



Public Health Crises and
Pharmaceutical Interventions:
Improving Access While
Ensuring Fiscal Sustainability

NGA CENTER FOR BEST PRACTICES

444 North Capitol Street NW, Suite 267

Washington, D.C. 20001

202-624-5300

www.nga.org/center

EXECUTIVE SUMMARY

Over the past several decades, persistent growth in health care costs has placed significant pressure on state budgets. Consequently, governors have a vested interest in pursuing value-based health care reforms that lead to better health for their residents while reducing costs. Governors may have to make difficult trade-offs between maximizing the availability of numerous services and treatments and ensuring the fiscal sustainability of the programs they administer. Recently, pharmaceutical innovations have become a central part of this discussion. For states, the balance between access and affordability is particularly difficult during a public health crisis, when the desire for widespread access to life-changing medicines is acute and strategies for rapid and effective dissemination present an operational and fiscal challenge.

Chief among the public health imperatives governors have been pursuing for years are reducing deaths due to opioid use disorder and treating Hepatitis C virus (HCV) infection, which is the deadliest infectious disease in the United States, surpassing all other major infectious diseases combined.¹ In addressing the opioid crisis, increased access to naloxone, the lifesaving overdose reversal agent, has been a primary policy objective for governments, first responders and families. At the same time, the increased price of overdose reversal agents highlights the need for a multi-stakeholder effort to support rapid dissemination that acknowledges the cost for governments and first responders. In addressing HCV, new treatments make eradicating the virus a possibility, but many states continue to struggle with increasing access to affected populations while managing the costs associated with treatment. The opioid and HCV crises are prime examples of why state policymakers are keenly interested in finding innovative ways to partner more effectively with the pharmaceutical industry, the federal government and other stakeholders to collectively respond to public health crises now and in the future.

In response to requests from states, the Health Division of the National Governors Association Center for Best Practices (NGA Center Health Division) launched a project in November 2017 to support states in their efforts to address current public health crises, such as the HCV and opioid crises, as well as future crises by ensuring access to evidence-based pharmaceutical interventions through more effective purchasing approaches and other mechanisms. In this project, NGA Center Health Division worked with states and engaged national experts and key stakeholders through expert roundtables and other discussions.

This paper provides a summary of the strategies states identified during the project to address public health crises by increasing access to pharmaceuticals while ensuring fiscal sustainability of public programs. The strategies identified include some that select states are currently executing or pursuing and more novel approaches yet to be tried. This paper also outlines considerations for states and key takeaways from discussions with stakeholders, which included pharmaceutical manufacturers, insurers, pharmacy benefit managers, distributors, health care providers, consumers, retailers and trade associations.

STRATEGIES GOVERNORS MAY CONSIDER

Governors seeking to increase access to pharmaceuticals critical to addressing public health crises by mitigating the costs of these important interventions may consider several strategies. The strategies noted here are not an exhaustive list of all approaches available to governors, but rather represent those vetted by participants from 11 states (**California, Delaware, Louisiana, Massachusetts, New Mexico, New York, Ohio, Oregon, Rhode Island, Virginia** and **Washington**) over the course of a project the National Governors Association Center for Best Practices (NGA Center) Health Division launched in November 2017. This project was designed to support states in their efforts to address public health crises by increasing access to evidence-based pharmaceutical interventions while ensuring fiscal sustainability of programs under the governors' purview.

Some strategies can be initiated through a governor's office; others may require action or approval by a state legislature or the federal government or partnership with pharmaceutical manufacturers and other key stakeholders in the pharmaceuticals supply chain. The strategies differ in scope and target population, and applicability may depend on the delivery system in each state. Some strategies are designed specifically to address immediate crises, associated pharmaceutical interventions and specific populations or state programs; others offer systemic changes that address both current and future crises and apply to more than one population or state program. The summary document that follows provides details on each approach; considerations for states; perspectives from different stakeholders; and highlights the opportunities, challenges and nuances in this complex policy domain.

A governor's office may consider the strategies on the next two pages »»

STRATEGIES GOVERNORS MAY CONSIDER

» **Establish a Medicaid Spending Cap for Pharmaceuticals**

Establish a target or capped Medicaid spending amount for pharmaceuticals, and develop policies that allow for negotiation or requirement of lower prices for certain products should spending exceed the established cap. This strategy can create a mechanism by which to address the unpredictability of prescription drug costs, including when new drugs without competition enter the market.

» **Pursue Alternative Payment Mechanisms (Subscription Model)**

Pursue alternative payment mechanisms such as a subscription model, which involves entering into an agreement with a pharmaceutical manufacturer in which the state pays a negotiated price for a certain volume of a drug over a specified period of time to increase access in a way that recognizes state budget constraints.

» **Consider Options for Excluding Select Drugs from Medicaid Coverage**

Consider options for excluding select drugs from Medicaid coverage to strengthen state negotiating power. Such flexibility would require federal approval, which under the current administration would likely require opting out of the federal Medicaid Drug Rebate Program (MDRP) altogether.

» **Engage in Bulk and Pooled Purchasing**

Leverage the purchasing power of one or more programs within or across states by purchasing products in bulk or in a pooled arrangement on behalf of those programs, with the goal of reducing costs through negotiated discounts for increased volume.

» **Determine and Pay Value-Based Prices**

Determine and pay value-based prices for drug treatments by incorporating value assessments, which could include a variety of methodologies and metrics, into policies and purchasing approaches within and across state health programs.

» Maximize Discounts for the Incarcerated Population through the 340B Drug Discount Program

Increase discounts for prescription drugs for the incarcerated population by contracting for the provision of those health care services by covered entities under the 340B Drug Discount Program (340B Program), where applicable.

» Explore Whether the Federal Government Would Invoke Section 1498 of Title 28 of the United States Code (U.S.C.)

Explore whether the federal government would invoke 28 U.S.C. 1498 (section 1498), which allows them to use or acquire patents (such as those for pharmaceuticals) in exchange for “reasonable and entire” compensation to the patent holder for such use.

» Pursue Legal and Regulatory Options to Foster Greater Transparency in the Pharmaceutical Market

Foster greater transparency in the pharmaceutical market by pursuing state laws and regulations that require manufacturers and others in the pharmaceutical supply chain, such as wholesalers, health plans, pharmacy benefit managers and pharmacies, to publicly report details on prices, price changes, research and development, business relationships, marketing and advertising costs and other information needed to inform policy and the public.

» Explore Whether the Federal Government Would Allow Nominal Pricing for Correctional Facilities

Explore whether the secretary of the U.S. Department of Health and Human Services (HHS) would include state and local correctional facilities among the safety net providers exempt from the best price requirement of the MDRP, which would create the regulatory conditions necessary for state and local governments to negotiate nominal prices (less than 10 percent of the average manufacturer price) for corrections populations.

BACKGROUND

Persistent growth in health care costs has placed significant pressure on state budgets. Medicaid spending alone accounts for roughly 30 percent of most state budgets (including state and federal outlays), outpacing spending on education and crowding out spending for other pressing needs.² Consequently, governors have a vested interest in pursuing value-based health care reforms that lead to better health for their residents while reducing costs. As almost all states are required to balance their budgets, governors must remain cognizant of limited resources for public programs while establishing policies that address the fiscal burdens employers and state residents bear.³ Given projections that health care costs will continue to rise, accounting for 20 percent of gross domestic product by 2025, governors' focus on achieving value in health care will remain a top priority, and innovative solutions are paramount.⁴

The value proposition requires a delicate balance between access to health care innovations, where indicated, and the affordability of making all innovations available. For governors, maintaining this balance can mean difficult trade-offs between maximizing availability to numerous services and treatments and ensuring the fiscal sustainability of the programs they administer. Recent advances in pharmaceutical interventions highlight this tension. Understanding the often life-changing benefit many pharmaceutical products provide and the importance of continued innovation and discovery in medicine, state policymakers are struggling to balance access to those innovations with the constraints of finite resources. Striking this balance will only become more difficult as pharmaceutical innovations move toward more personalized medicine and increased use of specialty medicines, few of which have direct competitors in the market.⁵

Arguably, the balance is most strained in the event of a public health crisis, when the desire for widespread access is acute and strategies for rapid and effective dissemination present an operational and fiscal challenge. In response to the challenges states have cited, NGA Center Health Division launched a project in November 2017 to support states in their efforts to address existing public health crises, such as Hepatitis C virus (HCV) infection and opioid use disorder, as well as future crises by increasing access to evidence-based pharmaceutical interventions through more effective purchasing approaches and other mechanisms. Ten states participated in the project (**Delaware, Louisiana, Massachusetts, New Mexico, New York, Ohio, Oregon, Rhode Island, Virginia** and **Washington**), and potential strategies were vetted with one additional state (**California**) during a roundtable convening. NGA Center Health Division also consulted an array of national experts and engaged with key stakeholders through expert roundtables and other discussions, including pharmaceutical manufacturers, insurers, pharmacy benefit managers, distributors, health care providers, consumers, retailers and trade associations.

This paper provides an overview of the strategies participating states considered to in-

crease access to pharmaceuticals through more effective purchasing and other mechanisms as well as the multi-stakeholder input gathered over the course of the project on these potential strategies. An in-depth discussion of all facets of this complex sector in health care is beyond the scope of this paper, but key trends that created the demand for new state approaches are briefly summarized to provide context for the strategies vetted and presented at the end of the paper. To complement this discussion, several recent analyses offer detailed information about the complexity of the pharmaceutical system and strategies under discussion among stakeholders.⁶

Addressing Public Health Crises by Ensuring Access to Pharmaceuticals: State Challenges

Defining Public Health Crisis

In its project, NGA Center Health Division limited its focus to state strategies for addressing public health crises. There is currently no standard definition of “public health crisis,” and many types of health conditions and environmental threats that affect the morbidity and mortality of large numbers of people have been deemed “crises.”⁷ For example, in the health sector, various infectious disease outbreaks and some chronic illnesses, such as diabetes and heart disease, are considered to be at crisis levels. To identify key crises in states and to facilitate a common starting point for discussions among all stakeholders engaged in the project, NGA Center Health Division used general parameters for a definition designed to guide public health preparedness approaches to mitigate crises.⁸ The working definition provided that a public health challenge may rise to the level of a crisis if it (1) includes significant morbidity and mortality; (2) has scale, rapid onset or unpredictability that stresses or overwhelms the routine capabilities of government, the private sector and individuals; and (3) requires proactive efforts by all sectors to prevent, detect and mitigate effects by adapting plans and resources to meet the situation’s emerging needs.⁹

When applying these criteria to affordability of and access to pharmaceutical interventions implicated in public health crises, two health challenges surfaced: HCV and opioid use disorder. As a result, NGA Center Health Division’s project focused on state strategies to address the HCV and opioid crises and to plan for similar crises that may arise in the future.

Pharmaceuticals Indicated in Public Health Crises

Pharmaceutical interventions are critical to addressing both HCV and opioid use disorder and related complications. In the case of HCV, the new direct-acting antiviral treatments offer a cure for a chronic infectious disease that progresses slowly and can cause serious liver problems and death.¹⁰ Intervening in the opioid crisis relies

heavily on the overdose reversal agent naloxone being available at the front lines and on medications used in Medication-Assisted Treatment to help people recover from opioid misuse over time.¹¹ For many states, however, the ability to leverage these important innovations to help mitigate the crises has been challenging. A variety of systemic barriers make it difficult to identify, engage, successfully treat and coordinate care for individuals with either condition, including lack of sufficient data to target resources, screening, treatment and engagement challenges, workforce limitations and stigma, among others. However, a significant contributor to the challenges, particularly for the HCV crisis, is the cost of the interventions.

