

**MEDICAID  
INSTITUTE**  
AT UNITED HOSPITAL FUND

# Medicaid Prescription Drugs: Purchasing and Management

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at United Hospital Fund**

Established in 2005, the Medicaid Institute at United Hospital Fund provides information and analysis explaining the Medicaid program of New York State. The Medicaid Institute also develops and tests innovative ideas for improving Medicaid's program administration and service delivery. While contributing to the national discussion, the Medicaid Institute aims primarily to help New York's legislators, policymakers, health care providers, researchers, and other stakeholders make informed decisions to redesign, restructure, and rebuild the program.

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AT UNITED HOSPITAL FUND BY

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## Introduction

The nation's current economic situation, combined with the passage of the Affordable Care Act (ACA),<sup>1</sup> has had an unprecedented impact on state Medicaid programs. Policymakers are facing challenges and opportunities as they strive to achieve cost containment while ensuring access to benefits and maintaining quality of care. While federal law generally requires that all state Medicaid programs offer certain basic benefits, each state program determines the extent to which it will cover optional benefits—including outpatient prescription drugs. All state Medicaid programs have elected to include prescription drugs in their benefit packages, and have witnessed how prescription drug expenditures continue to grow each year, consuming an increasing portion of Medicaid budgets.

Medicaid's pharmacy benefit is inherently complex. It must comply with state and federal regulations, ensure adequate reimbursement to providers across multiple delivery systems, and manage unique beneficiary populations with complex disease states, while also retaining affordable access to services and optimal quality of care. Historically, states have been motivated to implement a host of utilization management options to mitigate the double-digit rate of growth of pharmacy expenditures, including the introduction of reimbursement changes, as well as Preferred Drug Lists and supplemental rebates from manufacturers. Provisions within federal health care reform legislation will influence the net cost of drugs, expand eligibility, and increase utilization and state expenditures, imposing even greater emphasis on cost containment and optimization of prescription drug use in the delivery of all Medicaid health care benefits.

This analysis considers policy options and identifies best practices in the purchasing and management of prescription drugs in today's Medicaid environment; it also examines New York's Medicaid prescription drug program, which is administered by the state's Department of Health. With nearly \$2.7 billion in Medicaid pharmacy expenditures in New York State in federal fiscal year 2009, net of federal and state supplemental rebates,<sup>2</sup> State administrators and policymakers will need to create a strategy for ongoing and future management of the prescription drug program. This report is intended to provide an outline of the current landscape and opportunities for New York to develop a comprehensive road map toward its goal of creating sustainable health care strategies.

<sup>1</sup> On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA); on March 30, the President signed the Health Care and Education Reconciliation Act. Together, the two bills constitute what is known as federal health care reform; they are collectively referred to as the Affordable Care Act (ACA).

<sup>2</sup> Quarterly Statement of Expenditures for the Medical Assistance Program (Form CMS-64).

## Report Structure

The options discussed and best practices outlined throughout this report are intended to achieve one or a combination of the following goals: cost containment, maintenance or improvement of quality, and alignment with best practices employed in other states and in the commercial sector. The report addresses a range of purchasing and utilization management options, focusing on:

- Pharmacy program delivery systems;
- Reimbursement;
- Drug product and rebate optimization;
- Aggregate purchasing and other reimbursement tools; and
- Clinical program efficiency and quality management.

Within each of these areas we provide:

- Background, including a description of the purchasing or management option;
- Other states' policies and program procedures;
- Current policy and programs in New York;
- Best practices; and
- Conclusions, a synopsis of how New York's programs relate to best practices and compare with other states'.

The report does not include a comprehensive survey of how every state Medicaid program addresses each purchasing or management option, but does include relevant information from various states. Mercer interviewed several New York State Department of Health representatives to gather the information that appears in the current policy sections, including discussions of existing management policies and programs, baseline expenditure and utilization metrics, and related outcomes.

In developing the best practices subsections, Mercer obtained benchmark data on other Medicaid pharmacy programs through a review of publicly available materials and interviews with various state representatives, as well as from our knowledge of innovative programs implemented by both Medicaid and commercial-sector non-Medicaid payers. Mercer is familiar with the unique characteristics of Medicaid pharmacy programs—including regulatory constraints, population demographics, utilization patterns, and access issues—and, where applicable, the report highlights such elements.

This report is not intended to provide exhaustive detail on the options discussed nor to identify or study in detail the drivers of spending within New York’s pharmacy program. Rather, it can be used by New York and other states’ policymakers to identify potential options that could further optimize their prescription drug programs.

Mercer acknowledges and thanks the numerous staff at the Department of Health who met with us and provided background material, policy information, and insights that assisted in the development of this report.

## Pharmacy Program Delivery Systems

This section addresses how state Medicaid programs choose to deliver their prescription drug programs—either through inclusion in capitated managed care arrangements or delivery via their fee-for-service programs. The inclusion of prescription drugs in capitated benefits packages is commonly referred to as a “carve-in” model; some states opt to “carve out” some or all prescription drugs from capitation rates paid to managed care organizations.

When some or all of the prescription benefit is provided under fee for service, states must determine *who* will provide the associated services, based on staffing resources, including the availability of talented full-time employees to administer and manage the pharmacy program. A state may wish to deliver key pharmacy services with in-house resources or may contract with specialized external vendors for various pharmacy management activities, such as drug utilization review, preferred drug list and rebate administration, medication therapy management, clinical editing, and other services. External vendors offer expertise and technology that is often required to administer an efficient and effective pharmacy program—resources that a state may not possess.

With the passage of federal health care reform, states will likely reassess pharmacy program delivery options and explore the most appropriate means of administering their pharmacy programs to meet each state’s objectives.

### Pharmacy Program Carve-out

#### **Background**

For many years, states with Medicaid managed care programs have analyzed and reached various conclusions about the advantages and fiscal soundness of carving out the pharmacy benefit from their managed care capitation rates and administering it through Medicaid fee for service, while continuing to provide other health care services through managed care. This arrangement allows states to qualify for drug manufacturer rebate revenue available through

the federal Medicaid Drug Rebate Program (see page 25), as well as qualify for state supplemental rebates for all Medicaid beneficiaries.

With the passage of federal health care reform, which included the Medicaid Drug Equalization Act of 2009, the statutory federal rebates (a minimum of 23.1 percent of the average manufacturer price for branded drugs, and 13 percent for generics) can now be collected for medications dispensed to beneficiaries who receive pharmacy benefits through managed care plans. This component of the legislation is considered a game changer that will affect carve-out policy decisions across the country. Although the legislation equalized the rebate component across fee for service and managed care, other factors directly influence the total cost and successful delivery of the prescription benefit through each of those approaches. Such factors include, but are not limited to:

- Competitive provider reimbursement terms;
- Clinically sound and aggressive utilization management tools;
- Use of lowest-net-cost clinically effective drug products;
- Resources to monitor and manage the pharmacy program;
- Data sharing and integration;
- Flexibility to update pharmacy edits and program parameters with the changing pharmacy landscape; and
- Ability to comprehensively manage the recipient's health care needs.

*Federal rebates can now be collected on prescriptions from Medicaid managed care plans—resulting in policymakers reevaluating fee-for-service prescription drug programs.*

Advocates of managed care consistently argue that a pharmacy carve-in, with administration through the managed care plan, results in greater use of lower-cost medications (such as generics), lower utilization rates, lower reimbursement to pharmacy providers, and improved patient outcomes through integration of care. Advocates of a pharmacy carve-out and delivery through fee for service point to the use of a preferred drug list (PDL), or single formulary for the entire state Medicaid population, a single set of utilization edits and rules, enforcement of a uniform decision-making process, and the leverage associated with volume purchasing—all factors welcomed by providers as contributing to cost control and improved quality of care.

Other factors, beyond drug cost and utilization management methods, that influence pharmacy carve-out decisions include:

- State provider taxes or other fees that draw in federal revenue;
- Disruption of profits for contracted managed care entities; and
- Stakeholder influences.



## Other States

Because many states have taken a “partial carve-out” approach, a comprehensive, up-to-date summary of the pharmacy benefit across all states does not exist. In a “partial” approach, certain populations or aid categories are carved out while others receive their pharmacy benefit through managed care plans. Additionally, states may modify the benefit structure from one year to the next, carving one or more aid categories into managed care or out to fee for service. Of the 41 states that currently contract with Medicaid managed care organizations on a capitated basis, 28 include pharmacy in their capitated benefits packages. Thirteen states—Connecticut, Delaware, Illinois, Indiana, Iowa, Missouri, Nebraska, Ohio, Tennessee, Texas, Utah, West Virginia, and Wisconsin—have carved out their pharmacy benefits; Texas is actively considering legislation to carve pharmacy into managed care.<sup>3</sup>

*Rebate equalization gives renewed impetus to reevaluate previous policy decisions on pharmacy carve-outs.*

With rebate equalization, arguments about the merits of delivering the pharmacy program within each respective system have become even more relevant, resulting in a renewed impetus to reevaluate previous policy decisions on pharmacy carve-outs.

## Current Policy in New York

In New York, legislation enacted in 1998 required the carve-out of pharmacy services from mainstream Medicaid managed care plan benefit packages. The carve-out was intended to be a temporary solution, and after three years New York attempted to transition pharmacy responsibilities back into managed care, but was unsuccessful. Only Family Health Plus, a Medicaid expansion implemented in 2001, had its pharmacy benefit carved into managed care coverage. In 2000 and 2001, Department of Health (DOH) staff cited rising drug costs as one of the reasons to continue to carve out the pharmacy benefit from managed care; this historical carve-out has been used as a means of keeping managed care organizations from losing money and fostering their continued participation in capitated programs. New York State continued to expand the pharmacy carve-out, with Family Health Plus removing pharmacy benefits from its capitated managed care organizations in October 2008.

In a major policy shift, New York’s recently enacted budget for State Fiscal Year 2011-2012 carved pharmacy back into the Medicaid managed care benefit package for all beneficiaries enrolled in managed care plans. The policy change reflects a stronger emphasis on care models as vehicles to pursue utilization management and cost containment.

<sup>3</sup>The Lewin Group. February 2011. *Projected Impacts of Adopting a Pharmacy Carve-In Approach Within Medicaid Capitation Programs*. Accessible at <http://www.lewin.com/content/publications/MHPAPaperPharmacyCarve-In.pdf>.

## **Best Practices**

Numerous influencing factors make the decision to carve out the pharmacy program unique to each state, requiring an extensive fiscal analysis of the various factors specific to that state. Ingredient cost and provider reimbursement terms, drug mix, use of lowest-net-cost and clinically appropriate products, and related tax incentives continue to be important in evaluating whether or not to carve out the benefit. Additional factors stemming from the Affordable Care Act include:

- Federal rebate offset amounts and the corresponding impact on previous rebate revenue collection and the general fund;
- The efficiency and effectiveness of optimizing rebate collection on managed care encounter claim data;
- The ability to continue to collect similar supplemental rebate revenues; and
- The impact on capitation rates, as applicable, due to changes in managed care organizations' ability to collect manufacturer rebates independent of the federal rebate program.

As states contemplate a fiscal analysis, they should also consider additional factors that are predictors of a successful carve-out and delivery of the pharmacy program within fee for service. These include:

- Strong pharmacy department leadership, and an adequate number of experienced staff;
- A comprehensive claims processing system with inherent flexibility allowing for timely updating of point-of-sale edits, coverage rules, and eligibility;
- A PDL that includes clinically effective drugs and evaluates lowest net cost;
- Reporting and analytic services and capabilities that allow for informed decision making;
- Utilization management edits and programs that prevent inappropriate and overprescribing;
- Elimination of statutory rules that keep certain drugs or drug classes from being included on the PDL or subject to utilization restrictions;
- Timely delivery of prescription claims data to managed care organizations for integrated delivery of care; and
- Willingness to collaborate with managed care organizations to create a patient-centric care model that results in coordinated delivery of effective and efficient care and services.

## **Conclusions**

New York State's administration of a fee-for-service carve-out created a single set of parameters for its pharmacy benefit, for uniformity and consistency that eased the administrative burden on providers. Now that the State has opted to carve the prescription drug benefit into managed care, plans will need to individually evaluate each of the pharmacy "levers" described throughout this report and determine how best to use them to structure the benefit.

## In-House or Vendor Administration

### Background

To administer the Medicaid program, states are required to have a Medicaid Management Information System (MMIS).<sup>4</sup> All states operate an MMIS to support Medicaid business functions and maintain information on claims processing, provider enrollment, beneficiary eligibility and enrollment, and benefit package maintenance. Of these services, the one most relevant to the fee-for-service prescription drug program is the claims processing system, as all pharmacy claims are adjudicated at the point of sale. When states are evaluating MMIS vendors, it is critical to determine the functionality and flexibility of their claims administration systems as they relate to the pharmacy benefit.

In addition to evaluating critical MMIS functions, each state must determine which additional vendor services and contracts might be necessary for successful in-house administration of the fee-for-service prescription drug benefit. Pharmacy-specific services for which states might seek additional contracts with vendors include administration of drug utilization reviews, supplemental rebate contracting, clinical resources for PDL development and maintenance, provider services and call centers, and other specialized services as discussed throughout this report. Outside vendors may offer necessary expertise and technology that will supplement or enhance core MMIS functions.

Vendors that offer these specialized services often refer to themselves as pharmacy benefit managers or pharmacy benefit administrators. This industry works with both public- and private-sector clients, since both require the same administrative services. There are, however, specialty vendors that typically contract with state Medicaid agencies because of their knowledge of applicable regulations and requirements.

### Other States

In-house administration of one or all of the services associated with the prescription drug benefit is an option for consideration by each state. Beyond core MMIS functions, states may:

- Contract with multiple vendors;
- Contract with a single claims processing/fiscal agent, which may subcontract out other specialized pharmacy services;
- Contract with a single claims processing/fiscal agent while administering and managing all other components of the pharmacy program with existing State resources, including clinical staff, systems staff, and technology; and/or
- Administer the entire program, including claims processing, primarily with State resources.

<sup>4</sup>Section 1903(a)(3) of the Social Security Act, and defined in regulation 42 CFR 433.111.

Again, the multitude of options and the ability to modify contracted services from one year to the next mean there is no single, comprehensive summary of how fee-for-service Medicaid agencies are administering their respective prescription drug programs.

### **Current Policy in New York**

The Department of Health’s Bureau of Pharmacy Policy and Operations within the Office of Health Insurance Programs currently employs 29 full-time-equivalent (FTE) and three temporary staff, compared with 38 FTEs roughly four years ago—a result of retirements and movement to other departments or State positions.

DOH currently has pharmacy contracts with the following vendors:

- MMIS: Computer Sciences Corporation (contract currently out to bid);
- Retrospective drug utilization review: Health Information Design;
- Clinical support for drug utilization review interventions: University of Buffalo School of Pharmacy;
- PDL: Magellan Health Services;
- Drug effectiveness reviews: Oregon Health and Science University Center for Evidence-based Policy;
- Medication Therapy Management pilot program: State University of New York;
- Third-party liability/coordination of benefits: Computer Sciences Corporation and HealthCare Management System;
- Quality Wise<sup>5</sup> and utilization thresholds: APS Healthcare and Thompson Reuters.

