



States and Prescription Drugs: An Overview of State Programs to Rein in Costs

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States are significant purchasers of health care for Medicaid, inmates in correctional facilities, and public employees. Despite considerable efforts to maintain affordability, drug pricing continues to vex state budgets. While Medicaid is the largest single health expenditure in state budgets, spending on health care for public workers including state employees and retirees, legislators, judicial employees, and public university employees, among others is substantial. In 2013, the cost of coverage was almost \$31 billion (including employee contributions) to insure 2.7 million public employee families.¹ Spending on prescription drugs represents 19 percent of costs under employer health plans – closing in on the amount such plans spend on inpatient services.² Assuming public employee plans reflect trends observed in the private sector, the spotlight on drug spending grows brighter as states wrestle with rising benefit costs for employees. Medicaid has seen an overall increase in prescription drug spending of 3 percent, although in expansion states, where the federal government is footing 100 percent of the costs until 2017, that rise is 25 percent.³

While spending on prescription drugs represents a relatively small proportion of all spending on health care in this country, it is growing rapidly. After many years of relatively slow year over year increases, spending on prescription drugs spiked dramatically in 2014, up more than 13 percent in one year⁴, hitting the highest level of growth since 2001.⁵ This increase is primarily attributable to growth in spending on new, high cost specialty medicines for hepatitis C, cancer and multiple sclerosis, higher spending on diabetes medicines, fewer patent expirations and price increases for brand name drugs.⁶

The rapid increases in drug costs, along with the increase in attention to the issue through recent news events involving some of the pharmaceutical manufacturers have contributed to a public sense of urgency and even crisis. In an October 2015 Kaiser Health Tracking Poll,⁷ the top two health care priorities cited by respondents related to prescription drugs. Seventy-seven percent of respondents said that access to high cost pharmaceuticals for chronic conditions like hepatitis, HIV, mental illness and cancer should be the top priority for the President and Congress. Sixty-three percent of respondents cited government intervention to lower drug prices.

The public is also aware of the high cost of specialty drugs, including those used to treat the hepatitis C virus (HCV). What the public may not realize, however, is that Merck has recently introduced a drug in this class that is priced markedly below that of those produced by Gilead or AbbVie. Competition in this market space is growing and bringing down the cost of treatment in this instance.

The very real issue of access to prescription drugs exacerbates the public's concern about prescription drug prices. While more Americans have health insurance coverage today, out of pocket payment obligations are also on the rise, resulting in the potential for impaired access to prescription drugs, making the sense of crisis that more acute on a personal level.

At the same time, the introduction of new, innovative drugs offers the opportunity to improve health outcomes, improve health and even cure certain medical conditions that are threatening public health in this country. The new drugs for HCV are indeed very costly, but they have a high cure rate, allowing avoidance of other costs down the road.

Although there is considerable public outcry over shocking stories about individual circumstances related to prescription drug prices, perhaps the most concerning issue is the underlying steady increase in costs.

Over the years, states have employed many tools to rein in the costs of prescription drugs, while still making them accessible to their residents. Some have worked better than others. NASHP is launching the Rx Cost Workgroup, a new and diverse collaborative of state officials who will be taking a hard look at the collective work around drug costs and contemplating new approaches. As new prescription drugs are developed they bring with them both the promise of better health and blockbuster prices. States need to work together to identify new approaches to balance that access/cost conundrum.

Attempts to control the rising cost of prescription drugs

Rebates

Rebate programs are an enduring tool used by both states and the federal government to mitigate the impact of drug costs on Medicaid programs. The Omnibus and Budget Reconciliation Act of 1990⁸ established the Medicaid Drug Rebate Program, which is intended to ensure that Medicaid always receives the best price for any drug purchased with program dollars. In exchange for entering into drug rebate agreements with the Secretary of Health and Human Services (HHS), drug manufacturers are assured that state Medicaid programs will cover their products in their fee for service programs. Although only 20 percent of Medicaid beneficiaries are cared for in a fee for service setting, this remains a substantial portion of spending for the program. States remain free, however, to place reasonable restrictions on access to drugs through various means, including the use of prior authorization requirements and preferred drug lists.

