

Medicaid and Specialty Drugs: Current Policy Options

Policy Brief

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Objective

To describe Medicaid policy options available to states for managing prescription specialty drugs, focusing on: drug payment and pricing strategies, utilization management, and managed care.

Introduction

Prescription drug costs are the fastest growing segment of U.S. health care spending. With the continued release of new and innovative therapies, state Medicaid programs are under increasing pressure to provide access to these drugs, while managing competing priorities and program budgets. As states' recent experiences with new hepatitis C drugs illustrate, soaring costs of specialty drugs have exceeded Medicaid budgets, forcing state agencies to request additional funding from their legislatures, straining allocation of public resources, and putting other programs at risk.

Faced with this challenge, state Medicaid programs are in need of policy options to manage costs and ensure beneficiary access to effective and safe specialty medications. Under the federal Medicaid Drug Rebate Program (MDRP), states have access to rebates that have historically helped to control outpatient prescription drug spending. In exchange, however, state Medicaid programs must cover all drugs produced by manufacturers who have signed federal rebate agreements. For new, high-cost specialty therapies with few or no competitors, states have raised concern that federal rebate requirements hinder states' ability to negotiate drug pricing and coverage (National Association of Medicaid Directors [NAMD], 2016).

Given these concerns, this report reviews current state strategies to manage specialty drugs, and considers how coverage of new drugs entering the market is driving the need for policy changes. The report focuses on state policy options in three major areas:

- Medicaid drug payment and pricing strategies
- Utilization management
- Managed care coverage of specialty drugs

States highlighted throughout the report illustrate a diversity of state approaches in each of these areas.

Report Methods and Terms

This report is based on a review of federal and state laws and policies, policy literature, and interviews with state Medicaid pharmacy directors and managers. States interviewed were selected to represent a range of Medicaid program sizes and structures, representing both fee-for-service (FFS) and managed care delivery models (See Table 1). See Appendix A for detailed report methods.

Pharmacy policy is a topic involving many acronyms and specialized terms. As a general reference, Appendix B defines acronyms and terms used throughout this report.

Table 1. States' Program Size and Structure

| State | Program Size | FFS | Managed Care |
|----------------|------------------|------|-----------------|
| Idaho | ~282,000 | 100% | |
| New York | ~6.2 million | 25% | 75% |
| North Carolina | ~1.9 million | 100% | |
| Oklahoma | ~ 787,000 | 100% | |
| Pennsylvania | ~ 2.8 million | 20% | 80% |
| Texas | ~ 4.7 million | 15% | 85% |

Current Medicaid Policy Strategies and Key Takeaways

States' experiences with managing high-cost specialty drugs reflect key components of effective management strategies for Medicaid populations, as well as the limits of existing policy tools. This section reviews key strategies and takeaways from current state efforts to manage specialty drugs in three focus areas: drug payment and pricing, utilization management, and coverage of prescription drug benefits through managed care plans.

Drug Payment and Pricing Strategies

- High-cost specialty drugs have underscored the limits of the MDRP as a tool for controlling Medicaid prescription drug costs. In exchange for entering into a national rebate agreement with the Secretary of Health and Human Services (DHHS), manufacturers are assured Medicaid coverage of their drugs (Social Security Act, Section 1927). Although historically the MDRP has helped to reduce Medicaid drug costs, state Medicaid policymakers are increasingly concerned that the program's coverage requirements hinder states' ability to effectively negotiate pricing and coverage of newer specialty drugs, particularly those that don't have therapeutically equivalent competitors.
- Medicaid payments to pharmacies and providers for specialty and other prescription drugs are calculated based on percentages of what the pharmacies and providers pay for the drugs these formulas do not address the underlying rationale of the drug price itself. Over the last decade, legal challenges and government research have raised concern that the benchmarks used to calculate drug reimbursement amounts are significantly higher than actual amounts paid by pharmacies and providers. Most recently, in February 2016, the Centers for Medicare and Medicaid Services (CMS) released a final rule requiring states to shift to actual acquisition cost (AAC) reimbursement models for drugs provided through outpatient pharmacies. The AAC reimbursement model is based on survey data of pharmacies to determine actual costs paid for drugs.
- State Medicaid programs may seek to maximize drug savings through 340B drug prices, although limited access to the federally determined 340B ceiling prices makes 340B policy implementation administratively burdensome to implement. Most states expect entities participating in the 340B program to bill the state at the AAC for 340B drugs, which is generally lower than Medicaid drug prices. However, because 340B ceiling and sub-ceiling prices are proprietary, states must rely on post-payment reviews to determine payment accuracy. To avoid duplicate discounts, states may forgo submitting 340B drug claims for federal Medicaid rebates. Some states have developed programs to take advantage of drug pricing offered through 340B Hemophilia Treatment Centers, requiring Medicaid beneficiaries with hemophilia to receive care through these providers.

• There is growing interest among Medicaid policymakers to move toward alternative drug pricing models that reflect the underlying value a drug provides with respect to effectiveness and clinical outcomes. In March 2016, the NAMD submitted a letter to the U.S. Senate Finance Committee underscoring state Medicaid agencies' concern with the fundamental sustainability of Medicaid programs and the limits of existing policy levers to negotiate pricing for new drugs with record-breaking price tags. Prescription drugs have been left outside of value-based payment models developed for other health care services, and NAMD emphasized the need to consider the role of "value" in the prescription drug context and determination of drug price (NAMD, 2016).

Utilization Management

- States use prior authorization as a primary tool to manage high-cost specialty drugs, focusing on criteria to encourage appropriate use of the drugs, patient adherence, and discouraging waste. For newly released drugs, some states require prior authorization for an initial period to allow time to determine whether ongoing prior authorization or other tracking is needed. A number of states have limited the number of brand prescriptions that beneficiaries may fill. States' ability to prior authorize certain specialty drugs classes may also be limited by state law protecting conditions such as oncology, human immunodeficiency virus (HIV), hepatitis C, from coverage restrictions.
- In recent months, CMS issued guidance raising concerns that state prior authorization criteria in the case of hepatitis C drugs were more restrictive than allowed by federal law (CMS, 2015b). Federal law allows states to limit coverage of drugs to treatment of "medically accepted indications," defined as Food and Drug Administration (FDA)-approved indications and offlabel uses supported by certain drug compendia (Social Security Act, §1927(k)(6)). States underscored concern that the recent CMS guidance undermines state authority and well-established processes through state advisory committees and drug utilization review (DUR) boards to review evidence and make these determinations. In the case of hepatitis C drugs, states were also forced to create narrow coverage requirements based on the available medical evidence and impact of the drugs' costs on state budgets.
- Care management involving close monitoring of side effects and response to treatment is essential for optimizing patient use of specialty medications and managing costs. Many states have developed disease-specific care management programs for conditions such as hemophilia, multiple sclerosis, hepatitis C and hereditary angioedema, where patient adherence to high-cost medications is important to successful outcomes. In addition, states have developed medication therapy management programs or contracts with specialty pharmacies to assist beneficiaries with understanding and managing their health conditions and medications. States also work to link patients to broader care management services to support beneficiaries with multiple health conditions, behavioral health needs, and socioeconomic challenges such as stable housing or transportation to medical appointments.

• Clinician-administered medications often fall outside of states' (and other payers') traditional pharmacy management systems. Given the significant number of high-cost specialty drugs that are clinician-administered, states have undertaken efforts to more closely manage these drugs. Efforts include management and payment of clinician-administered medications through state pharmacy systems and expansion of pharmacy management of clinician-administered medications that continue to be billed and reimbursed as a medical benefit.

Managed Care

- States have made a significant shift of prescription drug coverage into Medicaid managed care since 2011. Managed care prescription drug spending grew from 14% of overall prescription drug spending in 2011 to 47% of overall drug spending in 2014 (Medicaid and CHIP Payment and Access Commission [MACPAC], 2016). Medicaid managed care plans generally contract with pharmacy benefit managers to manage drug benefits and negotiate prices with manufacturers and pharmacies.
- The final Medicaid managed care rules released in April 2016 reinforce CMS expectations that Medicaid managed care plans are subject to the same prescription drug coverage requirements of Section 1927 of the Social Security Act (i.e., the MDRP and prior authorization processes) as state fee-for-service (FFS) programs [42 CFR § 438.3(s); 81 Fed. Reg. 27544 (2016)]. In addition, managed care coverage requirements cannot be more stringent than state FFS standards. However, managed care plan preferred drug lists (PDL) and prior authorization clinical criteria and review requirements do not have to be identical to state FFS standards.
- States have allowed plans varied levels of control over preferred drug lists. Most states allow plans to develop independent PDLs, although some states have retained control over PDLs for some or all drug classes. A few states manage a single state PDL that plans are required to follow. This allows states to leverage drug pricing negotiation and placement on the PDL across a broader population of beneficiaries. Other states have carved out certain drug classes for the state to leverage price negotiations (Menges Group, 2014). Similar to state PDLs, managed care plan PDLs must cover all Medicaid-covered drugs, and may be used to encourage use of certain drugs over others, but not as a tool to exclude coverage entirely.
- States generally do not require plans to adopt their state FFS coverage criteria, but work to align FFS and managed care criteria. For some high-cost drugs, such as those to treat hepatitis C, some states required that plans follow the state's FFS coverage criteria. Plans have also joined state pharmacy and therapeutics committees, which has resulted in greater alignment of managed care and FFS policies. States have taken varied approaches to reviewing plan policies. Some states conduct an upfront review of all plan coverage policies prior to implementation, and other states review policies only upon request or if problems are identified through utilization review or beneficiary complaints.

• Some states are designing payment models for high-cost drugs that hold plans accountable for providing appropriate management and support to beneficiaries. In the case of hepatitis C drugs, one state included in this review reimburses plans for the drugs conditioned on submission of sustained viral response for 12 weeks (SVR-12) results for each beneficiary treated by the managed care plan. This approach has been somewhat unique in that there is a clinical outcome that can be measured and tracked, there could be ways to adapt this model to other high-cost drugs to ensure that plans are providing appropriate coverage and management of high-cost specialty drugs.

With the shift of prescription drug benefits into managed care, some states have adjusted pharmacy staffing from FFS operations to oversight of managed care plans. State pharmacists bring clinical expertise as well as in depth knowledge of program operations, which has helped states oversee plan services and respond to managed care plan requests for rate adjustments.

Background

Specialty medications are typically high-cost drugs used to treat patients with complex and serious health conditions such as cancer, autoimmune diseases, and blood disorders. Some drug advances in the last decade have offered patients life-sustaining support, but other drugs have not shown evidence of benefit over existing alternatives (Abboud et al., 2013). At the same time, drugs may cost hundreds of thousands of dollars per year and are placing enormous pressure on payers and patients to pay record-breaking price tags (NAMD, 2016).

