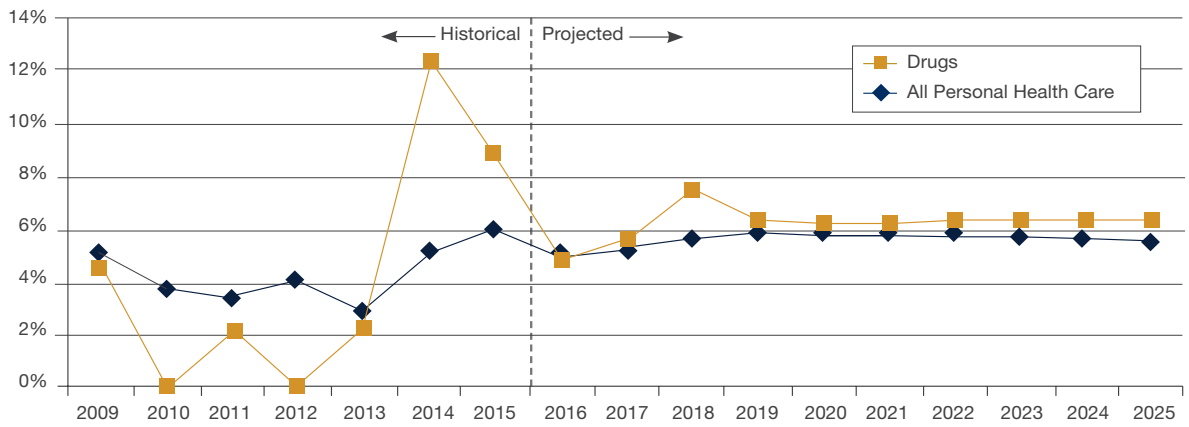
Some states impose additional requirements on the MCOs that use preferred drug lists. The state of Washington requires health plans to eliminate prior authorization requirements for patients who have existing prescriptions for drugs in certain drug classes, including atypical antipsychotics, antidepressants and medications for ADHD. Similarly, New York allows a prescriber's professional judgment to prevail, effectively bypassing the prior authorization process for certain drug classes.[47]

Reducing States' Medicaid Prescription Drug Costs

In 2015, overall personal health care expenditures in the United States increased at a rate of 6 percent, while prescription drug spending outpaced overall growth with an increase of 9 percent.[48] Historically, drug spending growth was low in some years as generic drugs replaced brand drugs in many drug classes, and high in other years when expensive new drugs came on the market (Figure 2). While the rate of drug spending growth in future years is projected to be lower than the 2015 rate, it is still projected to outpace overall health spending consistently over the next decade.[49] High-cost specialty drugs are expected to be a major driver of this higher growth rate. For instance, the high cost of the new drugs for hepatitis C contributed to a dramatic spike in spending a few years ago. A second driver of future cost growth is that fewer brand drugs are losing patent protection after 2017, triggering faster growth in drug prices in 2018.

In nearly all situations, Medicaid protects children and their families from bearing the cost of the drugs the children take. As a result, they are shielded both from the high costs associated with many drugs that are new to the market and from large price increase for older drugs, such as EpiPen.[50] But children can see an indirect effect. High and growing drug costs put pressure on state budgets, which can lead to cost-containment measures of the kind described above and create access problems.

Figure 2. Comparing Historical and Projected Spending Trends for Drugs and All Personal Health Care, 2009-2025



Source: CMS, National Health Expenditures Data, https://www.cms.gov/Research-Statistics-Data-and-Systems/statistics-Trends-and-Reports/NationalHealthExpendData/index.html.

The impact of high drug prices as a contributor to health care costs is broadly addressed by federal law. The federal government requires pharmaceutical manufacturers—as a condition of including their drugs under the Medicaid benefit—to pay a basic rebate to the Medicaid program.[51] Rebates, however, do not apply to separate CHIP programs. These rebates create a discount from the drugs' list prices. Base rebate amounts are 23.1 percent of the standard price for brand drugs and 13 percent for generic drugs.