*Factors influencing in-house management include size of program, hiring of qualified staff and associated costs, and federal funding match.*

### **Best Practices**

As with making decisions on carve-outs, states must consider many factors in determining which services should be contracted to vendors and which administered in-house. The number of beneficiaries covered by the fee-for-service pharmacy program is a key factor; other important influences include:

- The ability to hire and/or retain qualified pharmacy staff;
- The Federal Medical Assistance Percentages (FMAP) match available for in-house versus vendor-contracted services; and
- Federal regulatory reporting requirements dictating sufficient and qualified resources and administrative staff.

<sup>5</sup>The New York State Medicaid Quality Wise Program promotes quality health care and improved outcomes for beneficiaries enrolled in New York’s fee-for-service Medicaid program through retrospective claims analysis and collaboration with the provider community. State of New York Department of Health. August 2010. *Medicaid Update*.

To address an inability to hire and retain qualified resources, some states have opted to hire “independent contractors” as pharmacy staff, rather than State employees. This allows states to hire staff “at will” and provide compensation more commensurate with that of the commercial marketplace. States may require contractors to meet pre-established program goals, metrics, or savings prior to renewal of their contracts.

### **Conclusions**

Selecting the right balance of in-house pharmacy resources and specialized vendor resources remains a complicated decision for any state. The size of the population served and the associated expenditures demand careful evaluation to optimize the use of vendor partners and in-house resources. Although New York State has reduced in-house staffing over time, an in-depth evaluation of resource allocation is essential to determining the overall efficiency of the administration and management of the pharmacy program.

## **Reimbursement Options**

Two primary elements enter into Medicaid reimbursement to contracted pharmacies—ingredient cost, which varies depending on whether a drug is branded or generic, and dispensing fee, which should be based on the non-drug costs of prescription fulfillment.

Additionally, the introduction of high-cost specialty pharmaceuticals has resulted in reimbursement strategies tailored specifically to these types of drugs. Even with aggressive pricing, specialty pharmaceuticals tend to have exorbitantly high ingredient costs, with an average of \$2,080 per prescription reported during 2010.<sup>6</sup> Appropriate reimbursement for ingredient cost must be matched with appropriate dispensing fees that take into consideration special handling requirements, as well as clinical monitoring and inventory management processes that are more complex than those for non-specialty medications.

An additional component of overall pharmacy reimbursement that must be considered is the patient’s copayment on prescriptions. For both commercial and Medicaid payers, total reimbursement to pharmacies includes the copayment. For Medicaid beneficiaries, copayments must be nominal (a maximum of \$3.00 per prescription) and, most importantly, cannot be mandatory. Because pharmacy providers must absorb the value of copayments of Medicaid beneficiaries who are unable or unwilling to pay, their reimbursement is effectively reduced. (With non-Medicaid or commercial plans requiring member copayments, it is rare for pharmacy providers to absorb those costs.)

<sup>6</sup> Nease R, S Miller, S Frazee, A Behm, R Greer, AH Milhous, A Kautzner et al. April 2011. *2010 Drug Trend Report: A Market and Behavioral Analysis*, page 62. St. Louis: Express Scripts. Accessible at <http://www.express-scripts.com/research/studies/drugtrendreport/2010/dtrFinal.pdf>.

Given the increasing focus on Medicaid spending, as well as changes within the pharmacy industry, states have begun to reevaluate and modify their methods for determining ingredient cost and dispensing-fee payments to pharmacies for both specialty and non-specialty drugs. Copayments are also an important consideration as reimbursement rates are established or updated.

## Ingredient Cost

### Background

State Medicaid programs consider several methods for reimbursing pharmacies for ingredient costs. Generally, states base their retail pharmacy Medicaid reimbursement for a covered outpatient prescription drug on the lowest of:

- Estimated acquisition cost, the program’s estimate of the price generally paid by pharmacies in that state for a particular drug;
- Any federal upper limit for the drug, a maximum reimbursement rate established by the Centers for Medicare & Medicaid Services (CMS) for several hundred generic products;
- The state’s maximum allowable cost, the maximum reimbursement rate established by the State or its contractor, if applicable; or
- Usual and customary charge, the price for a given drug or service that a pharmacy, or other provider, would charge a cash-paying customer without the benefit of insurance provided through a payer.

**Table 1.**  
**Pricing Benchmarks**

<b>Benchmark</b>	<b>Definition</b>
Actual Acquisition Cost (AAC)	AAC is the actual cost that a pharmacy incurs or is invoiced in acquiring a product from a wholesaler or manufacturer.
Average Manufacturer Price (AMP)	AMP, an unpublished price point defined in federal legislation, is contained in contracts between CMS and drug manufacturers, and serves as the basis for rebate calculations.
Average Wholesale Price (AWP)	AWP is derived from either wholesalers’ suggested list prices or from the average markup reported by wholesalers on their wholesale acquisition costs or from other information provided by the manufacturer. AWP is a widely used benchmark listed in national pharmaceutical industry compendia.
Wholesale Acquisition Cost (WAC)	WAC is statutorily defined in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 as the manufacturer’s suggested purchase price for a wholesaler or direct purchaser, not including specific discounts. WAC is listed in national pharmaceutical industry compendia.

State agencies are responsible for determining estimated acquisition and maximum allowable costs, as well as appropriate dispensing fees. Estimated acquisition cost is often calculated from manufacturer-reported price benchmarks that include the average wholesale price, wholesale acquisition cost, average manufacturer price, or actual acquisition cost (Table 1).

The federal upper limit (FUL)—imposed by federal law and established by CMS—is the ceiling on ingredient cost that the federal government will pay for multisource generic products. Due to litigation, the FUL has not been expanded or routinely updated for many years. To contain costs for generically available products, states therefore generally rely on their maximum allowable cost programs, which typically include a greater number of drugs with more aggressive price points than the FUL.

For most states, the estimated acquisition cost is calculated by using average wholesale price less a discount percentage. However, the use of average wholesale price as the benchmark price point came under scrutiny when a lawsuit against First DataBank, Inc. (a drug information compendium) and McKesson Corporation became public in 2006. First DataBank was alleged to have made a systematic change that created markups on average wholesale price of approximately 4 percent between 2001 and 2005. In March 2009, a judge ruled against First DataBank and Medispan (another drug information compendium), requiring them to reduce or “roll back,” by September 26, 2009, the average wholesale prices of approximately 1,400 National Drug Code-identified products (NDCs) listed in the original complaint. Following the ruling, First DataBank stated that it would voluntarily roll back pricing for other NDCs as well, on the required date, and cease publication of average wholesale price by September 2011. Payers subsequently scrambled to modify their reimbursement methodologies by either adjusting the average wholesale price discount percentage or moving to an alternative reimbursement strategy—typically a wholesale-acquisition-cost-plus-percentage model.

*An ingredient-cost pricing benchmark needs to be timely, accessible, comprehensive, transparent, and trustworthy.*

Both the pharmaceutical industry and payers widely acknowledge that an alternative pricing benchmark for deriving ingredient cost must be timely, accessible, comprehensive, transparent, and trustworthy.<sup>7</sup> The alternative pricing benchmarks noted above each have pros and cons, with none encompassing all the best traits of a pricing benchmark; as a result, no single one has been widely adopted across the pharmacy industry. Among their shortcomings:

<sup>7</sup> Curtiss FR, P Lettrich, and K Fairman. September 2010. What is the price benchmark to replace average wholesale price? *Journal of Managed Care Pharmacy* 16(7): 492-501.

- Average wholesale price (AWP) has been under legal scrutiny and will no longer be published by all national compendia;
- Wholesale acquisition cost (WAC) is a timely alternative but is self-reported by manufacturers and subject to the same artificial inflation as average wholesale price. WAC is also not published for all NDCs, so an alternative benchmark is needed in its absence;
- Average manufacturer price is unpublished and, therefore, not accessible to Medicaid programs;
- Actual acquisition cost (AAC) is transparent and representative of actual ingredient costs for pharmacies but is also unpublished and is inconsistent from pharmacy to pharmacy. AAC also may not be representative of a chain store's ability to negotiate bulk purchasing discounts or incentives, as it does not account for some larger pharmacies acting as their own suppliers and thus inflates the end-user pharmacy's acquisition costs.

### Other States

Most Medicaid programs to date have opted to make no modifications to the ingredient-cost price benchmark despite the controversy and average wholesale price rollback of 2009, essentially subjecting providers to a decrease in reimbursement. Despite the shortcomings of AWP being made clear in the litigation, most states continue exclusive use of this measure as the basis of their estimated acquisition cost calculations. One reason for the status quo is that payers and providers are most familiar with AWP, which is used in the private-payer market for most contracts with pharmacies. Fifteen states do vary the AWP discounts used for their estimated acquisition cost calculations by drug type or pharmacy type. Arkansas, for example, calculates estimated acquisition cost to be AWP minus 20 percent for generic drugs and AWP minus 14 percent for brand-name drugs. Michigan varies estimated acquisition cost by pharmacy type, using AWP minus 13.5 percent for independent pharmacies (defined as one to four stores) and AWP minus 15.1 percent for chains (five or more stores).<sup>8</sup>

Although there is no ideal alternative price benchmark, Medicaid programs are considering how to optimize wholesale acquisition cost, which is statutorily defined and takes into account actual acquisition cost, which can be calculated through a survey of pharmacy providers or their wholesalers.

Alabama recently received news coverage for its approach to pharmacy reimbursement, which includes calculation of an “average acquisition cost” for *all* drug products, plus an increased dispensing fee of \$10.64 per prescription. Efforts to achieve CMS approval for this reimbursement strategy were twofold. Alabama addressed each reimbursement component (ingredient cost and dispensing fee) separately. The State will issue semiannual surveys of *actual* acquisition cost to determine an *average* acquisition cost for each drug product, which

<sup>8</sup> A summary of reimbursement terms by state, updated by CMS, is accessible at [http://www.cms.gov/Reimbursement/20\\_StateMedicaidRxReimb.asp](http://www.cms.gov/Reimbursement/20_StateMedicaidRxReimb.asp).



will be used for reimbursement and posted publicly on its website. Average acquisition cost is transparent and attempts to provide an accurate representation of historical acquisition costs; its disadvantages, however, include its lack of timeliness, its basis in a survey whose validity depends on the number of responses received, and the provider-specific nature of reported costs, which may vary greatly by provider type and location.

### **Current Policy in New York**

New York's pharmacy reimbursement for ingredient cost is mandated by state law, using a "lower-of" logic that includes estimated acquisition cost, federal upper limit, state maximum allowable cost, and pharmacies' usual and customary charge. This approach does not allow overrides for federal upper limit reimbursement that has not been updated by CMS, and is set at a reimbursement level that may be below the pharmacy provider's actual acquisition cost. The State's 2011-2012 budget adds average acquisition cost as a potential pricing source. It also reduces the estimated acquisition cost for sole- or multisource brand-name drugs to AWP minus 17 percent or wholesale acquisition price minus 0.41 percent. For multisource generic drugs, it retains reimbursement at the lesser of AWP minus 25 percent or the state maximum allowable cost, or SMAC. (The SMAC list is managed by Magellan Health Services, with estimated program savings reported to the State monthly.) The budget also eliminates the higher reimbursement designation for specialized HIV pharmacies.

At this time, there are no plans to conduct a statewide survey for pharmacy reimbursement, as all changes would require legislative approval. Because state law does not specify a drug compendium that must be used, the State will likely move to another data source, or multiple data sources, when First DataBank ceases publication of the average wholesale price.

### **Best Practices**

States that are not legislatively mandated to use a specific formula, and thus have the flexibility to modify their approach, can optimize their ingredient-cost reimbursement to coincide with the changing environment. As of September 2010, for example, 12 states are using pricing based on wholesale acquisition cost (WAC) in some way, often in conjunction with average wholesale price, to set reimbursement rates. States that elect to include WAC in their reimbursement rates often do so to ensure that payment is made at the "lower of" multiple pricing benchmarks, because WAC is published for only some 85 percent of all NDCs (but for approximately 98 percent of specialty-drug NDCs). Additionally, WAC has more variability across NDCs for the same drug product, reinforcing the need to optimize multiple ingredient-cost pricing benchmarks.

Nearly all states have established SMAC pricing for multisource generic products, which provides deeper savings than the CMS federal upper limit pricing for these products. States can optimize their generic reimbursement by utilizing a SMAC list that is both broad (covering most generic products) and deep (containing price points aggressively discounted from estimated acquisition cost). Because the underlying actual acquisition cost at which pharmacies purchase drugs from wholesalers changes frequently, states must ensure that their SMAC lists are updated frequently (at least monthly, if not more often).

## **Conclusions**

The concepts surrounding ingredient-cost calculations remain complex, but average wholesale price, as used in New York, remains consistent among the majority of public and private purchasers nationwide. Although this methodology is currently mandated by state law, policymakers should continue to investigate alternative ingredient-cost reimbursement methodologies, to yield transparent and fair provider payments for pharmaceuticals.

## Specialty Pharmacy Reimbursement

### **Background**

The term “specialty pharmacy” generally refers to those drugs that are high-cost biologics, which may require special handling, clinical monitoring, and/or administration by a health care provider—medications used to treat rheumatoid arthritis, cancer, or multiple sclerosis, for example. Specialty drugs comprise approximately 1 percent of total prescriptions, but account for 10 percent to 15 percent of overall prescription drug costs. In addition, costs are increasing for specialty drugs at an annual rate that is two to four times faster than for non-specialty drugs. With over 600 new specialty drugs now in various stages of development,<sup>9</sup> specialty drug spending in the United States was expected to reach \$99 billion in 2010, nearly double the \$54 billion spent in 2006. As specialty drugs comprise increasingly larger portions of state Medicaid pharmacy budgets, states must address ways to manage the cost of these medications.

Due to the nature of specialty products, a retail pharmacy may not be equipped to purchase or store these medications. Manufacturers themselves may impose “limited distribution” status on these specialty products, making them available only to “specialty pharmacy vendors” rather than standard retail pharmacies. Typically, these specialty vendors not only dispense these products but also provide clinical outreach to physicians and beneficiaries to ensure proper use of the medications, including waste minimization, side effect management, compliance monitoring, and management of dosing changes. Specialty pharmacy vendors can also offer aggressive pricing discounts due to volume purchasing, and can provide the nursing services that are necessary for the administration of certain specialty medications.

<sup>9</sup> *Drug Trend Report* 13:41. 2011. Medco Health Solutions. Accessible at <http://www.drugtrendreport.com/2011-report>.

## **Other States**

The majority of specialty drugs are branded products and not available as generics. State Medicaid program reimbursement for these products is similar to that for other branded drugs. The summary of reimbursement terms maintained and published by CMS does not currently capture information on states that reimburse for specialty medications differently than under their standard ingredient-cost reimbursement terms.

## **Current Policy in New York**

New York State reimbursement for specialty pharmaceuticals is no different than for any other single-source, multisource, or generic drug, optimizing a lower-of logic that considers estimated acquisition cost, federal upper limit, state maximum allowable cost, or the pharmacy's usual and customary price. Estimated allowable cost is average wholesale price minus 17 percent for brand drugs (as of the state's fiscal year 2011-12 budget) and AWP minus 25 percent for generics. In State Fiscal Year 2009, the fee-for-service Medicaid program reimbursed pharmacy providers approximately \$366 million for specialty products for approximately 30,000 beneficiaries, and spent approximately \$8.9 million on physician-administered specialty pharmacy products. Within the past two years the Department of Health has issued and withdrawn two requests for proposals for a specialty pharmacy program; while it continues to use prior authorization, quantity limits, and step therapy to manage specialty pharmacy utilization, it also continues to monitor the landscape for new specialty management strategies to help reduce the reported 7 to 9 percent annual increase in specialty drug costs.