There is no universal definition of "specialty drug". Payers and providers have developed independent lists to classify drugs within the specialty drug category. In general, specialty drugs share a number of common characteristics, including, but not limited to, treatment of serious conditions for which there are few or no alternative treatments, requiring special storage, handling, or administration, and high cost (MACPAC, 2016; CMS, 2015a). Elevated cost is a common characteristic across payer specialty drug classifications. Medicare, for example, defines specialty drugs as those costing more than \$600 per month (CMS, 2015a).

Trends in Spending on Specialty Drugs

Prescription drug spending is growing at a faster rate than overall health care spending, and projected to be a major contributor in health care spending growth. Based on National Health Expenditure Accounts data, prescription drug expenditures are projected

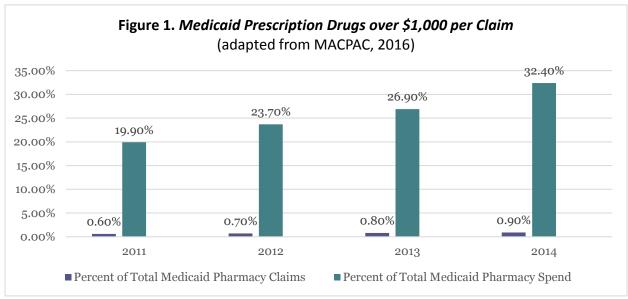
to grow at an annual rate of 7.3% between 2013 and 2018 (Office of the Assistant Secretary for Planning and Evaluation [ASPE],

2016). Specialty drug spending is projected to increase at an even faster rate with estimates of 11.8%, 13.7%, and 15.4% growth in 2016, 2017, and 2018, respectively (Express Scripts, 2016). Some estimates place the projected specialty drug cost growth rate at upwards of 19% per year (Segal Consulting, 2016).

Currently, there are 300 specialty drugs on the market, and nearly 700 specialty drugs under development. By 2020, some estimates project that specialty drug spending will comprise more than half of all drug expenditures, and 9.1% (\$400 billion) of total national health spending (PEW Charitable Trusts, 2015).

Within Medicaid programs, states are experiencing an increase in the cost and utilization of prescription drugs, with a particularly sharp increase in specialty drug expenditures. Some estimates place overall Medicaid drug spending growth at over 24% per year (MACPAC, 2016). Specialty drugs are a key driver in this spending growth. In 2014, high-cost drugs (defined as over \$1,000 per claim) accounted for 0.9% of pharmacy claims, but 32% of total Medicaid drug spending (MACPAC, 2016) (see Figure 1).

Certain drug classes, such as those to treat hepatitis C or HIV, make up the largest share of Medicaid spending on specialty drugs (Express Scripts, 2016). Table 1 details Medicaid spending and cost growth in the top



ten specialty therapy classes, as reported by Express Scripts, a pharmacy benefit manager working with Medicaid managed care plans in over 25 states. For certain specialty drug therapy classes, such as hepatitis C and HIV, Medicaid populations may have disproportionately higher rates of the disease and therefore higher utilization of these drugs.

It is important to note that the spending figures in Table 1 represent Medicaid spending on specialty drugs billed through the pharmacy benefit, and do not include spending on specialty drugs billed under the medical benefit (i.e., specialty medications administered by clinicians in clinics, hospitals, or other institutional settings). Spending on specialty drug therapy classes, such as oncology, is therefore underrepresented where a majority of drug spending may be covered under the medical benefit. In general, clinician-administered medications reimbursed through the medical benefit are estimated to comprise almost one-third (28.1%) of overall drug spending, although many estimates of prescription drug spending omit these figures (ASPE, 2016). An even

greater proportion of specialty drug spending (55%) is estimated to be reimbursed through the medical benefit.

In response to a 50-state survey of Medicaid programs, the majority of states identified specialty and other high-cost drugs as a significant cost driver within their programs, including several specific drug classes (i.e., hepatitis C, oncology drugs, cystic fibrosis agents, hemophilia factor) (Smith et al., 2015). In fiscal years 2015 and 2016, approximately 29 states reported policy actions targeting specialty prescription drugs, such as implementation of prior authorization requirements, negotiation of lower drug prices, and standardization of managed care and FFS clinical criteria (Smith et. al., 2015).

Table 1. Medicaid Specialty Drug Therapy Class Growth in 2015

| Specialty Drug Therapy Class | Specialty Drug Examples | 2015 PMPY Spend | Cost Growth since 2014 | | | |
|---|---|-----------------|------------------------|--|--|--|
| HIV | Truvada, Atripla, Stiribild, Complera | \$131.80 | 4.9% | | | |
| Hepatitis C | Harvoni, Solvaldi | \$62.96 | -9.7% | | | |
| Inflammatory Conditions | Enbrel, Humira, Remicade | \$41.30 | 45.6% | | | |
| Oncology | Revlimid, Gleevec, Tarceva, Avastin, Provenge | \$27.5 | 29.4% | | | |
| Multiple Sclerosis | Aubagio, Plegridy | \$24.36 | 16.0% | | | |
| Growth Deficiency | Nutropin, Genotropin | \$9.55 | 23.7% | | | |
| Cystic Fibrosis | Kalydeco, Orkambi | \$7.89 | 19.2% | | | |
| Pulmonary Hypertension | Opsumit, Remodulin | \$5.32 | 9.8% | | | |
| Anti-coagulants | Pradaxa, Xarelto, Eliquis | \$4.78 | -6.1% | | | |
| Hemophilia | Alprolix, Recominate | \$4.12 | 94.8% | | | |
| Adapted from CVS Specialty, 2016; Express Scripts, 2016 | | | | | | |

Major Shift of Drug Coverage into Medicaid Managed Care

An additional trend in Medicaid pharmacy coverage is the significant shift of pharmacy benefits into managed care delivery systems since 2011. This has been driven by the new opportunity for states to claim federal drug rebates on managed care pharmacy claims, as authorized by the Affordable Care Act. Many states that had previously retained pharmacy as a FFS benefit have begun to carve pharmacy into their managed care contracts. In addition, states have expanded populations covered by managed care, further increasing pharmacy spending through managed care

plans. Between 2011 and 2014, managed care drug spending grew from 14% to 47% of total gross Medicaid drug spending (MACPAC, 2016).

Increasing Political Attention

During 2016 state legislative sessions, more than 1,000 prescription drug-related bills had been introduced as of April 2016, including over 75 bills in 25 states addressing specialty drugs (National Conference of State Legislatures [NCSL], 2016). In California, a 2016 ballot measure that will be voted on in November targets the issue of drug pricing

after failure of the state legislature to address the issue. Sponsored by the California-based AIDS Healthcare Foundation, the measure proposes requiring the state to pay no more for prescription drugs than the U.S. Department of Veteran Affairs, which negotiates the lowest drug prices in the U.S. (Cook & Karlin-Smith, 2016).

Policymaker Interest in Alternative Drug Payment Models

To address rising drug costs, policymakers are focusing increased attention on the need for alternative drug payment models. In March 2016, NAMD released a letter to the U.S. Senate Finance Committee underscoring Medicaid agency concerns with the limits of Medicaid's existing policy levers to negotiate drug prices, and the need to move toward valued-based payment models. Although the MDRP has reduced Medicaid drugs costs historically, the experience with newer hepatitis C treatments underscores how the MDRP's coverage requirements have hindered states ability to effectively negotiate pricing and coverage. Prescription drugs have been left outside of value-based payment models developed for other health care services, and NAMD emphasized the need for federal flexibility to allow states to move in this direction for prescription drugs (NAMD, 2016).

At the federal level, the CMS Innovation
Center issued a proposed rule in March 2016
to test alternative payment models for
Medicare Part B drugs administered in
physician offices or hospital outpatient
departments [81 Fed. Reg. 13230-13261.
(2016)]. The first phase would change
Medicare's current "add-on" payments for
doctors and hospitals from average sales price
(ASP) of a drug plus 6% to ASP plus 2.5% with

an additional flat fee of \$16.80. The second phase would implement value-based purchasing tools similar to those employed by commercial health plans and other entities managing drug benefits. These strategies include: discounting or eliminating patient cost-sharing for effective drugs; indicationbased pricing that would vary drug payment amounts based on a drug's effectiveness for different conditions; reference pricing that sets a standard payment rate for a group of therapeutically similar drugs; and risk-sharing agreements that adjust manufacturer drug prices based on patient outcomes. The proposed rule generated significant stakeholder response, and CMS is currently considering public comment submitted (CMS, 2016a; Appleby, 2016; 81 Fed. Reg. 13230-13261 [2016]).

Box A: NAMD Statement on Value-Based Drug Payment Models

"We continue to believe that the policy levers available to state Medicaid programs are not designed to address fundamental sustainability issues posed by high-cost, high-impact products...States are interested in designing value-based reimbursement strategies for prescription drugs provided by the Medicaid program. To do so, state Medicaid agencies require new flexibility and tools to pioneer innovative solutions."

-- National Association of Medicaid Directors, Letter to Senate Finance Committee (March 2016) State Medicaid and Medicare officials' interests in prescription drug value-based payment models align with payment models that are already in use in the commercial sector and internationally. These models are not necessarily new, and have been in use for many years in other sectors. Federal law, however, has restricted the ability of Medicaid programs to adopt them.

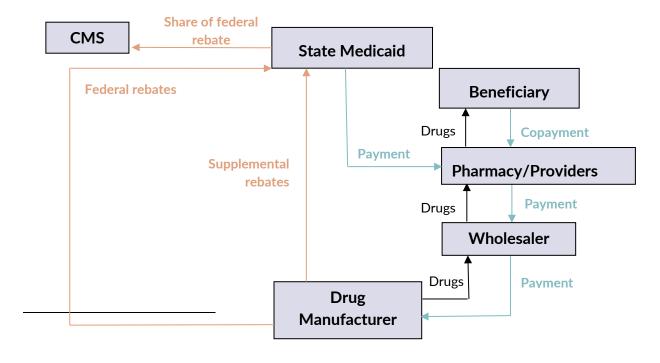
Medicaid Drug Payment and Pricing Strategies

At a very general level, Medicaid spending on prescription drugs reflects three primary components: drug price rebates negotiated with manufacturers, the amount that states pay pharmacies or other providers, and drug utilization rates among Medicaid populations, which may be disproportionately higher for certain specialty therapy conditions, such as hepatitis C and HIV/AIDs.

In 2014, state Medicaid programs spent approximately \$42 billion on outpatient prescription drugs, and received about \$20 billion in rebates from manufacturers for a net outpatient drug spending of \$22 billion (MACPAC, 2016).¹

To understand the Medicaid pharmacy payment and pricing policy options landscape, it is helpful to consider the range of entities involved in drug payments and rebate

Figure 2. Medicaid Pharmacy Payment and Rebate Funding Flow Fee-for-Service Structure (adapted from Cook, Somers & Christensen, 2009; MACPAC, 2015)



¹ These figures include Medicaid FFS and managed care spending (managed care figures are based on permember-per-month payment to managed care plans).