In addition, the rebate is higher in two circumstances. First, for brand drugs, Medicaid is guaranteed the lowest or best price obtained by the manufacturer in most market transactions by increasing the amount of the rebate to match the best discounts obtained by other commercial payers. By contrast, the Medicare program is not guaranteed the best market prices for Part D enrollees (including Part D coverage for those dually eligible for Medicare and Medicaid).

Second, Medicaid is mostly protected from large price increases through an increased rebate when a drug price rises faster than inflation. The inflation rebate was originally applicable only to brand drugs, but was extended to generic drugs (starting in 2017) by the Bipartisan Budget Act of 2015. This rebate protects state and federal budgets from price increases, but offers no deterrent effect against excessive price increases that affect the market more generally.

Collectively, these provisions provide Medicaid with substantial discounts that are shared between the federal government and the states. In addition, most state Medicaid programs (but not necessarily separate CHIP programs) get even lower prices for selected drugs, beyond the requirements in federal law.[52] These discounts come in the form of supplemental rebates negotiated in conjunction with placement on preferred drug lists. For example, a manufacturer would offer a lower price if its drug is included on the state preferred drug list and other competing drugs are denied such placement. Typically, states enforce the PDLs by requiring prior authorization for drugs not on the list, since states may not deem that a particular drug is not covered by Medicaid.[53] A well-managed PDL uses the leverage of placing drugs on the list to negotiate price discounts for the state, while maintaining clinical oversight to ensure that the list is adequate to meet the needs of beneficiaries.

When first created in 1990, Medicaid rebates were available only for drugs paid for by states on a fee-for-service basis. This policy was changed in the Affordable Care Act so that manufacturers must now pay rebates on drugs purchased through managed-care organizations. Like the states, plans can negotiate additional rebates with manufacturers based on their use of PDLs.

These discounts help the Medicaid program manage costs. But neither the states nor the federal government are protected from high launch prices for new drugs. Drugs that enter the market at high prices impose budgetary pressures on Medicaid. As illustrated by hepatitis C drugs or the new drug for spinal muscular atrophy, these high prices have led many states to limit access to the drugs in order to manage their budgets.[54] But even for high-priced drugs, Medicaid is still guaranteed the best prices obtained elsewhere in the commercial market and is protected against future price increases. Furthermore, the federal government shares in the costs of these drugs with states on an open-ended basis.

Conclusion and Recommendations

The growing cost of prescription drugs is a challenge for the health care system writ large, not just for Medicaid and CHIP. In recent years, we have seen large price increases for brand-name drugs, such as EpiPen, that are well established in the market and even large increases for some generic drugs. New drugs continue to enter the market with high price tags. Even when they offer significant clinical advances, these high price tags make broad access difficult.

Medicaid protects families from most of these costs by guaranteeing that drugs are covered and that out-of-pocket costs are eliminated for most Medicaid children and minimized for the rest. CHIP provides most of these same protections. These protections and coverage standards must be preserved to ensure that children have access to the treatments they need. Families with private health insurance are more vulnerable to high and rising drug costs and need better protections to ensure access to needed drugs.

A large and growing share of Medicaid children are enrolled in managed care, meaning that private plans are charged with managing their drug benefits. There is some evidence that management of a drug benefit with tools such as prior authorization can create obstacles to access. These issues point to the importance of the recent Medicaid managed-care regulations, which reiterate the principle that protections in Medicaid law flows through to managed-care organizations. In a March 14, 2017, letter to governors, the Secretary of Health and Human Services and the Administrator of CMS noted their intent to "conduct a full review" of those regulations.[55] Access protections in law and regulations—such as prompt responses to prior authorization requests and emergency supplies of a drug—are designed to ensure that access to drugs for Medicaid beneficiaries is not impeded.