## **Best Practices**

Since specialty drug products are costly and state Medicaid programs must reimburse based on estimated acquisition cost, some state programs (including those of Iowa, Minnesota, Missouri, North Carolina, South Carolina, Virginia, and Wisconsin) have instituted differential reimbursement for pharmacy providers on specialty medications. These states have implemented a more aggressive discount in comparison to the traditional brand-name ingredient-cost reimbursement, targeting select specialty products or numerous therapy classes.

An additional option that focuses on the management of specialty medication utilization, and not just the ingredient cost, is to contract with one or multiple preferred specialty pharmacy vendors to provide not only these medications but also clinical outreach services. This option is used by a few Medicaid programs and virtually all commercial programs. Outreach services are particularly important because of the high costs of these medications, but equally important and challenging is the transient nature of the Medicaid population. Specialty pharmacy vendors will optimize "teachable time" by personally calling patients and, on

reaching them, providing immediate consultations, rather than using automated calls to attempt to schedule future consultations. These providers can also integrate medical and laboratory data and records of hospital and ER visits with prescription drug data, to optimize the specialty medication treatment regimen.

Pennsylvania currently contracts with two specialty providers to service its specialty pharmacy program for approximately 2,000 fee-for-service Medicaid beneficiaries. The State also employs a nurse case manager who works closely with the specialty providers or the Department of Health's case management staff to identify specific beneficiaries requiring immediate intervention; vendor field representatives also provide face-to-face outreach to patients who can't be reached by phone. Since this program began in January 2009, it has decreased overall reimbursement for specialty products, and reported outcomes suggest that total per-member-per-month (PMPM) beneficiary costs decreased immediately post-implementation, driven primarily by decreased inpatient PMPM costs. Pennsylvania reports that overall PMPM costs have continued to trend downward quarter after quarter.

### **Conclusions**

New York State is not currently reimbursing for specialty pharmaceuticals differently than for other medications. In many cases this may be reasonable due to the deep discount of average wholesale price minus 17 percent on brand-name medications. There are opportunities for deeper discounts, however, on several classes of specialty medications. If the "AWP minus" methodology is retained, consideration could be given to a review of practices in other states that have implemented variable discounts for select products or therapy classes, and to a review of the current reimbursement for specialty medications administered in physicians' offices or health centers, to promote equitable rates for both pharmacy and medical providers. Alternative pricing benchmark methodologies, such as "wholesale acquisition cost plus" or "average sales price plus," should also be considered if a change in reimbursement for specialty medications is pursued.

Few Medicaid payers are offering comprehensive specialty pharmacy programs that focus on management of the recipient and not solely on the terms of reimbursement. There are costs and benefits to such programs and policymakers should carefully evaluate the associated return on investment.

## **Dispensing Fees**

### **Background**

Historically, the dispensing fee has, in a sense, been a placeholder, a nominal amount intended to provide payment for professional pharmacy services. Pharmacy dispensing fees paid by commercial payers average approximately \$1.50 per prescription, which does not cover

staff salaries, ancillary goods (e.g., pill containers, labels), rent, utilities, and other business costs for which these fees are intended to compensate. Pharmacies are, however, able to offset this loss in service component reimbursement by the margin received from ingredient-cost reimbursement.

Dispensing fees paid by Medicaid programs vary greatly by state. CMS has provided a comprehensive definition of the costs that states should include in the development of the dispensing fee for the Medicaid program:

*“Dispensing fee” (i) is incurred at the point of sale and pays for costs other than the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed; (ii) includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and (iii) does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit, including systems costs for interfacing with pharmacies.<sup>10</sup>*

### **Other States**

While some states, such as New Hampshire, have decreased their dispensing fees to bring them more into line with the commercial environment and to generate program savings, other states are attempting to increase their dispensing fees. CMS requires ample justification for the *need* for a dispensing fee change, whether an increase or decrease, and states that make any dispensing fee change must also separately take into account the ingredient cost payment, so that total reimbursement to pharmacies adheres to the statutory requirement that payments be consistent with the efficient and economic administration of the State Plan for Medicaid services.<sup>11</sup>

*CMS requires ample justification for a change in dispensing fee to ensure that total reimbursement to the pharmacy provider adheres to the statutory requirement.*

<sup>10</sup>Federal Register 72(136). July 17, 2007. Accessible at <http://edocket.access.gpo.gov/2007/07-3356.htm>.

<sup>11</sup>A summary of dispensing fees by state, updated by CMS, is accessible at [http://www.cms.gov/Reimbursement/20\\_StateMedicaidRxReimb.asp](http://www.cms.gov/Reimbursement/20_StateMedicaidRxReimb.asp).

### Current Policy in New York

As with ingredient cost, pharmacy reimbursement levels for dispensing fees are mandated by state law. The 2011-2012 budget reduced dispensing fees for generics from \$4.50 to \$3.50, which is the same amount paid for brand-name drugs. No dispensing fee is paid for over-the-counter medications.

### Best Practices

As ingredient-cost reimbursement in Medicaid programs moves to a more aggressive benchmark more reflective of actual acquisition cost, a complementary review of dispensing fees would be useful to validate that they accurately approximate the professional costs of doing business. Some states and national pharmacy organizations have completed dispensing fee surveys, collecting relevant data directly from pharmacies; Table 2 shows some of the results.

**Table 2.**  
**Dispensing Fee Surveys**

State	Old Dispensing Fee	Publication Date	New Dispensing Fee Based on Survey	Number of Pharmacies Surveyed	Cost to Change to New Dispensing Fee
Oregon	\$3.50 retail; \$3.91 institutional	April 2010	Weighted mean: \$10.72	723 (usable data obtained from 265)	Not reported
Maryland	\$3.69 preferred brand and generic at retail; \$2.69 other brand drugs at retail; \$4.69 preferred brand and generic for long-term care (LTC); \$3.69 other brand drugs for LTC	2006	Average: \$11.71; Median: \$10.67	1,100 (387 responses obtained)	\$8 million annually
National – Grant Thornton LLP on behalf of National Association of Chain Drug Stores and National Community Pharmacists Association	N/A	January 2007	Mean: \$10.50; Median: \$9.86	Over 24,400 (usable data obtained from 23,152)	N/A

Contracting with an independent third party to conduct dispensing fee surveys has helped states ensure confidentiality and the validity of the results. Surveys should review, separately, the actual cost of the drugs dispensed and the cost of dispensing. States that mandate survey

participation by pharmacy providers have more robust and accurate data from which to evaluate and determine dispensing fees. States must be aware that survey results may necessitate an increase in overall program costs, since dispensing costs may be higher than currently assumed.

Some states have created differential dispensing fees, recognizing that the cost of doing business varies among providers. Differential dispensing fees can be based on a variety of factors, including prescription volume, geography, provider type, and drug type. Some states have elected to use dispensing fees as a vehicle to drive utilization of generics, as noted earlier, offering higher fees for the dispensing of non-branded drugs. Table 3 provides a sample of states that have differential dispensing fees.

**Table 3.**  
**Dispensing Fees**

<b>State</b>	<b>Dispensing Fee by Provider Type</b>
Utah	Urban \$3.90; rural \$4.40
Oregon	Retail \$3.50; institutional \$3.91
Colorado	Retail \$4.00; institutional \$1.89
Alaska	Minimum (low Medicaid volume) \$3.45; maximum (high Medicaid volume) \$11.46
Florida	Standard provider \$3.73; 340B provider \$7.50*
Massachusetts	Standard provider \$3.00; 340B provider \$10.00*
<b>Dispensing Fee by Drug Type</b>	
Illinois	Brand \$3.40; generic \$4.60
North Dakota	Brand \$4.60; generic \$5.60
North Carolina	Brand \$4.00; generic \$5.60
Georgia	Brand \$4.63; generic \$5.13

\* See page 36.

### **Conclusions**

As policymakers evaluate possible modifications to ingredient-cost terms, through optimization of an alternative benchmark price or differential reimbursement for specialty medications, appropriate payments for dispensing fees should also be considered.

## Drug Product and Rebate Optimization

In recent years, Medicaid programs have placed a greater emphasis on policies and practices that optimize drug product selection and maximize pharmaceutical manufacturer rebates. States have adopted preferred drug lists (PDLs) and implemented clinical prior-authorization reviews to encourage providers to prescribe and dispense the most clinically appropriate and cost-effective medications. In addition, many states have invested in and improved upon their federal rebate collection programs and joined multistate purchasing pools, or implemented single-state purchasing arrangements to enhance their bargaining power with drug manufacturers and maximize supplemental rebate collection.

With the adoption of the Affordable Care Act, however, states are anticipating significant changes in how federal and supplemental rebates will be shared between the states and the federal government. States and their rebate contractors will, therefore, need to continuously monitor and react to these developments and be adept at coordinating final rebate changes for not only their fee-for-service programs but also for Medicaid managed care programs, where applicable.

### Preferred Drug List and Prior Authorization

#### **Background**

Over the past decade, state Medicaid programs have begun to utilize PDLs, making any medication not deemed “preferred” subject to prior authorization. States utilize prior authorization, in conjunction with a PDL, to encourage the prescribing of the most clinically appropriate and cost-effective drug within a specific therapeutic drug category. A PDL may be voluntary or mandatory.

- With a voluntary PDL, a list of preferred medications is developed and communicated to prescribers, but reimbursement of non-preferred medications is not restricted. The State relies on prescribers to voluntarily change their habits and prescribe medications included on the PDL.
- With a mandatory PDL, preferred drugs do not require prior authorization and may be prescribed and dispensed without any further clinical documentation or verification. Under federal law, non-preferred products must be made available through a prior-authorization review process, which must provide a response within 24 hours and allow for a 72-hour supply of the drug in emergency situations. The complexity of the prior authorization process varies and determines the extent to which it deters the use of non-preferred medications or encourages trials of preferred medications first.

In both the commercial and Medicaid sectors, PDL and prior authorization programs have proven to be valuable in shifting market share to clinically appropriate, less-costly preferred



products, without compromising the quality of patient care. In the private-payer marketplace, restrictive formularies (i.e., those requiring prior authorization or significant employee cost sharing for non-preferred drugs) typically cause an 80 percent to 90 percent market shift to preferred agents. State Medicaid programs, in contrast, typically experience a slightly smaller shift to preferred agents, due to federal exception allowances and statutory limitations regarding certain drug therapy classes, such as behavioral health or HIV/AIDS medications.

States with PDLs may also negotiate and collect supplemental rebates upon CMS approval (see page 25). Although state PDLs must adhere to federal exceptions and certain statutory limitations, pharmaceutical manufacturers offer supplemental rebates in exchange for having their products receive preferred status and avoid clinical prior-authorization review.

*Supplemental rebates—  
beyond those mandated by  
federal requirements—  
are paid by pharmaceutical  
manufacturers for  
placement of drug  
products on a state PDL.*

### **Other States**

Currently, 45 states and the District of Columbia operate mandatory PDL programs and participate in either single-state or multistate supplemental rebate arrangements. The only states that do not currently have PDLs and supplemental rebate arrangements in place are Arizona, New Jersey, New Mexico, North Dakota, and South Dakota (see Table 4).

### **Current Policy in New York**

New York State currently administers two prior-authorization programs—the Preferred Drug Program and the Clinical Drug Review Program.

- The Preferred Drug Program uses a mandatory PDL to encourage prescribing of drugs that are therapeutically appropriate and cost-effective. Preferred drugs on the PDL can be prescribed without any additional action, while non-preferred drugs require prior authorization.
- The Clinical Drug Review Program focuses on reviews of clinical appropriateness for select medications. It requires prior authorization for those drugs, based on concerns about safety, public health, or the potential for significant fraud, abuse, and/or misuse.

The Preferred Drug Program, implemented in 2006, utilizes a Pharmacy and Therapeutics Committee to make recommendations for the PDL. The Committee includes practicing physicians, nurse practitioners, pharmacists, and consumer representatives; all meetings are open to the public, and their agendas are posted in advance on the Internet. New York State contracts with the Drug Effectiveness Review Project (see page 24), which provides clinical

**Table 4.**  
**Supplemental Rebate Arrangements, by State**

<b>State</b>	<b>Single-State (Effective Date)</b>	<b>Multistate (Effective Date)</b>
Alabama	September 1, 2003	NA
Alaska	NA	January 1, 2004
Arizona	NA	NA
Arkansas	October 15, 2004	NA
California	1980s	NA
Colorado	January 1, 2008	NA
Connecticut	August 1, 2004	NA
Delaware	April 1, 2005	October 1, 2005
District of Columbia	NA	February 1, 2007
Florida	January 1, 2001	NA
Georgia	July 1, 2009	NA
Hawaii	NA	April 1, 2004
Idaho	April 1, 2003	May 1, 2006
Illinois	January 1, 2002	NA
Indiana	July 1, 2004	NA
Iowa	November 15, 2004	January 1, 2006
Kansas	October 1, 2002	NA
Kentucky	NA	October 1, 2004
Louisiana	April 1, 2002	October 1, 2004
Maine	January 1, 2003	January 1, 2006
Maryland	July 1, 2003	October 1, 2004
Massachusetts	January 1, 2004	NA
Michigan	NA	October 1, 2003
Minnesota	NA	July 1, 2004
Mississippi	February 1, 2006	NA
Missouri	January 1, 2004	NA
Montana	NA	July 1, 2004
Nebraska	NA	October 1, 2009
Nevada	NA	January 1, 2004
New Hampshire	NA	July 1, 2004
New Jersey	NA	NA
New Mexico	NA	NA
New York	NA	January 1, 2006
North Carolina	NA	October 1, 2009
North Dakota	NA	NA
Ohio	January 1, 2003	NA
Oklahoma	October 1, 2003	NA
Oregon	NA	July 1, 2009
Pennsylvania	October 1, 2005	January 1, 2007
Rhode Island	NA	January 1, 2007
South Carolina	NA	January 1, 2007
South Dakota	NA	NA
Tennessee	July 1, 2003	NA
Texas	November 1, 2003	NA
Utah	August 1, 2007	August 1, 2007
Vermont	NA	January 1, 2006
Virginia	January 4, 2004	NA
Washington	January 1, 2002	NA
West Virginia	April 1, 2002	August 1, 2008
Wisconsin	NA	April 1, 2005
Wyoming	NA	January 1, 2008
<b>Total</b>	<b>28</b>	<b>27</b>

Notes: As of March 2010. NA denotes No Agreement.

Source: [http://www.cms.gov/Reimbursement/22\\_SupplementalDrugRebateAgreements.asp](http://www.cms.gov/Reimbursement/22_SupplementalDrugRebateAgreements.asp).

evidence-based reviews to help the Committee make its recommendations. The State's 2011-2012 budget expanded the role of the Department of Health in the Pharmacy and Therapeutics Committee by having DOH staff chair the Committee, allowing the Department to make recommendations directly to it. The budget also allows the Commissioner of Health to designate as "preferred" drugs that have not yet been scheduled for Committee review, pending completion of the review, so that supplemental rebates can be collected.

Prior authorization activities are conducted by a clinical call center managed and operated by Magellan Health Services. The call center, operating 24 hours per day, seven days per week, is staffed by certified pharmacy technicians, pharmacists, and a physician available for peer reviews.