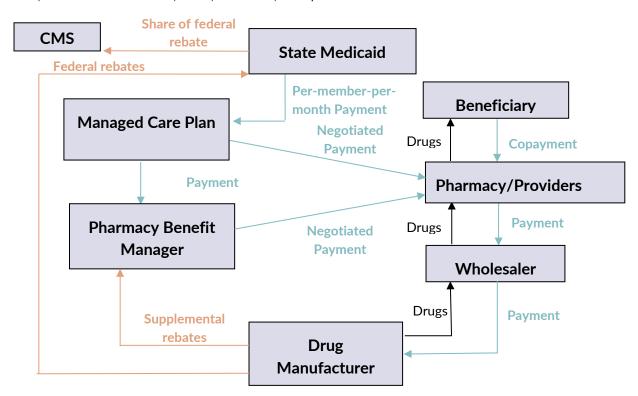


Figure 3. Medicaid Pharmacy Payment and Rebate Funding Flow Managed Care Structure (adapted from Cook, Somers & Christensen, 2009; MACPAC, 2015)

negotiations. Figures 2 and 3 outline the flow of funding between CMS, state Medicaid agencies, pharmacies, providers, managed care plans, pharmacy benefit managers, drug manufacturers, and beneficiaries.

Drug Rebates

State Medicaid programs are eligible to participate in federal and supplemental rebate programs to offset the cost of purchasing prescription drugs. Between 2011 and 2014, manufacturer rebates ranged between 44% and 49% of Medicaid gross drug spending. With rebates fairly constant, much of the recent spike in spending is driven by other factors, including Medicaid expansion and high-cost specialty drugs (MACPAC, 2016). This has led states and policymakers to question whether rebates are the most appropriate tool

to address the increasing costs of newer specialty drugs.

Federal Medicaid Rebates

Authorized under Section 1927 of the Social Security Act, the federal MDRP was created in 1990 to ensure that Medicaid programs receive the lowest or "best price" for drugs sold by manufacturers. In exchange for entering into a national rebate agreement with the Secretary of DHHS, manufacturers are assured Medicaid coverage of their drugs, subject to reasonable limits that states may place through prior authorization or other utilization management tools (Social Security Act, Section 1927). Rebate amounts are calculated based on statutory formulas for specific drug types. The Affordable Care Act increased the level of rebates, although this

increased value accrues solely to the federal government. For brand drugs, rebates increased from 15.1% to 23.1% of average manufacturer price (AMP), and from 11% to 13% of AMP for generic drugs (Medicaid.gov, 2016). Table 2 outlines the statutory rebate formula for each drug type.

States claim rebates for drugs covered under both FFS and managed care delivery systems. In addition, states are required to track and submit rebates for physician-administered drugs that may be paid as medical claims outside of state outpatient pharmacy claims systems (CMS, 2006).

State Supplemental Rebates

In addition to the federal rebate program, states can enter into supplemental pharmacy rebate agreements directly with manufacturers for placement of a drug on the state's PDL based on review of a drug's effectiveness and costs as compared to therapeutically equivalent drugs, and/or application of clinical coverage criteria. Manufacturers negotiate these rebates in order to obtain preferred status and potentially bypass prior authorization

Table 2. Medicaid Drug Rebate Program Rebate Formulas

| Drug Type | Rebate Formula |
|---|--|
| Innovator drugs (brand name) | Greater of: (adjusted by CPI-U) 23.1% of AMP/unit Diff between AMP and best price/unit |
| Blood clotting factors | Greater of: (adjusted by CPI-U)17.1% of AMP/unitDiff between AMP and best price/unit |
| Drugs approved exclusively for pediatric indications | Greater of: (adjusted by CPI-U)17.1% of AMP/unitDiff between AMP and best price/unit |
| Line extensions | Greater of: Rebate for new drug Product of AMP for line extension; highest add'l rebate for any strength of original brand name drug; and total # of units of each dosage form and strength of line extension drug |
| Cap on total rebate amount for innovator drugs | 100% of AMP |
| Non-innovator drugs (generic) | 13% of AMP |

Abbreviations: add'l is additional; AMP is average manufacturer price; CPI-U is consumer price index-urban; diff is difference. Adapted from Medicaid.gov (2016)

Table 3. Multistate Drug Purchasing Pools (NCSL, 2015; SSDC, 2015)

| Multi-State Drug Purchasing Pool | Date Established | Participating States |
|--|---------------------|---|
| National Medicaid Pooling Initiative (NMPI) | 2003 | AK, KY, MI, MN, MT, NH, NY, NC, RI, SC, D.C. |
| The Optimal PDL Solution (TOP\$) | 2005 | CT, ID, LA, MD, NE, PA, WI |
| Sovereign States Drug Consortium (SSDC) | 2005 | DE, IA, ME, MI, ND, OH, OK, OR, UT, VT, WV, WY |
| Northwest Prescription Drug Consortium (NPDC) ¹ | 2007 | OR, WA |
| Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) ² | Mid-1990's | Agencies and clinics in 45 states |

- 1. Non-Medicaid pharmacy programs
- 2. Non-Medicaid or public employee programs

requirements. Supplemental rebates are generally established based on a guaranteed net price for a drug, and calculated in proportion to the federal rebate amount. With the increase in federal rebates under the Affordable Care Act, the Office of Inspector General (OIG) has found that states are receiving lower supplemental rebates (OIG, 2014).

States can negotiate rebates either as a single state and/or through multi-state purchasing pools. There are currently five multistate purchasing pools available to states, although only three are open to Medicaid programs. Table 3 details a list of national purchasing pools and participating states.

According to a CMS survey from December 2015, almost all states (47) participate in some type of supplemental rebate agreement (CMS, 2015c). Thirty-one states have single-state supplemental rebate agreements with an

effective date ranging from the 1980s through 2015. Twenty-eight states participate in multistate supplemental rebate agreements with effective dates ranging from 2004 through 2015. Twelve of those states participate in both single-state and multi-state supplemental agreements.

In the Medicaid managed care context, states have taken varied approaches to negotiation of supplement rebates. Some states allow plans to negotiate these rebates independently for managed care populations. Other states, such as Texas and New York, have retained state authority to negotiate supplemental rebates for all or select drugs or drug classes that apply across managed care and FFS populations (see Box B, next page). According to CMS, ten states include managed care prescription drug use in state supplemental rebate collection (CMS, 2015c).

Multistate purchasing pools have several

advantages to states, such as increasing the market power of states as a pooled entity, reducing administrative costs, gaining information about other state experiences with pharmacy challenges, and working with a pharmacy benefits manager to refine formularies and/or PDLs and utilization management strategies (National Governors Association, 2004).

Pharmacy and Provider Payment Methodologies

Medicaid programs use a variety of methodologies to determine reimbursement amounts for specialty medications to pharmacies and providers. States may use a single drug reimbursement formula, or establish separate formulas for outpatient prescription drugs, specialty pharmacies, clinician-administered medications, brand versus generic drugs, or reimbursement of 340B providers. States also pay pharmacy dispensing fees for pharmacists' work filling prescriptions, and physician or other provider fees to administer the drugs.

Actual Acquisition Cost (AAC) Pricing

In February 2016, CMS released a final rule requiring states to shift to AAC reimbursement models for drugs provided through outpatient pharmacies. This shift is intended to establish Medicaid pharmacy payments that more accurately reflect the amount that pharmacies pay for drugs (CMS, 2016b).

Traditionally, states have used a range of drug pricing benchmarks to determine pharmacy reimbursement, such as average wholesale price (AWP) or wholesale acquisition cost (WAC). See Appendix C for a 50-state overview of current state pharmacy reimbursement

Box B. State Approaches to Supplemental Rebates and Medicaid Managed Care

In the managed care context, states have taken varied approaches to negotiation of supplemental rebates. Some states allow managed care plans to negotiate these rebates independently for their members, which are often negotiated by contracted pharmacy benefit managers. Other states, such as Texas and New York, have retained state authority to negotiate supplemental rebates for all or select drugs or drug classes.

The Texas Health and Human Services Commission manages a single state PDL for the entire Texas Medicaid population. All Medicaid managed care plans are required to follow the state formulary. The state leverages the single formulary to negotiate supplemental rebates with manufacturers.

The New York Department of Health has legislative authority to negotiate supplemental rebates for select drugs and drug classes (hepatitis C agents and antiretrovirals for treatment of HIV/AIDS) across the entire Medicaid population (FFS and managed care) (Social Services Law, Section 367-A, subdivision 7(e)).

methodologies. During the last decade, legal challenges and government research have raised concern that these benchmarks are significantly higher than actual amounts pharmacies pay to purchase drugs (MACPAC, 2015).

With the new federal rule, many states are now in the process of evaluating and determining plans to comply with AAC requirements (CMS, 2016b). States may develop an AAC pricing model based on a variety of methodologies, including state or federal surveys of pharmacies, and WAC or other benchmarks if states can demonstrate a relationship to AAC. The AAC pricing methodology governs state FFS outpatient pharmacy reimbursement, and does not apply to managed care pharmacy reimbursement or clinician-administered medications.

Approximately eight states have already adopted AAC pharmacy reimbursement methodologies, including Alaska, Alabama, Colorado, Delaware, Idaho, Iowa, Louisiana, Nevada, and Oregon (CMS, 2015a). Idaho has noted overall savings with this methodology, although this savings has been partially offset by high pharmacy dispensing fees (*see Box C*).

Specialty Pharmacy Pricing

A number of states have established separate pricing methodologies to reimburse specialty pharmacies. A 50-state summary of state pharmacy reimbursement methodologies as of December 2015 identified separate specialty pharmacy reimbursement methodologies that have been established by Georgia, Maine, Tennessee, and Vermont (CMS, 2015a).

Pennsylvania also has developed separate specialty pharmacy pricing through the state's Specialty Pharmacy Drug Program, which requires FFS beneficiaries and providers to acquire all medications on the state's specialty

Box C: Idaho Implementation of AAC Pharmacy Reimbursement

Idaho implemented an AAC pricing methodology in 2011. To determine drug price, the state's AAC vendor surveys pharmacies once a year to set a base AAC price. This price may then be adjusted throughout the year based on percentage increases or decreases in the WAC.

The state also used a pharmacy survey approach to develop tiered dispensing fees. While Idaho's AAC dispensing fees (ranging from \$11 to \$15 depending of pharmacy annual claims volumes) are higher than previous fees, the state elected to base the dispensing fees on the survey findings because it had communicated this expectation to pharmacies prior to conducting the survey.

drug list through one of two preferred specialty pharmacies. These pharmacies ship the drugs directly to the site of administration (e.g., physician's office, patient's home). The state pays the specialty pharmacies based on pricing that is negotiated per drug twice a year using AWP and WAC-based pricing. Pennsylvania's program is authorized under a 1915(b) waiver, allowing the state to limit the pharmacy network to the two preferred pharmacies. Other states with specialty pharmacy rates do not necessarily limit their pharmacy network to preferred pharmacies.