The rising costs of drugs, with growth rates above those for other health costs, are a continuing source of pressure on the federal and state budgets that pay for Medicaid and CHIP. High prices for specialty drugs create a particular challenge to programs that seek to manage costs while maintaining access. Although Medicaid drug price rebates are a key tool in managing costs, they do not address high launch prices for new drugs—a challenge that is not unique to Medicaid. Many of the potential means of addressing launch prices, such as modifications to the laws governing patents and patent term extensions, are beyond the scope of Medicaid.[56]

Recommendations

- **Maintain coverage of drugs,** including the EPSDT policies that guarantee coverage for children, and elimination of most cost sharing for children—both of which are critical components of Medicaid. At the same time, further steps may be needed to ensure that coverage restrictions are clinically justified and do not restrict access to needed drugs.
- **Maintain discounts now available to Medicaid** in the form of statutory rebates and extend these rebates to standalone CHIP programs as a critical tool to guaranteeing that these programs get the best available drug prices. Policymakers may also want to consider ways to strengthen the protections against price increases as a further deterrent to excessive price increases.
- **Develop solutions in the broader health system** to address high launch prices for new drugs, which are a continuing burden for Medicaid programs.
- **Preserve protections in the May 2016 Medicaid managed-care rule** that ensure access to needed drugs. Furthermore, more steps should be taken to promote compliance by managed-care plans with Medicaid rules:
  - Risk contracts should reflect regulatory requirements.
  - Plans should have an incentive to comply with EPSDT requirements.
  - States should engage with external quality review organizations to ensure appropriate drug access.

Endnotes

[1] A. Coukell, C. Shih, and E. Reese, "Beyond EpiPen: Prices of Lifesaving Epinephrine Products Soar" (Washington: The Pew Charitable Trusts, September 22, 2016).

[2] K. Young and R. Garfield, "Spending and Utilization of EpiPen within Medicaid" (Washington: The Kaiser Family Foundation, October 7, 2016).

[3] J. Alker and A. Chester, "Children's Health Coverage Rate Now at Historic High of 95 Percent" (Washington: Georgetown University Center for Children and Families, October 2016).

[4] National Center for Health Statistics, "Health, United States, 2015: With Special Feature on Racial and Ethnic Disparities" (Hyattsville, MD: National Center for Health Statistics, May 2016), available at https://www.cdc.gov/nchs/data/hus/hus15.pdf.

[5] A. Bagchi, J. Verdier, and D. Esposito, "Chartbook Medicaid Pharmacy Benefit Use and Reimbursement in 2009" (Washington: Mathematica Policy Research, December 21, 2012).

[6] Data Resource Center for Child & Adolescent Health, "National Health Interview Survey-Child and Family Core, NHIS-Child 2014" (accessed March 22, 2017). Available at www.childhealthdata.org.

[7] Q. Gu, C. Dillon, and V. Burt, "Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007-2008" (Hyattsville, MD: National Center for Health Statistics, September 2010).

[8] Centers for Disease Control and Prevention, "Asthma Facts—CDC's National Asthma Control Program Grantees" (Atlanta: Centers for Disease Control and Prevention, July 2013), available at https://www.cdc.gov/asthma/pdfs/asthma_facts_program_grantees.pdf.

[9] S. Frazee, "Asthma Hits Medicaid Hardest" (St. Louis: Express Scripts, March 21, 2013).

[10] L. Howie, P. Pastor, and S. Lukacs, "Use of Medication Prescribed for Emotional or Behavioral Difficulties Among Children Aged 6-17 Years in the United States, 2011-2012" (Hyattsville, MD: National Center for Health Statistics, April 2014).

[11] L. Akinbami et al., "Attention Deficit Hyperactivity Disorder Among Children Aged 5-17 Years in the United States, 1998-2009" (Hyattsville, MD: National Center for Health Statistics, August 2011).

[12] L. Howie, P. Pastor, and S. Lukacs, op. cit.

[13] "Understanding How ADHD Medication Affects School Performance," M. Cooney, Study.com, http://study.com/blog/understanding-how-adhd-medication-affects-school-performance.html; and R .Baweja, R. Mattison, and J. Waxmonsky, "Impact of Attention-Deficit Hyperactivity Disorder on School Performance: What are the Effects of Medication?" *Pediatric Drugs* 17, no. 6 (December 2015): 459-477.

[14] These data—the most recent available to break out use by Medicaid children—are limited to Medicaid beneficiaries whose drug benefits were managed by the pharmacy benefit manager Express Scripts. It also excluded specialty drugs. A separate analysis using 2009 Medicaid program data for fee-for-service Medicaid beneficiaries yielded similar results. This latter analysis was limited to the top ten drug classes for Medicaid beneficiaries of all ages. Among those drug classes, the top three for Medicaid spending on behalf of children were anti-asthma drugs, stimulants to treat ADHD, and anti-psychotic drugs. See S. Frazee et al., "2011 Drug Trend Report" (St. Louis: Express Scripts, April 17, 2012).