In the past, the Preferred Drug Program could not require prior authorization for atypical antipsychotics, antidepressants, HIV/AIDS (antiretroviral) medications, and organ and tissue transplant anti-rejection (immunosuppressant) medications. Due to changes enacted in the 2011-2012 budget, however, all non-preferred drugs—including those in these drug classes—are now subject to prior authorization, thus increasing market share of preferred drugs, and increasing supplemental rebate revenue. It is important to understand, however, that although New York's PDL is mandatory, the Department of Health is still legislatively prohibited, through a "prescriber prevails" provision, from denying a prior-authorization request even when clinical appropriateness criteria are not met.

Each fiscal year, DOH prepares a report on the Preferred Drug Program for the Legislature and Governor, which includes:

- An overview of the program and description of any changes made to it during the fiscal year;
- A description of that fiscal year's outreach and education efforts;
- Results of a pharmacy and prescriber survey conducted annually by an independent third party; and
- Current program outcomes and cost savings.

For State Fiscal Year 2008-2009, New York State reported gross savings of \$268.6 million for 52 drug classes included in the Preferred Drug Program. The majority of the savings, \$171.6 million, came from supplemental rebates. The remaining savings, \$97 million, were attributable to a shift in utilization from more-expensive non-preferred drugs to less-expensive preferred drugs within a drug class.<sup>12</sup>

<sup>12</sup> New York State Medicaid Preferred Drug Program. August 2009. *Annual Report to the Governor and Legislature, State Fiscal Year April 1, 2008 – March 31, 2009*, pg. 13.

## **Best Practices**

The most efficient and successful mandatory PDL and prior-authorization programs have the following in common:

- A clinically based process for drug selection;
- A prior authorization system;
- Outreach and education;
- Continual monitoring; and
- Supplemental rebate procedures.

**Clinically Based Process for Drug Selection.** Clinical, evidence-based review is the basis for preferred medication selection; to be selected as preferred agents, medications must be clinically proven to be at least as effective and safe as any other medications in their therapy class. Clinical prior-authorization and PDL programs typically utilize a Pharmacy and Therapeutics Committee comprising physicians, pharmacists, and other appropriate individuals to review drug effectiveness and safety of drug categories in the development of clinical criteria edits; other clinicians, consumers, or advocacy representatives may also be included to ensure greater representation of Medicaid beneficiaries' issues and concerns, such as mental health, children's health, and HIV/AIDS. Some states utilize an existing Drug Utilization Review Committee to fulfill the responsibilities of a Pharmacy and Therapeutics Committee.

Pharmacy and Therapeutics committees often rely on additional resources to provide robust drug class clinical reviews. Eleven states, including New York, contract with Oregon's Drug Effectiveness Review Project—a collaboration of the Center for Evidence-based Policy and the Oregon Evidence-based Practice Center—to access its comprehensive, respected, evidenced-based clinical reviews.

PDL and prior-authorization programs that are clinically based, transparent, and developed collaboratively with legislatures, advocacy groups, and other stakeholders are the most successful, as measured by shifts in utilization to preferred medications, as well as increases in rebate revenues.

**Prior Authorization.** States use a variety of methods for processing prior-authorization requests, including faxes, real-time clinical review software that relies on historical pharmacy and medical claims to evaluate requests, automated voice-response systems, and call centers staffed by State employees or outsourced to a call center vendor. Successful prior-authorization systems provide adequate coverage during regular business hours, have after-hours/weekend emergency dispensing programs, and meet the federal requirement for a 24-hour response time.

**Outreach and Education.** All states post their PDLs on their Medicaid websites, for provider and public access. Many states also provide ongoing education and outreach in the form of meetings, publications, and direct written or oral communication with stakeholders (e.g., provider bulletins, e-mail alerts, brochures, etc.). These communications focus on program modifications and changes to PDL reviews and clinical prior-authorization criteria, to help facilitate smooth transitions.

**Continual Monitoring.** States that continually monitor the clinical and financial outcomes of their PDL and clinical prior-authorization programs, and act upon the findings, have the most efficient programs, best accepted by providers and beneficiaries alike. At a minimum, most states evaluate financial impact, but many also survey and review provider and beneficiary satisfaction, and review health outcomes and impact as well as compliance statistics.

**Supplemental Rebate Procedures.** Although states are not required to collect supplemental rebates from manufacturers if they have a PDL, the states that do collect supplemental rebates realize significant cost savings. Mercer has previously estimated the range of savings for mandatory PDLs with supplemental rebates to be between 2 percent and 11 percent of total drug expenditures in a variety of states. These estimated savings depend on a number of factors, including the type of rebate program (i.e., single- or multistate), number of drug classes included in the PDL, legislative mandates related to program structure and/or therapeutic class exclusions, mandates regarding minimum rebate values, and the resources available to support the supplemental rebate contracting process and program infrastructure. Successful programs capitalize on their purchasing power, infrastructure, and relationships with vendors to maximize supplemental rebate negotiations and collections.

## **Conclusions**

New York State has implemented a clinically sound Preferred Drug Program and has recently expanded the number and types of drug classes undergoing clinical review and included in the program. The State is limited in its ability to optimize the program, however, due to a “prescriber prevails” legislative provision. Policymakers should consider the extent to which this restriction prevents the PDP program from achieving the next level of efficiency and cost savings.

## **Federal and Supplemental Rebate Optimization**

### **Background**

The Medicaid Drug Rebate Program, created by the Omnibus Budget Reconciliation Act of 1990, requires pharmaceutical manufacturers to enter into rebate agreements with CMS and pay quarterly rebates to the states in exchange for Medicaid coverage of their drug products. Pharmaceutical manufacturers that do not sign an agreement with CMS are not eligible for

federal Medicaid coverage of their product(s).<sup>13</sup> Except for statutory limitations, state Medicaid programs must provide coverage and reimbursement for all covered outpatient drug products manufactured by companies that have entered into a rebate agreement with CMS.<sup>14</sup> The states and the federal government both share in the savings from the rebate program. Rebate agreements are applicable to brand-name and generic drugs, oral medications, and biologic products dispensed by a pharmacy or administered by a physician in an outpatient setting.

As a condition of participation in the program, pharmaceutical manufacturers must report two prices—average manufacturer price and “best price”— to CMS within 30 days of the end of each calendar quarter. These are confidential, but serve as the reference points to determine the manufacturer’s rebate obligation. CMS uses this information to compute a Unit Rebate Amount for each drug’s respective dosage form and strength, and provides this value to the states for creation of their rebate invoices for each manufacturer, based on utilization data. CMS rebates vary each quarter, adjusted based on changes in “best price” and on whether the drug price rises faster than the Consumer Price Index–Urban.

In addition to federal rebates, states have the option of pursuing supplemental manufacturer rebates. These generally apply only to brand-name drugs, for which manufacturers are willing to pay rebates in return for preferential status on the PDL. Most supplemental rebates consist of a guaranteed net unit price, meaning that the State pays a guaranteed maximum net price for each drug product and is protected against manufacturer price increases over time.

Supplemental rebates are thus closely tied—in inverse relationship—to CMS rebate amounts: if a CMS rebate increases, the supplemental rebate decreases by an equal amount, and vice versa.

*Supplemental rebate programs are either single-state direct-purchasing or multistate pooled-purchasing arrangements.*

Supplemental rebate programs are constructed as either single-state (also referred to as direct-purchasing) programs or multistate pooled purchasing arrangements, in which states combine their purchasing power to influence drug manufacturers to provide greater rebates. Some supplemental rebate programs also seek supplemental rebates for other products, such as durable medical equipment, most often diabetic supplies such as meters and test strips. Participation in a pooled purchasing program requires federal approval, to continue to receive federal match appropriations. Currently, there are three multistate purchasing pools approved by CMS (see Figure 1):

<sup>13</sup> Centers for Medicare & Medicaid Services. *History of the Medicaid Drug Rebate Program*. Accessible at <https://www.cms.gov/MedicaidDrugRebateDispR/downloads/mdrphistory.pdf>.

<sup>14</sup> There are five allowable exclusions: 1) anorexia, weight loss, or weight gain drugs; 2) fertility drugs; 3) cosmetic or hair-growth drugs; 4) drugs for symptomatic relief of coughs and colds; and 5) prescription vitamin and mineral products.

- National Medicaid Pooling Initiative, administered by Magellan Medicaid Administration, a subsidiary of Magellan Health Services, and including 11 member states and the District of Columbia;
- TOP\$, administered by Provider Synergies, a subsidiary of Magellan Health Services, and including seven member states; and
- Sovereign States Drug Consortium, independently administered by its seven member states with the assistance of a contracted supplemental rebate vendor.

The Affordable Care Act contains numerous provisions directly affecting both federal and supplemental rebates, including increases in minimum rebate percentages, new definitions of average manufacturer price (AMP), inclusion of Medicaid beneficiaries enrolled in managed care organizations, and extension of the 340B program (see page 36) to new covered entities.

A number of noteworthy provisions apply specifically to the Medicaid Drug Rebate Program:

- For generic drugs, an increase in the minimum rebate from 11 percent of AMP to 13 percent;
- For brand-name drugs, an increase in the minimum rebate from 15.1 percent of AMP to 23.1 percent;
- For brand-name blood-clotting factors and drugs approved exclusively for pediatric indications, an increase in the minimum rebate from 15.1 percent of AMP to 17.1 percent.

ACA requires that all funds attributable to these increased rebates be returned to the federal government. This was clarified by a September 2010 letter to state Medicaid directors, explaining that the federal government will only retain, or “offset,” the lesser of the difference between the increased minimum rebate value and “AMP minus ‘best price.’” For example, for the majority of single-source and innovator multiple-source (i.e., brand-name) drugs, the federal government will keep all rebates within the additional eight percentage-point range. States will continue to share in rebates below 15.1 percent and above 23.1 percent. For generic products, states must return the 2 percent rebate increase to CMS.<sup>15</sup>

### **Other States**

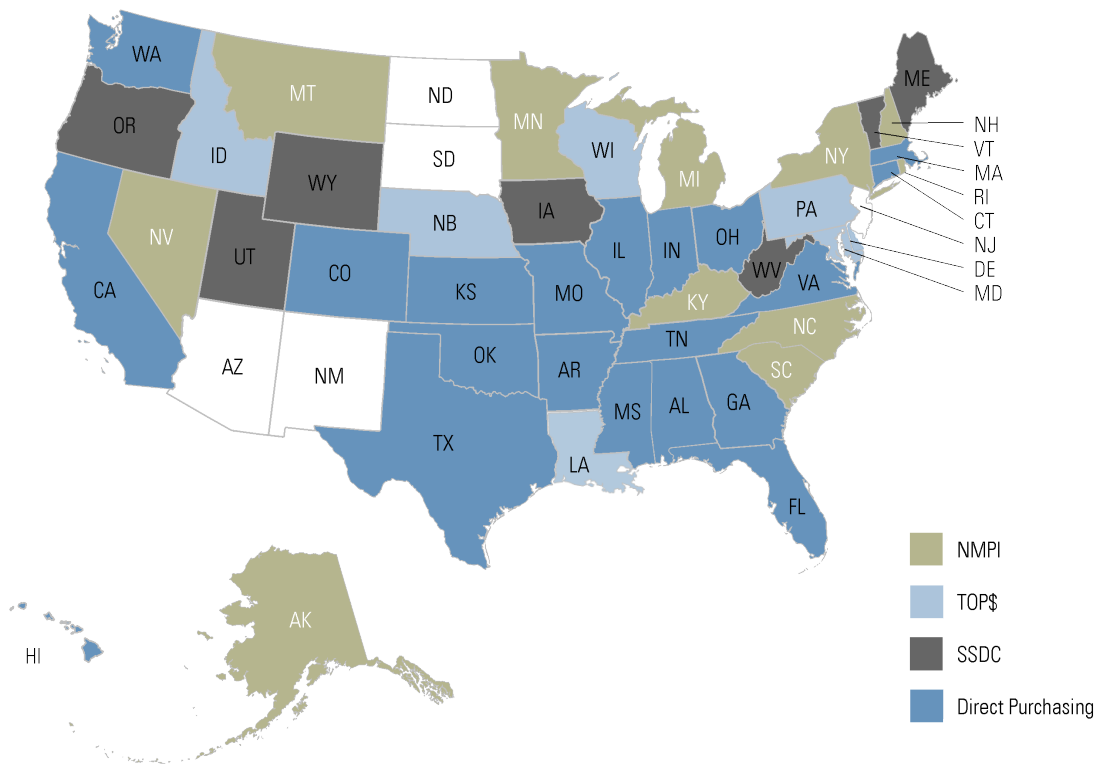
Figure 1 shows enrollment, by state, in the three CMS-approved Medicaid multistate supplemental rebate purchasing pools, and identifies the states that are, alternatively, involved in direct-purchasing arrangements.

### **Current Policy in New York**

New York State currently manages most of the CMS rebate process internally, but does contract with Computer Sciences Corporation for assistance with mailing of rebate invoices to manufacturers, and with reconciliation activities. All manufacturer disputes are processed by

<sup>15</sup> Centers for Medicare & Medicaid Services. September 28, 2010. State Medicaid directors letter #10-019. Accessible at <https://www.cms.gov/smdl/downloads/SMD10019.pdf>.

**Figure 1.**  
**State Enrollment in Supplemental Rebate Purchasing Pools and Direct-Purchasing Arrangements**



the Medicaid Rebates Unit, which works closely with DOH’s Formulary Operations and Systems Interface Unit to implement point-of-sale billing edits. These are reported by DOH to be successful at reducing the risk of payment errors due to pharmacy providers’ billing for inaccurate quantities.

In 2006, the State contracted with Magellan Health Services (formerly First Health Services Corporation) and joined the National Medicaid Pooling Initiative multistate purchasing pool. Magellan assists with clinical drug reviews for the Preferred Drug Program, operates the call center, provides provider/pharmacy education services, and manages the supplemental drug rebate negotiation process.

DOH representatives report that, in 2009, approximately 4.75 percent of total drug expenditures were returned to the State in supplemental rebates; federal rebate collections equaled approximately 33 percent of State drug expenditures. As previously noted, several new drug classes—notably atypical antipsychotics—have been added to the PDL. Adding highly utilized drug classes allows the State to designate products within each drug class as preferred, move market share to those preferred products, and ultimately achieve cost savings



through increased supplemental rebate collections and/or increased utilization of lower-cost generic products.

In April 2009, New York passed a budget agreement to enter into direct supplemental rebate negotiations with pharmaceutical manufacturers and to develop single-state supplemental rebate arrangements.<sup>16</sup> As a result, DOH began to work with Magellan Health Services to forge rebate agreements—notably for diabetic supplies—with pharmaceutical manufacturers that currently do not participate in National Medicaid Pooling Initiative efforts. Initially, DOH accepted all bidders as preferred, but manufacturers are required to submit bids annually and DOH has the option of limiting the number of preferred providers in coming years. Prior to implementation of this program, DOH’s expenditures for diabetic supplies were approximately \$68 million annually; in the first year following implementation, DOH reported savings of approximately \$14 million. The State’s 2011-2012 budget allows the Commissioner of Health to directly negotiate supplemental rebates with pharmaceutical manufacturers, and to categorize all of a manufacturer’s drugs as “non-preferred” when an agreement cannot be reached.