Clinician-Administered Drug Pricing

Many specialty drugs are administered by physicians or other clinicians and are

reimbursed as a medical benefit with pricing separate from state pharmacy reimbursement rates. States may develop reimbursement for clinician-administered medications based on medical and/or pharmacy program pricing formulas. Many states reimburse clinician-administered drugs based on Medicare's rates, which are established based on drug Healthcare Common Procedure Coding System (HCPCS) codes (typically J-codes) and set at the ASP plus 6%.

States have worked to align pricing for drugs that may be billed under both medical and/or pharmacy benefits. In Oklahoma, the state prices clinician-administered medications based on Medicare Part B J-code pricing (ASP plus 6%), and applies this methodology across medical and pharmacy reimbursement in order to reduce incentives to bill through one benefit over the other.

340B Pricing

State Medicaid programs may also seek to maximize drug savings through the 340B drug discount program (see Box D on next page for a 340B primer). Most states expect 340B entities to bill the state at the AAC for 340B drugs (OIG, 2011). In the final Medicaid outpatient drug reimbursement rule released in February 2016, CMS also established expectations that state 340B drug reimbursement methodologies are consistent with the rule's AAC requirements, and do not exceed 340B ceiling prices (CMS, 2016b).

Implementation of policies for Medicaid to access 340B pricing is administratively challenging. Because 340B ceiling and subceiling prices are confidential, states do not have access to 340B acquisition costs and are therefore unable to employ reimbursement

limitation edits. States must rely on postpayment reviews to determine 340B payment accuracy (OIG, 2011). In addition, states are required to develop systems to ensure that 340B claims are not submitted for "duplicate discounts" through the MDRP.

Providers have also raised concern that 340B savings were intended to help the covered entities offset losses resulting from drugs provided to uninsured or underinsured populations. Passing savings onto Medicaid, therefore, essentially eliminates provider revenue from the drugs. Providers may also face the administrative challenge of segmenting Medicaid claims from other payer claims for purposes of billing at 340B acquisition costs.

States have taken varied approaches to maximizing discounts for drugs billed by 340B providers and addressing these administrative hurdles. In Oklahoma, the Medicaid program has taken a unique approach and allows 340B entities to bill their usual and customary fees so they do not have to separate Medicaid from other claims. Approximately 95% of 340B claims are clinician-administered medications, and therefore paid at ASP plus 6%. At the end of the quarter, the state generates an invoice for 340B entities based on the unit rebate amount for billed drugs. This allows the state to realize discounts from 340B providers that were otherwise foregone given concerns about duplicate discounts. In contrast, other states such as Illinois and California require providers to participate in 340B if they are eligible, and to bill Medicaid at 340B acquisition costs.

Box D. 340B Drug Pricing Program Primer

The 340B Drug Pricing Program provides reduced price prescription drugs to certain health care facilities (referred to as "covered entities") participating in the program. Established in 1992, the program was created to ensure access to drug discounts for government-supported facilities that serve vulnerable populations who may or may not be covered by Medicaid or other insurance. Similar to Medicaid rebates, drug manufacturers must offer drug discounts to 340B entities as a condition of Medicaid coverage of the manufacturer's drugs. Drugs included in the 340B program generally include outpatient prescription drugs and drugs administered by physicians in an outpatient setting.

The Program is administered by the Office of Pharmacy Affairs within the Health Resources and Services Administration (HRSA). Eligible health care organizations/covered entities include hospitals¹; federally qualified health centers (FQHC); FQHC look-alikes; Ryan White HIV/AIDS program grantees; tuberculosis, black lung, family planning or sexually transmitted disease clinics; hemophilia treatment centers; public housing primary care clinics; homeless clinics; urban Indian clinics; and Native Hawaiian health centers (HRSA, n.d.).

The 340B program provides covered entities with statutorily defined drug discounts (340B ceiling prices), and these covered entities can also negotiate further "sub-ceiling" rates. Statutorily defined drug ceiling prices are calculated based on the AMP minus the unit rebate amount. These prices are often similar to or lower than the Medicaid prices negotiated under the federal Medicaid rebate program (HRSA, n.d.), and are reported to range from 25% to 50% of AWP (340B Prime Vendor Program, 2016).

All entities participating in the 340B program have access to the 340B Prime Vendor Program free of cost. The Prime Vendor Program provides access to sub-ceiling prices for certain branded and generic drugs and additional discounts on other types of products and services such as blood glucose monitoring supplies, apothecary/operational supplies, U.S. pharmacopeia convention (USP) 797 compliance products, and vaccines (340B Prime Vendor Program, 2016). The Prime Vendor Program provides price transparency through a secure website (HRSA, n.d.). Apexus, a not-for-profit organization, is contracted to administer the 340B Prime Vendor Program through September 29, 2019 (Stencel et al., 2014).

The SMART Act in Illinois requires all entities eligible for the 340B program to apply for enrollment with the federal government, and to use the program to purchase drugs for Medicaid clients and bill at 340B acquisition costs (Illinois Department of Healthcare and Family Services, 2016).

States have also developed programs focusing on hemophilia to take advantage of 340B pricing. In Oregon, for example, the Medicaid program has a sole-source contract with a 340B Hemophilia Treatment Center to provide anti-hemophilic factors and care coordination for Medicaid members with hemophilia or other clotting disorders. Approximately 100 of the 140 Hemophilia Treatment Centers across the U.S. participate in the 340B program (National Hemophilia Foundation, 2015).

Pharmacy Dispensing Fees

In addition to negotiated drug reimbursement prices for the cost of prescription ingredients, Medicaid programs reimburse pharmacies a predetermined dispensing fee. State approaches to dispensing fees vary. Several states provide a tiered dispensing fee based on specific criteria. Table 4 outlines dispensing fee variations across states. See Appendix C for a full list of state dispensing fees. For example, some states provide higher dispensing fee reimbursement for drugs purchased under the 340B program. Almost half of states use a single dispensing fee ranging from \$1.70 (Connecticut) to \$11.73 (Iowa).

Utilization Management Strategies

States are employing many traditional pharmacy management tools to manage high-

cost specialty drugs. State experience with these strategies has underscored both the opportunities and limitations of these existing tools.

Preferred Drug Lists

Preferred drug lists are used by state Medicaid programs to classify certain drugs as "preferred" or "non-preferred" based on a review of a drug's effectiveness and costeffectiveness as compared to drug alternatives. When there are multiple drug options within a therapeutic class, PDLs can be an important tool for states to favor drugs that are more effective and to negotiate drug discounts. Although similar to formularies, PDLs are distinct from formularies in that they do not exclude coverage of a drug entirely. States must still cover all drugs from manufacturers that have signed federal rebate agreements, and PDLs function as a tool to set coverage criteria that favor certain drugs over others.

State PDLs may include some but not all specialty drug therapy classes, depending on the extent to which there are therapeutic alternatives, or whether certain conditions or drug classes are exempt from PDL placement. Some states, for example, have carved out entire classes of medical conditions from PDLs, such as HIV/AIDs, hemophilia and cancer.

States have also taken different approaches to management of PDLs in the managed care context. Some states have retained authority to manage PDLs that apply across managed care and FFS populations; other states allow plans to negotiate separate PDLs. See Box B, State Approaches to Supplemental Rebates and Medicaid Managed Care.

Table 4. Medicaid Pharmacy Dispensing Fees

| Dispensing Fee Criteria | States |
|-------------------------|--------|
|-------------------------|--------|

| Tiered by pharmacy claims volume | CO, ID, OR, WA |
|--|--|
| Dispensing setting (e.g., FQHC, nursing facilities, government pharmacies) | AZ, CA, CO, MD, MI, RI, TN |
| Geographic location (e.g., rural, urban, on road system) | AK, CO, NJ, UT |
| Not-for-profit status | GA |
| Drug formulation (e.g., single source, multiple source, cream, ointment) | IL, ME, MI |
| Brand vs. generic | KY, MD, ME, MS, NC, ND, TN, WI, WV |
| Compounding | ME, MT, NY, PA, TN, VT, WI |
| In-state vs out-of-state | ME, VT |
| Pharmacist selection | NM |
| 340B Program participation | FL, IL, MA, UT, WV |
| Single dispensing fee | AL, AR, CT, DE, D.C., IN, IA, KS, LA, MO, MT, NE, NV, NH, NM, OH, OK, PA, SC, SD, TX, VA, WY |

Prior Authorization

Prior authorization is a primary tool that states use to manage and ensure appropriate use of high-cost specialty drugs. State prior authorization policies may include medical necessity criteria as well as other requirements, such as frequency of authorization or quantity limits that allow states to oversee appropriate use of the medications. States generally make drug prior authorization policies publically available online, and continually review prior authorization criteria through their pharmacy and therapeutics committee or contracted vendors.

Federal Medicaid law requires states to cover drugs for "medically accepted indications," including any FDA-approved indications for the drug, as well as off-label uses supported by at least one of several drug compendia listed in the Social Security Act. Recognized compendia listed in the Act include: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information or successor publications, and the DRUGDEX information system [SSA, Section 1927(k)(6)].

For some specialty drug classes, states are also limited by state law in the extent to which they may define medical necessity. In New

Box E: Oklahoma Prior Authorization Impact on Appropriate Use of Specialty Drugs

In the case of hepatitis C drugs, Oklahoma state law initially prohibited the Medicaid program from requiring prior authorization. With the release of Solvadi®, the state was unable to manage the drug through prior authorization tools and found significant rates of non-adherence among Medicaid patients. Given concerns with the drug's costs, patient non-adherence, and the potential for developing viral resistance, the Medicaid program worked with the legislature to remove the prohibition. The program then worked with the state DUR Board to develop a three-part drug management strategy:

- 1. The State must authorize hepatitis C drugs monthly (other drugs are commonly approved for 6 to 12 month periods)
- 2. Pharmacies must agree to manage the member's prescription limits, including the maximum of two brand drugs
- 3. Members must sign an "intent to treat" contract where members are advised of adverse events, and the importance of adherence, contraception, and abstaining from substance abuse.

Following implementation of this strategy, the state experienced a 33.7% increase in medication possession ratio, a measure of patient continued access to medications and adherence.

York, for example, a "prescriber prevails" law requires the state, including managed care plans, to cover prescriptions that a provider deems medically necessary (defined as FDA approved or compendia supported), regardless of the payer's coverage policy. This requirement applies to all drug classes under the FFS program and to selected drug classes in managed care, including atypical antipsychotic, antidepressant, antiretroviral, antirejection, seizure, endocrine, hematologic, and immunologic therapeutic drug classes (New York State Department of Health, 2013).