[15] Medicaid and CHIP Payment and Access Commission, "Report to Congress on Medicaid and CHIP" (Washington: Medicaid and CHIP Payment and Access Commission, June 2015), available at https://www.macpac.gov/publication/june-2015-report-to-congress-on-medicaid-and-chip/.

[16] "Rare Diseases Treated with Enzyme Replacement Therapy," R. Harrison, Rare Disease Report, http://www.raredr.com/news/rare-diseases-treated-with-enzyme-replacement-therapy; S. Tribble and S. Lupkin, "High Prices for Orphan Drugs Strain Families and Insurers," *National Public Radio*, January 17, 2017; and A. Smith, "Cashing in on 'Orphans': Pharmaceutical Companies Like Genzyme Reap Huge Profits Off Treatments for Obscure Diseases," *CNN Money*, March 16, 2007.

[17] Food and Drug Administration, *FDA Approves First Drug for Spinal Muscular Atrophy: New Therapy Addresses Unmet Medical Need for Rare Disease*, Press Release (December 23, 2016).

[18] R. Weisman, "Hope for Devastating Child Disease Comes at a Cost $750,000 a Year," *The Boston Globe*, March 28, 2017.

[19] T. Brooks and K. Whitener, "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT" (Washington: Georgetown University Center for Children and Families, June 2017).

[20] K. Whitener, "EPSDT: A Primer on Medicaid's Pediatric Benefit" (Washington: Georgetown University Center for Children and Families, March 4, 2016).

[21] Although drugs are by law an optional Medicaid benefit, all states have incorporated drug coverage into their benefit packages.

[22] In 2007 (the last available survey), all states covered at least some OTC drugs. A check on coverage in various states confirms that coverage of OTC drugs remains common and may still be true in all states. National Pharmaceutical Council, Inc., "Pharmaceutical Benefits Under State Medical Assistance Programs," (Reston, VA: National Pharmaceutical Council, Inc., January 1, 2007).

[23] A. Leibowitz et al., "Effect of Cost-Sharing on the Use of Medical Services by Children: Interim Results from a Randomized Controlled Trial," *Pediatrics* 75, no. 5 (May 1985): 942-951; and RAND Health, "The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate," (Santa Monica: RAND Health, 2006), available at http://www.rand.org/content/dam/rand/pubs/research_briefs/2006/RAND_RB9174.pdf.

[24] National Health Law Program, "Researchers Repeatedly Find Cost Sharing Harms Medicaid Beneficiaries' Access to Care and Health Status" (Los Angeles: National Health Law Program, August 5, 2011), available at http://www.healthlaw.org/publications/browse-all-publications/researchers-repeatedly-find-cost-sharing-harms-medicaid-beneficiaries-access-to-care-and-health-status#.WP5OhfnyuUk; B. Stuart and C. Zacker, "Who Bears the Burden of Medicaid Drug Copayment Policies?" *Health Affairs* 18, no. 2 (March/April 1999): 201-212; A. Nelson, C.E. Reeder, and W.M. Dickson, "The Effect of Medicaid Drug Copayment Program on the Utilization and Costs of Prescription Services," *Medical Care* 22, no. 8 (August 1984): 724-736; and C.E. Reeder and A. Nelson, "The Differential Impact of Copayment on Drug Use in a Medicaid Population," *Inquiry* 22, no. 4 (Winter 1985): 396-403.

[25] P. Karaca-Mandic et al., "Out-of-Pocket Medication Costs and Use of Medications and Health Care Services Among Children with Asthma," *Journal of the American Medical Association 307*, no. 12 (March 28, 2012): 1284-1291; and W. Ungar et al., "Effect of Cost-Sharing on Use of Asthma Medication in Children," *Journal of the American Medical Association Pediatrics*, 162, no. 2 (February 2008): 104-110.