### **Best Practices**

Historically, most states have hired outside contractors to manage both the federal and supplemental rebate processes, to optimize rebate collections and comply with federal regulations. Rebate collection requires a comprehensive, accurate system for collecting prescription claims data; proper accounting processes, including preparation of invoices, reconciliation, and calculation of interest payments; and proper reporting and record retention. In addition, supplemental rebate contractors must have extensive knowledge of the federal rebate program, as they are often responsible for negotiating the guaranteed net unit price with drug manufacturers. Best practices for optimization of both federal and supplemental rebates therefore include:

- Experience and knowledge, including documented processes and procedures that comply with CMS regulations;
- Intimate knowledge of the State’s claims system, and of appropriate and expected pharmacy units;
- Open communication and strong working relationships between rebate contractors and State staff;
- Adequate staffing to ensure timely filing, tracking, and resolution of disputes.

<sup>16</sup> National Conference of State Legislatures. July 2010 (update). Pharmaceutical bulk purchasing: Multi-state and inter-agency plans. Accessible at <http://www.ncsl.org/default.aspx?tabid=14464>.

States that are able to achieve high federal rebate collection percentages attribute a portion of their success to ongoing maintenance and updating of their drug coverage files and optimal use of the CMS drug product data file,<sup>17</sup> which contains National Drug Code-level information on the active drugs that are part of the drug rebate program for the most recent quarter.

As previously noted, average total savings, including rebate collections, for PDL programs with supplemental rebates can vary widely. Both single-state and multistate supplemental rebate programs can be considered best-in-class arrangements. The success of either program for a given state depends on several factors, such as:

- Program size, the volume of Medicaid pharmacy dispensing and total drug expenditures;
- Relative bargaining power of the state with pharmaceutical manufacturers, on its own or within a multistate pool;
- Number of drug classes included on the PDL;
- Legislative mandates related to program structure and/or therapeutic class exclusions;
- Mandates regarding minimum rebate values; and
- Resources available to support the supplemental rebate contracting process and program infrastructure.

In addition, successful supplemental rebate programs that coordinate with state PDLs typically have the following components in common:

- Significant staffing resources and systems coordination for implementation, clinical reviews, reporting, and oversight;
- Expertise in rebate negotiation and identifying supplemental rebates for other products or services;
- Robust communication and education, throughout implementation, for prescribers, pharmacies, beneficiaries, and advocacy groups; and
- Experienced and tested negotiation processes with manufacturers.

### **ACA's Impact on Rebate Collection**

The Affordable Care Act's provisions will influence the amount of federal and supplemental rebates that states will receive under the Medicaid Drug Rebate Program. A primary concern is the potential loss of rebates stemming from CMS's retention of the incremental increase in rebate amounts. Although many states are attempting to analyze and estimate the impact these changes will have on future rebate collections, accurate impact analyses cannot be completed as CMS continues its interpretation of the new legislation. Specifically, states have not received CMS unit rebate amounts for any quarter during 2010, nor has CMS fully defined average manufacturer price. Also, best price data remain confidential and are not readily available to allow states to calculate their future rebate amounts.

<sup>17</sup> [http://www.cms.gov/MedicaidDrugRebateProgram/09\\_DrugProdData.asp](http://www.cms.gov/MedicaidDrugRebateProgram/09_DrugProdData.asp).

## Conclusions

With the many changes resulting from ACA, it is evident that, more than ever, states need formalized rebate processes, knowledgeable resources, and reliable contractors to optimize both federal and supplemental rebate collection in the new environment. The size of the New York State prescription drug program offers the leverage and negotiating power needed to positively influence supplemental rebate agreements with pharmaceutical manufacturers, as evidenced by the program's ability to garner supplemental rebates even for drug products that previously could not be subject to prior authorization. Policymakers should evaluate whether the current rebate program structure is optimal, or whether modifications are needed to achieve the highest level of rebate revenue.

## Aggregate Purchasing and Other Reimbursement Options

As with any good or service, the concept of volume-based purchasing power applies to pharmaceuticals as well. A supplier will readily offer discounts, rebates, or kickbacks in exchange for contractually binding purchasing agreements. These agreements may arise from purchasers autonomously aggregating together or through legislative mandates. For Medicaid programs, better price points can be achieved through the following channels, alone or in combination:

- Intrastate purchasing: Consolidated purchasing by multiple state and municipal agencies, in addition to Medicaid, to negotiate better prices;
- Interstate purchasing: Purchasing by multiple states that have formed alliances to exert regional or national leverage on drug manufacturers to provide rebates or preferred pricing in exchange for market share;
- 340B purchasing: Purchasing under legislation that allows health care providers for extremely vulnerable populations to acquire drugs at a deep discount, via a generous price ceiling.

These are all potent tools that states can use to drive down net costs, but each comes with contractual restrictions that can limit a Medicaid program's control and flexibility.

### Intrastate Purchasing Coalitions

#### Background

Intrastate purchasing, also commonly referred to as consolidated purchasing, allows a state to aggregate, or consolidate, the administration of various programs providing prescription services under the auspices of a single agency. The consolidation of prescription drug contracts into a single administrative purchasing unit under or within a state agency leverages

purchasing clout to obtain more favorable financial and service arrangements and secure greater economies of scale.

While intrastate purchasing of pharmaceuticals is often likened to the purchasing of other commodities, there are some important differences. In addition to purchasing per se, it requires the coordination of services (e.g., claims processing, enrollment, utilization management, and provider network management) associated with delivering the drug products and administering the pharmacy benefit. As a result, intrastate purchasing programs typically try to partner with one or more vendors—often a full-service pharmacy benefit manager—that offer the complete range of required specialized services.

If designed well, intrastate purchasing can not only produce significant cost savings but also improve access and clinical outcomes for all agencies involved, resulting in improved prescription drug utilization management and health management programs, administrative efficiencies, and increased bargaining power.

### **Other States**

Only a handful of states have designed and implemented intrastate purchasing programs. Georgia was one of the first: in 1999, the State created the Department of Community Health to manage health benefits for the Board of Regents (University) and state employee health plans, and for Medicaid and the Children’s Health Insurance Program. Between October 2000 and January 2003, the program saved Georgia an estimated \$60 million.<sup>18</sup> According to the National Conference of State Legislatures, Georgia ended the program in 2005, however. As one State official acknowledged, “With the exception of the negotiated financial arrangement for the commercial programs and the indirect savings associated with application of consistent pharmacy management strategies across all programs, the majority of the cost savings realized will be the direct result of program changes that could have been implemented absent an aggregate purchasing arrangement.”<sup>19</sup>

A number of other states have attempted intrastate purchasing as well:

- California’s legislature passed a law, in 2005, creating the Office of Pharmaceutical Purchasing, to aggregate the state’s drug purchases. Governor Schwarzenegger vetoed it, however, citing concerns about the cost of creating a new bureaucracy and arguing that bulk purchasing could be achieved through administrative changes within existing agencies;
- Maine and Illinois have state-negotiated discounts for specific groups of residents, such as the uninsured or elderly;

<sup>18</sup> NGA Center for Best Practices. August 2004. State purchasing pools for prescription drugs: What’s happening and how do they work? Accessible at <http://www.nga.org/cda/files/0408PRESCRIPTION.pdf>.

<sup>19</sup> National Conference of State Legislatures. Accessible at <http://www.ncsl.org/default.aspx?tabid=14464>.

- Texas combines pharmaceutical purchasing for Medicaid with purchasing for state employees, retirees, teachers, and the prison system;
- Washington State's Prescription Drug Purchasing Consortium passes along drug savings from its multistate purchasing pool to individuals, businesses, and labor unions, and uninsured and underinsured consumers. This program provides discounts on all prescription drugs and does not utilize a PDL;
- In 2006, Washington's State Health Care Authority coordinated a prescription drug program for the state's Medicaid, public employee, and workers' compensation programs, using an integrated approach to value-based pharmaceutical purchasing. The evidence-based drug review process used to develop the program's formulary thoroughly analyzes quality and effectiveness before applying cost considerations. The program's evidence-based preferred drug list and supplemental rebates have produced savings of \$22 million annually for the state.<sup>20</sup>

### **Current Policy in New York**

In past years, New York State has dedicated resources to exploring the option of intrastate bulk purchasing for various programs and agencies—including Medicaid, state employee health insurance, and for other populations—but differing administrative procedures and business models make forming such an intrastate coalition challenging, and the idea has not been developed. The State does, however, use a single vendor to provide administrative services for three programs—Elderly Pharmaceutical Insurance Coverage (EPIC), the New York Prescription Saver (NYPS) program, and the American Indian Health Program.

### **Best Practices**

An intrastate strategy must be defined and developed uniquely for each state, considering the needs of the respective agencies that are part of the collaborative effort. Fundamental to the development of a collaborative model are motivated leaders and/or change agents who:

- Understand how each agency delivers its prescription drug benefit, including identification of the third-party payers and agencies that are direct purchasers of prescription drugs; and
- Understand the similarities and differences between agencies in terms of population(s) served, existing delivery systems, vendor relationships, services provided, and funding sources/mechanisms.

### **Conclusions**

An intrastate bulk purchasing model appears an attractive and cost-effective solution for state Medicaid agencies, but it is a challenging endeavor to coordinate multiple program structures,

<sup>20</sup>The Commonwealth Fund. March 2006. Washington State: An integrated approach to evidence-based drug purchasing. *States in Action* (newsletter). Accessible at <http://www.commonwealthfund.org/Content/Newsletters/States-in-Action/2006/Mar/March-2006/Profiles--In-Depth-Looks-at-Initiatives-that-Are-Making-a-Difference/Washington-State--An-Integrated-Approach-to-Evidence-Based-Drug-Purchasing.aspx>.

populations, and program objectives. New York State identified this option as a potential savings opportunity in prior years, but has been faced with these real-world challenges. Careful evaluation of bulk purchasing opportunities across agencies is important, but should also be recognized as a complex endeavor.

## Interstate Purchasing Coalitions

### Background

To gain better control of pharmaceutical spending, states have also investigated and/or formed purchasing alliances or coalitions across state lines to leverage advantageous prices, discounts, and rebates from pharmaceutical manufacturers. Combining the purchasing power of multiple states to form a “critical mass” allows coalitions to lower each state’s drug costs beyond what it could achieve individually.

### Other States

**Medicaid Interstate Purchasing Coalitions.** Medicaid programs that have PDLs are very familiar with interstate purchasing coalitions for supplemental rebates. As noted earlier (see page 26), multistate arrangements use combined purchasing power to influence pharmaceutical manufacturers to provide greater rebates. Currently, 24 states and the District of Columbia have implemented PDLs and are also participating in multistate pooled purchasing programs.

The Northwest Prescription Drug Purchasing Consortium is an interstate effort established in 2006 when the Oregon Prescription Drug Program joined the original Washington Prescription Drug Program. Similar to the original program’s parameters, the Consortium allows public- and private-sector groups to join, and provides uninsured and underinsured residents with access to a discount prescription drug card. Through the combined purchasing power of the Consortium, both states report substantial savings on their purchases of prescription medications, as well as shared efficiencies that reduce each program’s administrative cost.

**Non-Medicaid Interstate Purchasing Coalitions.** There are two interstate collective pharmacy purchasing coalitions used by state agencies outside of Medicaid pharmacy programs. The Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), created in 1985, is a free, voluntary group-purchasing organization operated and managed by the State of Minnesota’s Department of Administration for government health care facilities. Agencies from 46 states and the cities of Chicago and Los Angeles participate in this program. The Massachusetts Alliance for State Pharmaceutical Buying (MASPB) is similar to the MMCAP, except that MASPB uses the services of a professional pharmaceutical group-purchasing organization, Managed Health Care Associates, Inc., to provide reporting services and establish acquisition

pricing. In 2001, California joined as the second state in this purchasing program. These coalitions are beneficial to purchasing agencies within a state, but are not optimal for Medicaid pharmacy programs because of the loss of federal rebates—and resulting impact on the net cost of pharmaceuticals—they would entail.

### **Current Policy in New York**

As noted in the discussion of supplemental rebates, in 2006 New York contracted with Magellan Health Services and joined the National Medicaid Pooling Initiative multistate purchasing pool. Since 2009, DOH has worked with Magellan Health Services outside the Initiative to solicit rebate bids from manufacturers of diabetic supplies. The state is also a member of the Minnesota Multistate Contracting Alliance for Pharmacy, which claims more than 500 New York facilities and agencies as current participants in the group, but New York's Medicaid program is not among them.

### **Best Practices**

**Medicaid Interstate Purchasing Coalitions.** States report that joining a multistate coalition yields a significant increase in savings on drugs, attributed to:

- An increase in the number of drug classes included in their PDLs within a short timeframe;
- Increased market share of preferred drugs within their Medicaid populations;
- An increase in individual supplemental rebates due to increased purchasing power and leverage from existing contracts.

State Medicaid pharmacy programs have also expanded their vendor relationships and individual purchasing power—whether as large purchasers within multistate purchasing pools or as large direct purchasers—to obtain supplemental rebates or superior discounts on medical supplies, most commonly diabetes testing-related. Pennsylvania's Medicaid program has utilized its supplemental rebate vendor, Provider Synergies, to solicit and negotiate market share rebate bids for diabetic supplies. The program has contracts with six manufacturers and collects, on average, 84.4 percent of the total diabetic supply spend in market share rebates. Massachusetts, which purchases directly from drug manufacturers, sought bids and awarded a sole-source contract to one diabetic supply manufacturer for MassHealth, the state's Medicaid program. Massachusetts has reduced the net cost for these supplies by 50 percent through this use of a sole-source provider.

Pennsylvania is also attempting to use its membership in an interstate purchasing coalition in a novel way, requesting CMS approval to allow the joint Medicaid/Medicare PACE<sup>21</sup> senior prescription assistance program to join the National Medicaid Pooling Initiative multistate

<sup>21</sup> The Program of All-Inclusive Care for the Elderly (PACE) is a capitated benefit, authorized by the Balanced Budget Act of 1997, that features a comprehensive service delivery system and integrated Medicare and Medicaid financing. For more information, see <https://www.cms.gov/pace/>.

rebate purchasing pool. State Department of Aging officials report, “If approved, PACE rebates [will] increase by 30 percent—which translates to \$15 million in savings.”

## **Conclusions**

New York is on par with the majority of states in its participation in a multistate supplemental rebate purchasing pool, and is progressively negotiating with manufacturers outside the National Medicaid Pooling Initiative to garner additional rebate revenues. The size of New York’s prescription drug program offers the leverage and negotiating power to positively influence supplemental rebate agreements with pharmaceutical manufacturers. Policymakers should evaluate whether the current rebate program structure is optimal or if modifications are necessary to achieve the highest level of rebate revenue.

## **340B Payment Options**

### **Background**

The Federal government requires pharmaceutical manufacturers to provide significantly reduced pricing for health care providers that have achieved the designation of “340B covered entity.” The legislation supporting this program was enacted to provide vulnerable populations with greater access to medications by offering steep discounts for pharmaceuticals to the “covered entities” that serve these populations. Such 340B organizations include federally funded facilities serving people with specified illnesses or belonging to designated populations—federally qualified health centers (FQHCs), hemophilia treatment centers, public education institution health centers, disproportionate share hospitals (DSHs), and others. For an entity to provide pharmaceuticals at 340B discounts, it must provide patient care and treatment.