The cost of pharmaceuticals to states, other health care payers and consumers is determined by several interactive factors in the pharmaceutical sector, which features a highly complex distribution and supply chain that includes manufacturers, wholesalers, pharmacy benefit managers, retailers, private and public health care payers, clinicians and consumers. Figure 1 depicts the complex interplay in the pharmaceutical supply chain and Medicaid drug purchasing.

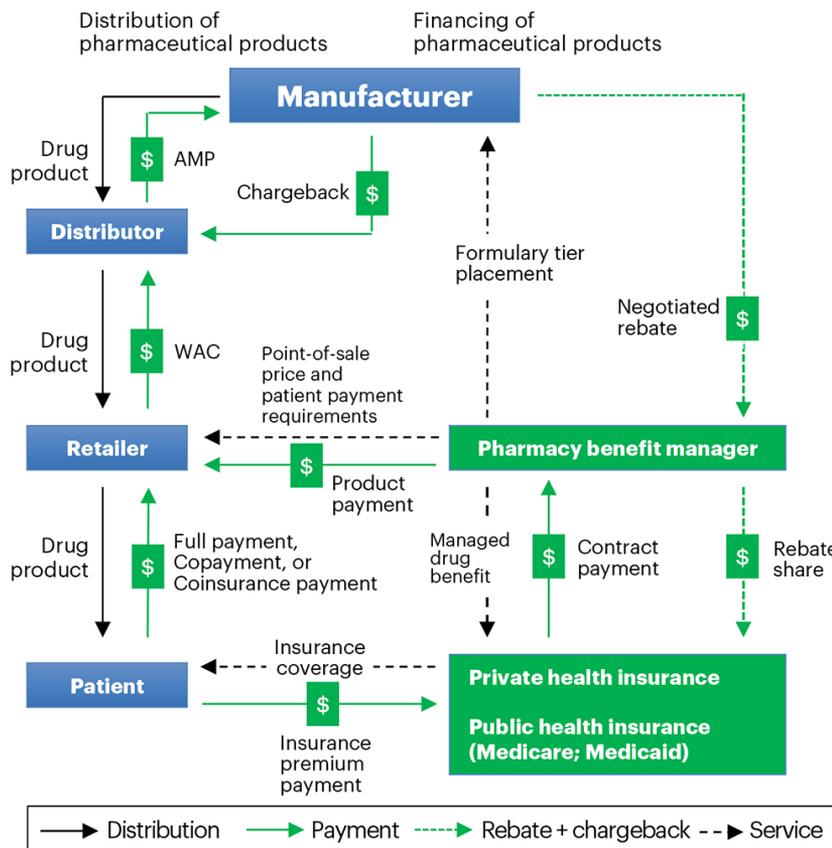


Figure 1. Flow of pharmaceutical funds, products and services. Adapted from a figure by the Congressional Budget Office.¹² “Services” represent contractual relationships among entities. “Rebates” are payments from manufacturers to pharmaceutical benefit managers. “Chargebacks” are payments from manufacturers to distributors. “Retailers” include pharmacies, hospitals, group purchasing organizations and mail-order programs.

AMP = average manufacturer price; WAC = wholesale acquisition cost.

Source: Dabora, M. C., Turaga, N., & Schulman, K. A. (2017). Financing and distribution of pharmaceuticals in the United States. *Journal of the American Medical Association*, 318(1), 21–22. doi:10.1001/jama.2017.5607

A key factor is the price the manufacturer sets, including how it sets launch prices or establishes price increases, how market forces influence prices, and whether and how purchasers can negotiate price discounts.¹³ Another key contributor is the role of pharmacy benefit managers, who support health care payers in managing pharmacy costs and share in those savings – a factor that many believe may keep prices high while offering limited benefits to consumers.¹⁴ Wholesalers, which have significantly consolidated over the past decade, and retail pharmacies may play similar roles in contributing to price markups.¹⁵ Little is known about the extent to which these dynamics contribute to higher prices, which is why a number of states seeking greater transparency believe that those efforts must include a focus on the distribution and supply chain as well as manufacturers. In 2017, the National Academies of Sciences, Engineering, and Medicine released a comprehensive report that features an in-depth discussion of the supply chain, its origin and the effect of this complex interplay. This report serves as a reference for those interested in a more detailed account of the broader dynamics.¹⁶

State Budgeting and Cost Management

As executors of Medicaid and corrections programs, among others, states are primary payers in our nation's health system and play a pivotal role in ensuring coverage and access to care for some of the country's most vulnerable populations. In this role, states must define budgets and allocate funding for each program based on previous-year cost assessments, anticipated trends in spending growth and availability of resources. All payers establish defined budgets by which they operate their business, but states — unlike the federal government or private corporations — are further constrained because they are required by law to balance their budgets each cycle, meaning that spending cannot exceed revenue.¹⁷ Balanced budget requirements coupled with short-term budget cycles (one to two years) and regular changes in administrations and state leadership make it difficult for states to manage unpredictable expenses and find revenue to support significant increases in spending in a given year, even if that spending might result in longer term return on investment. With respect to pharmaceuticals, states' ability to predict when the U.S. Food and Drug Administration (FDA) will approve a drug and for which indications requires close analysis of the pharmaceuticals pipeline and approval trends — a challenging task given limited resources in some states and federal laws that limit the details manufacturers can disclose about the anticipated prices of drugs in the pipeline.¹⁸ Even with knowledge of what is on the horizon, newly approved drugs that have high prices and no competition can overwhelm predetermined state budgets (and those of other payers).¹⁹ This dynamic was the case with new HCV treatments in 2014 and 2015 and is expected to be an ongoing challenge with new pharmaceuticals in the drug approval pipeline.²⁰ Further, even when states can predict the path of certain drugs to market, it can remain challenging to pay for them. (For details, see the section "Hepatitis C and Specialty Medicines.")

Budgeting constraints are further exacerbated by the challenges states face in managing their Medicaid pharmacy benefit, especially in the case of high-cost specialty

drugs. The MDRP, established in 1990 and authorized by Section 1927 of the Social Security Act (Section 1927), provides states with both mandated discounts and limits on how they can structure prescription drug coverage.²¹ States are not required to offer prescription drug coverage as part of their Medicaid benefit, but if they choose to do so (which all states currently do), under the MDRP they are required to cover all FDA-approved drugs, with few exceptions. In exchange, pharmaceutical manufacturers are required to offer state Medicaid programs rebates based on statutory formulas. Those rebates must ensure that Medicaid's payment for any drug product matches or exceeds the "best price" in the market — that is, the lowest price that other purchasers pay, factoring in all discounts or other price adjustments that those payers may be receiving. In addition, states can negotiate supplemental rebates. The MDRP's best price requirement helps states and the federal government offset a certain level of prescription drug costs, as it was designed to do, but some states have identified that the requirement to cover all FDA-approved drugs limits states' ability to negotiate with manufacturers and design coverage in a way that directs patients to the most cost-effective therapies. State Medicaid programs do have some utilization management tools to encourage the use of particular products, such as prior authorization and preferred drug lists (PDLs) and states vary in maximizing their use of these tools. Unlike payers in the commercial market, however, states are prohibited by federal law to exclude drugs that have low efficacy or that have multiple competitors with lower prices.²²

Examples of Public Health Crises and Key Trends Facing States

HCV and Specialty Medicines

HCV is associated with more deaths than 60 other infectious disease in the United States, surpassing all other major infectious diseases combined. The high and growing disease burden is creating urgency for access to new treatments.²³ An estimated 3.6 million people are infected with the virus, and the infection rate has grown in recent years, especially among young people who inject drugs.²⁴ In late 2013, a new treatment for HCV shifted the clinical treatment framework from complicated disease management to the possibility of eradicating a virus.²⁵ However, when FDA approved the new breakthrough treatment for HCV and the first product entered the market, it was recognized not only for its remarkable achievement in providing a cure for HCV but also for its high launch price.²⁶

Prior to the release of the new HCV treatment, prices of the same magnitude were typically reserved for drugs that treated rare or orphan diseases — that is, diseases with patient populations of 200,000 or fewer across the country.²⁷ With over 3 million people infected with HCV in the United States, the new treatment created a scenario

in which high price coupled with the high volume of patients in need of treatment resulted in high costs for states. For example, in 2014 — the first year the treatment was available — Medicaid prescription drug spending increased by 24.3 percent compared with an increase of 4.6 percent for all other national health expenditures. This increase was attributed primarily to the new HCV treatments.²⁸

Prices for novel HCV treatments have significantly declined with competition in the market and negotiated discounts in the past several years, resulting in lower average cost per treatment (estimated to average \$25,200 for Medicaid populations and \$58,000 for corrections).²⁹ Even with this lower cost, however, providing access for Medicaid and corrections populations is still a significant challenge for some states because of the disproportionate incidence of the disease in these populations. Epidemiological studies of HCV by population are still being conducted; most estimates of prevalence are considered low, but the most recent data show that prevalence rates are 7.5 times higher in Medicaid managed care populations than in commercially insured populations, and approximately 50 percent of those who have the disease are incarcerated.³⁰ In addition, both of these populations show significantly higher rates of common comorbidities such as human immunodeficiency virus (HIV) infection and substance use disorders. Given the prevalence of HCV, even with significantly reduced prices, most states would need to spend hundreds of millions to treat all individuals in their Medicaid programs and correctional facilities to eradicate this infectious disease. Looking forward, some experts believe that HCV treatment has set a new standard and that states may see similar scenarios for other high-prevalence conditions, further complicating the trade-offs between access to innovation and affordability in the future.³¹

HCV treatments are examples of “specialty medicines” — that is, medicines that treat chronic, complex or rare diseases, are typically higher in cost and often have additional care delivery or distribution requirements.³² In 2017, specialty medicines accounted for \$9.8 billion of \$12 billion net growth in brand-name drug spending, a trend that is expected to continue.³³ IQVIA (formerly Quintiles IMS Holdings), a multinational company well known and respected for its analyses of pharmaceutical industry data and dynamics, projects that specialty medicines will account for all spending growth in developed markets in 2018 and surpass half of all medicine growth in the United States by 2022.³⁴ Specialty medicines have been a key driver in Medicaid spending growth in particular, accounting for 0.9 percent of claims and 32 percent of Medicaid drug spending.³⁵ Many specialty medicines will be indicated for small populations, but others are anticipated for high-volume conditions. Most specialty drugs in development are in oncology, neurology and autoimmune classes.³⁶ Three-quarters are expected to be breakthrough therapies or “first in class,” meaning that they represent a novel class of treatment for a specific condition.³⁷ Many potential breakthrough therapies are for cancers, but others being developed to treat high-volume conditions such as diabetes, cardiovascular disease, psychiatric conditions and Alzheimer’s disease are on the horizon.³⁸