For specialty drugs, particularly those involving complex conditions and requiring patient adherence, state prior authorization policies may have a significant impact on appropriate use of a drug. In Oklahoma, for example, the state developed a comprehensive prior authorization strategy for hepatitis C that increased the patient medication possession ratio (a measure of patient continued access to medications and adherence) by 33.7% as compared to the previous open access policy to hepatitis C drugs without prior authorization (see Box E). States noted the need to tailor prior authorization strategies to different conditions and the underlying issues impacting appropriate drug use.

Idaho uses a number of prior authorization tools that allow the state to actively manage specialty drugs. For all "new" drugs that are released and covered by Medicaid, the state's internal pharmacy staff conducts manual prior authorization of all medical and pharmacy claims for the first six months that the drug is available. Idaho includes a number of specialty drug classes on its PDL, and requires prior authorization for many

specialty drugs, including any drug claims over \$7,500. The state's pharmacy and therapeutics committee manages the PDL and develops the prior authorization criteria.

States can also take management approaches that are tailored to address factors unique to each specialty drug class and the conditions being treated. In North Carolina, for example, hemophilia products are a protected class and Medicaid is prohibited from managing them through prior authorization or use of a PDL. The state has therefore taken a care management approach focusing on the quality of providers and monitoring standards.

Clinician-administered Medications

Many specialty drugs are administered by clinicians and paid through medical claims rather than the pharmacy claims system. Historically, this has meant that clinician-administered drugs have fallen outside of states' (and other payers') traditional pharmacy management systems. Given the high-cost, risks, and clinical complexity of these drugs, a number of states and other payers have undertaken efforts to more closely manage clinician-administered specialty medications.

In 2010, for example, Idaho's Medicaid pharmacy program began to manage clinician-administered medications billed as medical claims in order to align coverage criteria and management of drugs across the pharmacy and medical programs. Previously, these drugs were largely unmanaged and the state pharmacy program had identified concerns that certain drugs billed through the pharmacy side were highly controlled, whereas the same drugs billed by a physician's office were open access.

Oklahoma Medicaid has taken a similar approach, where the pharmacy department manages clinician-administered medications and applies the state's prior authorization requirements regardless of whether drugs are billed as a medical or pharmacy benefit. Recently, Oklahoma also implemented prior authorization requirements for oncology drugs, which providers indicated was consistent with commercial payer expectations.

States can also manage and structure clinician-administered medications as part of the state's outpatient pharmacy benefits. Pennsylvania, for example, manages clinicianadministered medications entirely as outpatient drug benefits. For drugs on the state's specialty drug list, the specialty pharmacies bill the state directly based on the negotiated reimbursement amount, and clinicians bill for administration of the drugs through professional claims. Clinicianadministered medications that are not on the specialty drug list are also structured as an outpatient drug benefit and integrated within the state's overall outpatient drug management and payment methodologies (Medicaid Evidence-based Decisions Project, 2013).

Specialty Pharmacies

Pennsylvania manages specialty drugs for FFS beneficiaries through its Specialty Pharmacy Drug Program. As authorized under a 1915(b) waiver, all medications on the <u>specialty drug list</u> must be obtained through one of two preferred specialty pharmacies (Pennsylvania Department of Human Services, n.d.).

The specialty pharmacies ship the drugs to the site of administration (e.g., physician's office,

patient's home), and provide patients and providers with clinical support to ensure optimal therapy management. This clinical support includes, for example, regular monthly calls to beneficiaries to track adherence and health status, as well as maintenance of a 24-hour call center with clinical staff to address patient concerns. The pharmacies provide the state with regular reports tracking patient utilization, compliance issues, and identification of patients needing additional support.

Pennsylvania's Department of Human Services pharmacy department manages the program and retains certain functions such as the operation of an in-house call center to conduct prior authorization of the drugs, as well as coordination with the state's medical program for broader care management services for patients identified by the pharmacies as needing additional support.

Care Management

Care management involving close monitoring of side effects and response to treatment can be essential for optimizing patient use of specialty medications and managing costs. Many states have developed disease-specific care management programs for conditions such as hemophilia, multiple sclerosis, hepatitis C, and hereditary angioedema, where patient adherence to high-cost medications is important to successful outcomes. In North Carolina, the state's primary care case management program (Community Care of North Carolina, or CCNC) has developed a Pharmacy Home Project centered on serving patients with complex medical conditions in primary care settings (see Box F).

Box F: North Carolina's Pharmacy Home Project

The CCNC organization operates a Pharmacy Home Project for high-risk Medicaid populations. The project's goal is to support a "well-coordinated, goaloriented, continually reinforced drug use plan" among Medicaid populations with the highest needs. The project includes a coordinated network of pharmacists, health care providers, and care managers using a range of tools to develop and implement a plan of care to optimize the effectiveness of medications. As an example, the transitional care program alone serves approximately 30,000 patients per year, with a focus on reconciling changes made to the patient's medications in the hospital with the patient's chronic regimen prior to admission, and ensuring discrepancies are resolved and communicated among the care team and with the patient. The programs target populations identified by CCNC's internal analytics department based on clinical risk groups and analysis of patient "impactability" factors.

Although the program is centered in primary care, management of specialty drugs can be part of the full array of medications managed for the targeted high-risk patients. Chronic pain and behavioral health drugs are among the most commonly encountered specialty medications within the highest risk population with multiple chronic conditions.

Prescription Limits

Approximately 14 states set prescription limits, ranging between three and eight prescriptions per month. These limits may cap the number of prescriptions that beneficiaries are allowed per month, or require prior authorization for prescriptions over certain amounts (Smith et. al., 2015; The Council of State Governments, 2013).

State prescription limits may impact state spending on specialty medications. In Oklahoma, for example, Medicaid limits adult beneficiaries to six covered prescriptions per month, including up to two brand-name prescriptions, with certain exceptions such as drugs for cancer, hemophilia, and HIV (See OAC 317:30-5-72 (2016)). Oklahoma's limit on brand drugs therefore also applies to certain specialty drug classes, such as hepatitis C, multiple sclerosis, and rheumatologic conditions. Pharmacies and prescribers are expected to work with members to tailor drug therapy within these limits.

Managed Care Delivery Systems Strategies

States have made a significant shift of prescription drug coverage into Medicaid managed care plans since 2011. Managed care prescription drug spending grew from 14% of overall prescription drug spending in 2011, to 47% of overall drug spending in 2014 (MACPAC, 2016). As of 2014, approximately 28 states included prescription drugs within capitated managed care plan contracts (i.e., pharmacy "carve in" managed care models) (Menges Group, 2015).

The final Medicaid managed care rules released in April 2016 reinforce CMS

expectations that Medicaid managed care plans are subject to the same prescription drug coverage requirements of section 1927 (i.e., the MDRP and prior authorization processes) as state FFS programs [81 Fed. Reg. 27544. (2016)]. In addition, plans coverage requirements cannot be more stringent than state FFS standards. However, managed care plan PDLs and prior authorization clinical criteria and review requirements do not have to be identical to state FFS standards.

Scope of Prescription Drug Coverage

States that cover prescription drugs through managed care plans may "carve out" coverage of certain drugs. For example, while covering the majority of prescription drug medications within managed care, some states may carve out and provide FFS coverage of therapeutic classes, such as HIV medications in California and behavioral health medications in Maryland (Menges Group, 2015). States have also carved out certain high-cost specialty medications, such as hepatitis C drugs, from plan capitation payments (e.g., New Hampshire, South Carolina, Texas, Washington, District of Columbia). These carve-outs may, in some cases, be temporary policies to allow states to collect utilization data to calculate plan capitation payments in the future (Smith, et. al., 2016).

Payment

For drugs covered through managed care plans, states generally pay plans per-member-per-month fees that reflect estimated drug costs as a component of their monthly capitation rate approved by the federal government. As noted above, some states have carved out certain high-cost specialty drugs from plan capitation payments, and reimburse these drugs on a fee-for-service basis.

Managed care plans then use a pharmacy benefit manager to negotiate drug prices and supplemental rebates with manufacturers, determine payment terms with pharmacies and providers, and manage drug utilization.

Some states are designing payment models for high-cost specialty drugs that hold plans accountable for providing appropriate management and support to beneficiaries. See Box G, Pennsylvania's Hepatitis C Risk Sharing and Quality Risk Pool.

Preferred Drugs Lists

Plans often use the term "formulary," but they are required to cover all Medicaid-covered drugs that are included within their contracted rates. Plan "formularies," therefore, serve the same function as state PDLs, and are used to encourage the use of more effective and cost-effective drugs over others, but may not function to exclude coverage of Medicaid-covered drugs.

Most states allow plans to develop independent PDLs; some states have retained control over PDLs for some or all drug classes. A few states such as Florida and Texas manage a single state PDL that plans are required to follow, allowing the state to negotiate drug pricing across broader populations of beneficiaries. Other states have carved out certain drug classes for the state to leverage price negotiations (Menges Group, 2014). See Box B State Approaches to Supplemental Rebates and Medicaid Managed Care.

Coverage Criteria

States generally do not require plans to adopt state FFS coverage criteria, but work to align FFS and managed care criteria. For some highcost drugs, such as those to treat hepatitis C, states have required that plans follow the state's FFS coverage criteria. In some cases, plans have joined state pharmacy and therapeutics committees, which has resulted in greater alignment of policies across managed care and FFS.

States have taken varied approaches to reviewing plan prescription drug coverage policies. Some states conduct an upfront review of all plan coverage policies prior to implementation, and other states review policies only upon request or if problems are identified through utilization review or beneficiary complaints.

Box G. Pennsylvania's Hepatitis C Risk-Sharing and Quality-Risk Pool

In Pennsylvania, the state created a hepatitis C risk-sharing and quality risk pool in response to plan requests for rate adjustments to compensate for the increased costs of hepatitis C drugs. The state actuaries recognized the increased managed care plan costs attributed to hepatitis C but also wanted to hold the plans accountable for appropriate utilization management and successful treatment of each individual beneficiary treated. Pennsylvania created the hepatitis C risk-sharing and quality risk pool arrangement as a mechanism to pay plans additional funds conditioned on submission of SVR-12 results for each beneficiary treated by the managed care plan.

State Staffing and Organization to Oversee Plans

Some states have adjusted pharmacy staffing to reflect the movement of prescription drug coverage from FFS to managed care plans by shifting staff duties from FFS operations to oversight of plans. In Pennsylvania, for example, as the state shifted coverage of outpatient prescription drugs into managed care plans, the state pharmacy staff became actively engaged and integrated into the state's oversight of plans' outpatient drug services. This integration has helped the state to develop plan contract expectations, as well as oversee the plans to ensure appropriate management of covered drugs.