The initial legislation defining 340B providers mandates that in billing Medicaid fee-for-service programs for drugs, “a Section 340B entity can bill no more than its actual acquisition cost (AAC), plus a reasonable dispensing fee established by the state Medicaid agency.” The 340B discount is calculated using the Medicaid rebate formula and is deducted from the manufacturer’s selling price rather than paid as a rebate. For state Medicaid agencies, access to 340B pricing discounts is cost-effective, as studies have calculated that 340B discounts equate to approximately average wholesale price minus 51 percent.

It is important to note that the federal government protects manufacturers against duplicate discounts by exempting 340B drug discounts from the federal rebate program. Covered entities thus have the option of carving out Medicaid and purchasing all covered outpatient drugs dispensed to Medicaid beneficiaries outside of the 340B program, therefore only obtaining the usual federal manufacturer rebates.



In 2010, federal health care reform modified several elements of the 340B program, including an expansion of the types of covered entities eligible to participate in the program. These now include children’s hospitals, critical-access hospitals, rural referral centers, sole community hospitals, and free-standing cancer hospitals.

As discussed previously, ACA also extended federal rebates to Medicaid managed care organizations. It is important to note, however, that the legislation specifically exempts drugs prescribed by 340B providers from the new managed care rebate collection allowance. Thus, for 340B-eligible claims for Medicaid beneficiaries that are dispensed and paid by managed care contractors, states will likely not receive the benefit of any discounted drugs costs, either through federal rebates or the pass-through of actual acquisition costs.

*340B pricing offers savings to state Medicaid agencies; however, legal and procedural complexities impart challenges that states must manage in order to optimize this option.*

### **Other States**

While there are opportunities for significant savings with 340B pricing, the complexity of the program does create several issues to consider, including:

- Administrative burden on the State. This will vary with the approach selected, but all require a significant commitment to implement;
- Political resistance. If channeling participants to 340B entities is allowable under current law and/or code, the State should expect opposition from patient advocacy and non-340B provider groups;
- Financial incentive. Covered entities may see no financial incentive to purchase drugs at the 340B discount, only to be required to bill the State for actual acquisition cost plus a “reasonable” dispensing fee;
- Coordination of care with covered entities. The 340B legislation expressly prohibits a covered entity from dispensing discounted drugs to anyone other than its own patients.

Despite very low pricing, few Medicaid agencies have optimized 340B discount pricing as a standard approach. Unique approaches implemented by a handful of states are outlined in “Best Practices,” below.

### **Current Policy in New York**

To tap into the additional savings generated by 340B prices, New York State’s 2005 budget bill implemented the 340B Pharmacy Savings Program, prohibiting covered entities or contracted pharmacies from carving out their Medicaid outpatient drug purchases. In exchange, the covered entities would receive reimbursement for their administrative costs through an

enhanced dispensing fee. Due to system resource requirements associated with the Medicare Modernization Act and Medicare Part D at the time of enactment, however, development of this enhanced dispensing fee was never completed. The State has since implemented claim enhancements, instead, to give pharmacy and ambulatory (hospital and health center) providers the ability to easily identify 340B drug claims, which bypass prior-authorization edits and are reimbursed at the generic dispensing-fee rate, as an incentive for participation. In addition, beneficiaries must pay the copayment for generics.

### **Best Practices**

A number of options exist for maximizing 340B pricing discounts for Medicaid pharmacy programs, including:

- **Targeted care management.** States can explore sole-source or limited network options with 340B entities to provide targeted drugs at 340B pricing, when enrolled in the network provider's case management program. Utah and Arizona, utilizing 1915(b) "freedom of choice" waivers, steer targeted high-cost Medicaid populations into care management/disease management programs operated by 340B providers for hemophilia patients. Both states are currently considering expanding their programs to include beneficiaries with other chronic diseases, such as HIV, arthritis, and hepatitis;
- **Expanding the current 340B entity network.** States can educate and encourage community health centers (CHCs)/federally qualified health centers (FQHCs) and other qualified entities to obtain 340B status, opt in to the Medicaid program, and bill at actual 340B acquisition cost;
- **Providing enhanced dispensing fees.** States can pay 340B providers a dispensing fee significantly higher than the normal Medicaid dispensing fee, while paying actual acquisition costs for 340B drugs. States paying enhanced dispensing fees include Florida (\$7.50), West Virginia (\$8.25), Massachusetts (\$10.00), and Louisiana (\$10.10). In Alaska, a variation on this model has the Medicaid program pay a "freight charge" in addition to the normal Medicaid dispensing fee and actual acquisition cost for each drug. Kansas and Massachusetts set a separate dispensing fee for clotting factor—12.5 cents per unit dose in Kansas and 9 cents per unit in Massachusetts.<sup>22</sup>
- **Shared savings.** Connecticut and Minnesota pay for 340B drugs at rates above the drugs' actual acquisition costs, but less than non-340B post-rebate reimbursement rates.

If the 340B model appears an attractive and cost-effective solution, states will need to encourage pharmacy providers and beneficiaries to shift reimbursement to covered 340B entities. This can be accomplished through enhanced dispensing fees and other provider incentives, as described above, to participate in and collaborate with the state Medicaid program; reducing beneficiaries' copays for drugs dispensed by 340B pharmacies; or building

<sup>22</sup> von Oehsen W. State 340B Medicaid billing best practices. *Safety Net Hospitals for Pharmaceutical Access*. [http://www.phpcrx.org/public/documents/pdfs/state\\_340b\\_medicaid\\_billing\\_bp.pdf](http://www.phpcrx.org/public/documents/pdfs/state_340b_medicaid_billing_bp.pdf).

disease- or care-management programs around participating 340B providers. Mail-order programs or contracting with retail pharmacies within the limits of 340B contract pharmacy guidelines can also minimize access limitations.

Massachusetts has expanded the number of 340B entities participating in its MassHealth Medicaid program from two retail pharmacies to roughly 35, through the use of multiple incentives. Under the direction of the state's Secretary of Health and Human Services, MassHealth implemented an educational and outreach program in 2002 that promoted community health center-based services for the Medicaid program, including expanded use of 340B pharmacies. As part of this program, Massachusetts provided grants to 340B entities to create pharmacies, which 22 CHCs subsequently did. And, as previously mentioned, MassHealth also pays an enhanced dispensing fee. The intent of MassHealth's 340B program was to increase 340B provider enrollment not as a cost savings initiative—the program has accounted for marginal cost savings of approximately \$2 million—but to help prepare the State to move forward with its “medical home” model, with all of the CHCs currently contracted as medical homes having 340B pharmacy services included in their programs.

### **Conclusions**

The 340B pricing model appears to be an attractive and cost-effective solution for state Medicaid agencies. New York State identified this option as a potential savings opportunity with the implementation of the 340B Pharmacy Savings Program, and has begun to align provider incentives through the claim adjudication enhancements recently implemented.

By maximizing the number of organizations that achieve 340B designation and developing programs that utilize these providers, Medicaid and other state programs may have an opportunity for additional pharmaceutical cost savings. A careful evaluation of additional 340B opportunities and potential savings is an important, yet complex and challenging, next step.

## **Clinical Program Efficiency and Quality Management Options**

Like other treatment modalities, medications may be overutilized or misprescribed, resulting in unnecessary costs and poor outcomes. This section addresses tools used in the management of pharmaceuticals to help ensure that prescribing and dispensing is appropriate, reasonable, and safe, while also serving the needs of Medicaid beneficiaries. An efficient pharmacy program should embrace concepts that include a focus on strategies to encourage lowest-net-cost therapies, such as optimizing the use of generics and clinically appropriate point-of-sale edits. Medicaid pharmacy programs should also focus on

minimizing or eliminating the use of drugs that have little to no proven medical benefit, and should have care management strategies to ensure that patients properly understand their medical conditions and appropriate use of medications and other therapy. This section provides detail on each of these areas of pharmacy management.

Two additional pharmacy management tools—prescription drug limits and copayments—are not included in this report. Although limits and copayments are options available to state Medicaid programs, they are not considered best practice because there are no widely accepted benchmarks for them. Prescription limits can minimize overutilization but may also result in limiting access to necessary medications. Medicaid copayments are nominal as established by CMS, but still have an impact on pharmacy reimbursement when beneficiaries are unwilling or unable to make those copayments. While these options are still worthy of consideration they are not addressed in detail in this report.

## Promoting Use of Generic Medications

### Background

Ensuring utilization of generic medications is one of the most effective ways to drive down prescription drug costs. The Hatch-Waxman Act of 1984 allowed for the expiration of brand-drug patents so that generic drugs could be produced by multiple manufacturers. Generic drugs are chemically identical compounds to their brand-name counterparts, but because their formulation rests on clinical research already completed by the manufacturers of those brands they are 30 percent to 80 percent less expensive, thus lowering overall unit cost through market competition. Because generic drugs are considered safe and equally efficacious—they are approved by the FDA on the basis of equal bioavailability, absorption by the body in a nearly identical way to that of their branded predecessors—they allow for equal clinical benefit at a large discount.

Many commercial insurance plans, pharmacy benefit managers, and state Medicaid programs use their generic dispensing rate, the percentage of all drugs dispensed that were generics, as a key metric for determining savings potential. A *Wall Street Journal* article has suggested that every 2 percent increase in generic dispensing rate for Medicaid beneficiaries equates to an annual savings of one billion dollars.<sup>23</sup> Another key metric is the generic substitution rate, the rate at which generics were dispensed, or substituted, for all drugs with available generic equivalents. It should be recognized that, with access to federally mandated rebates, state Medicaid programs are in a unique situation in which generic products may not always produce the lowest net cost for a particular drug. To optimize this situation, some states favor multisource brand products over their generic equivalents as long as the brand-name drugs yield lower net costs. As such, it is inappropriate to directly compare generic dispensing or

<sup>23</sup>Hobson K. July 26, 2010. GPhA report: Generics offer big Medicaid savings opportunity. *Wall Street Journal*. WSJ Health Blog. Accessible at <http://blogs.wsj.com/health/2010/07/26/gpha-report-generics-offer-big-medicaid-savings-opportunity/>.

generic substitution rates of Medicaid programs to those of commercial plans without knowledge of a state's individual policies and, ultimately, net drug cost.

High-dollar specialty biologics are also worth mentioning in discussing generic substitution. These products are often protein-based, and their production is time- and resource-intensive. Historically, there has been no path for approval of generic equivalents, since manufacturers assert that their patents are for their processes rather than their products. If biogenerics were available in the U.S., economists speculate, savings would range from ten billion to hundreds of billions of dollars over the next ten years. The Biologics Price Competition and Innovation Act<sup>24</sup> passed as part of health care reform legislation is a cautious first step toward establishing a regulatory approval process that will introduce biogeneric products.

### **Other States**

In 2004, Minnesota began requiring physicians to obtain preauthorization from the state Medicaid agency if they prescribed brand-name drugs for Medicaid beneficiaries when generic equivalents were available. This requirement increased the state's rate of generic drug utilization from 55 percent to 57 percent over a nine-month period, saving the state \$10 million annually. Implementation of the Idaho Medicaid program's mandatory substitution policy, requiring a patient to first try two generic drugs before a brand-name drug is used, increased its generic utilization by 13 percent (six percentage points) in one year, saving nearly \$12 million in that first year.

In Massachusetts, reports the Generic Pharmaceutical Association, Medicaid officials took a series of steps between 2001 and 2004 that the State estimates shaved \$150 million. A large part of the savings came from a change in the policy requiring pharmacists to dispense generic drugs unless doctors specified that they wanted brand-name drugs instead. With physicians routinely completing prescriptions with "dispense as written," Medicaid was paying \$10 million to \$11 million a month for brand-name drugs that had generic equivalents. Once a new policy requiring written explanation of the need for a brand-name drug, and authorization for it, went into effect, spending on those drugs dropped dramatically to \$200,000 to \$300,000 a month.<sup>25</sup>

<sup>24</sup>The Biologics Price Competition and Innovation Act of 2009, a subtitle of the federal health care reform bill, creates a framework for Food and Drug Administration approval of "follow-on" biologics. This new law bears a conceptual resemblance to the Hatch-Waxman Act, which created a path to market entry for generic small-molecule pharmaceuticals. See [http://www.martindale.com/health-care-law/article\\_Edwards-Angell-Palmer-Dodge-LLP\\_976250.htm](http://www.martindale.com/health-care-law/article_Edwards-Angell-Palmer-Dodge-LLP_976250.htm).

<sup>25</sup>Stein C. February 17, 2004. Tough medicine is paying off for state: New rules cut cost of Medicaid drugs, but the moves are far from popular. *Boston Globe*. Accessible at [http://www.boston.com/business/globe/articles/2004/02/17/tough\\_medicine\\_is\\_paying\\_off\\_for\\_state/](http://www.boston.com/business/globe/articles/2004/02/17/tough_medicine_is_paying_off_for_state/).

## **Current Policy in New York**

In New York State, prescribers may specify “dispense as written” if they also write “brand medically necessary.” Patient consent to substitution of a generic for a brand-name drug is not required.

A “Dispense Brand Drugs When Less Expensive” program also exists, under which pharmacy providers may substitute brand-name drugs with lower net costs than their comparable generics, without specific “dispense as written” instructions. Providers are reimbursed based on the brand discount and the generic dispensing fee, and Medicaid beneficiaries are charged the generic copay. The Department of Health compiles and communicates to providers a list of such drugs, which include Adderall XR®, Astelin®, Diastat®, Duragesic®, Lovenox®, and Valtrex®.

New York’s generic dispensing rate average improved throughout calendar year 2009, reaching 63 percent. That rate is tracked weekly, and DOH staff reported that it reached 64.8 percent in November 2010. They also noted that the figure would likely reach 66 percent if drugs filled through the Dispense Brand Drugs When Less Expensive program were considered to be generics for the purpose of the calculation.

## **Best Practices**

With the significant increase in the number of generics in many drug classes in recent years, there are several strategies states can use to increase generic utilization, including:

- Use of prior authorization, requiring verification of intended use prior to coverage, for brand-name drugs;
- Use of generic-first step-therapy edits—requiring patients to start with a preferred generic product within a drug class before moving to a more expensive, therapeutically similar brand-name medication;
- Reducing or eliminating copayments for generic drugs;
- Requiring that the prescriber complete an FDA MedWatch form when using “dispense as written” to request a branded product instead of a generic one, or when requesting a branded product on the PDL instead of a generic alternative also on the PDL;
- Enforcing mandatory generic substitution laws and eliminating recipient consent prior to generic substitutions.

A recent Medicaid-specific study<sup>26</sup> reported the potential savings of those last-mentioned generic substitution laws. The researchers studied utilization of Zocor®, a drug commonly prescribed for high cholesterol, as a marker for estimated post-patent-expiration generic substitution savings. In the first six months after loss of patent, states mandating generic

<sup>26</sup> Shrank WH, NK Choudhry, J Agnew-Blais et al. July 2010. State generic substitution laws can lower drug outlays under Medicaid. *Health Affairs* 29(7): 1383-90.

substitution dispensed generics nearly 50 percent of the time, versus 30 percent in states without a mandate. Additionally, in states requiring prior recipient consent for dispensing of an equivalent generic, it took about twice as long, 12 months, to reach their maximum generic substitution rates, and those maximums were lower (90 percent versus 99 percent) than in states that enforce generic substitution and do not require recipient consent.