FDA can designate a pharmaceutical as a “breakthrough therapy” at the request of the drug’s sponsor if preliminary clinical evidence indicates that it may demonstrate a substantial improvement over available therapies for patients with serious or

life-threatening diseases.³⁹ Such designation also comes with an expedited review process. These expedited processes have the important objective of getting innovative therapies to market quickly and have been successful in increasing approvals. For example, more than 100 products — including the novel, direct-acting antiviral treatments for HCV — have received breakthrough therapy approval since the designation began in 2012.⁴⁰ It is important to note the trade-offs involved in this approach, however. Expedited approvals can lead to significant clinical gains and new opportunities to address unmet needs in serious or life-threatening conditions, and they also allow less rigorous evidence of safety and clinical efficacy, which can raise concerns about the quality of the therapies, and additional benefits offered.⁴¹ In addition, many of the drugs receiving expedited approval are specialty medications that come at a higher cost.⁴² These trade-offs have significant implications for the health system and raise important questions about how value is measured and what various stakeholders are willing and able to pay. In the past five years, the largest share of new pharmaceuticals has been specialty medicines, and spending on these drugs as a proportion of overall pharmacy spending rose from 24.7 percent in 2008 to 46.5 percent in 2017.⁴³ According to a report from the UnitedHealth Group, this trend is expected to continue, with estimates suggesting that specialty drug spending will reach \$400 billion by 2020, or about 9.1 percent of all health care spending, which is just shy of current spending on all pharmaceuticals in the health system.⁴⁴

Opioid Overdose Treatment and Price Increases on Existing Drugs

Another public health imperative of critical importance to governors is stemming the opioid crisis and the associated rising death rate from opioid overdose. According to the Centers for Disease Control and Prevention, 115 Americans on average die every day from an opioid overdose.⁴⁵ In total, 350,000 people died from opioid overdose between 1999 and 2016, with the rate increasing steadily over time and a significant uptick in 2013 following the introduction of synthetic opioids.⁴⁶ The president of the United States and several states have declared the opioid crisis an emergency, and associated strategic responses routinely prioritize immediate access to naloxone for first responders, emergency service providers and family and friends of individuals with opioid use disorder.⁴⁷ Accordingly, widespread demand for naloxone, which was once primarily used in emergency departments, has increased dramatically over the past few years.⁴⁸ At the same time, the price of naloxone rose sharply for one product — from \$690 to \$4,500 — and to a lesser degree for all other products on the market.⁴⁹ Table 1, reproduced from a summary in *The New England Journal of Medicine* based on publicly available data, provides details on the pricing dynamics for naloxone.⁵⁰ Notably, a popular injectable form of naloxone was priced at less than \$1 as recently as 10 years ago.⁵¹

These price increases occurred at the same time as drug overdoses fueled by the opioid crisis caused the largest single-year spike in accidental deaths in 80 years and federal and state governments were making substantial investments in mortality-reduction and treatment efforts.⁵² An analysis of national and state-by-state Medicaid usage and expenditures for naloxone from January 2013 through September 2015 conducted by The Menges Group showed that national naloxone use in Medicaid increased significantly more than average use of all drugs in Medicaid. The increase in naloxone use

Recent and Current Prices for Naloxone*

Naloxone Product	Manufacturer	Previous Available Price (year)	Current Price (2016)
Injectable or intranasal, 1 mg-per-milliliter vial (2 ml)	Amphastar	\$20.34 (2009)	\$39.60
Injectable			
0.4 mg-per-milliliter vial (10 ml)	Hospira	\$62.29 (2012)	\$142.49
0.4 mg-per-milliliter vial (1 ml)	Mylan	\$23.72 (2014)	\$23.72
0.4 mg-per-milliliter vial (1 ml)	West-Ward	\$20.40 (2015)	\$20.40
Auto-injector, two-pack of single-use prefilled auto-injectors (Evzio)	Kaleo (approved 2014)	\$690.00 (2014)	\$4,500.00
Nasal spray, two-pack of single-use intranasal devices (Narcan)	Adapt (approved 2015)	\$150.00 (2015)	\$150.00

Table 1.

Source: From The New England Journal of Medicine, Gupta, R., Shah, N. D., & Ross, J. S., The rising price of naloxone – risks to efforts to stem overdose deaths, 375:2213-2215 Copyright © (2016) Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

was 66 percent from 2013 to 2014 (compared with 12 percent for all drugs) and 101 percent from 2014 to 2015 (compared with 10 percent for all drugs).⁵³ National naloxone expenditures increased proportionally more – from 24 percent between 2013 and 2014 to 259 percent between 2014 and 2015.⁵⁴ Notably, states that expanded their Medicaid programs experienced 16 percent overall growth in Medicaid prescription drug usage during 2015 but 165 percent growth in naloxone use.⁵⁵ These trends are notable for the timing of price increases, with a clear and sustained increase in demand that has presented fiscal challenges for certain states and local partners seeking to finance rapid acquisition and distribution of high volumes of the drug.⁵⁶

The naloxone example highlights another trend that has contributed to pharmaceutical cost growth in recent years: price increases on existing therapies (and associated higher launch prices for new market entrants).⁵⁷ Price increases on existing drugs are occurring across both brand-name and generic drug categories. Notable examples of recent price increases that have received public attention include those for certain drugs that treat severe allergic reactions and severe infections that could be life threatening in immunocompromised individuals.⁵⁸ Price increases for existing therapies are more common than these isolated examples convey, however, occurring for hundreds of products every year. For example, according to a Government Accountability Office report, more than 20 percent of generic drugs in the Medicare Part D program showed a significant price increase in a five-year period.⁵⁹

To a large degree, states are uniquely protected from significant price increases in Medicaid because of a regulation known as the “Consumer Price Index (CPI) penalty,” which requires drug manufacturers to provide rebates to state Medicaid programs in the amount the price of their product has exceeded inflation, as measured by the CPI for urban consumers.⁶⁰ This protection does not extend to other state programs, however, such as corrections and state employees. Price increases for these populations remain challenging, particularly in the case of public health crises that require response well beyond health insurance programs.

POTENTIAL STATE STRATEGIES

These examples highlight the challenges states face in ensuring access to pharmaceutical interventions critical to addressing public health crises while maintaining fiscal sustainability. Overcoming those challenges and identifying strategies that can help balance access and cost for pharmaceuticals in the event of public health crises are critical to governors and state leaders. Recent federal proposals also signal the importance of action at the state level to address these challenges. In May 2018, the Trump administration released its blueprint for addressing drug pricing and out-of-pocket costs for patients titled “American Patients First.”⁶¹ A significant proportion of the proposal focuses on Medicare, placing even greater emphasis on the need for state-led approaches to address issues in Medicaid and other state populations. Although the blueprint does not specifically outline immediate actions to help states address drug pricing, it does offer possible future opportunities, such as reforming the MDRP. Thus, there may be some opportunity for states to work with the federal government around meaningful MDRP reform to increase flexibility and improve their ability to address public health crises by providing access to pharmaceuticals at affordable costs.

Through NGA Center Health Division’s project, 11 states (**California, Delaware, Louisiana, Massachusetts, New Mexico, New York, Ohio, Oregon, Rhode Island, Virginia** and **Washington**) identified nine state strategies that should be considered to address these challenges. Some strategies select states are currently executing or pursuing; others are more novel approaches yet to be tried. States may differ in terms of which strategies they ultimately pursue, but there was consensus among those participating in NGA’s project that all nine strategies give states options for developing a comprehensive approach to increasing access to needed pharmaceuticals in public health crises.

All strategies are aligned with this ultimate goal but differ in how to strike the balance between access and cost. For instance, some strategies involve policies that apply to all pharmaceuticals, including those implicated in public health crises, while others narrowly target therapeutic classes critical to addressing a specific crisis. In addition, some strategies involve more immediate approaches to increasing access and lowering cost within existing legal and regulatory frameworks to address current crises, while others focus on longer term structural changes in how states analyze and pay for pharmaceuticals to better position themselves for future crises. The strategies also vary with respect to the state programs and populations they target, such as Medicaid and corrections, which is an important factor in how well an individual strategy may be able to address certain public health crises.

The nine strategies states identified through the NGA Center Health Division project are outlined below, including a high-level description of each approach; key considerations for states that arose during conversations with states and national experts; and takeaways from discussions with key stakeholders over the course of the project that included pharmaceutical manufacturers, insurers, pharmacy benefit managers, distributors, health care providers, consumers, retailers and trade associations.

STRATEGY: Establish a Medicaid Spending Cap for Pharmaceuticals

Establish a target or capped Medicaid spending amount for pharmaceuticals, and develop policies that allow for negotiation or requirement of lower prices for certain products should spending exceed the established cap. This strategy can create a mechanism by which to address the unpredictability of prescription drug costs, including when new drugs without competition enter the market.

This strategy focuses exclusively on the Medicaid population. States interested in a comprehensive approach to addressing public health crises may want to consider additional strategies that target corrections and potentially other state populations.

Key Considerations for States

To implement this strategy, states need to enact legislation that creates a spending target or cap for pharmaceuticals in Medicaid or give state officials the authority to do so. States would also need to adapt regulations to reflect changes set forth in legislation.

One of the primary decisions for states pursuing this approach is whether to focus exclusively on avenues for negotiation with manufacturers or to also implement one or more retribution policies that would be triggered in the case of unsuccessful negotiation. For example, states could require reporting on factors that determine price or strict formulary management techniques, which could be based on value assessments. Engaging in successful negotiations would likely be preferable and more efficient for states, but having policies in place that provide leverage for those negotiations may help increase a state's likelihood of reaching agreement with a pharmaceutical manufacturer. It is important to note that some of the policies a state may implement as part of this approach could require federal approval.

Several operational and capacity challenges may arise for states pursuing this strategy. Specifically, states will need the capacity to develop and implement policies and processes to (1) conduct actuarial analyses to set an appropriate spending cap and establish a year-over-year growth rate, (2) identify products that are major contributors to spending in excess of the cap, (3) engage pharmaceutical manufacturers in negotiation and (4) build capacity to implement selected approaches for bringing down cost should negotiations fail to result in lower prices. States will need to collect and analyze data to establish a spending cap and growth rate for pharmaceuticals; hire or contract with actuaries, economists and other experts as necessary to conduct assessments of spending and value; and interact with existing Drug Utilization

Review Boards (DURBs). Senior staff time and resources would also be needed to engage in negotiations and implement solutions should negotiations fail. Establishing a cap for pharmaceuticals may be more difficult for states that do not already have a Medicaid spending cap or managed care plans with capped financing arrangements operating significant portions of their program.

To date, only one state — **New York** — has implemented this approach. New York’s approach includes several levers to help foster successful negotiation and ensure spending in line with its established cap should it not reach a negotiated solution. Since the state implemented its strategy in August 2017, it has identified 30 pharmaceuticals from 12 manufacturers that have contributed to spending in excess of their spending cap and have only referred one product to its DURB for further review, suggesting that the state has successfully negotiated or engaged in negotiations for all other pharmaceuticals thus far.

Notable Takeaways from Stakeholder Discussions

Many stakeholders felt that this strategy could help states establish budget predictability and create a new pathway for price negotiation that strengthens the state’s leverage with manufacturers. Many stakeholders considered the inclusion of a value-based pricing assessment should negotiations be unsuccessful (as done in New York and discussed in more detail below) an important addition to existing state processes for review of the safety, efficacy and clinical cost-effectiveness of pharmaceuticals.⁶² Certain stakeholders, however, felt strongly that the strategy would be undesirable if it involved a requirement rather than simply an avenue for negotiation. Other stakeholders raised concerns about how this strategy could affect innovation if it targeted high-priced drugs that treat rare diseases, which are sometimes developed by small companies that have limited resources. Stakeholders agreed that this strategy would require significant operational capacity and that setting an appropriate cap and growth rate is complex but paramount to success. Finally, a key concept that stakeholders discussed was how this broad strategy applies to public health crises. Some noted that in the context of public health crises, there may be unique considerations for the correct amount to spend to address the problem and that elevated spending or, alternatively, negotiated discounts to treat more people during a crisis may be necessary. It was also noted that flagging pharmaceuticals that caused spending to exceed an established threshold could effectively highlight specific access and cost challenges in pharmaceuticals needed during public health crises.