[26] H. Huskamp et al., "Impact of 3-Tier Formularies on Drug Treatment of Attention-Deficit/Hyperactivity Disorder in Children," *Journal of the American Medical Association Psychiatry* 62, no. 4 (April 2005): 435-441.

[27] P. Karaca-Mandic et al., "Family Out-of-Pocket Health Care Burden and Children's Unmet Needs or Delayed Health Care," *Academic Pediatrics* 14, no. 1 (January-February 2014): 101-108.

[28] C. Roebuck et al., "Increased Use of Prescription Drugs Reduces Medical Costs in Medicaid Populations," *Health Affairs* 24, no. 9 (September 2015): 1586-1593.

[29] T. Brooks et al., "Medicaid and CHIP Eligibility, Enrollment, Renewal, and Cost Sharing Policies as of January 2017: Findings from a 50-State Survey" (Washington: Kaiser Family Foundation, January 2017).

[30] For children, Medicaid gives states the ability to use out-of-pocket charges to promote the most cost-effective use of prescription drugs (CHIP allows cost sharing on all drugs). Generally, states have more latitude in their use of cost sharing for those with incomes above 150 percent of the federal poverty level. To encourage the use of lower-cost drugs in Medicaid programs, states may establish different copayments for generic versus brand-name drugs or for drugs included on a preferred drug list. States must specify which drugs are considered either "preferred" or "non-preferred." Cost sharing for non-preferred drugs may be as high as 20 percent of the agency's cost for a drug.

[31] Medicaid and CHIP Payment and Access Commission, "Report to Congress on Medicaid and CHIP," op. cit.

[32] I. Schmid, M. Burcu, and J. Zito, "Medicaid Prior Authorization Policies for Pediatric Use of Antipsychotic Medications," Journal of the American Medical Association 313, no. 9 (March 3, 2015): 966-968.

[33] Center for Medicaid and CHIP Services, "Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2015 Annual Report: Prescription Drug Fee-For-Service Programs" (Washington: Center for Medicaid and CHIP Services, December 2016), available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2015-dur-summary-report.pdf.

[34] Medicaid and CHIP Payment and Access Commission, "Report to Congress on Medicaid and CHIP," op. cit.

[35] M. Jonas, "Hepatitis C Virus Infection in Children" (UpToDate, June 2017), available at http://www.uptodate.com/contents/hepatitis-c-virus-infection-in-children.

[36] No recent source provides a complete compilation of state-specific prescribing limits. Two sources were consulted for this report, supplemented by review of various state Medicaid websites. National Pharmaceutical Council, Inc., "Pharmaceutical Benefits Under State Medical Assistance Programs 2007," op. cit; and Council of State Governments (CSG) Midwest, "Details of State Limits on Prescriptions for Medicaid Recipients," available at http://www.csgmidwest.org/policyresearch/documents/scriptlimits.pdf.

[37] "What Mississippi Medicaid Can Do For You!" (Jackson, MS: Mississippi Division of Medicaid, November 1, 2012), available at https://medicaid.ms.gov/wp-content/uploads/2014/03/MS-Medicaid-Overview.pdf.

[38] M. Fischer and J. Avorn, "Step Therapy—Clinical Algorithms, Legislation, and Optimal Prescribing," J*ournal of the American Medical Association* 317, no. 8 (February 28, 2017): 801-802; A. Fischer, N. Choudhry, and W. Winkelmayer, "Impact of Medicaid Prior Authorization on Angiotensin-Receptor Blockers: Can Policy Promote Rational Prescribing?," *Health Affairs* 26, no. 3 (May 2007): 800-807; and M. Fischer et al., "Medicaid Prior-Authorization Programs and the Use of Cyclooxygenase-2 Inhibitors," *New England Journal of Medicine* 351, no. 21 (November 18, 2004): 2187-2194.

[39] M. Shepherd, "Examination of Why Some Community Pharmacists Do Not Provide 72-Hour Emergency Prescription Drugs to Medicaid Patients when Prior Authorization Is Not Available," *Journal of Managed Care & Specialty Pharmacy* 19, no. 7 (September 2013): 523-533.