Managed Care Specialty Pharmacy Networks

Managed care plans may also encourage members to obtain specialty medications through specialty pharmacies. In Texas, for example, the state has developed a specialty drug list, as a subset to the state's PDL, to define drugs that managed care plans may provide exclusively through a specialty pharmacy network. The State works with the managed care plans to develop the list that plans can use to enter into selective contracts with specialty pharmacies to dispense the selected specialty drugs. Plans can steer clients towards specialty pharmacies, but must still approve claims from clients using non-specialty pharmacies.

Express Scripts, a major pharmacy benefit manager for commercial, Medicare, and Medicaid populations that works with managed care plans, also offers a specialty pharmacy network, Accredo®, to plans as a tool for managing the drugs. The program offers specialty trained pharmacists to advise

patients on specialty drug use and medication management and monitor adherence, concentrating on 13 specialty disease areas (cancer, bleeding disorders, endocrine, fertility, hepatitis C, HIV, immune disorders, multiple sclerosis, oncology, pulmonary, pulmonary arterial hypertension, rare diseases, rheumatoid arthritis/inflammatory conditions, and transplants). Contracted health plans may choose whether to offer Accredo® as a limited or exclusive pharmacy network for patients. Express Scripts has found improved drug adherence and reduced costs among patients obtaining medications through Accredo®. For example, among patients with cancer, Express Scripts reported that drug adherence improved by 16 percentage points. Drug adherence improved by 32 percentage points for patients with multiple sclerosis (Express Scripts, 2015).

Predictive Modeling to Target High-Risk Populations

Managed care programs have also developed predictive modeling tools to target interventions for high-risk populations.

Express Scripts, for example, has developed the Screen Rx® tool based on its pharmacy data and analytics program to identify Medicaid members at risk for non-adherence or unsafe use of medications and provide targeted interventions. The screening tool can be tailored across populations served by Express Scripts, including commercial plans and Medicare.

Value-based Prescription Drug Programs

Managed care plans may also be using valuebased prescription drug payment programs for specialty medications. Express Scripts, for example, has developed a number of "valuebased" programs for high-cost drugs that pose significant financial risk for managed care plans, such as oncology, hepatitis C, and cholesterol drugs. These value-based programs generally cap financial risk for plans, and place Express Scripts at risk for negotiating drug pricing and managing drugs appropriately. To date, however, these value-based programs have generally not been adopted by Medicaid managed care plans due to the challenges in tailoring the programs to meet Medicaid-specific requirements. Each value-based program is tailored to unique factors involved with the drugs or associated health conditions, although the programs share several common elements:

- 1) Involvement of high-cost drugs
- 2) Negotiation of substantial drug discounts in exchange for plan participation in the program
- 3) Distribution of drugs through specialty pharmacies
- 4) Capped financial risk for plans

See Box H on the next page for further detail describing Express Scripts' value-based prescription drug programs.

Conclusion

Specialty drugs are used for patients with complex and serious health conditions, such as cancer, hemophilia, hepatitis C, and HIV/AIDS. In addition to these severe conditions, Medicaid beneficiaries might have chronic health and behavioral health concerns and socioeconomic challenges such as housing, income, or cultural barriers to care.

Given these patient needs, Medicaid efforts to manage specialty drugs focus not only on appropriate coverage and use of the medications themselves, but also on the broader set of health and social issues that can impact a patient's ability to gain benefits from these drugs. Medicaid specialty drug management strategies involve traditional pharmacy management tools (such as use of preferred drugs and prior authorization), combined with additional supports to assist beneficiaries with understanding and managing their medications, as well as efforts to connect individuals with broader care management services.

In the last five years, Medicaid programs have also shifted a significant portion of prescription drug coverage from FFS programs into managed care. Although states have robust FFS pharmacy management systems based on extensive federal requirements, the shift of pharmacy benefits into managed care has required states to develop new capacities to oversee and hold managed care plans accountable for these services. For high-cost specialty drugs, states have also had to limit plan financial risk, and in some cases carve payment for these drugs out of plan capitation rates or develop alternative risk-sharing payment models.

Despite these efforts, state spending on specialty drugs continues to climb. Specialty drug prices have risen drastically in the last decade. Medicaid, however, has limited tools to address the underlying price of a drug itself. Recognizing this limitation, NAMD has called for more flexibility in paying for prescription drugs, and expressed interest in "value-based" payment models that align with the evolving payment approaches for other health care services (NAMD, 2016). Although value-based prescription drug payment arrangements are prevalent in the commercial sector and

internationally, federal laws have restricted the ability of Medicaid programs to adopt these models. As Medicaid program officials consider strategies to manage specialty drugs, policy options to address drug pricing will be a key area for further development in the coming years.

Box H. Express Scripts SafeGuardRx™ Value Programs

Hepatitis Care Value Program

Express Scripts negotiated with manufacturers for lower prices in exchange for offering treatment to all patients, not only patients with advanced disease (F3s and F4s). AbbVie agreed to discounts for Viekira Pak™, making it \$10,000 less expensive than Gilead's drug Harvoni®. Express Scripts chose Viekira Pak™ for its formulary and guaranteed plans patient adherence rates, with a full refund of expenditures on the drug if patients did not adhere. With a range of tools to support patient adherence (e.g., predictive models, specialty pharmacy, mobile apps), the program achieved a 95% adherence rate and 96% cure rate for patients who adhered. In 2015, the program treated over 50,000 patients with hepatitis C and saved payers more than \$1 billion on drug therapies.

Cholesterol Care Value

Express Scripts negotiated significant discounts on both PCSK9 inhibitor drugs (Praluent® and Repatha™), and placed both on the formulary with stringent prior authorization criteria. Express Scripts then guaranteed plans per-member-per-year costs for PCSK9 inhibitors, and went at risk for costs, implementing utilization management properly and ensuring coverage of patients with indications for the drugs.

Oncology Care Value

This program incorporates indication-based pricing, a concept of paying for a drug differently depending on its effectiveness for various indications. Express Scripts has calculated a blended drug discount rate based on assumptions of the utilization of a drug with different FDA-approved indications. With the blended discount approach, Express Scripts addressed manufacturer concerns about setting a precedent for Medicaid Best Price benchmarks, and at the same time more closely aligned reimbursement with the effectiveness of a drug for varied conditions.

Inflation Protection

This program guarantees a fixed inflation amount for branded products. Based on negotiations with manufacturers, and analysis of pharmacy data and trends, the program guarantees fixed inflation amount and bears the risk of excess inflation increases. In addition to these programs, Express Scripts has plans in 2016 to announce several additional value-based programs focused on indications-based pricing outside of oncology drugs.

Appendix A. Methods

Center staff conducted a search of Medicaid Evidence-based Decisions Project (MED) policy core sources (*see list below*) to identify relevant policy briefs, national policy summaries, and relevant laws and regulations using the terms "drug Medicaid" and "pharmacy Medicaid." In addition, staff searched Google ten pages deep using the terms "drug Medicaid" and "pharmacy Medicaid," and reviewed key sources from reference lists. Staff also interviewed individuals in Idaho, New York, North Carolina, Oklahoma, Pennsylvania, and Texas, and from Express Scripts. States were selected to illustrate strategies in states with varied program sizes and structures (managed care and fee-for-service). Policy sources searched included:

Academy Health

Alliance for Healthcare Reform

Association of State and Territorial Health Officials

Center for Budget and Policy Priorities

Center for Health Care Strategies, Inc.

Centers for Medicaid and Medicaid Services, Research, Statistics, Data & Systems

Commonwealth Fund

Health Affairs

Health Resources and Services Administration

Health Systems Evidence

Kaiser Family Foundation

Mathematica Policy Research

National Academy of Insurance Commissioners

National Academy for State Health Policy

National Association of State Medicaid Directors

National Association of State Mental Health Program Directors

National Conference of State Legislatures

National Governors Association

National Health Law Program

Office of Inspector General

RAND

Robert Wood Johnson Foundation

Urban Institute

Medicaid.gov

Medicaid and CHIP Payment and Access Commission (MAPAC)

Substance Abuse and Mental Health Services Administration

U.S. Government Accountability Office

Appendix B. Common Terms and Definitions

- Actual acquisition cost (AAC) Actual price paid by a pharmacy to acquire drug products
- Average manufacturer price (AMP) Average price paid to manufacturers for drugs distributed through retail community pharmacies
- Average wholesale price (AWP) Suggested list price from drug wholesaler to a pharmacy or other provider (published in commercial clearinghouses such as Redbook, Medi-Span, First DataBank, and Elsevier Gold Standard)
- Average sale price (ASP) Average sale price of a drug reported to CMS on quarterly basis by manufacturer
- Best Price Lowest price available to any private sector purchaser (includes discounts, rebates, chargebacks, other price adjustments)
- Federal Upper Limit (FUL) Federal financial contribution limit on state drug expenditures for innovator (brand name) and non-innovator (generic) drugs
- National Average Drug Acquisition Cost (NADAC) Annual survey of average retail pharmacy invoices to estimate a national average acquisition cost for each drug
- State Maximum Allowable Cost (SMAC) States can establish a maximum allowable amount that the state will pay for a drug, similar to FUL, but not a federal requirement
- Usual and customary charge A pharmacy's usual and customary charge to the public
- Wholesale Acquisition Cost (WAC) Estimated drug cost of what retail pharmacies pay wholesalers for single source drug (publically available)

(Adapted from CMS, 2015a; MACPAC, 2015)

Appendix C: State Medicaid Covered Outpatient Prescription Drug Reimbursement

(adapted from CMS, 2015a; NCSL, 2015; OIG, 2011)

| State | Ingredient Cost | Specialty Pricing | Dispensing Fee | Multi-state Drug Purchasing Pool | 340B Written Policy |
|------------|--|---|--|---|---------------------------|
| Alabama | Lower of AAC, FUL, or U&C (WAC if AAC not available) | Blood Clotting Factors: ASP + 6% | \$10.64 | n/a | V |
| Alaska | NADAC (WAC + 1% if not available) | n/a | \$13.36 (pharmacy on road system) \$16.58 (mediset pharmacy) \$21.28 (pharmacy not on road system) \$10.76 (out-of-state pharmacy) | NMPI | V |
| Arizona | AWP minus 15% FQHCs and FQHC look-alikes: less of billed charges or 340B ceiling price | n/a | \$2.00 (FFS) \$8.75 (FQHCs and FQHC look-alikes) | n/a | |
| Arkansas | AWP minus 20% (generic) AWP minus 14% (brand) | n/a | \$5.51 | n/a | V |
| California | AWP minus 17% | Physician- administered drugs: ASP + 6% | \$7.25 \$8.00 (legend drugs dispensed to residents in skilled nursing | n/a | V |

| State | Ingredient Cost | Specialty Pricing | Dispensing Fee facilitates or intermediate care facilities) | Multi-state Drug Purchasing Pool | 340B Written Policy |
|-------------|---|----------------------|---|---|---------------------------|
| Colorado | Lower of (1) U/C minus copayment, OR (2) allowable ingredient cost Allowable ingredient cost: lesser of AAC or submitted ingredient cost ² (WAC or submitted ingredient cost if AAC not available) | n/a | \$13.40 (<60,000 prescriptions filled/yr) \$11.49 (60,000 – 90,000 prescriptions filled/yr) \$10.25 (90,000 – 110,000 prescriptions filled/yr) \$9.31 (> 110,000 prescriptions filled/yr) \$14.41 (rural pharmacies) \$0.00 (gov't pharmacies) | n/a | |
| Connecticut | AWP minus 72% to step down tiers through AWP minus 20% (based on meeting specific invoice pricing criteria) (selected multisource brand, generic) AWP minus 16% (brand) | n/a | \$1.70 | TOP\$ | V |