CASE EXAMPLE: NEW YORK

Medicaid Drug Cap (Public Health Law §280)

Since 2011, Medicaid drug expenditures have continually outpaced other cost components in New York's Medicaid program. To protect New Yorkers from increasing prescription drug costs, Governor Andrew Cuomo and the state legislature established the Medicaid Drug Cap (in the state fiscal year [SFY] 2017-2018 budget) as part of an effort to balance the growth of drug expenditures with the growth of total Medicaid expenditures, making New York the first state to cap the growth of prescription drug spending in its Medicaid program.

The program caps the growth of prescription drug spending in the Medicaid program to an annual limit. If spending is projected to exceed the annual limit, the state department of health (DOH) has additional authority to negotiate rebates with pharmaceutical manufacturers and, if necessary, refer a drug to its DURB. The DURB is authorized to determine whether a drug is overpriced relative to the benefit it provides to patients based on clinical and economic studies as well as other information and to recommend a target supplemental rebate amount.

Process for Initial Identification of Drugs for Possible DURB Referral (Visual Flowchart)

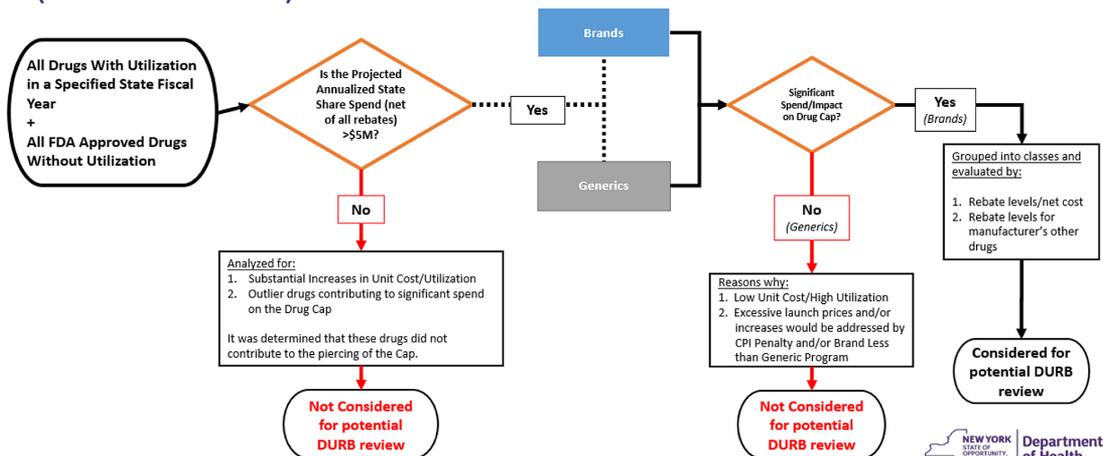


Figure 2. New York's methodology for identifying pharmaceuticals for DURB review

CASE EXAMPLE: NEW YORK (CONTINUED)

Setting the Cap

New York used the following methodology to set its cap for prescription drug spending in Medicaid.

Step 1: Set the baseline spending target

- » The Medicaid Drug Cap statute sets a baseline drug spending target based on actual drug expenditures and rebates for the previous SFY that is then trended by the 10-year rolling average of the medical component of the CPI plus 5 percent in SFY 2017-2018 (the 5 percent is reduced to 4 percent in SFY 2018-2019).
- » The state's pharmacy savings for SFY 2017-2018 (target of \$55 million) then reduces the new baseline spending target for the Medicaid Drug Cap for the next fiscal year. The state will increase its targeted pharmacy savings to \$85 million for SFY 2018-2019.

Step 2: Project drug spending and identify drugs

- » When the Medicaid Drug Cap is set, the New York DOH, the Division of Budget and the state's actuary conduct an analysis to determine whether expenditures are on track to exceed the cap.
- » If spending is projected to exceed the Medicaid Drug Cap, DOH then engages in an empirical and analytical process to identify drugs that contributed the greatest pressure on the Medicaid Drug Cap.
- » DOH assesses drugs contributing the greatest pressure on the cap for potential review by the DURB.

Implementation

In the first year of implementing the Medicaid Drug Cap, the New York DOH has successfully negotiated supplemental rebate contracts with several pharmaceutical manufacturers, avoiding DURB referrals and exceeded the statutory target of \$55 million in savings to the state. The final analysis of year-one results show that in the absence of the Medicaid Drug Cap, state drug spending would have grown by \$274 million in SFY 2017-2018.

The success of the Medicaid Drug Cap builds on Governor Cuomo's commitment to controlling the rising costs of prescription drugs without limiting access to medications for patients in the program.

STRATEGY: Pursue Alternative Payment Mechanisms (Subscription Model)

Pursue alternative payment mechanisms such as a subscription model, which involves entering into an agreement with a manufacturer in which the state pays a negotiated price for a certain volume of a drug (which could be unlimited) over a specified period of time (such as one year) to increase access in a way that recognizes serious budget constraints.⁶³ This strategy has the potential to help states establish budget predictability, amortize spending and negotiate significant discounts for volume trade-offs with manufacturers.

A subscription payment model could be applied to Medicaid, corrections and potentially other state populations.

Key Considerations for States

States can structure a subscription payment model in different ways, each of which offers unique benefits and can be more or less challenging to implement. The time frame of the arrangement, the payment level and structure and the agreed-upon volume are critical components of this approach.⁶⁴

In terms of timing, states will need to consider a time frame for potential contracts that fits within existing budgeting structures and accounts for potential changes in administrations and associated policy priorities. The time frame will also need to be long enough (or the new market share large enough) to draw manufacturers to the table to negotiate but short enough to minimize potential risk to the state should more cost-effective products enter the market. States need to be aware of the pipeline for pharmaceuticals and may consider establishing clauses within contracts that account for unforeseen shifts in clinical breakthroughs and market dynamics.

The mode and amount of payment for products under a subscription model can vary. For instance, a subscription payment could involve one upfront payment, or it could involve an upfront payment with additional payments or discounts rendered at certain milestones or at the end of the contract depending on volume or other stipulations. Alternatively, states may want to consider how they can use existing structures, such as the MDRP, to furnish payments and apply discounts. For example, instead of making one upfront payment, a state and a manufacturer could establish an agreed-upon payment level that, once surpassed under existing Medicaid payment and rebate structures (meaning that a certain level of volume is reached), a larger rebate is applied for the remainder of prescriptions filled during the contract period. Such an approach would be specific to the Medicaid population, and states would need to consider how to most appropriately structure payments if they are implementing a subscription model across additional state populations, such as corrections.

In addition to the structure of the payment, the volume tied to the payment is an important decision point for states. For instance, the model could involve unlimited access to a product over the contract period, or it could involve a tiered arrangement where the level of payment varies based on volume, meaning that the state pays X for 500 units, Y for 1,000 units, and Z for 2,000 units. Under this scenario, the assumption is that a state would pay less per unit for arrangements that involve a greater commitment to volume, but be on the hook for the payment even if the targeted volume is not met. Ultimately, in negotiating contract terms, including time frame, payment and volume, states should consider what volume is possible and ensure that financial commitments are not higher than what they might have otherwise paid.

Consideration of which products are appropriate for this model and the factors involved in developing a successful arrangement will require skillful analyses and negotiation on the part of states. This strategy also requires reaching agreements with pharmaceutical manufacturers and perhaps seeking approval of a Section 1115 waiver. For example, states that seek to make an upfront payment in Medicaid under a subscription model would likely need to seek federal approval of a Section 1115 waiver to supplant existing payment mechanisms under the MDRP. If a state chooses to include corrections or other populations outside of Medicaid, it may need to seek approval of a waiver of the Medicaid best price requirement if negotiated discounts set a new price in corrections that is lower than that offered in Medicaid programs across the country. States should also consider whether they require the ability to exclude competitor products outside of a subscription contract to ensure that volume is directed to the contracted product. Some argue that states could achieve this result through PDLs, an existing lever under the MDRP; others suggest that some states may not have the resources or expertise to maintain this level of oversight. Should a state choose to implement an approach that requires waiver authority, it must also consider the time and resource investment required to develop and seek approval of a waiver request. In addition, states can consider approaches that would not require a Section 1115 waiver, such as not making an upfront payment and ensuring that negotiated prices for correction populations are not lower than prices offered through Medicaid programs across the country.

Notable Takeaways from Stakeholder Discussions

Alternative payment mechanisms, such as the subscription model, sparked interest among many stakeholders. Several noted that the strategy offers an innovative financing option that could help address state budgeting challenges and open new avenues for negotiation but that the success or workability of the strategy would depend on how the arrangement is structured. Certain stakeholders expressed concern about the inclusion of federal waivers as part of this strategy, noting that from their perspective, it would be possible to successfully execute the strategy without a waiver. They noted significant differences in the cost of specific products in the Medicaid program and other programs, such as corrections, that may provide room for price negotiation without triggering the best price requirement in Medicaid. Further, certain stakeholders suggested that waiving one MDRP requirement in isolation of others would represent a departure from the original intent of the statute. Others felt that prices in Medicaid alone may be too high and that a waiver may be necessary for the resulting agreement to benefit the state in the

tradeoff between price and market share. It was also noted that engaging key stakeholders (such as providers) in the delivery system to increase access to the contracted product would be important and require additional resources. Stakeholders raised questions about how federal and state anti-kickback laws could affect this strategy and suggested seeking guidance from the HHS Office of Inspector General as well as state attorneys general. Finally, some underscored the notion that states would need skillful economic analysis and negotiation approaches to achieve the best outcome for their residents and avoid the risk of financial commitment that does not reflect value.

STRATEGY: Consider Options for Excluding Select Drugs from Medicaid Coverage

Consider options for excluding select drugs from Medicaid coverage by requesting federal approval to waive the MDRP requirement to cover all FDA-approved drugs. This strategy would allow states to exclude select drugs from their Medicaid formularies, equipping them with the same tools currently available to federal and commercial health plans to manage their Medicaid pharmacy benefit and affording them negotiating power consistent with a more competitive market. Notably, under the current administration, this strategy may require states to consider whether they are willing to obtain this flexibility in exchange for opting out of the federal MDRP altogether.

An MDRP waiver is exclusively for the Medicaid population. States interested in a comprehensive approach to addressing public health crises may want to consider additional strategies that target corrections and potentially other state populations.

Key Considerations for States

A number of states have pursued or expressed interest in this approach, but to date, the federal government has not approved any Section 1115 waivers that would allow a state to exclude coverage of select drugs. In September 2017, Massachusetts submitted a waiver request to the Centers for Medicare & Medicaid Services (CMS) to exclude select drugs from its Medicaid formulary if certain conditions are met. The request included robust protections for consumers, including processes for exceptions and appeals, a public comment period and other guardrails. In November 2017, Arizona submitted a letter to CMS indicating its interest in pursuing this approach and potentially submitting a waiver request in the future. A few other states have indicated interest in this approach through less formal channels.