The Medicaid Drug Rebate Program statute lays out the formula used to determine the level of rebate for each drug, based on the average manufacturer's price (AMP) for that drug. The AMP is the average price wholesalers pay to manufacturers for drugs that are then sold to retail pharmacies. States pay drug claims as they are received, based on price before rebate. Medicaid programs subsequently receive manufacturer rebates on a quarterly basis, based on the volume of each drug purchased. The value of this rebate is shared proportionally with the federal government, based on the federal matching rate in effect for each individual state.

The Affordable Care Act (ACA) amended the Medicaid Drug Rebate program by increasing the level of the rebates. The value of the incremental increase, however, accrues solely to the benefit of the federal government. The ACA also allows the extension of the Rebate Program to Medicaid Managed Care Organization Programs where prescription drugs are carved in. Previously, the rebates applied only to fee for service claims. The Centers for Medicare and Medicaid Services (CMS) has recently issued a new Medicaid Outpatient Drug Rule, which went into effect on April 1, 2016, implementing the ACA provision. States have until June 30, 2017 to submit State Plan Amendments to reflect the allowed ACA changes in their individual Medicaid programs, should they chose to do so.

According to the Medicaid and CHIP Payment and Access Commission, the Medicaid Drug Rebate Program reduces gross spending on prescription drugs by almost half.^{9, 10} The ACA provisions increase the rebate levels to 23.1 percent for brand name drugs (from 15.1 percent) and 13 percent for generics. Again, the incremental savings derived from these increases accrues only to the benefit of the federal government.

States may choose to layer individually negotiated supplemental rebates over the federal Medicaid drug rebates. States leverage their ability to subject certain drugs within classes to prior authorization and Preferred Drug List (PDL) status to drive deeper discounts from manufacturers looking for a competitive edge. As of December 2015, 47 states and the District of Columbia operate single and/or multi-state supplemental rebate arrangements.¹¹ Only Hawaii, New Jersey, New Mexico and South Dakota do not have supplemental rebates in place; Arizona and Massachusetts began collecting supplemental rebates for the first time in 2015.¹²

State Medicaid Directors have criticized the Rebate Program as tying their hands. In a letter to the US Senate Finance Committee, which is investigating issues related to prescription drug pricing and spending, the National Association of Medicaid Directors noted that the Rebate Program effectively establishes a floor for the price of prescription drugs used by Medicaid, but fails to establish a corresponding ceiling. The requirement that Medicaid formularies include drugs from manufacturers who have entered into Rebate Program agreements is seen as eroding the negotiating position of states as they seek supplemental discounts.

At the same time, states may want to be cognizant of the criticism some opponents of higher mandatory rebates have expressed, which is that forcing manufacturers to deliver high rebates to Medicaid programs may lead to higher costs for the same drugs for other public purchasers and for the private sector.¹³ Although cost savings to the Medicaid program may be first and foremost on the Medicaid agenda, states may want to consider balancing savings in public dollars against potential upward spending pressure for non-Medicaid populations, including state and municipal employees and retirees.

Utilization management

Managing the use of prescription drugs is a common tool used by Medicaid programs (and others) to curb the use of certain drugs and to bend the Rx cost curve. There are many types of formulary restrictions: preferred drug lists; prior authorization; step therapy; limits on quantities dispensed; and cost sharing, to name a few. These strategies may be used broadly to encourage the use of generic drugs over brand name drugs. This strategy can also be used to narrowly focus on particular therapeutic classes of drugs, for instance drugs used to treat certain types of mental illnesses or long acting narcotics like methadone.

Cost sharing, for example, is an approach used by many states to promote preference for cost-effective drugs, particularly generics. According to the Kaiser Family Foundation, in 2012, 42 states and the District of Columbia included prescription drug copays in the State Plan provisions.¹⁴ Federal regulations allow the use of drug copays for certain groups of Medicaid enrollees. People with incomes over 150 percent of the federal poverty limit may be charged copays as high as 20 percent for non-preferred drugs (copay for generic drugs is limited to \$4); people living below that income level may only be assessed nominal copays (\$4 per generic prescription or \$8 per brand name prescription). States also can establish differing copay levels for drugs obtained via mail order and those obtained at a retail pharmacy.