### **Conclusions**

New York State's current overall generic dispensing rate of approximately 65 percent is on par with that of other state Medicaid programs that have similar statutory limitations, but falls short of highly efficient Medicaid managed care programs that achieve generic dispensing rates of 80 percent or higher. Those rates are expected to increase across all payers over the next few years due to a multitude of patent expirations, but the increase will be relative to the starting point for any given program. Policymakers should consider removal of restrictions that currently limit the maximization of generic drug product alternatives.

## Point-of-Sale Utilization Edits

### **Background**

Point-of-sale pharmacy edits use predetermined thresholds to block dispensing of prescriptions. The purpose of these edits is essentially to provide the safest and most cost-effective therapy by driving utilization away from potentially dangerous—and more costly—treatments. The downside is the disruption this utilization management strategy creates for the patient.

**Prospective Drug Utilization Review (Pro-DUR).** Claims processors are able to match information on new claims against a clinical database, as well as a recipient's prior prescription history, to find any clinical issues with prescriptions, based on dosage, potential drug interactions, duplication of concurrent therapy, and even compatibility with recipients' disease and allergy histories. These checks can yield "hard" or "soft" edits—either completely stopping the claim at the point of sale or allowing it to be filled, but with a warning to the dispensing pharmacist. Pharmacists can bypass soft edits based on their clinical judgment and knowledge of the recipient's medical history and medication regimen. Hard edits are typically reserved for the most severe adverse events, such as drug-related allergies, contraindicated therapies, and the potential overuse of drugs such as narcotics and sedatives. State Medicaid programs report Pro-DUR edits and their outcomes on an annual basis.

**Quantity Limits.** Quantity limit edits are meant to prevent inappropriate medication use or inappropriate prescribing by disallowing the dispensing of prescriptions that could result in dangerous over- or under-dosage. Quantity edits are typically applied to medications that have a defined duration of treatment or the potential for inappropriate duration of treatment. These

edits focus on both quality of care and cost management and are typically established consistent with FDA-approved dosing guidelines. For example, if a drug is FDA-approved for once-daily dosing, then generally speaking a patient should not receive a quantity of more than one dose per day.

**Step Therapy.** Step therapy focuses on encouraging initial utilization of a clinically appropriate first-line agent. When a claim for a new medication for a recipient is submitted, the claims processor looks for prior treatment with more cost-effective therapeutically equivalent drugs. If there is no history of prior therapy with a “first-line” medication, the payer may require use of an alternative product prior to filling the prescription.

**Refill Too Soon.** Early refill edits, commonly referred to as “refill too soon,” set thresholds on the frequency with which refills are authorized and paid. The goal is to maintain convenience for beneficiaries while minimizing unnecessary costs and preventing potential misuse/abuse, waste, or stockpiling of medications. Early refill edits also serve as a means of verifying compliance with a prescribed regimen or necessary clinical follow-up.

Some states have legislation prohibiting the use of point-of-sale edits for certain drug classes—often those for behavioral health conditions and addiction recovery, HIV/AIDS, or hemophilia—because of concerns that these edits pose barriers to therapy, restricting prescribers’ acting in patients’ best interests, or potentially limiting patient access to critical-need medications.

### **Other States**

Concurrent or prospective drug utilization review is a universal utilization management approach, a basic element of electronic claims processing. All state Medicaid programs are required by law to have drug utilization review programs for outpatient drugs, and nearly all states contract with outside vendors to run these systems. The level of sophistication, scope of Pro-DUR edits, and requirements for pharmacist-provider interaction does vary by state and vendor, however.

Quantity limit programs are also standard utilization management tools, easily implemented by both private-sector and state Medicaid programs. As of 2005, nearly all Medicaid programs (35 of 37 responding) limited the quantity of medication that can be dispensed per prescription.<sup>27</sup> The majority of Medicaid quantity limit programs include mental health medications as clinically appropriate. Implementation primarily revolves around clinical review, determination of maximum quantities that reflect FDA-approved dosage guidelines, and subsequent programming of edits into the claims adjudication system. Quantity limits

<sup>27</sup> Crowley J, D Ashner, and L Elam. October 2005 (update). *State Medicaid Outpatient Prescription Drug Policies: Findings from a National Survey*. Washington, DC: Henry J. Kaiser Family Foundation.



and dosage restrictions should be tested prior to implementation and reviewed at appropriate intervals (e.g., annually, or with drug class review) for updates and to ensure continued clinical appropriateness.

Step therapy programs are also common within both Medicaid fee for service and managed care. Since 2003, many state Medicaid programs have adopted step therapy edits for one or more drugs; for mental health medications, those edits may be for either a specific medication or an entire group of meds. By 2005, some type of “fail-first” step therapy policy for mental health drugs had been implemented by approximately one-third of state Medicaid programs.<sup>28</sup> Since then, with the introduction of new generics, Medicaid programs—like many private-sector programs—have adopted step therapy edits for many additional therapy classes, including sedative-hypnotic drugs.

Several states have implemented refill-too-soon edits that restrict early refills for controlled substances, such as opiate narcotics, more closely than for non-controlled medications. Typically, controlled substance medications cannot be refilled until 85 percent to 90 percent of the full number of days for which the prescription is written has elapsed. For non-controlled drugs, these edits commonly require that 75 percent to 80 percent of the days covered must elapse before refill.

### **Current Policy in New York**

New York State granted legislative authority to implement frequency, quantity, duration, and step therapy edits in April 2009. A Drug Utilization Review Board and the University of Buffalo College of Pharmacy assist the Department of Health in developing clinical criteria for these point-of-sale hard edits.

While DOH has implemented select quantity limits and continues to work with the Drug Utilization Review Board to establish the criteria, each edit must be prioritized for coding into the claims processing system. These limitations have restricted, to some degree, the amount and types of point-of-sale edits that have been implemented, but DOH staff report that recent system improvements have resulted in greater flexibility.

All drugs, including opiates, require prior authorization review if a refill is requested prior to a 75 percent elapsed-time threshold. This edit has been established at a drug hierarchy level that identifies drug products that are similar but not the same chemical compound, to help avoid activating a false refill-too-soon threshold that could result in disrupting the patient’s therapy. Dispensing pharmacies are no longer allowed to override refill limitations for travel or vacation; DOH must now be contacted for approval of early refills. Recently enacted changes

<sup>28</sup> Koyanagi C, S Forquer, E Alfano. March/April 2005. Medicaid policies to contain psychiatric drug costs. *Health Affairs* 24(2): 536-544.

in the 2011-2012 budget further tighten the requirements for obtaining reauthorization related to a refill-too-soon denial.

### **Best Practices**

Point-of-sale edits should always focus on ensuring safety, clinical efficacy, and cost-effectiveness. In states with robust clinical utilization management, the point-of-sale program typically includes the following key attributes:

- Clinical staff who monitor the changing marketplace, including drug additions, withdrawals, new indications, and clinical practice guidelines affecting prescribing habits;
- A claims adjudication system that is flexible and can accommodate timely updating, with the ability to establish edits that would be applicable to any of the key data fields accompanying prescription drug claims (i.e., drug identifier, number of days' supply, member name and number, prescriber, and dispensing pharmacy);
- A claims adjudication platform that utilizes a central data source housing all relevant recipient information, medical claims history, prescription history, and drug information, and updated point-of-sale edit tables to ensure online, real-time access;
- Removal of statutory limitations that protect certain therapy classes or that result in lengthy review and approval processes for point-of-sale edits;
- Refill-to-soon thresholds that can vary for controlled and non-controlled medications, and system technology to ensure that the thresholds are cumulative and reset with each refill;
- A call center with appropriate numbers of trained staff to ensure patients' access to clinically necessary medications.

### **Conclusions**

The New York State Department of Health pharmacy program has embraced many of the managed care principles related to point-of-sale edits and optimal prescription drug management. Legislation allowing adoption of these edits was a step in the right direction, but system limitations continue to result in less than ideal implementation and updating of new edits. Future work with in-house resources or through outside vendors will provide additional value for this program initiative.

## Coverage Rules

### **Background**

Medicaid is very prescriptive about the classes of medications that can be excluded from the pharmacy benefit. These optional exclusions, based on federal law,<sup>29</sup> include agents used for:

- Anorexia, weight loss, or weight gain;
- Promotion of fertility;
- Cosmetic purposes or hair growth;

<sup>29</sup> Social Security Act, Title XIX, Section 1927(d)(2). Accessible at [http://www.ssa.gov/OP\\_Home/ssact/title19/1927.htm](http://www.ssa.gov/OP_Home/ssact/title19/1927.htm).

- Symptomatic relief of cough and colds;
  - Promotion of smoking cessation;
- as well as:
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations;
  - Nonprescription drugs;
  - Covered outpatient drugs for which the manufacturer requires that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee;
  - Barbiturates;
  - Benzodiazepines;
  - Agents used for the treatment of sexual or erectile dysfunction, unless used to treat another condition for which the agents have been approved by the Food and Drug Administration.

Within this framework, states may customize their coverage rules; some states, for example, elect to cover selected drugs within an optional class while excluding the rest of that therapy class.

These excludable groups of drugs would not typically comprise a large part of states' overall drug spending, and some states cover them as a statement of their commitment to general wellness, regardless of direct or indirect cost savings their exclusion might provide.

### **Other States, and Current Policy in New York**

States evaluate optional drug classes in conjunction with their medical coverage and overarching health care coverage priorities, such as wellness and disease management. Coverage rules therefore vary by state, and best practices are difficult to generalize. Table 5 provides a summary of coverage rules in New York and several other states.

### **Best Practices**

Although excluded drug classes are not a huge part of state Medicaid programs' overall drug spending, they may still provide opportunities for savings; the point of pharmacy benefit restrictions is, after all, to produce the best medical value for each dollar spent. A review of state experiences in this area did not reveal standard best practices, but rather a menu of diverse examples from the states.

For example, benzodiazepines and barbiturates, in their generic form, offer clinical benefit at a fairly low cost, which is why there is widespread inclusion of them. Notably, however, Missouri has opted to exclude some of the rarer benzodiazepines; these drugs can sometimes be a little costlier, and restricting coverage is an attempt to guide prescribers to less expensive options.

**Table 5.**  
**Coverage of Optional Drug Categories, By State**

State	Weight Loss/ Weight Gain	Cough/Cold	Vitamins	OTCs	Benzodiazepines	Smoking Cessation
New York	None	Benzonatate	B-vitamins, Vitamins K and D, iron, iodine	Allergy, sinus, anal- gesics, insulin, digestive products, topicals, vitamins, minerals	All	All
California	All	All	Excludes combi- nation products and supplements	All	All	None
Florida	None	Only for members under 21 years old	Prenatal vitamins	Insulin, aspirin, phosphate binders, vaginal antifungals, folic acid	All	All approved products (for non-Part-D- eligibles)
Missouri	None	Select products	All	All (with Rx)	All (except estazolam, halazepam, prazepam, quazepam)	None
New Jersey	Weight-gain drugs	Select products	Therapeutic vitamins	Insulin and antacids	All	None
Pennsylvania	None	None	Some therapeutic vitamins	Most	All	All
Texas	Stimulants, anorexic agents, fat-absorption- decreasing agents	Antihistamines, antitussives, decongestants, expectorants	Some	Some	All	All

No fertility or hair growth drugs were covered in any of the states included in the table; barbiturates, however, were covered by all the states.

Coverage of supplements offers another example. Unlike prescription drugs, which must contain the labeled amount of their chemical compounds and be proven effective, supplements are not regulated for efficacy or even content. As a result, their value has been questioned, and the vitamin and supplement industry as a whole has been under close scrutiny by the FDA and the media. California has chosen to exclude supplements from its benefit, while New Jersey and Pennsylvania cover only therapeutic vitamins.

Decisions on the coverage of smoking-cessation products are a bit more varied. With questionable efficacy of these products and high price tags, some states have chosen to exclude this class from coverage as well.

### Conclusions

The number of drug classes open to exclusion from state pharmacy benefits is very small, and New York's choice of exclusions is similar to those of other states. Smoking cessation products are an interesting case, since they often spur discussions about questionable efficacy and

social responsibility. Policymakers should continue to evaluate drug exclusions to ensure adequate access to drug products that may complement or augment other treatment programs, and ultimately result in better outcomes.

## Population-Based Care Management

### Background

Chronic medical conditions are major contributors to morbidity, disability, and death in the U.S.,<sup>30</sup> and more than 80 percent of all Medicaid spending is for individuals with chronic illness. Developing programs that will efficiently address the needs of these beneficiaries can be challenging because of this population's unique characteristics, but such programs are recognized as critical to improving health outcomes while managing the costs of caring for these beneficiaries.

Chronic care and disease management programs, using specific criteria to help identify beneficiaries in need of some form of care management, have evolved over the years and take many forms. These programs can be resource-intensive to implement, monitor, and maintain. Evidence of their cost-effectiveness has evolved as programs and tracking tools have become more sophisticated; evaluations often focus on clinical outcomes, with the understanding that savings should follow improvements in those outcomes. In general, activities in case and disease management programs support proactive diagnosis and management of chronic conditions; encourage physician and patient adherence to evidence-based practice guidelines, through education and involvement; and incorporate wellness activities, compliance, and self-care. Although not specifically designed to focus on prescription drug control or use, these programs do integrate prescription drug data to support and enhance their interventions.

Medication therapy management (MTM) is essentially a targeted form of care management, often bringing pharmacists face-to-face with patients to review the drugs prescribed for them and the patient's compliance and response. MTM was officially recognized by Congress in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.<sup>31</sup> The effectiveness of these programs, based in good measure on individuals' personal relationships with their pharmacists, has helped Part D plans optimize therapeutic outcomes and reduce the risk of adverse events.

### Other States

Although Medicare Part D programs have been utilizing medication therapy management since 2003, Medicaid programs have been less consistent in adopting them. Florida,

<sup>30</sup> Sommers A and M Cohen. March 2006. *Medicaid's high cost enrollees: How much do they drive program spending?* Washington, DC: Kaiser Commission on Medicaid and the Uninsured.

<sup>31</sup> Public Law 108-173. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, HR1. December 8, 2003. A summary of the Act's provisions is accessible at <https://www.cms.gov/MMAUpdate/downloads/PL108-173summary.pdf>.

Louisiana, Mississippi, and North Carolina have passed legislation that emphasizes the role of the pharmacist in patient care and the importance of these services, and provides Medicaid beneficiaries with access to them. New York has passed similar legislation allowing for a pilot MTM, described below. Other states that have implemented MTM programs include Iowa, Maryland, Minnesota, Missouri, Montana, Ohio, Texas, Virginia, and Wyoming. Missouri has calculated an annualized savings of \$2.4 million through a disease management program that includes collaboration with pharmacists.

### **Current Policy in New York**

Under New York's Chronic Illness Demonstration Project, six pilot programs in regions across the state have targeted fee-for-service Medicaid beneficiaries with a range of conditions. Pharmacy management strategies play a minor role in these programs, which have a broad clinical focus and interface with pharmacy primarily to exchange relevant prescription drug data.

The State does currently have a pilot MTM program focused on prescription drug education and utilization review operating in 47 retail pharmacies in the Bronx. Eligible Medicaid beneficiaries are entitled to an initial visit and six return visits per year. Visits are billed in 15-minute increments, to a maximum of 60 minutes per date of service; pharmacies are reimbursed \$35 for the first 15 minutes of the initial visit, \$25 for the first 15 minutes of a return visit, and \$15 for each additional 15-minute increment (with a maximum of 12 additional 15-minute increments allowed per year). The program has been in effect since January 2010, and enrollment and outcomes continue to be monitored.