In June 2018, CMS denied this part of Massachusetts' waiver request, indicating that it will not approve broad authority for states to exclude drugs from their formularies but may consider doing so if a state opts to forgo all MDRP provisions, including manufacturer rebates and best price.⁶⁵

The federal government has approved more limited waivers of MDRP provisions in the past. At least five states (**Arizona, Arkansas, Michigan, New Hampshire** and **Tennessee**) have received federal approval to waive certain provisions of Section 1927 (which established the MDRP) through a Section 1115 waiver. For example, in 1993, Tennessee received CMS approval of a Section 1115 waiver amendment that gave managed care organizations participating in the state's Medicaid program the flexibility to establish formularies that did not comply with all requirements of Section 1927.⁶⁶ Seeking a targeted waiver of certain provisions of Section 1927 for the purpose of addressing a public health crisis, such as for a specific therapeutic class related to addressing that crisis, has not been attempted. Any state interested in this strategy should be aware that federal approval of this type of waiver under the current administration, even in a narrow manner, may only be an option if the state is willing to opt out of the MDRP.

Notable Takeaways from Stakeholder Discussions

Certain stakeholders felt that waiving the requirement that state Medicaid programs cover all FDA-approved drugs is a logical and fair pathway for states to reduce costs and increase access to pharmaceuticals, noting that a state should have the same flexibility to manage its pharmacy benefit as a commercial health plan. Some stakeholders felt that the federal government does not have the authority to waive part of the MDRP, while others felt there could be a legal pathway for such action. As noted in the previous strategy, the concept of waiving one MDRP provision in isolation of others was again cited as a problematic feature given the perceived intentional linkage of existing policies. Certain stakeholders also raised concerns that the strategy could potentially limit Medicaid beneficiaries' access to pharmaceuticals and that robust policies and processes for exemptions and a meaningful and accessible appeals process should be in place and clearly communicated to beneficiaries under this strategy. Others noted that exemption policies may disproportionately affect drugs without competition, making it more challenging for states to control costs for those products. States interested in this approach agreed that these protections are critical and stressed that the objective of a waiver would not be to deny coverage but rather to prioritize the most effective medicines for beneficiaries and establish more robust channels for negotiation with pharmaceutical manufacturers. These discussions, however, were held before CMS issued its decision on the waiver proposal that Massachusetts submitted.

STRATEGY: Engage in Bulk and Pooled Purchasing

Leverage the purchasing power of one or more programs within or across states by purchasing products in bulk or in a pooled arrangement on behalf of those programs to reduce costs through negotiated discounts. This strategy would allow states to negotiate larger discounts with manufacturers by establishing leverage through collective volume. This strategy may also apply to the federal government negotiating the bulk purchase of certain drugs that could then be distributed across the states.

Bulk and pooled purchasing arrangements could be applied to Medicaid, corrections and potentially other state populations.

Key Considerations for States

Many states already use bulk and pooled purchasing arrangements to increase access to pharmaceuticals by enhancing their purchasing power through a greater commitment to volume either through the direct purchase of products or by broadening the population base. However, as with many state efforts, implementation success across states is varied, and opportunity remains to enhance the number and scope of these arrangements to better support state purchasing objectives for pharmaceuticals. These efforts may be particularly powerful for smaller states that lack significant purchasing power.

Bulk purchasing, which can also be executed through pooled arrangements, is a practice that involves buying a pharmaceutical product in bulk rather than paying for the product based on use. Buying in bulk may not work for all pharmaceutical products; factors such as expected volume, time frame and distribution channels are important considerations for determining when it may make sense to purchase a product in bulk. However, this approach may be particularly impactful in addressing public health crises, where there may be an imminent threat or need for large and quick distribution of specific products. State and federal examples of bulk purchasing exist that provide helpful guidance for how states can structure their efforts, as explained in detail below.⁶⁷

Pooled purchasing is a practice that involves aligning one or more programs within or across states to purchase pharmaceuticals together, often through a pharmacy benefit manager or other third party. Pooled purchasing can be done for all drugs in a formulary or only for select drugs or drug classes. Several multistate pooled purchasing arrangements are currently in operation, including the National Medicaid Pooling Initiative, the Top Dollar Program, the Sovereign States Drug Consortium, the Northwest Prescription Drug Consortium and the Minnesota Multistate Contracting Alliance for Pharmacy.⁶⁸

Several of these initiatives focus on Medicaid exclusively, while others focus exclusively on non-Medicaid populations. One of the primary challenges for state pooled purchasing efforts is that combining Medicaid and non-Medicaid populations into a single purchasing pool (both within and across states) can trigger Medicaid's best price requirement by lowering prices paid in non-Medicaid populations to a level that Medicaid populations across the country may not be receiving. Similarly, pooled purchasing arrangements for non-Medicaid populations are limited in the level of discount they can negotiate (despite the purchasing power they may establish) without triggering Medicaid best price. States that are interested in pooled arrangements that can be combined with a subscription financing approach or other strategies may consider whether a proposed waiver of best price would help optimize those efforts. In addition to MDRP requirements, a major challenge for many states considering pooled arrangements is the need to unify formularies, PDLs, utilization management tools and other aspects of pharmacy benefit design across unique programs to maximize the capacity of these arrangements. Unique programs that span multiple states, or even exist within one state, often have different requirements and objectives that can complicate a uniform purchasing strategy. For example, state corrections programs vary in the degree of public and private purchasing. A recent study by The Pew Charitable Trusts provides a national snapshot of pharmaceutical purchasing arrangements for corrections across states.⁶⁹

Massachusetts serves as a good example for how a state can use both pooled and bulk purchasing.⁷⁰ In 1992, the commonwealth established its State Office for Pharmacy Services (SOPS) to integrate pharmacy services across its departments of Public Health, Mental Health, Developmental Services and Corrections. Since then, SOPS has grown to incorporate additional state agencies and now provides for all aspects of budgeting and purchasing for pharmacy services.⁷¹ In 2015, Massachusetts established a Municipal Naloxone Bulk Purchasing program within SOPS that involved the establishment of a Bulk Purchase Trust Fund that allows the office to pre-pay for naloxone at a discounted rate; municipalities can then purchase the product from the commonwealth (at or sometimes below the SOPS discounted rate) on an ad hoc basis.⁷² The Bulk Purchase Trust Fund has several revenue sources in addition to direct payments from municipalities that participate in the program. To pursue a similar approach, states would likely need to pass authorizing legislation for the development of a dedicated trust fund.

A version of Massachusetts' Municipal Naloxone Bulk Purchasing program exists at the federal level for vaccines wherein the federal government negotiates the bulk purchase of certain vaccines directly from manufacturers.⁷³ The vaccine products are then shipped to states, which distribute them to participating health care providers, who administer the vaccines and agree not to charge for the products. It is unclear whether federal agencies have existing authority to administer this type of program for nonvaccine drugs or if it would require an act of Congress.⁷⁴ States interested in this approach may consider engaging the federal government in dialogue about the potential viability of this strategy.

Notable Takeaways from Stakeholder Discussions

Given that states already use this strategy as a mechanism to more effectively purchase pharmaceuticals, stakeholders universally agreed that the strategy is within states' authority and can serve as a tool for price negotiations. Stakeholder discussions focused on the potential for states to further use bulk and pooled purchasing in new and expanded ways that may require federal approval or other actions, such as arrangements that include Medicaid and other populations. Some stakeholders noted the potential for negotiation of bulk purchase arrangements across multiple manufacturers and the use of a narrow federal waiver to enable bulk purchasing of certain products across populations without triggering best price. One concern raised by certain stakeholders was the level of risk a state may undertake if it becomes the owner and distributor of a product through a bulk purchasing arrangement. Other stakeholders, however, noted that states can mitigate risk by committing to a certain invoice level versus acquiring the product directly.

There were differing views on the effectiveness of pooled purchasing initiatives. Some felt that health plans and pharmacy benefit managers have significant market leverage but are still unable to secure significant discounts; others noted that enhanced size and scale of purchasing arrangements has contributed to highly successful negotiations on price. Several stakeholders expressed interest in federal involvement in the bulk purchase of certain drugs, particularly in regard to the opioid crisis.

STRATEGY: Maximize Discounts for the Incarcerated Population Through the 340B Drug Discount Program

Increase discounts for prescription drugs for the incarcerated population by contracting for the provision of those health care services by covered entities under the 340B Program, where applicable. This strategy would allow state prisons and jails to obtain a minimum discount of 23.1 percent for most brand-name prescription drugs purchased through the program.

In the NGA Center Health Division project, discussions of the 340B Program focused exclusively on the incarcerated population. States interested in a comprehensive approach to addressing public health crises may want to consider additional strategies that target Medicaid and potentially other state populations.

Key Considerations for States

The 340B Program, administered by the Health Resources & Services Administration, ensures a certain level of discounts on outpatient drugs for eligible providers, referred to as "covered entities."⁷⁵ The 340B Program covered entities include hospitals, certain federal grantees, the Indian Health Service and other providers that serve a disproportion-

ate share of low-income or uninsured patients.⁷⁶ To have their drugs covered by Medicaid, pharmaceutical manufacturers must offer 340B Program discounts to covered entities, which serves as a powerful incentive for their participation in the program.⁷⁷

Although correctional facilities do not qualify as covered entities under 340B, they can partner with 340B Program covered entities to provide services to inmates and obtain the discounted price offered under the program by complying with rules to ensure that the covered entity is the true provider of care for a given patient versus simply a pass-through for the purchase of medicines.⁷⁸ Rules include that the entity must have an established relationship with a patient, such as a health care record, and that the individual receive services beyond dispensing of drugs from a provider employed by the entity, among others.⁷⁹

Sixteen states currently use the 340B Program for purchasing and providing care related to certain drugs.⁸⁰ In a recent report issued by The Pew Charitable Trusts, state departments of corrections that reported using the 340B Program noted that they typically restrict use to individuals with expensive-to-treat diseases, such as HCV, HIV/AIDS or hemophilia, because complying with 340B Program rules can be complex and costly, potentially mitigating the ability to achieve savings.⁸¹ For instance, because care must be provided at the 340B Program covered entity or through teleconsultation, prisons that lack teleconsultation capabilities and are located long distances from covered entities may have to dedicate significant resources to facilitate transportation, security and other functions critical to ensuring safe transitions.⁸² States considering this approach must fully understand the requirements under the 340B Program to ensure compliance and should conduct careful analyses of which products or drug classes they could effectively purchase through the 340B Program as well as how new expenses may offset savings from the 340B Program to maximize resources.

Notable Takeaways from Stakeholder Discussions

Most stakeholders agreed that correctional facilities' use of the 340B Program, assuming that they meet the requirements of the program, is an appropriate and viable strategy for states. Certain stakeholders commented on the feasibility of the strategy in certain states where transportation to and from covered entities or the use of telemedicine may be difficult. Notably, many stakeholders raised concerns about the use of the 340B Program more broadly than corrections, noting that significant abuses of the program have been uncovered in other settings. Certain stakeholders cautioned that states should be aware and attentive to the possibility of federal action or other implications for the program overall given existing concerns. They noted that congressional hearings have been held to better understand the function and oversight of the program and that members of Congress have introduced legislation aimed at closing loopholes and preventing abuses. In raising these concerns, however, stakeholders acknowledged that the corrections population would be an appropriate extension of the 340B Program, assuming that all requirements were met.

STRATEGY: Determine and Pay Value-Based Prices

Determine and pay value-based prices for pharmaceutical treatments by incorporating value assessments, which could include a variety of methodologies and metrics, into policies and purchasing approaches within and across state health programs. This approach would enable states to use evidence and standard methodologies to assess and render payment for products that reflect their contribution to health and wellness in the context of existing health system structures.

Value-based prices could apply to Medicaid, corrections and potentially other state populations.