Both public and private payers as well as Pharmacy Benefit Managers have sharpened their focus

on value based purchasing, employing strategies that are intended to favor value over volume. Value based purchasing extends to prescription drugs. Payers sometimes discount or eliminate cost sharing requirements for drugs determined to be cost effective. Similarly, some benefit packages are designed to encourage patients to comply with treatment regimens by reducing or eliminating copays for prescription drugs used to manage chronic illnesses.

There is a large body of research that indicates imposing cost sharing on vulnerable populations does, in fact, lead to marked declines in the use of prescription drugs subject to the copay and lower costs to the Medicaid program.¹⁵ At the same time, copayments can lead to patients opting to forego or cut back on prescribed dosages in an effort to save money.^{16, 17} This practice can lead to degradation in health status and, in turn, the potential for increased use of other costly health care services.¹⁸

Preferred Drug Lists (PDLs) - also known as formularies – specify which drugs are available without prior authorization, thereby constraining access to “non-preferred” drugs. Drugs may be deemed preferred by virtue of their therapeutic value as determined by a Medicaid program’s clinical management and protocols, lower per unit costs, and/or is often reflective of the level of supplemental rebate. Most every state utilized a PDL for at least some therapeutic classes of drugs. For example, in early 2012, at least 48 states and the District of Columbia had published PDLs for therapeutic classes of drugs used in the treatment of mental health and substance use disorders.¹⁹

Prior authorization – another tool to control access to certain drugs – is used in conjunction with PDLs, allowing exceptions to the restrictions posed by the list, if certain conditions are met. These conditions can vary, but may include meeting a test of medical necessity or failing step therapy.

The use of a formulary can be very effective at controlling program costs through restricted use by encouraging the use of drugs that are lower in terms of per dose costs (e.g. some generics) and by discouraging the use of very high priced drugs. At the same time, formularies may lead to shifts in therapies for specific patients, which can also have implications – sometimes for the better, but sometimes for the worse.²⁰

Many states have enacted statutory language that requires pharmacists to substitute generic or lower-priced therapeutic equivalent drugs, when available, if the prescriber has not specified on the script “DAW” or “dispense as written.” This rule is intended to ensure that whenever available and appropriate, a lower priced drug is dispensed.

In recent years, a number of states have enacted legislation permitting pharmacists to substitute FDA-approved biosimilar, interchangeable drugs for what are ordinarily much more costly biologics, so long as the prescriber has not indicated that such substitutions are not to be made, and so long as the prescriber and the patient are given notice of the substitution. At least 14 states have enacted this type of legislation^{21, 22} and enabling language is close to passage in at least four others. Many other states have proposed legislation pending.

The State of Washington has taken a slightly different tact on this issue. The Washington Health Authority is the agency responsible for purchasing care for that state’s Medicaid population, as well as for public employees/retirees. As part of its charge, the Authority operates the Prescription Drug Program, which establishes a discount Rx program that is available to any Washington resident. As part of this program, the Authority convenes the Pharmacy and Therapeutics Committee and Medicaid Drug Utilization Review (DUR) Board. This single group is responsible for assessing the safety, effectiveness and

efficacy of drugs within classes of prescription medicines, and recommending which drugs should be included on the state's Preferred Drug List; the same group serves as the state's DUR group, a statutorily required function under Medicaid law.²³

In 2001, the Oregon Health Resource Commission established the state Medicaid program's PDL. Assisted by the Evidence-based Practice Center of Oregon Health Sciences, Oregon State University, they opted for a scientific approach to consideration of the safety, efficacy and effectiveness of drugs in select therapeutic classes, identifying those most clinically effective and recommending those drugs for the state PDL and allowed therapeutic interchange at the pharmacy level.²⁴ While other states operate similar clinical groups reviewing pharmaceutical and therapeutic products, Oregon's program is distinguished by the involvement of experts in the field of evidence-based policy making, introducing a heightened level of independent scrutiny to the process, and that process is transparent to the public.