[40] National Health Law Program, "Hernandez v. Meadows Settlement Agreement Materials" (Washington: National Health Law Program, January 01, 2004), available at http://www.healthlaw.org/issues/medicaid/medicaid-expansion-toolbox/hernandez-vs-meadows-settlement-agreement-materials#.WV01TlKZOi5.

[41] Medicaid and CHIP Payment and Access Commission, "MACStats: Medicaid and CHIP Data Book" (December 2016).

[42] V. Smith et al., "Implementing Coverage and Payment Initiatives: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2016 and 2017" (Washington: Kaiser Family Foundation, October 13, 2016).

[43] Medicaid and CHIP Payment and Access Commission. "MACStats: Medicaid and CHIP Data Book," op. cit.; and Medicaid and CHIP Payment and Access Commission, "Medicaid Spending for Prescription Drugs," (Washington: Medicaid and CHIP Payment and Access Commission, January 2016), available at https://www.macpac.gov/publication/medicaid-spending-for-prescription-drugs/.

[44] J. Hoadley and J. Alker, "Uncertain Access to Needed Drugs: Florida's Medicaid reform creates challenges for patients," (Washington: Georgetown University Health Policy Institute, July 2007).

[45] The Express Scripts Lab, "2014 Drug Trend Report," (St. Louis: Express Scripts, March 2015), available at http://lab.express-scripts.com/lab/drug-trend-report/previous-reports.

[46] J. Alker and J. Messner, "How is Florida's Medicaid Managed Care Working for Children?" (Washington: Georgetown University Center for Children and Families, June 2016).

[47] The Express Scripts Lab, "2014 Drug Trend Report," op. cit.

[48] A. Martin et al., "National Health Spending: Faster Growth in 2015 As Coverage Expands And Utilization Increases," *Health Affairs* 36, no. 1 (January 2017): 166-176.

[49] S. Keehan et al., "National Health Expenditure Projections, 2016-25: Price Increases, Aging Push Sector To 20 Percent of Economy," *Health Affairs* 36, no. 3 (March 2017): 553-563.

[50] Although children were protected from EpiPen's price increases, Medicaid paid more (received a lower rebate) because EpiPen was misclassified as a generic drug. There is a proposed $465 settlement between the manufacturer (Mylan) and the government to rectify this, but it remains a subject of dispute. L. Rapaport, "Mylan Underpayment on EpiPen Could Exceed Proposed Settlement—Study," *Reuters*, March 27, 2017.

[51] Medicaid and CHIP Payment and Access Commission, "Medicaid Payment for Outpatient Prescription Drugs," (Washington: Medicaid and CHIP Payment and Access Commission, March 2017), available at https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf.

[52] Centers for Medicare & Medicaid Services, "Medicaid Pharmacy Supplemental Rebate Agreements (SRA)," (Washington: Centers for Medicare and Medicaid Services, March 2017), available at https://www.medicaid.gov/medicaid-chip- program-information/by- topics/prescription-drugs/downloads/xxxsupplemental-rebates- chart-current- qtr.pdf.

[53] D. Bergman et al., "Using Clinical Evidence to Manage Pharmacy Benefits: Experiences of Six States," (New York: The Commonwealth Fund, March 2006); and D. Bergman "State Design and Use of Prior Authorization Processes," (Portland, ME: National Academy for State Health Policy, March 2006).

[54] Centers for Medicare & Medicaid Services, "Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs," *Medicaid Drug Rebate Program Notice* #172 (November 5, 2015), available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf.

[56] U.S. Department of Health and Human Services, *Secretary Price and CMS Administrator Verma Take First Joint Action: Affirm Partnership of HHS, CMS, and States to Improve Medicaid Program*, Press Release (March 14, 2017).

[55] L. Nichols, "What Price Should We Pay for Specialty Drugs?" (Fairfax, VA: Center for Health Policy Research & Ethics, George Mason University, May 15, 2015); Hutchins Center, "Ten Challenges in the Prescription Drug Market—And Ten Solutions" (Washington: Brookings Institution, May 2, 2017); H. Waxman et al., "Getting to the Root of High Prescription Drug Prices: Drivers and Potential Solutions" (New York: The Commonwealth Fund, July 2017).

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