Key Considerations for States

Many countries use value-based prices to determine payment for pharmaceuticals and other health services. The United Kingdom, Canada and Australia, for example, all use a quality-based life-year (QALY) formula in cost-utility analyses as the measure of health benefits of interventions and to compare the value of different medicines.⁸³ QALYs assess the effect of a given treatment on how long a patient will live multiplied by their quality of life in remaining years using that treatment.⁸⁴ The QALY approach combines two factors — (1) how much the treatment would extend a patient's life and (2) how much it would improve its quality — into a single measure of all the potential benefits of the treatment under assessment.⁸⁵

In the United States, the Patient Protection and Affordable Care Act explicitly instructed the Patient-Centered Outcomes Research Institute, the entity tasked with comparative effectiveness research to inform value-based care, not to develop a threshold for value (such as QALY).⁸⁶ To inform the value discussion with concrete information, however, nongovernmental institutions and academic scholars have been actively working to develop comprehensive approaches to value-based pricing for pharmaceuticals and other health services. For states considering this strategy, determining which value-based methodologies or metrics to use may be challenging given various interpretations and strongly held convictions in the quantification of value in health care. The field is evolving, but relying on existing standards, considering ranges when taking a quantitative approach and methodological transparency will be important for ensuring that decisions are evidence-based and concerns mitigated.

Several existing efforts to quantify value target specific conditions, such as cancer or heart disease.⁸⁷ One such effort, not exclusively targeted to pharmaceuticals, is that

of the Institute for Clinical and Economic Review (ICER).⁸⁸ As part of its work in this space, ICER has developed a value framework that provides considerations for metrics to establish a value-based price for pharmaceuticals in addition to budget considerations.⁸⁹ ICER's framework includes population-level analyses and incorporates metrics to address both long-term value for money and short-term affordability.⁹⁰ Details about ICER's framework and methodological approach as well as its process for engaging stakeholders and incorporating feedback is available on the organization's website.⁹¹

For states to determine and pay value-based pharmaceutical prices, changes in state programs such as Medicaid would likely be necessary. In addition, to use value-based methodologies effectively, states must have leverage to ensure that manufacturers adhere to a value-based price. For instance, a state could mandate adherence to a value-based price across all state programs or the entire state. Such action may also have implications for the MDRP's best price requirement and may require federal approval of a Section 1115 waiver, if the price in a non-Medicaid program were below the price offered through Medicaid programs. States could also combine this approach with bulk or pooled purchasing initiatives that offer enhanced leverage through collective volume. Essentially, a value-based price is a tool that states can use to establish evidence-informed policies or ground negotiations in an array of purchasing approaches.

Ultimately, any state that seeks to determine and pay value-based prices for pharmaceuticals should understand that it will take significant time to develop effective and palatable metrics that it can implement effectively. This approach will not likely work for more immediate public health crises but could help position a state to better address access and cost challenges related to future crises. States interested in pursuing this strategy must also consider possible political hurdles (which may be more or less challenging in individual states) to the government determining value for pharmaceuticals.

Notable Takeaways from Stakeholder Discussions

A majority of stakeholders felt that establishing and shifting to value-based pricing is a difficult endeavor that will require significant expertise, resources and political will. Although most stakeholders agreed that determining value is difficult, a number noted that ICER has established a useful framework that can serve as a meaningful and important starting point for ongoing discussions of value-based pricing metrics and methodologies. Others, however, expressed strong disagreement with ICER's methodology. Several stakeholders discussed the challenges in accounting for time horizons associated with return on investment that reflect real-world affordability concerns of states and other health care payers.

STRATEGY: Explore Whether the Federal Government Would Invoke Section 1498

Explore whether the federal government would invoke section 1498, which allows them to use or acquire patents (such as those for pharmaceuticals) without permission from the patent holder in exchange for “reasonable and entire” compensation for such use.⁹² This strategy would allow the federal government to quickly develop and distribute pharmaceutical products at lower prices to help solve public health crises.

The federal government invoking section 1498 could apply to Medicaid, corrections and potentially other state populations.

Key Considerations for States

States considering this approach will need to have a clear understanding of the precedent for use of section 1498 and the authority and actions necessary at the federal level to invoke it. Further, states may consider whether to pursue this approach collectively, across several states or individually.

The federal government, including the U.S. Department of Defense (DoD), the U.S. Department of the Treasury and the U.S. Army Corps of Engineers, has used section 1498 to use or acquire patented technologies, such as waste-removal techniques, night vision goggles and electronic passport verification.⁹³ The government most prominently used section 1498 for the purchase of pharmaceuticals in the 1960s, with some sources citing that the authority was used by DoD for roughly 50 pharmaceutical products in a three-year period.⁹⁴ A relatively small body of case law clarifies the application of section 1498 to pharmaceutical patents, however, because many of the cases regarding compensations were settled before going to judgement. For largely unknown reasons, the use of section 1498 for pharmaceuticals declined after the 1960s; since then, it has been considered a strategy to obtain a pharmaceutical patent only once — in 2001, when DoD considered invoking it to acquire the patent for anthrax vaccinations (which ultimately it did not pursue).⁹⁵

Federal statutes and case law do not name specific federal authorities with the purview to invoke section 1498. If the federal government did decide to invoke it and use a patented product, a manufacturer’s only recourse would be to take action against the United States in the Court of Federal Claims for the recovery of “reasonable and entire compensation” for use of the patented product. It is unclear how the court would determine “reasonable and entire compensation” to a pharmaceutical patent holder, however, previous settlements have not typically measured compensation based on lost profits

to a patent holder but rather on potential government savings and compensation for the cost of research and development.⁹⁶ Importantly, for states considering this strategy, case law also makes it clear that patent holders can only take action against the “United States” for payment of reasonable and entire compensation and may not take action against other entities for inducing federal action.⁹⁷

There are undoubtedly significant political challenges to this strategy given the level of precedent involved and the need for federal action. However, several participants of NGA’s project noted that the need to address public health crises quickly and efficiently may warrant consideration of such an action.

Notable Takeaways from Stakeholder Discussions

Stakeholders agreed that this strategy would set significant precedent for government intervention in the pharmaceuticals market. Certain stakeholders were unconditionally opposed to this strategy and felt that it would have a detrimental effect on innovation; others were not opposed to the approach but questioned the likelihood of such action at the federal level.

STRATEGY: Pursue Legal + Regulatory Options to Foster Greater Transparency in the Pharmaceutical Market

Foster greater transparency in the pharmaceutical market by pursuing state laws and regulations that require manufacturers and others in the pharmaceutical supply chain, such as wholesalers, health plans, pharmacy benefit managers and pharmacies, to publicly report details on prices, price changes, research and development, business relationships, marketing and advertising costs and other information needed to inform policy and the public.

Transparency efforts could apply to Medicaid, corrections and potentially other state populations.

Key Considerations for States

States pursuing this strategy would need to establish clear policy objectives for enhanced transparency, pass legislation and develop and implement regulations inherent to achieving those goals. Many policy considerations are related to the development of legislation and regulation, including (1) determining the data needed to achieve policy aims; (2) determining which information can legally be shared; (3) establishing reporting and other requirements to obtain necessary data, including thresholds or other qualifying factors that would trigger reporting; (4) identifying stakeholders that new requirements would affect and establishing processes for engaging them in the development of regulations; (5) building or using existing data governance, standards and infrastruc-

ture to efficiently and securely receive data; and (6) determining how data will be used and made public to achieve policy aims.

States considering this approach should also consider whether and when such efforts would ultimately affect price. Transparency efforts could have an immediate impact on price by discouraging price increases, high launch prices or supplier behavior that drives up costs, but much is unknown about how impactful these policies will be at spurring voluntary changes in the market. Therefore, transparency efforts that are not directly tied to or implemented in conjunction with other policies (such as a lawsuit by an attorney general or a fine for dramatic increases) may not, in and of themselves, change pharmaceutical pricing dynamics. However, the information disclosed as part of transparency efforts may be an important step in helping generate support for additional policies to more immediately address drug costs. The value in generating interest among the public and other audiences will likely depend heavily on how the information is made available, including the forum and how it is communicated. Given these considerations, transparency efforts would likely be most useful in positioning states to better address future public health crises or in conjunction with other strategies (such as the Medicaid spending cap for pharmaceuticals) to address more immediate crises by identifying and mitigating persistently high-cost drugs or increases in drug prices that push spending above a certain threshold.

Over the past several years, states have introduced an array of legislation aimed at fostering greater price transparency for pharmaceuticals.⁹⁸ These efforts can provide guidance to states interested in similar policies. Legislative efforts have varied in scope regarding the information sought and the stakeholders that would be affected (such as manufacturers, pharmacy benefit managers, pharmacies or payers). State legislation focused on price transparency for pharmaceuticals has included but not been limited to (1) reporting, collection, and public display of pharmaceutical prices, including wholesale acquisition cost; (2) manufacturer reporting on planned price increases or launch prices over a certain threshold; (3) justification for manufacturer price increases or launch prices over a certain threshold; (4) health plan reporting on costs and utilization of pharmaceuticals; and (5) mandating or removing barriers for pharmacists to inform consumers of lowest cost alternatives. Fourteen state laws focused on price transparency for pharmaceuticals were passed in 2017 and early 2018, and nearly 40 additional bills are currently pending in states.⁹⁹ One important lesson already emerging from recent efforts across states is that transparency legislation may result in legal action by certain stakeholders. States will need to consider the time and resources necessary to respond to such potential litigation. Another emerging consideration based on existing state efforts is the level to which the uniformity of data collected and associated policy levers may aid implementation across states and send consistent signals to key stakeholders. States considering this approach would likely benefit from coordinating with their counterparts in other states that have already undertaken similar approaches to understand the strategy and lessons learned from implementation.

Notable Takeaways from Stakeholder Discussions

Many stakeholders felt that price transparency is a critical component of an effective

approach to addressing pharmaceutical costs and access but is not sufficient in itself to solve existing challenges. They noted that transparency and a greater understanding of existing business dynamics are paramount to building trust among entities and ensuring the development of strategies that can reliably ensure access to innovation while maintaining fiscal sustainability. Several stakeholders noted that efforts to foster transparency should apply to all players in the pharmaceutical market, including not only manufacturers but also insurers, distributors, suppliers and providers. Certain stakeholders also recommended that states consider the implementation burden and impact ratio when designing transparency efforts.

These stakeholders questioned whether states would have the capacity to use the information collected and whether this strategy would result in increased cost for those subject to reporting requirements.

STRATEGY: Explore Whether the Federal Government Would Allow Nominal Pricing for Correctional Facilities

Explore whether the secretary of HHS would include state and local correctional facilities among the safety net providers exempt from the best price requirement of the MDRP, which would create the regulatory conditions necessary for state and local governments to negotiate nominal prices (less than 10 percent of the average manufacturer price) for those populations.¹⁰⁰

As discussed in NGA's project, this nominal pricing approach focuses exclusively on the corrections population. States interested in a comprehensive approach to addressing public health crises may want to consider additional strategies that target Medicaid and potentially other state populations.

Key Considerations for States

For this approach to succeed, two key actions must occur: (1) The secretary of HHS must approve the use of nominal pricing by state prisons and local jails by determining that correctional facilities are "safety net providers" within the meaning of the MDRP statute, and (2) manufacturers must agree to nominal pricing for correctional facilities. If the secretary deems that correctional facilities are safety net providers under the MDRP statute, the statute would allow but not require nominal pricing arrangements in these settings that would not trigger the MDRP best price requirement.¹⁰¹ Given that there would be no requirement for such arrangements, the success of the strategy also depends on manufacturers agreeing to nominal prices in these settings. The likelihood of either of these actions is unclear.