Value based purchasing may also be used in conjunction with PDLs. CMS recently announced plans to test a variety of approaches to improving care and value for drugs covered by Medicare Part B. The model CMS seeks to test incorporates financial incentives for prescribers to opt for drugs deemed to be of higher value.²⁵

Dispensing limits are a common form of direct utilization limits. This strategy can take a variety of shapes including, at one extreme, exclusion of a particular drug or class of drugs from coverage. Excluding coverage of lifestyle drugs and weight-loss drugs is an example of this policy in action. By law, Medicaid programs choosing to provide the optional prescription drug benefit (which all states do) may exclude coverage of drugs for: anorexia; weight loss/gain; drugs prescribed for cosmetic purposes such as hair growth; vitamins/minerals; drugs prescribed for treatment of infertility; over the counter drugs; barbiturates; benzodiazepines; and drugs for symptom relief related to cough and cold. As a practical matter, many states opt to cover some of the allowable exclusions, although this is sometimes done by subjecting those drugs to a higher-level copayment.²⁶ Private payers – including non-Medicaid public coverage programs for state employees – have much more latitude to exclude classes of drugs.

Another approach is limiting the number of days' dosage allowed to be dispensed at any one time. Most Medicaid programs include this type of limitation,²⁷ limiting dispensed drugs to 30, 60 or 90-day supplies; this approach is also utilized by many private insurance plans. Similarly, programs and plans often limit the number of times a prescription may be refilled without a new script being written by the attending physician or place limitations on the number of scripts that may be filled per month. There is some research suggesting that this type of dispensing limitation (e.g. one refill per month) contributes to a decline in spending without associated increases in use of other health care services.²⁸

Benefit Management – Drug Utilization Review is universally employed in Medicaid programs. In fact, prospective utilization review is required by federal law of every Medicaid program.²⁹ Prospective review includes pre-dispensing screening for therapeutic duplication; contraindications and potential interactions; inappropriate or incorrect dosage and duration of treatment; drug allergies; and clinical misuse or abuse. DUR is also a common feature of private health care coverage plans.

Studies of the effectiveness of this strategy find they contribute to modest reductions in prescription drug spending, but may help avoid complications that could arise from drug-drug interactions or drug-disease interactions. The most impact was seen in the use of DUR with elders, who are more often on multiple prescription drugs, some inappropriate for their condition or circumstances.³⁰

Medication adherence programs are tools that may be used to maximize the effectiveness of drugs prescribed to patients. If drugs are not taken as prescribed, the chances they will be helpful are vastly reduced and can lead to what can otherwise be avoidable hospitalizations, increased use of downstream medical services and even early death.³¹ This is especially true for low-income populations, whose health status tends to be generally poorer and who tend to have a greater prevalence of chronic disease.³² And it is important for state employees who are generally older than the general population. A 2010 study found that state employees also had higher rates of prevalence across a broad range of chronic conditions than their counterparts in the private sector.³³ Obviously, poor adherence impacts not only outcomes but the cost of coverage, as well.

Many factors can influence a patient's compliance with a prescribed drug regimen and it can be especially challenging for a lower income patient to follow "doctor's orders" for taking their prescription drugs. Some of these challenges arise from educational, cultural, language and transportation barriers that can make accessing care and following therapeutic directions difficult. Persistence rates for eligibility can also impact a Medicaid patient's consistent ability to access care and obtain prescription drugs. Similarly, strategies employed to manage the prescription drug benefit can also impact compliance. Cost sharing requirements, for example, can discourage use as prescribed, even when copays are not mandatory.

In an attempt to boost compliance, many health care plans – including Medicaid Managed Care Organizations – have implemented medication adherence programs. These programs come in many flavors, but all focus on helping the patient. A 2012 study³⁴ found the most effective interventions – in terms of improving short-term adherence – involve those focused on patients with asthma, case management for patients taking medications to address depression, and pharmacist-led efforts to improve blood pressure in patients with hypertension. Evidence of efficacy is less clear for other types of interventions and it remains unclear whether any intervention results in better health outcomes and, therefore, yields a positive return on investment.