² Pharmacy's calculated ingredient cost. For drugs purchased through 340B program, this is the 340B ceiling price.

| State | Ingredient Cost | Specialty Pricing | Dispensing Fee | Multi-state Drug Purchasing Pool | 340B Written Policy |
|-------------------------|---|--|--|---|---------------------------|
| Delaware | NADAC | n/a | \$10.00 | TOP\$, SSDC | |
| District of Columbia | WAC + 3% | n/a | \$4.50 | NMPI | |
| Florida | Lower of AWP minus 16.4% OR WAC + 1.5% | n/a | \$3.73 (non-340B drugs) \$7.50 (340B drugs) | n/a | V |
| Georgia | AWP minus 11% | Select specialty rate for certain rare and/or complex diseases, reimbursement determined by wholesaler/ manufacturer data, comparison to other states' reimbursement, and publically available drug prices from other payers Provider administered | \$4.63 (for-profit pharmacy) \$4.33 (not-for-profit pharmacy) | n/a | √ |

| State | Ingredient Cost | Specialty Pricing drugs (injectable): ASP | Dispensing Fee | Multi-state Drug Purchasing Pool | 340B Written Policy |
|------------|---|--|--|----------------------------------|---------------------------|
| Hawaii | WAC | + 6% | \$5.00 | n/a | √ |
| Idaho | AAC (WAC if not available) | n/a n/a | \$5.00 \$15.11 (<39,999 claims/yr) \$12.35 (40,000 – 69,999 claims/yr) \$11.51 (≥ 70,000 claims/yr) | TOP\$ | |
| Illinois | WAC + 1% (multiple or single source legend) WAC + 25% (over-the-counter drugs) | AAC (implantable contraceptive devices purchased under 340B via FQHC or rural health center) | \$5.50 (multiple source) \$2.40 (single source) \$12.00 (single or multiple source purchased under 340B program) | n/a | V |
| Indiana | AWP minus 20% (generic) AWP minus 16% (brand) | Physician- administered drugs: WAC + 5% (or ASP + 6% if not available) | \$3.90 | n/a | |
| Iowa | AAC (as determined by survey; WAC if not available) | n/a | \$11.73 | SSDC | V |

| State | Ingredient Cost WAC minus 8.6% (generic) | Specialty Pricing | Dispensing Fee | Multi-state Drug Purchasing Pool | 340B Written Policy |
|-----------|---|--|---------------------------------------|----------------------------------|---------------------------|
| Kansas | WAC minus 4.6% (brand) Invoice pricing for drugs without a WAC or state max allowable cost | n/a | \$3.40 | n/a | |
| Kentucky | WAC + 3.2% (generic) WAC + 2% (brand) (provider req' to contact manufacturer for WAC or invoice price, if not available) | n/a | \$5.00 (generic) \$4.50 (brand) | NMPI | V |
| Louisiana | ACC (WAC if not available) | Influenza vaccine (intramuscular injection, preservative free): \$17.37 Influenza vaccine (intramuscular injection): \$13.22 Influenza vaccine (intranasal): \$22.03 or billed | \$10.51 (includes state provider fee) | TOP\$ | \checkmark |

| State | Ingredient Cost | Specialty Pricing charges, | Dispensing Fee | Multi-state Drug Purchasing Pool | 340B Written Policy |
|---------------|---|--|--|---|---------------------------|
| | | whichever is less | | | |
| Maine | AWP minus 13% (generic) AWP minus 16% (brand) AWP minus 20% (mail-order brand) AWP minus 60% (mail-order generic) | AWP minus 17% (specialty pharmacy) | \$3.35 \$2.50 (mail order brand and generic) \$4.35 and \$5.36 (compounding) \$12.50 (filling insulin syringe) | SSDC | |
| Maryland | Lowest from AWP minus 12%, WAC + 8%, direct price + 8% or distributor price | n/a | \$3.51 (generic) \$2.56 (brand) \$4.46 (generic to nursing home) \$3,51 (brand to nursing home) \$6.89 (home IV therapy) | TOP\$ | |
| Massachusetts | WAC plus 5% (all drugs outside 340B) AAC (340B drugs) | n/a | \$3.00 (all drugs outside 340B) \$10.00 (340B drugs) | n/a | V |
| Michigan | AWP minus 13.5% or WAC + 3.8% (independent pharmacies, chain pharmacies with <5 stores) AWP minus 15.1% or WAC plus 1.88% (chain pharmacies, | n/a | \$3.00 (long term care) \$2.75 (all other providers) \$6.00 (cream, emulsion, nasal drops, ointments or optic drugs) | NMPI | V |

| State | Ingredient Cost pharmacies serving nursing facilities) | Specialty Pricing | Dispensing Fee \$10.00 (compounded capsules, powders, suppositories) | Multi-state Drug Purchasing Pool | 340B Written Policy |
|-------------|---|---|--|---|---------------------------|
| Minnesota | WAC + 2% WAC + 4% (independent pharmacies located in small rural or isolated rural location) WAC minus 40% (340B drugs) | n/a | \$3.65 (+ \$0.30 for legend unit dose drugs) | NMPI | V |
| Mississippi | AWP minus 25% (generic) AWP minus 12% or WAC + 9% (brand) | Chemotherapy drugs and concomitant non- chemotherapy drugs administered through chemotherapy treatment and billed on same claim as chemotherapy treatment: ASP + 6% | \$4.91 (generic) \$3.91 (brand) | SSDC | |

| State | Ingredient Cost | Specialty Pricing | Dispensing Fee | Multi-state Drug Purchasing Pool | 340B Written Policy |
|-------------------|---|---|---|---|---------------------------|
| Missouri | Lower of AWP minus 10.43% or WAC + 10% | n/a | \$4.09 | n/a | |
| Montana | WAC + 2% | n/a | \$6.78 \$12.50 to \$22.50 (compounding) | NMPI | V |
| Nebraska | AWP minus 11% or WAC +6.8% | n/a | \$4.45 | TOP\$ | |
| Nevada | NADAC | n/a | \$9.47 | n/a | |
| New Hampshire | AWP minus 16% or WAC + 0.8% | n/a | \$1.75 (regular and compounding) | NMPI | |
| New Jersey | WAC minus 1% | n/a | \$3.73 to \$3.99 (24-hr emergency service and impact area) | n/a | |
| New Mexico | Lower of AWP minus 14%, WAC, manufacturer price, pharmacy invoice price | n/a | \$2.50 \$3.65 (pharmacist uses product selection) | n/a | |
| New York | Lower of FUL, AWP minus 25%, or SMAC (generic) Lower of FUL or AWP minus 17% (brand) | n/a | \$3.50 (generic, brand) \$4.25 (compounding) | NMPI | V |
| North Carolina | WAC + 6% | Physician- administered drugs: ASP + 6% | Generic tiered system \$7.52 (≥ 80% claims/quarter) \$5.34 (75%–79.9% claims/quarter) | NMPI | V |

| State | Ingredient Cost | Specialty Pricing | Dispensing Fee | Multi-state Drug Purchasing Pool | 340B Written Policy |
|--------------|---|--|--|---|---------------------------|
| | | or AWP minus 10% Contraceptive drugs (Implanon and Mirena): WAC + 6% | \$1.94 (70%–74.9% claims/quarter) \$0.97 (≤ 69.9% claims/quarter) \$1.94 (brand) | | |
| North Dakota | Lower of AWP minus 10% or WAC + 12.5% | n/a | \$5.60 (generic legend drugs) \$4.60 (brand legend drugs) 1.5x allowed amount (EAC, FUL, MAC) up to max \$4.60 (non-legend drugs, plus \$0.15 / pill) | SSDC | |
| Ohio | WAC + 7% (AWP minus 14.4% if not available) | n/a | \$1.80 | n/a | |
| Oklahoma | Lower of AWP minus 12%, WAC + 5.6%, ASP + 6% (injectable drugs) | n/a | \$4.02 | n/a | V |
| Oregon | ACC | n/a | \$14.01 (< 30,000 claims/yr) \$10.14 (30,000 – 49,999 claims/yr) \$9.68 (≥ 50,000 claims/yr) | SSDC ¹ | V |
| Pennsylvania | Lower of AWP minus 14% or WAC + 3.2% (brand) Lower of FUL, SMAC, AWP minus 25%, or WAC (generic) | n/a | \$2.00 (non-compounds) \$3.00 (compounds) | n/a | √ |

| State | Ingredient Cost | Specialty Pricing | Dispensing Fee | Multi-state Drug Purchasing Pool | 340B Written Policy |
|-------------------|--|---|--|---|---------------------------|
| Rhode Island | WAC | n/a | \$3.40 (outpatient) \$2.85 (long term care) | NMPI | |
| South Carolina | Lower of AWP minus 16% or WAC + 0.8% | n/a | \$3.00 (independent or institutional pharmacy) | NMPI | |
| South Dakota | Consolidated price (WAC x 1.2) minus 13% (direct price if not available) | n/a | \$4.40 + \$0.80 for unit dose dispensing | n/a | V |
| Tennessee | AWP minus 13% (generic) AWP minus 15% (brand) Lower of MAC or FUL for TennCare Pharmacy Network | Specialty pharmacy rates set separately | \$3.00 (generic) \$2.50 (brand) \$6.00 (generic nursing home) \$5.00 (brand nursing home) \$10.00 (compounded prescription, 0- 15 min preparation) \$15.00 (compounded prescription, 16-30 min preparation \$25.00 (compounded prescription, ≥ 31 min preparation) | n/a | V |
| Texas | Estimated acquisition cost: lower of AWP minus 15%, net cost to wholesaler + 12%, average direct chain contract price, MAC | n/a | \$6.50 | n/a | V |