The secretary's willingness to approve the use of nominal pricing in correctional settings may depend on the number of states requesting such action and the rationale they provide. It may also depend on whether a particular administration is focused on this issue and political dynamics. The willingness of manufacturers to agree to nominal prices in correctional settings may depend on the level of volume they can expect under such arrangements. There may be interest among manufacturers because for certain drugs, such as new treatments for HCV, correctional settings represent a largely untapped market. Because the broader market demands a much higher price, however, the nominal arrangement (price times volume) would likely need to yield revenue for a manufacturer that exceeds what they would otherwise expect in these settings over a certain period of time. Should the secretary grant approval, states interested in this approach should carefully analyze their incarcerated population to set parameters for negotiation with manufacturers. States would also need to understand and implement strategies to overcome capacity and other service-level challenges in their prisons and local jails that may impede the ability to expand access quickly.

Notable Takeaways from Stakeholder Discussions

Many stakeholders agreed that significant uncertainty exists about the viability of this strategy, including whether the secretary or manufacturers would take the steps necessary for successful implementation. Some stakeholders signaled openness to discussions with certain states about the possibility of nominal arrangements for correctional facilities, while others signaled a lack of interest in this approach.

CONCLUSION

Governors and state leaders are committed to taking action to address public health crises that affect the health and well-being of their residents. Evidence-based pharmaceutical interventions are often critical to addressing those crises but can sometimes create fiscal challenges that inhibit states' ability to ensure access. Through the NGA Center Health Division project, states, national experts and an array of stakeholders weighed in on potential strategies to help solve the challenge of balancing access and cost in the event of public health crises. Identified strategies vary in their applicability and appeal to every state but serve as a comprehensive set of options for states to consider. Indeed, all participating states indicated that a comprehensive set of options is warranted. The strategies presented in this paper are not an exhaustive representation of the options available to states. In fact, recent activity in states has signaled interest in other approaches, such as importing drugs from other countries or aligning Medicaid drug purchasing approaches with other federal programs such as the U.S. Department of Veterans Affairs, which may also be viable avenues for addressing access and cost of pharmaceuticals to help respond to current or future public health crises.

As this paper highlights, states can and will likely need to consider multiple strategies together to address needs across populations and programs. A majority of the strategies also rely on engagement and partnership across an array of stakeholders, including the federal government, manufacturers, insurers and others. The feasibility of reaching agreement with the federal government and manufacturers varies depending on the strategy and what a state may want to achieve. States participating in NGA's project agreed that to ensure robust access to critical pharmaceutical interventions in the event of public health crises, all parties must come to the table and be part of the solution. Multi-stakeholder involvement is also critical to ensuring that strategies are not considered in a vacuum. Given the complex supply, distribution and payment system for pharmaceuticals, it is important that states and others understand the broader implications of policy decisions — for example, whether implementation of a strategy to lower costs for the Medicaid population may result in higher costs for other populations in a state, potentially hindering collective efforts to address a crisis.

Ultimately, the focus of the NGA Center Health Division project as outlined in this paper is only one piece of a much larger puzzle: the vast and complex pharmaceutical sector and how it fits in continued efforts to move the health system to one that improves the health of all Americans and reins in unsustainable cost growth. This broader scope is reflected in dialogue taking place across the country, perhaps most notably that which has been initiated by the Trump administration. Efforts at the federal level, in conjunction with state interest and that of other stakeholders, suggest that the opportunity may be ripe for collaboration on paths forward. Supporting the development and implementation of strategies that help states better address some of the nation's most pressing public health crises, such as opioid use disorder and HCV, is an essential starting point. Building these strategies now will also be critical for states to prepare for and effectively address public health crises in the future.

AUTHORS

Kate Johnson

Senior Policy Analyst
Health Division
NGA Center for Best Practices

Sandra Wilkniss

Program Director
Health Division
NGA Center for Best Practices

Hemi Tewarson

Director
Health Division
NGA Center for Best Practices

Acknowledgements

The National Governors Association Center for Best Practices (NGA Center) Health Division would like to thank the state officials who participated in its project and vetted potential strategies. The NGA Center Health Division would also like to thank the numerous stakeholders and other experts who participated in roundtable discussions and provided valuable feedback. Finally, the NGA Center would like to thank the Laura and John Arnold Foundation for its generous support of the NGA Center's work with states, which informed this paper.

Recommended citation format

Johnson, K., Wilkniss, S., Tewarson, H., *Public Health Crises and Pharmaceutical Interventions: Improving Access While Ensuring Fiscal Sustainability*. Washington, D.C.: National Governors Association Center for Best Practices, 2018.

**NGA CENTER FOR BEST PRACTICES**

444 North Capitol Street NW, Suite 267

Washington, D.C. 20001

202-624-5300

www.nga.org/center

FOOTNOTES

- ¹ Ly, K.N., Hughes, E.M., Jiles, R.B., & Holmberg, S.D. (2016). Rising mortality associated with hepatitis C virus in the United States, 2003-2013. *Clinical Infectious Diseases*, 62(10): P. 1287-1288. doi:10.1093/cid/ciw111
- ² National Association of State Budget Officers (NASBO). (2017). *Fiscal survey of states: An update of state fiscal conditions*. Retrieved from <https://www.nasbo.org/mainsite/reports-data/fiscal-survey-of-states>
- ³ National Association of State Budget Officers. (2015). *Budget processes in the states*. Retrieved from https://higherlogicdownload.s3.amazonaws.com/NASBO/9d2d2db1-c943-4f1b-b750-Ofca152d64c2/UploadedImages/Budget%20Processes/2015_Budget_Processes_-_S.pdf
- ⁴ Keehan, S. P., Stone, D. A., Poisal, J. A., Cuckler, G. A., Sisko, A. M., Smith, S. D., . . . Lizowitz, J. M. (2017). National health expenditure projections, 2016–25: Price increases, aging push sector to 20 percent of economy. *Health Affairs*, 36(3), 553–563. Retrieved from <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1627>
- ⁵ IQVIA Institute for Human Data Science. (2018). *2018 and beyond: Outlook and turning points*. Retrieved from <https://www.iqvia.com/institute/reports/2018-and-beyond-outlook-and-turning-points>
- ⁶ Augustine, N. R., Madhavan, G., & Nass, S. J. (Eds.). (2018). *Making medicines affordable: A national imperative*. Retrieved from <http://www.nationalacademies.org/hmd/Reports/2017/making-medicines-affordable-a-national-imperative.aspx>; IQVIA, 2018 and beyond.
- ⁷ Emergencies. (n.d.). Retrieved from <http://www.who.int/hac/crises/en>
- ⁸ Nelson, C., Lurie, N., Wasserman, J., Zakowski, S., & Leuschner, K. J. (2008). *Conceptualizing and defining public health emergency preparedness* (RAND Working Paper). Retrieved from https://www.rand.org/pubs/working_papers/WR543.html
- ⁹ Ibid.
- ¹⁰ Liang, J., & Ghany, M. G. (2014). Therapy of hepatitis C—back to the future. *The New England Journal of Medicine*, 370, 2043–2047. doi:10.1056/NEJMe1403619; National Governors Association (NGA). (2015). *New hepatitis C treatments: Considerations and potential strategies for states*. Retrieved from <https://classic.nga.org/files/live/sites/NGA/files/pdf/2015/1502NewHepCTreatments.pdf>
- ¹¹ Medication-Assisted Treatment (MAT). (2018, February 7). Retrieved from <https://www.samhsa.gov/medication-assisted-treatment>
- ¹² Congressional Budget Office (2007). *Prescription drug pricing in the private sector*. Retrieved from <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf>
- ¹³ Dabora, M. C., Turaga, N., & Schulman, K. A. (2017). Financing and distribution of pharmaceuticals in the United States. *Journal of the American Medical Association*, 318(1), 21–22. doi:10.1001/jama.2017.5607
- ¹⁴ Augustine et al., *Making medicines affordable*.
- ¹⁵ Ibid.
- ¹⁶ Ibid.; Oregon Health & Science University, Center for Evidence-based Policy. (2016). *Medicaid and specialty drugs: Current policy options* (Policy Brief). Retrieved from http://smart-d.org/wp-content/uploads/2016/09/MED_Medicaid_and_Specialty_Drugs_Current_Policy_Options_Final_Sept-9-2016.pdf
- ¹⁷ NASBO, *Budget processes in the states*.
- ¹⁸ IQVIA Institute for Human Data Science. (2018). *Medicine use and spending in the U.S.: A review of 2017 and outlook to 2022*. Retrieved from <https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022>; IQVIA, 2018 and beyond.
- ¹⁹ Institute for Clinical and Economic Review. (2014). *The comparative clinical effectiveness and value of simeprevir and sofosbuvir in the treatment of chronic hepatitis C infection: A technology assessment*. Retrieved from https://icer-review.org/wp-content/uploads/2016/02/CTAF_Hep_C_Apr14_final.pdf
- ²⁰ IQVIA, *Medicine use and spending in the U.S.*; IQVIA, 2018 and beyond.
- ²¹ Social Security Administration. (n.d.). Payment for covered outpatient drugs. Retrieved from https://www.ssa.gov/OP_Home/ssact/title19/1927.htm
- ²² Ibid.
- ²³ Ly et al., *Rising mortality*.
- ²⁴ Centers for Disease Control and Prevention. (2017, December 21). *Increase in hepatitis C infections linked to worsening opioid crisis* [Press release]. Retrieved from <https://www.cdc.gov/nchhstp/newsroom/2017/hepatitis-c-and-opioid-injection.html>
- ²⁵ Hill, A. M., Nath, S., & Simmons, B. (2017). The road to elimination of hepatitis C: Analysis of cures versus new infections in 91 countries. *Journal of Virus Eradication*, 3(3), 117–123. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518239>
- ²⁶ NGA, *New hepatitis C treatments*.
- ²⁷ America's Health Insurance Plans. (2016). *Orphan drug utilization and pricing patterns* (2012–2014) (Data Brief). Retrieved from <https://www.ahip.org/orphan-drug-utilization-and-pricing-patterns-2012-2014>
- ²⁸ Centers for Medicare and Medicaid Services. (2018, February 14). *CMS Office of the Actuary releases 2017–2026 projections of national health expenditures* [Press release]. Retrieved from <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-02-14.html>; Medicaid and CHIP Payment and Access Commission. (2016, January). *Medicaid spending for prescription drugs*. Retrieved from <http://www.macpac.gov/publication/medicaid-spending-for-prescription-drugs>
- ²⁹ Based on data NGA collected from a sample of states.
- ³⁰ Johnson, R. L., Blumen, H. E., & Ferro, C. (2015). *The burden of hepatitis C virus disease in commercial and managed Medicaid populations*. Retrieved from <http://www.milliman.com/uploadedFiles/insight/2015/milliman-hcv-burden.pdf>; Spaulding, A. C., Anderson, E. J., Khan, M. A., Taborda-Vidarte, C. A., & Phillips, J. A. (2017). HIV and HCV in U.S. prisons and jails: The correctional facility as a bellwether over time for the community's infections. *AIDS Review*, 19(3), 134–147.
- ³¹ NGA, *New hepatitis C treatments*.
- ³² For a complete discussion of “specialty medicines” as defined by IQVIA, go to <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf>.
- ³³ IQVIA, *Medicine use and spending in the U.S.*
- ³⁴ IQVIA, 2018 and beyond.
- ³⁵ Center for Evidence-based Policy, *Medicaid and specialty drugs*.
- ³⁶ Pharmaceutical Research and Manufacturers of America (PhRMA). (2017). *The biopharmaceutical pipeline: Innovative therapies in clinical development*. Retrieved from <https://www.phrma.org/report/the-biopharmaceutical-pipeline>; Lotvin, A. (2017). A robust

and evolving specialty pipeline: Eight first-in-class, seven breakthrough drugs among those approved in 2016. Retrieved from <https://payorsolutions.cvshealth.com/insights/a-robust-and-evolving-specialty-pipeline>

³⁷ PhRMA, *The biopharmaceutical pipeline*.