Promoting greater transparency is a strategy that is receiving greater attention. There is growing sentiment that the public's inability to access information regarding how pharmaceutical companies price their products effectively precludes the development of any viable, sustainable policy solution to rising prices. A recent letter from the National Association of Medicaid Directors submitted to the US Senate Finance Committee explicitly cites transparency into how therapies are priced and the potential value of those therapies to Medicaid beneficiaries as necessary to efforts to develop new and effective reimbursement strategies for prescription drugs.³⁵

Over the last two years, several states have seen legislative proposals calling for transparency with regard to manufacturers' cost of development and production of high cost drugs, but these bills have not been universally well received. They are languishing in committee in North Carolina, Oregon and Pennsylvania, having been introduced in 2015, without additional action since last session. Recently, Virginia legislators voted to carry over a transparency bill introduced this year.

There are currently two active transparency bills pending before state legislators. Massachusetts Senate Bill would require manufacturers of certain critical prescription drugs specified by the Massachusetts Health Policy Commission to provide to the Commission information regarding the total cost of production and cost per dose of each drug on the list, the research and development costs of the drug (including those costs paid for with public funds), the cost of marketing/advertising the drug, the prices charged for the drug outside of the US and prices typically charged to Massachusetts purchases.

California Senate Bill 1010 would require insurers and managed care organizations doing business in the state to annually report on rate-specific information related to prescription drugs. Reporting would focus on the drugs most frequently prescribed to people insured by each plan, as well as the drugs representing the highest rate of spending by each plan. It would also require manufacturers to provide advance notice of the introduction of any new drug with a wholesale acquisition cost in excess of \$10,000 (either per course of treatment or annual cost) and advance notice of planned price increases of 10 percent or more.

In his latest budget, Governor Cuomo of New York proposes capping the price on certain critical prescription drugs and requiring manufacturers of such drugs to provide a view into the costs underlying those prices. Much like the pending Massachusetts legislation, the Governor is proposing that pharmaceutical companies be compelled to divulge the cost of R&D, manufacturing and distribution of the drug, including marketing and advertising, along with prices charged to purchasers in NY, the average rebates granted by type of purchaser and the profit margin realized or projected for each drug.

On a related note, the Attorney General of Massachusetts recently told Gilead Sciences, a leading pharmaceutical company which manufactures two widely used and very highly priced HCV drugs – Solvaldi and Harvoni – that she will consider bringing a legal action against the company unless it acts to lower the price of these drugs. Attorney General Healey has indicated that her office is investigating whether the pricing practices engaged in by Gilead constitute unfair trade practices under Massachusetts law.³⁶ Similar actions in other states against a manufacturer alleging price gouging have failed.

Use of Pharmacy Benefit Management (PBM) is another tool available to states as public purchasers, either for employee health plans or in some cases, Medicaid programs; PBMs are also used by Medicaid Managed Care Organizations. PBMs ordinarily offer a suite of services ranging from claims adjudication, to administration of prior authorization protocols, support of Medicaid DUR processes, development/maintenance of the pharmacy network and formulary construction. PBMs are also relied upon to negotiate prices with manufacturers for deeper discounts and with pharmacies for discounts on dispensing fees.

Although there are many PBMs, this market has undergone considerable consolidation in recent years. In 2014, four companies commanded almost 80 percent of the market³⁷, with the third largest company acquiring the fourth largest company in mid-2015. Although these players have differentiated strategies to support clients, their large size (the largest, Express Scripts, covers 85 million people) and market domination crowd out competition.

While PBMs aim to streamline program administration for plan sponsors and ensure that covered patients receive prescribed drug therapies in a safe, effective and efficient manner, they also make money. Because they represent so much aggregated purchasing power, they have respectable negotiating power. For instance, in 2015, Express Scripts negotiated a substantial discount with AbbVie for Viekira Pak, a treatment for hepatitis C, and excluding from its formulary Gilead's treatments³⁸- in favor of a deep discount from AbbVie. Express Scripts projected this deal would generate more than \$1 billion in savings for its clients in 2015 alone, and claimed that the ripple effect of this deal would generate more than \$4 billion in savings to the US health care system in the same year.³⁹

The ability to drive hard bargains with manufacturers and with retailers holds the promise of savings for plan sponsors. But PBMs have been criticized for failing to be transparent about just how much of the savings is being passed on to clients.⁴⁰ Similarly, the process these companies employ to develop their

formularies and make prior authorization decisions are proprietary; black boxes can be problematic for programs that have to be publicly accountable, even when they are used in the context of contracting health insurance plans like MCOs. Also, the exclusion of drugs from coverage may pose issues of patient access under Medicaid rules and law.