| State | Ingredient Cost | Specialty Pricing | Dispensing Fee | Multi-state Drug Purchasing Pool | 340B Written Policy |
|---------------|--|---|--|----------------------------------|---------------------------|
| Utah | AWP minus 17.4% 340B ceiling price (340B drugs) | n/a | \$3.90 (urban) \$4.40 (rural) \$12.39 (340B drugs) | SSDC | |
| Vermont | AWP minus 14.2% (multiple, single source) AWP minus 16.5% (large volume out-of-state mail order specialty pharmacies) | n/a | \$4.75 (in-state) \$2.50 (out-of-state) \$19.75 (compound drug, in-state) \$17.50 (compound drug, out-of-state) | SSDC | V |
| Virginia | AWP minus 13.1% | n/a | \$3.75 | n/a | |
| Washington | AWP minus 16% (single source, multisource drugs with ≤ 4 manufacturers/labelers) AWP minus 50% (multi-source drugs with ≥ 5 manufacturers/labelers and no MAC or FUL) | Physician- administered Drugs: ASP + 6% | \$4.24 to \$5.25 (based on 3-tiered pharmacy volume) | n/a¹ | V |
| West Virginia | AWP minus 30% (generic) AWP minus 15% (brand) | n/a | \$5.30 (generic) \$2.50 (brand) \$8.25 (340B drugs) | SSDC | V |
| Wisconsin | WAC + 2% (single source drugs) | n/a | 3.94 (generic) \$3.44 (brand) | TOP\$ | |

| | | Specialty | | Multi-state Drug Purchasing | 340B Written |
|---------|-----------------------------|-----------|--------------------------------------|-----------------------------------|-----------------|
| State | Ingredient Cost | Pricing | Dispensing Fee | Pool | Policy |
| | WAC minus 3.8% (multisource | | \$0.015/unit (repackaging) | | |
| | drugs) | | \$9.45 to 22.16 (compound drug fee) | | |
| | | | \$9.45 to 40.11 (pharmaceutical care | | |
| | | | dispensing fee) | | |
| Wyoming | AWP minus 11% | n/a | \$5.00 | SSDC | |

Abbreviations: AAC = actual acquisition cost; ASP = average sale price; AWP = average wholesale price; FQHC = federally qualified health center; FUL = federal upper limit; MAC = maximum allowance cost; min = minute; NADAC = national average drug acquisition cost; NMPI – National Medicaid Pooling Initiative; req' = required; SSDC = Sovereign States Drug Consortium; TOP\$ = The Optimal PDL \$olution; U/C = usual and customary; WAC = wholesaler acquisition cost; yr = year

Notes:

1. Washington and Oregon participate in the Northwest Prescription Drug Consortium (NPDC), which does not include Medicaid pharmacy programs.

References

- Abboud, C., Berman, E., Cohen, A., Cortes, J., DeAngelo, D., Deininger, M., ... & Lomaia, E. (2013). The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: From the perspective of a large group of CML experts. *Blood*, *121*(22), 4439-4442.
- Appleby, J. (2016). *Medicare's drug-pricing experiment stirs opposition*. Retrieved from http://khn.org/news/medicares-drug-pricing-experiment-stirs-opposition/
- 340B Prime Vendor Program. (2016). 340B price/covered outpatient drugs. Retrieved March 30, 2016 from https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/
- 81 Fed. Reg. 13230-13261. (2016). *Medicare program; part B drug payment model; proposed rule.*Retrieved April 28, 2016 from https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05459.pdf
- 81 Fed. Reg. 27544. (2016). *Medicaid managed care; final rule*. Retrieved May 10, 2016 from https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-09581.pdf
- Centers for Medicare and Medicaid Services. (2006). *State Medicaid director letter on physician administered drugs*. Retrieved from https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMDD71106.pdf
- Centers for Medicare and Medicaid Services. (2016a). *Medicare part B drugs payment model*. Retrieved April 28, 2016 from https://innovation.cms.gov/initiatives/part-b-drugs
- Centers for Medicare and Medicaid Services. (2016b). *Re: Implementation of the covered outpatient drug final regulation provisions regarding reimbursement for covered outpatient drugs in the Medicaid program.* Baltimore, MD: CMS. Retrieved April 15, 2016 from https://www.medicaid.gov/federal-policy-guidance/downloads/smd16001.pdf
- Centers for Medicare and Medicaid Services. (2015a). *Medicaid covered outpatient prescription drug reimbursement information by state (as of December 2015)*. Retrieved March 25, 2016 from https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/xxxreimbursement-chart-current-qtr.pdf
- Centers for Medicare and Medicaid Services. (2015b). *Medicaid drug rebate program notice:*Assuring Medicaid beneficiaries access to hepatitis C (HCV) drugs. Retrieved March 25, 2016 from https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf
- Centers for Medicare and Medicaid Services. (2015c). *Medicaid pharmacy supplemental rebate* agreements (as of December 2015). Retrieved March 25, 2016 from

- https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-gtr.pdf
- Cook, A., Somers, J., & Christensen, J. (2009). *Prescription drug pricing*. Congressional Budget
 Office. Retrieved March 31, 2016 from http://www.nhpf.org/library/handouts/Cook.slides_01-30-09.pdf
- Cook, N. & Karlin-Smith, S. (2016). *Drug makers spend big to fight California price control* referendum. Retrieved April 28, 2016 from http://www.politico.com/story/2016/04/drug-makers-california-referendum-222334
- CVS Specialty. (2016). *Comprehensive specialty pharmacy drug list. CVS Pharmacy*. Retrieved April 14, 2016 from https://www.cvsspecialty.com/wps/wcm/connect/d5405d7b-685e-4377-b998-2e4c4daf0b13
- Express Scripts. (2015). 2014 Drug trend report. St. Louis, MO: Express Scripts. Retrieved March 23, 2016 from http://lab.express-scripts.com/lab/drug-trend-report
- Express Scripts. (2016). 2015 Drug trend report. St. Louis, MO: Express Scripts. Retrieved March 23, 2016 from http://lab.express-scripts.com/lab/drug-trend-report
- Health Resources and Services Administration. (n.d.) *340B drug pricing program*. Retrieved March 7, 2016 from http://www.hrsa.gov/opa/index.html
- Illinois Department of Healthcare and Family Services. (2016). 340B purchased drugs. Retrieved from http://www.illinois.gov/hfs/MedicalProviders/Pharmacy/Pages/340bfaq.aspx
- Medicaid and CHIP Payment and Access Commission (MACPAC). (2015). *Medicaid payment for outpatient prescription drugs*. Washington, D.C.: MACPAC. Retrieved March 25, 2016 from https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf
- Medicaid and CHIP Payment and Access Commission (MACPAC). (2016). *Medicaid spending for prescription drugs*. Washington, D.C.: MACPAC. Retrieved March 25, 2016 from https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf
- Medicaid.gov. (2016). *Medicaid drug rebate program*. Retrieved March 30, 2016 from https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/medicaid-drug-rebate-program.html

- The Menges Group. (2014). *State policies regarding Medicaid MCO preferred drug lists*. Retrieved April 15, 2016 from
 - http://communityplans.net/Portals/0/Fact%20Sheets/ACAP Menges State PDL Policies.pdf
- National Association of State Medicaid Directors (NAMD). (2016). *NAMD responses to senate* finance committee questions on drug policy. Retrieved March 15, 2016 from http://medicaiddirectors.org/wp-content/uploads/2016/03/NAMD-Response-to-SFC-on-drug-value-03-04-16.pdf
- National Conference of State Legislatures. (2015). *Pharmaceutical bulk purchasing: Multi-state and inter-agency plans*. Retrieved March 25, 2016 from http://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx
- National Conference of State Legislatures. (2016). *Specialty pharmaceuticals and states*. Retrieved April 28, 2016 from http://www.ncsl.org/research/health/specialty-pharmaceuticals-and-states.aspx
- National Governors Association (NGA), Center for Best Practices. (2004). *State purchasing pools for prescription drugs: What's happening and how do they work?* Washington, D.C.: NGA.

 Retrieved March 25, 2016 from

 http://www.nga.org/files/live/sites/NGA/files/pdf/0408PRESCRIPTION.pdf
- National Hemophilia Foundation. (2015). *Policy statement hemophilia treatment center*participation in the 340B drug discount program. Retrieved from

 https://www.hemophilia.org/sites/default/files/document/files/NHF-Position-StatementRegarding-Hemophilia-Treatment-Center-Participation-in-the-340B-Drug-DiscountProgram.pdf
- Office of the Assistant Secretary for Planning and Evaluation. (2016). *Observations on trends in prescription drug spending.* Baltimore, MD: United States Department of Health and Human Services. Retrieved March 7, 2016 from https://aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf
- Office of the Inspector General (OIG), Department of Health and Human Services. (2011). State

 Medicaid policies and oversight activities related to 340B-purcahsed drugs. Washington, D.C.:

 OIG. Retrieved March 30, 2016 from

 http://www.hrsa.gov/opa/programrequirements/reports/medicaidpoliciesandoversities06201

 1.pdf
- Office of Inspector General (OIG), Department of Health and Human Services. (2014). *States'* collection of offset and supplemental Medicaid rebates. Retrieved from http://oig.hhs.gov/oei/reports/oei-03-12-00520.pdf

- Pennsylvania Department of Human Services. (n.d.). *The specialty pharmacy drug program*. Retrieved from
 - http://www.dhs.pa.gov/provider/pharmacyservices/thespecialtypharmacydrugprogram/inde x.htm
- PEW Charitable Trusts. (2015). *Specialty drugs and health care costs*. Retrieved from http://www.pewtrusts.org/~/media/assets/2015/11/specialty-drugs-and-health-care-costs artfinal.pdf?la=en
- Segal Consulting. (2015). 2016 Segal health plan cost trend survey. Retrieved March 25, 2016 from https://www.segalco.com/media/2138/ps-trend-survey-2016.pdf
- Smith, V., Gifford, K., Ellis, E., Rudowitz, R., Snyder, L., & Hinton, E. (2015). *Medicaid reforms to expand coverage, control costs and improve care*. Retrieved from http://files.kff.org/attachment/report-medicaid-reforms-to-expand-coverage-control-costs-and-improve-care-results-from-a-50-state-medicaid-budget-survey-for-state-fiscal-years-2015-and-2016
- Sovereign States Drug Consortium (SSDC). (2016). *Medicaid supplemental drug rebate program*. Retrieved from https://www.rxssdc.org/sovereign-states-drug-consortium-medicaid-supplemental-drug-rebate-program
- Stencel, K., Farbstein, M., Wallack, M. C., Lott, R., & Gnadinger, T. (2014, November 17). Health policy brief: The 340B drug discount program. *Health Affairs*. Retrieved March 25, 2016 from http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=130
- The Council of State Governments Midwest. (2013.) Details of state limits on prescriptions for Medicaid recipients. Retrieved from
 - http://www.csgmidwest.org/policyresearch/documents/scriptlimits.pdf

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