³⁸ Ibid.

³⁹ U.S. Food and Drug Administration. (2018, March 28). Frequently asked questions: Breakthrough therapies. Retrieved from <https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendments-to-the-FDCA/FDASIA/ucm341027.htm>

⁴⁰ Ibid.

⁴¹ U.S. Department of Health and Human Services, Food and Drug Administration Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research. (2014). *Guidance for industry: Expedited programs for serious conditions—drugs and biologics*. Retrieved from <https://www.fda.gov/downloads/Drugs/Guidances/UCM358301.pdf> (accessed June 1, 2018); Darrow, J. J., Avorn, J., & Kesselheim, A. S. (2018). Breakthrough-drug designation—four years of experience. *The New England Journal of Medicine*, 378, 14444-1453. Retrieved from <https://www.nejm.org/doi/full/10.1056/NEJMhpr1713338>; Chambers, J. D., Thorat, T., Wilkinson, C. L., & Neumann, P. J. (2017). Drugs cleared through the FDA's expedited review offer greater gains than drugs approved by conventional process. *Health Affairs*, 36(8). doi:10.1377/hlthaff.2016.1541

⁴² IQVIA, *Medicine use and spending in the U.S.*

⁴³ Ibid.

⁴⁴ UnitedHealth Center for Health Reform & Modernization. (2014). *The growth of specialty pharmacy: Current trends and future opportunities* (Issue Brief). Retrieved from <http://www.united-healthgroup.com/-/media/UHG/PDF/2014/UNH-The-Growth-Of-Specialty-Pharmacy.ashx>

⁴⁵ Centers for Disease Control and Prevention. (2017, August 30). Opioid overdose: Understanding the epidemic. Retrieved from <https://www.cdc.gov/drugoverdose/epidemic/index.html>

⁴⁶ Ibid.

⁴⁷ National Governors Association (2016, July 13). *Governors sign compact to fight opioid addiction* [Press release]. Retrieved from <https://www.nga.org/news/governors-sign-compact-to-fight-opioid-addiction>; U.S. Department of Health and Human Services, Office of the Surgeon General. (n.d.). Surgeon general's advisory on naloxone and opioid overdose. Retrieved from <https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html>

⁴⁸ Gupta, R., Shah, N. D., & Ross, J. S. (2016). The rising price of naloxone—risks to efforts to stem overdose deaths. *The New England Journal of Medicine*, 375, 2213–2215. Retrieved from <https://www.nejm.org/doi/full/10.1056/NEJMp1609578>

⁴⁹ Ibid.

⁵⁰ Ibid.

⁵¹ Ibid.

⁵² National Safety Council. (2018, January 17). *Accidental injury becomes #3 cause of death for the first time in U.S. history* [Press release]. Retrieved from <https://www.nsc.org/in-the-newsroom/accidental-injury-becomes-3-cause-of-death-for-the-first-time-in-us-history-2>; Centers for Disease Control and Prevention, National Center for Health Statistics. (2017, March 17). Accidents or unintentional injuries. Retrieved from <https://www.cdc.gov/nchs/fastats/accidental-injury.htm>

⁵³ The Menges Group. (2018). *Historical naloxone use in Medicaid*. Arlington, VA: The Menges Group.

⁵⁴ Ibid.

⁵⁵ Ibid.

⁵⁶ Farmer, L. (2018, June 4). How to calculate what opioid overdoses cost government. *Governing the States and Localities*. Retrieved from <http://www.governing.com/topics/finance/gov-opengov-opioid-overdose-deaths-cost-governments.html>.

⁵⁷ Vizient. (2017). *Drug price forecast executive summary July 2017*. Retrieved from http://newsroom.vizientinc.com/sites/vha.newshq.businesswire.com/files/doc_library/file/VZT_Drug_Price_Forecast_July_2017_Condensed-v2.pdf; Jaret, P. (2015, July/August). Prices spike for some generic drugs. *AARP Bulletin*. Retrieved from <https://www.aarp.org/health/drugs-supplements/info-2015/prices-spike-for-generic-drugs.html>; U.S. Government Accountability Office (GAO). (2016). *Generic drugs under Medicare: Part D generic drug prices declined overall, but some had extraordinary price increases* (Report No. GAO-16-706). Retrieved from <https://www.gao.gov/assets/680/679022.pdf>

⁵⁸ Cha, A. E. (2016, August 23). U.S. lawmakers demand investigation of \$100 price hike of lifesaving EpiPens. *The Washington Post*. Retrieved from https://www.washingtonpost.com/news/to-your-health/wp/2016/08/23/u-s-lawmakers-demand-investigation-of-100-price-hike-of-life-saving-epipens/?utm_term=.b835c7a5b8d7; Lorenzetti, L. (2015, September 21). This 62-year-old drug just got 5,000% more expensive. *Fortune*. Retrieved from <http://fortune.com/2015/09/21/turing-pharmaceuticals-drug-prices-daraprim>

⁵⁹ GAO, *Generic drugs under Medicare*.

⁶⁰ Medicaid.gov. (n.d.). Unit rebate amount calculation for single source or innovator multiple source drugs. Retrieved from <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/s-or-i-drug-products/index.html>

⁶¹ The White House. (2018, May 11). *President Donald J. Trump's blueprint to lower drug prices* (Fact Sheet). Retrieved from <https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices>

⁶² Medicaid.gov. (n.d.). Drug Utilization Review. Retrieved from <https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/index.html>; NGA, New hepatitis C treatments.

⁶³ Sood, N., Ung, D., Shankar, A., & Strom, B.L. (2018). A novel strategy for increasing access to treatment for Hepatitis C virus for Medicaid beneficiaries. *Annals of Internal Medicine*, 169(2), 118-119. Retrieved from <http://annals.org/aim/article-abstract/2681481/novel-strategy-increasing-access-treatment-hepatitis-c-virus-infection-medicaid>

⁶⁴ Ibid.

⁶⁵ Centers for Medicare & Medicaid Services. Letter to Daniel Tsai, assistance secretary, MassHealth. (2018, June 27). Retrieved from <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma-ma-masshealth-ca.pdf>

⁶⁶ Oregon Health & Science University, Center for Evidence-based Policy. (2016). *State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)* (Legal Brief). Retrieved from <http://smart-d.org/wp-content/uploads/2016/09/SMART-D-Legal-Report-Sept-13-2016.pdf>

⁶⁷ National Council of State Legislators (NCSL). (2018, May 31). Pharmaceutical bulk purchasing: Multi-state and inter-agency plans. Retrieved from <http://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx>; National Academy for State Health Policy (NASHP). (2016). *States and the rising cost of pharmaceuticals: A call to action*. Retrieved from <https://nashp.org/states-rising-cost-pharmaceuticals-call-action>

⁶⁸ NCSL, *Pharmaceutical bulk purchasing*.

⁶⁹ PEW Charitable Trusts. (2017). *Pharmaceuticals in state prisons: How departments of corrections purchase, use, and monitor prescription drugs*. Retrieved from <http://www.pewtrusts.org/en/research-and-analysis/reports/2017/12/pharmaceuticals-in-state-prisons>

⁷⁰ Ibid.

- ⁷¹ Mass.gov. State Office for Pharmacy Services (SOPS). (2018). Retrieved from <https://www.mass.gov/service-details/state-office-for-pharmacy-services-sops>
- ⁷² Mass.gov. (2018). Information for municipalities, state agencies, and first responder departments: Additional naloxone resources and information. Retrieved from <https://www.mass.gov/service-details/information-for-municipalities-state-agencies-and-first-responder-departments>
- ⁷³ NASHP, *States and the rising cost of pharmaceuticals*.
- ⁷⁴ Ibid.
- ⁷⁵ Health Resources & Services Administration. (2018, July). 340B Drug Pricing Program. Retrieved from <https://www.hrsa.gov/opa/index.html>; Center for Evidence-based Policy, *Medicaid and specialty drugs*.
- ⁷⁶ Health Resources & Services Administration. (2018, May). 340B eligibility. Retrieved from <https://www.hrsa.gov/opa/eligibility-and-registration/index.html>
- ⁷⁷ Medicaid.gov, *Unit rebate amount calculation*; PEW Charitable Trusts, *Pharmaceuticals in state prisons*.
- ⁷⁸ Ibid.
- ⁷⁹ Ibid.
- ⁸⁰ PEW Charitable Trusts, *Pharmaceuticals in state prisons*.
- ⁸¹ Ibid.
- ⁸² Ibid.
- ⁸³ Sassi, F. (2006). Calculating QALYs, comparing QALY and DALY calculations. *Health Policy and Planning*, 21(5), 402–408. doi:10.1093/heapol/czl018
- ⁸⁴ Ibid.
- ⁸⁵ Ibid.
- ⁸⁶ Neumann, P. J., & Weinstein, M. C. (2010). Legislating against use of cost-effectiveness information. *The New England Journal of Medicine*, 363, 1495–1497. Retrieved from <https://www.nejm.org/doi/full/10.1056/NEJMp1007168>
- ⁸⁷ Neumann, P. J., & Cohen, J. T. (2015). Measuring the value of prescription drugs. *The New England Journal of Medicine*, 373, 2595–2597. Retrieved from <https://www.nejm.org/doi/full/10.1056/NEJMp1512009>
- ⁸⁸ Ibid.
- ⁸⁹ Institute for Clinical and Economic Review. (n.d.). ICER Value Assessment Framework. Retrieved from <https://icer-review.org/methodology/icers-methods/icer-value-assessment-framework>
- ⁹⁰ Ibid.
- ⁹¹ What does ICER do? (n.d.). Retrieved from <https://icer-review.org>
- ⁹² Kapczynski, A., & Kesselheim, A. S. (2016, May). “Government patent use”: A legal approach to reducing drug spending. *Health Affairs*, 35(5), 791–797. Retrieved from <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2015.1120?journalCode=hlthaff>
- ⁹³ Ibid.
- ⁹⁴ Brennan, H., Kapczynski, A., Monahan, C. H., & Rizvi, Z. (2017). A prescription for excessive drug pricing: Leveraging government patent use for health. *Yale Journal of Law and Technology*, 18(1), Article 7. Retrieved from <http://digitalcommons.law.yale.edu/yjolt/vol18/iss1/7>
- ⁹⁵ Ibid.
- ⁹⁶ Ibid.
- ⁹⁷ Ibid.
- ⁹⁸ National Academy for State Health Policy. (2018, June 22). State legislative action to lower pharmaceutical costs. Retrieved from <https://nashp.org/state-legislative-action-on-pharmaceutical-prices>
- ⁹⁹ Ibid.
- ¹⁰⁰ Spaulding, A. C., Adee, M. G., Lawrence, R. T., Chhatwal, J., & von Oehsen, W. (2018). Five questions concerning managing hepatitis C in the justice system: Finding practical solutions for hepatitis C virus elimination. *Infectious Disease Clinics of North America*, 32(2), 323–345. doi:10.1016/j.idc.2018.02.014
- ¹⁰¹ Ibid.



NGA CENTER FOR BEST PRACTICES
444 North Capitol Street NW, Suite 267
Washington, D.C. 20001
202-624-5300
www.nga.org/center