States do regulate PBMs – in 2013, more than 20 states had such regulations on the books.⁴¹ Many of these regulations address requirements for licensing or registration of the entities. Although some states have attempted to regulate a fiduciary duty by a PBM to a plan sponsor (to increase transparency and to decrease what some have characterized as profiteering), those attempts have thus far been successfully turned back by the PBM industry. On March 21, 2015, Anthem filed suit against Express Scripts – the two companies entered into a ten-year contract for PBM services. Anthem, Express Scripts' largest client with more than 38 million members, is alleging Express Scripts engaged in uncompetitive pricing practices, failing to re-price the drug discounts it provides to Anthem and thus providing discounts that are out of line with others in the marketplace.⁴²

Bulk purchasing of drugs is another strategy employed by states to lower the cost of prescription drugs. Some states take a “go it alone” approach to purchasing; others have joined together with other states to form even larger purchasing pools. While the large PBMs certainly command attention at the bargaining table, states have banded together to form large ventures of their own.

In 2004, CMS approved the first Medicaid state plan amendment allowing the formation of a multistate prescription drug purchasing pool,⁴³ intended to allow participating states to use volume as leverage at the negotiating table to secure more favorable supplemental rebates. Interestingly, CMS guidance issued at the time encouraged states considering similar strategies to stimulate competition in this arena by forming new, additional purchasing pools and, if using a vendor to assist with pool operations, to seriously consider an administrator not already working for an existing pool.⁴⁴ Also, the guidance makes clear that a state wishing to include a non-Medicaid program in the supplemental rebate program must receive CMS approval to do so.

In 1999, Massachusetts enacted authorizing language enabling the formation of a statewide prescription drug bulk-purchasing program. This initiative was developed in response to the rising cost of drugs and was intended to assist Massachusetts seniors, state employees, and the uninsured in accessing needed prescriptions.⁴⁵ Shortly thereafter, Maine enacted first-in-the-nation pharmacy cost control legislation, mandating that manufacturers provide Medicaid-level rebates to all Maine consumers.⁴⁶ By the end of 2015, there were five multistate bulk purchasing pools in operation, as well as several single state, multiagency purchasing pools.⁴⁷ Multistate initiatives include the National Medicaid Pooling Initiative; TOP\$; Sovereign States Drug; Northwest Prescription Drug Consortium; and the Minnesota Multistate Contracting Alliance for Pharmacy.

States have routinely projected savings associated with participation in multistate or interagency purchasing programs. Information regarding actual savings is harder to come by, but several states do report related savings. For example, the National Council of State Legislatures' annual update on pharmaceutical bulk purchasing initiatives notes that Delaware reported close to \$2 million in rebates associated with its participation in the now-defunct Rx Issuing States program.⁴⁸ Similarly, Iowa reported that through the use of a PDL and enhanced supplemental rebates gained through participation in the Sovereign States Drug Consortium, it has saved nearly \$250 million since 2005.⁴⁹

The high cost of specialty drugs is exerting a toll on all payers, public and private. These drugs hold

incredible promise. PCSK9 inhibitors, for example, are a new class of drugs that have the potential of greatly reducing the risk of stroke and heart attack in patients with high cholesterol. These therapies may be especially helpful to patients with familial hypercholesterolemia, who are at high risk for premature death from cardiovascular disease, and for whom statins may not be effective. Whereas the cost of statins is very low, the cost of PCSK9 inhibitors exceeds \$14,000 per patient per year. The difference in cost begs the question of how much should payers and patients be willing to pay for the potential benefit presented by these drugs.⁵⁰

Of particular interest lately are those drugs used to treat the hepatitis C virus (HCV). There are only a handful of drugs on today's market for treatment of HCV, but these drugs are impressively effective, often transforming the diagnosis of HCV from what would be, at best, a costly chronic condition to a curable condition. This treatment comes at a price, though, high enough to be crippling payers' budgets across the country. A recent investigation by the US Senate Finance Committee found that states had been unsuccessful at securing Medicaid supplemental rebates for HCV drugs (Solvadi and Harvoni), with only five of 48 states reporting having reached a rebate agreement with Gilead; states were thus turning to restricting access to the drugs as a strategy for controlling spiraling spending on this treatment.⁵¹

In response to this situation and guidance from CMS regarding the care which states must take when attempting to limit access to treatment, 25 Medicaid programs came together in 2015 to form a pool specifically focused on the purchase of AbbVie's Viekira Pak, for the treatment of hepatitis C. Missouri led this effort, and restricted Medicaid coverage to Viekira Pak to the exclusion of Solvaldi, in exchange for supplemental rebates representing an additional 20-30 percent savings.⁵² Because there is a lag before savings from supplemental rebates begin to show up, it is too early to assess the impact of this effort on Medicaid spending.

The notion of bulk purchasing is not a new one and has been particularly effective in ensuring access to critical pharmaceuticals in the form of vaccines for children. Vaccination programs have long been considered an important public health issue; the value to society at large (both here at home and globally) of controlling the prevalence of certain diseases is well known and quantifiable.

Vaccinations are primarily paid for in one of two ways: via private insurance coverage and via public coverage programs like Medicaid and Medicare. There are two sources of federal vaccine funding: the Vaccines for Children Program (VFC) and Section 317 of the Public Health Service Act. Section 317, reauthorized and amended by the PPCA, is a grant program administered by the CDC, to assist states, political subdivisions of states and other public entities in meeting the costs of preventive health programs.⁵³ It serves as the primary source of funding for state-level immunization programs for children,⁵⁴ with the Secretary of HHS contracting with vaccine manufacturers and allowing states to receive vaccines at a negotiated price. Research has found that the assistance provided by Section 317 has a significant, positive correlation with increases in childhood vaccination rates.⁵⁵ The ACA extended this program to vaccines for adults in recognition of the public health threat posed by infectious diseases.

The Vaccines for Children program (VFC) funds free vaccines for children across the country who are Medicaid-eligible, uninsured, underinsured, or a Native Americans. The program was enacted in 1994 to ensure that inability to pay would not put a child at risk for contracting a vaccine-preventable disease, and has been credited with substantially contributing to the high rate of vaccination among America's children.⁵⁶ The program, administered by the CDC and funded by federal appropriations, makes federally purchased vaccines available to public and private participating immunization providers. The bulk purchase of vaccines ensures lower-priced products and eliminates state-to-state differences in the cost

of vaccines. The CDC contracts with manufacturers at a discount, and distributes vaccines at no charge to enrolled providers. The Vaccines for Children program focuses only on those childhood vaccines listed by the federal Advisory Committee on Immunization Practices (ACIP), which is statutorily authorized to establish recommendations for vaccination practices for all US civilians.

Because the VCF does not cover all children, some states have elected to establish their own “universal” vaccine programs. And while the ACA requires coverage of preventive care including vaccines, some children remain uninsured and potentially without access to affordable vaccines. As recently as 2014, seven states have such programs, universal purchase programs that provide vaccine coverage for all recommended vaccinations, for all children, regardless of their insurance coverage. Several other states offer similar programs for a subset of recommended vaccines and a handful purchase vaccines for public providers only. In all of these states, the covered vaccines are distributed at no charge to participating providers. Providers are allowed to charge an administration fee for the vaccine, but the vaccine itself is free to the patient, helping make vaccines widely accessible to all children.

The VCF represents a successful strategy for ensuring broad-based access to care for which there is considerable public interest. An argument might be made for developing a similar strategy for some of today’s very high cost prescription drugs, particularly those used in treating communicable diseases like hepatitis C.

Congress established the federal 340B Drug Pricing Program in 1992 as part of the Public Health Service Act. The program, which is intended to help maximize the effectiveness of scarce federal resources, allows certain types of health care providers access to discounted prices on drugs from manufacturers. Like the Medicaid Drug Rebate Program, manufacturers are required to participate in the 340B program in exchange for their drugs being covered under Medicaid.⁵⁷ The program essentially establishes a ceiling price for what manufacturers may charge providers qualified and participating in the program. These ceiling prices mimic those used in the Medicaid drug Rebate Program – AMP minus 13 percent for generic drugs and AMP minus 23.1 percent (or best price, whichever is lower) for brand name drugs.

Only certain medical providers are able to participate in the program as “qualified entities.” These include several types of hospitals (disproportionate share, sole community providers, critical access hospitals, children’s hospitals and cancer hospitals) that are publicly owned or not-for-profit with a contract with state or local government to provide care to low income patients who are ineligible for Medicaid or Medicare coverage and which meet certain minimum Medicaid payer-mix standards. Similarly, health centers receiving federal grants from HHS – including federally qualified health centers – which provide pharmacy services or which contract with community pharmacies to dispense prescriptions to their patients, are required to participate as qualified entities. Qualified entities receive discounts on 340B covered prescription drugs dispensed to qualified patients. Qualified patients are patients receiving care – not just getting prescriptions filled by – a qualified entity.⁵⁸

Initially intended to play a limited role in federal efforts to address access to affordable prescription drugs, the program has grown significantly. By early 2014, nearly one third of all American hospitals participated in the program; spending for 340B drugs went from \$0.8 billion in 2004 to \$7.2 billion just nine years later, with 340B discounts applying to more than 25 percent of all prescription drugs dispensed in 2013.⁵⁹ This growth, and a perception that the program may no longer be serving the purpose for which it was originally intended, may make it the focus of federal reform efforts. The 340B program is a wholly federal initiative and not one that states may directly influence; still, it is an important piece of the puzzle that is helping to ease access to prescription drugs across the country.

Summary

Prescription drugs play a critical role in health care and are valuable tools in the promotion of health, and in protection and treatment of disease. Access to prescription drugs is therefore of vital importance to the American public. At the same time, spending on prescription drugs comprises a substantial and ever-growing portion of health care costs in this country. And though both public and private sector payers have long been tuned into the issue, the stark, rapid increases in prescription drug spending in recent years have put the issue in the public spotlight, increasing pressure to find effective ways to appropriately control these costs.

In the case of both the private and public sectors, barriers to access such as out of pocket payments, restrictive plan design, PDLs and other cost containment strategies have the potential problem of negatively impacting access to appropriate prescription drug therapies and/or compliance with recommended therapies. This potential raises not only the specter of putting a patient's health at risk, but of swapping short run savings for spending on more costly services down the road, should a patient's condition worsen due to a failure to comply with a prescribed drug regimen. It also holds a potential threat for the public's health if communicable diseases that might be effectively addressed using prescription drugs go untreated. The costs and benefits of prescription drugs must be weighed carefully both in the private sector and by state governments. These drugs hold great promise. At the same time, they hold the potential to crowd out spending for other critical services.

As states look broadly as payers not just for Medicaid but for other residents receiving publicly sponsored health care such as public employees, and state corrections' inmates, the issue of prescription drug cost growth takes on new urgency. States are responsible for protecting public health and prescription drugs plays a critical role in that effort. Hepatitis C is a case in point. Considered a threat to public health by the CDC, hepatitis C affects more than 3 million people in the US and is a leading cause of liver cancer. Most people infected with the virus are not aware they have it, and most will end up with a chronic form of the disease.^{60, 61} There are now highly effective drug treatments for hepatitis C, but they are extraordinarily costly, at least as a short-term proposition. With a high cure rate, these drugs help avoid downstream costs associated with a complicated chronic illness that is costly to treat and can result in death. Still, the cost burden of the HCV drug regimen threatens to crowd out other important uses for scarce public funds.

And state budgets need to consider the costs across programs. Indeed, the many activities in which states have been engaged generally are siloed and not comprehensive across all public payers. And despite the considerable work under way in states to lower prescription drug cost growth, those costs continue to rise and pressure state budgets, and/or consumer out of pocket payments and, in turn, access to needed drugs.

End Notes

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