### **Best Practices**

States that do not currently have a comprehensive care management program in place, or are attempting to integrate several existing programs, need a systematic approach to implementing appropriate programs that will yield the best return on investment initially, and gain stakeholder involvement over time. Several resources are available to state Medicaid programs, including a guide available from the Agency for Healthcare Research and Quality.<sup>32</sup>

Medication therapy management programs can be readily implemented and easily integrated with other existing programs. Key elements of successful programs include:

- Expansion of the scope of pharmacists' duties to include clinical activities such as providing immunizations and—under agreements with practicing physicians—authorized prescribing of common medications or refilling or modification of standing orders (e.g., modifying a blood-thinner medication regimen based on clinical lab results);
- Expansion of the pharmacist's role as "public health extender" to provide clinical services

<sup>32</sup> Arora R, J Boehm, L Chimento, L Moldawer, C Tsien [for the Lewin Group]. March 2008. *Designing and Implementing Medicaid Disease and Care Management Programs: A User's Guide*. Rockville, Md.: AHRQ. Accessible at <http://www.ahrq.gov/qual/medicaidmgmt/>.

such as chronic disease-state counseling and monitoring for patients with diabetes or chronic hypertension;

- Inclusion of pharmacists in statewide or regional health information technology initiatives.

Minnesota's Medicaid MTM program—one of the first, developed in 2005 and processing its first claims for fee-for-service beneficiaries in 2006—is instructive. Program pharmacists enhance Medicaid patients' adherence to their medication regimens by providing information, support, and resources, including comprehensive medication reviews; helping patients understand treatment plans; and monitoring and evaluating patients' responses to medication for safety and effectiveness. In 2009, the program worked with approximately 750 beneficiaries; the average pharmacy provider payment was \$86.50 per encounter. The Minnesota Department of Health estimates annual cost savings of \$403.30 per patient for individuals over the age of 18 achieving the "optimal care" benchmark for diabetes. In 2008, Minnesota health reform legislation was passed allowing the program to expand to home care settings. More recently, Minnesota Medicaid has encouraged the inclusion of MTM services in the medical home model, with services provided and billable in addition to the medical home's care coordination services.

### **Conclusions**

New York's medication therapy management pilot program is still underway, and outcomes are yet to be determined. Department of Health representatives indicate, however, that preliminary results reveal opportunities for improvement, to optimize the program.

## **Conclusion**

This report explores a number of policy options and best practices in pharmaceutical purchasing and utilization management, to achieve cost containment while ensuring access and maintaining or improving quality of care. It also compares New York State's pharmacy program to other states' to identify common challenges and potential opportunities. New York's policymakers and other key stakeholders must grapple with decisions that can fundamentally change the way Medicaid pharmacy programs are administered and delivered; we highlight key areas for consideration below.

### **Pharmacy Program Delivery Systems**

#### **Carve-out Versus Carve-in**

The current fee-for-service pharmacy program carve-out from managed care has allowed for the development of a single set of parameters governing the delivery of the Medicaid prescription drug benefit. With rebate equalization resulting from federal health care reform,

state policymakers should complete a comprehensive fiscal analysis to confirm that moving to a carve-in is the right solution for the future.

### **Vendor Versus In-house Administration**

Pharmacy carve-out or carve-in decisions directly influence decisions on the need for contracting with specialized vendors or administering services with Department of Health in-house resources. Once the primary delivery system—fee-for-service carve-out or managed-care carve-in—has been determined, an in-depth evaluation of resource allocation is critical.

## Reimbursement Options

### **Ingredient Cost and Dispensing Fee Reimbursement Options**

The majority of payers continue to use average wholesale price as the basis for reimbursement, despite the legal settlement related to it and the negative implications of using a non-transparent pricing benchmark. Alternatives—ingredient-cost reimbursement and dispensing fee methodologies—should continue to be investigated and tested for both non-specialty and specialty medications, to ensure transparent and fair payment to providers. Additionally, policymakers should consider opportunities to manage the increasing utilization of high-cost specialty medications.

## Drug Product and Rebate Optimization

### **Preferred Drug List and Prior Authorization**

The current preferred drug program is clinically sound, but New York’s ability to optimize it is somewhat limited because of the state’s “prescriber prevails” legislative provision. Policymakers should consider the extent to which this restriction is preventing the program from achieving the highest level of efficiency. The size of the New York State prescription drug program offers the leverage and negotiating power to positively influence supplemental rebate agreements with pharmaceutical manufacturers; policymakers should, therefore, continue to evaluate the current rebate program structure to identify opportunities in direct pharmaceutical manufacturer contracting.

### **340B**

The 340B pricing model appears to be an attractive option, offering an opportunity for additional pharmaceutical cost savings. The current 340B Pharmacy Savings Program has begun to align provider incentives, which will help foster this objective. Careful evaluation of additional 340B opportunities and potential savings is important for New York, yet policymakers should recognize this as complex and challenging.



## Clinical Program Efficiency and Quality Management Strategies

### **Generic Dispensing**

New York's current generic dispensing rate is on par with those of other state Medicaid programs with similar statutory limitations, but falls short of those in highly efficient Medicaid managed care programs. Policymakers should consider removing restrictions that currently limit the ability to maximize generic alternatives.

### **Point-of-Sale Edits and Coverage Rules**

Managed care principles, which ultimately influence utilization and appropriate dispensing and coverage of drug products, have been incorporated in New York's current program. Policymakers should recognize that system capabilities and flexibility are critical to ensuring that these principles are implemented efficiently and in a timely manner.

### **Population-Based Care Management**

In implementing its Chronic Illness Demonstration Project, New York recognizes that management of chronic illness is fundamental to improved clinical outcomes. An important component of achieving that goal is the involvement of pharmacists in medication therapy management services. As the current MTM pilot develops, policymakers should focus on understanding the levers that are most likely to result in a successful program, and that can be used to serve a larger population or on a statewide basis.

Although the challenges are numerous and the fiscal and political environment unpredictable, effective collaboration among state policymakers, Department of Health staff, providers, beneficiaries, and other interested parties can strengthen the overall quality and financial stability of New York State's Medicaid pharmacy program as it moves into the future.

## Appendix: Glossary

**Actual Acquisition Cost (AAC).** An alternative pricing benchmark that represents pharmacy providers' actual acquisition costs, or costs invoiced by a drug's wholesaler or manufacturer.

**Adjudication.** Prescription drug claims processing, including completing all validity, process, and file edits necessary to prepare a claim for final payment or denial.

**Authorized Generic Drugs.** Generic drugs sold (or licensed) by the manufacturer of the brand-name drug.

**Average Manufacturer Price (AMP).** The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. While AMP is not publicly available, all pharmaceutical manufacturers must report AMP to the Centers for Medicare & Medicaid Services; Medicaid federal rebate prices are based on AMP.

**Average Sales Price (ASP).** The weighted average of all non-federal sales to wholesalers, net of charge-backs, discounts, rebates, and other benefits tied to the purchase of the drug product, whether paid to the wholesaler or the retailer.

**Average Wholesale Price (AWP).** The average value at which wholesalers sell drugs to physicians, pharmacies, and other customers. Published by multiple sources, it has become an important benchmark for prescription drug pricing and reimbursement, and the generally accepted standard measure for calculating cost throughout the health care industry.

**AWP Discount.** The specific ingredient cost reimbursement allowed by the payer. When Medicaid is the payer, the AWP discount that reflects estimated acquisition cost is determined by statute, state plan amendment language, or agency policy.

**Best Price.** The "best price" paid by Medicaid agencies for prescription drugs is the lowest price available to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or the government (excluding the Indian Health Service, Department of Veterans Affairs, Department of Defense, Public Health Service, 340B covered entities, Federal Supply Schedule, state pharmaceutical assistance programs, depot prices, and nominal pricing). Best price includes cash discounts, free goods that are contingent upon purchase, volume discounts, and rebates.

**Brand-Name Drug.** A pharmaceutical whose name is trademarked by its originator or a

licensee. If the product is on patent, it is the only source of that particular formulation. Single-source brands have no generic alternative; multisource brands have one or more generic alternatives.

**Capitation.** A method of payment for health services in which a health care provider is paid a fixed amount, usually prospectively, for each person on the provider's patient roster, regardless of the quantity or nature of services actually provided.

**Carve-out Pharmacy Benefit.** Prescription and pharmacy services insurance coverage that is financially and administratively separated from the primary health care plan. When care is capitated, a carve-out is a service or package of services not provided within the contract, and thus carved out of the per member per month payment rate.

**Centers for Medicare & Medicaid Services (CMS).** Formerly known as the Health Care Financing Administration, this federal agency is responsible for administering Medicare and overseeing states' administration of Medicaid.

**Consumer Price Index–Urban.** A measure of the average change over time in prices paid by urban consumers for a market basket of consumer goods and services. The index is based on the expenditures of almost all residents of urban or metropolitan areas, including professionals, clerical workers, and other urban wage-earners, and self-employed, poor, unemployed, and retired persons—in all, about 87 percent of the total U.S. population. Not included in the CPI-U is spending by farm families and others living in rural nonmetropolitan areas, persons in the Armed Forces, and those in institutions, such as prisons and mental hospitals.

**Coordination of Benefits.** Coordination of benefits applies when a member is covered under more than one pharmacy plan. By requiring that payments be made first by the primary plan and then by secondary plans, it eliminates benefit duplication or double payment for services.

**Dispense As Written (DAW).** A prescribing directive to indicate that the pharmacist should dispense the drug specified on the prescription, and not substitute a generic product.

**Dispensing Fee.** The negotiated professional fee paid to a dispensing pharmacy for processing/filling of a prescription claim. The dispensing fee is added to the negotiated formula for reimbursing ingredient cost.

**Drug Effectiveness Review Project.** A collaboration of organizations that have joined together to obtain the best available evidence on the comparative effectiveness and safety of drugs

within therapeutic classes, and to apply the information to public policy and decision-making in local settings.

**Estimated Acquisition Cost.** A state Medicaid agency’s estimate of the price generally paid by pharmacies for a drug.

**Federal Rebates.** Federal manufacturer drug rebates are mandated under Medicaid law in Section 1927 of the Social Security Act. The complex formula used to calculate federal rebates includes average manufacturer price and other pricing indices, depending on whether a drug is a non-innovator (generic) or innovator (brand-name) medication. The calculation is the same across all fee-for-service Medicaid programs. Federal rebate revenue is shared by federal and state governments.

**Federal Upper Limit.** A maximum reimbursement rate established by CMS for several hundred generic products, based on 250 percent of average manufacturer price.

**Formulary.** A health care organization’s list of drugs designated as “preferred” for treating patients served by the organization.

**Generic Drug.** A prescription product, introduced after its brand-name counterpart loses marketing exclusivity, that the FDA has determined is a chemically identical version of a brand-name drug. Generic drugs are typically less expensive than their brand-name predecessors.

**List Price.** A published price—such as average wholesale price or wholesale acquisition cost—that is not an actual transaction price. Certain pharmaceutical transactions, such as setting payment rates to pharmacies, may be based on list prices.

**Long-term Care.** A broad array of services encompassing care provided in both institutional and community-based settings. LTC can occur in a skilled nursing facility or at home by a registered nurse, home health aide, or personal care attendant.

**Managed Care Organization.** A generic term applied to a managed care plan. Alternative names are health maintenance organization (HMO), preferred provider organization (PPO), and exclusive provider organization (EPO), although a managed care organization may not conform exactly to any of these formats.

**Maximum Allowable Cost (MAC).** Calculated by state Medicaid agencies, pharmacy benefit managers, or other contractors, maximum allowable cost is based on actual acquisition cost.

Most states apply MAC pricing only to generic drugs, although some states have begun establishing MAC prices for brand-name products as well. Most generic MAC lists cover 1,000 to 1,500 drugs.

**Medicaid Drug Rebate Program.** The Medicaid Drug Rebate Program requires manufacturers to enter into agreements with CMS to provide rebates for their drug products that are paid for by Medicaid. Manufacturers that do not sign an agreement with CMS are not eligible for federal Medicaid coverage of their product(s). Except for statutory limitations, state Medicaid programs must provide reimbursement for all covered outpatient drug products manufactured by companies that have entered into rebate agreements with CMS.

**Medicare Part B.** The component of Medicare that provides benefits to cover the costs of physicians' professional services, whether those services are provided in a hospital, physician's office, extended-care facility, nursing home, or insured's home.

**Medicare Part D.** The Medicare component, effective January 1, 2006, and administered through private health plans, that provides benefits to cover the costs of outpatient prescription drugs.

**Medication Therapy Management.** Intended to reduce drug contraindications, drug-drug interactions, and other issues related to use of multiple medications, Medicaid medication therapy management typically targets beneficiaries with complex medication regimens, such as those with chronic illness or mental illness, or receiving long-term care. Operationally, participating pharmacists manage medications in the context of a comprehensive medical and provider history, and conduct regular drug utilization and drug regimen reviews.

**Multiple-Source Brand.** A brand-name drug also available in generic versions from additional manufacturers.

**Multiple-Source Drugs.** Pharmaceutically equivalent drugs with the same active ingredient(s), dosage form, strength or concentration, and route of administration, produced by multiple manufacturers. These include non-innovator, or generic, drugs and the innovator drug that originally held the patent. Multiple-source drugs, rated as therapeutic equivalents by the FDA, are included in the process determining the federal upper limit.

**National Drug Code (NDC).** The unique 11-digit drug identification code maintained by the FDA. The first five digits identify a drug's manufacturer, the next four the manufacturer's product code, and the last two the manufacturer's package size code.

**Net Price.** The price, after discounts are deducted, paid at different levels of the prescription drug distribution chain (e.g., purchaser to provider, provider to wholesaler, and wholesaler to manufacturer).

**Outpatient Prescription Drug Benefit.** An optional Medicaid program benefit through which Medicaid beneficiaries can fill prescriptions for Medicaid-covered drugs at a pharmacy or outpatient facility.

**Over-the-Counter (OTC).** Drug, vitamin, supplement, and related products available without a prescription (e.g., aspirin).

**Payer.** A public or private organization that makes “third-party” payments for medical or pharmaceutical expenses on behalf of covered beneficiaries, who pay a premium for this coverage in all private and some public programs.

**Pharmacy Benefit Manager.** An organization that provides administrative services related to processing and analyzing prescription claims for pharmacy benefit and coverage programs. These services can include contracting with a network of pharmacies; establishing payment levels for provider pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; performing drug utilization reviews; and operating disease management programs.

**Pharmacy & Therapeutics (P&T) Committee.** An advisory committee to the pharmacy benefit manager, responsible for developing, managing, updating, and administering a drug formulary list.

**Physician-Administered Drugs.** Oncology and other drugs that can only be administered to a patient by a physician in a physician’s office.

**Polypharmacy.** The prescribing of many medications simultaneously for a patient.

**Preferred Drug List (PDL).** The PDL, or formulary, identifies a program’s preferred drug coverage based on clinical and cost effectiveness. A drug not on a Medicaid preferred drug list typically may be obtained with prior authorization.

**Prior Authorization.** A utilization management policy that requires prescribers or pharmacies to obtain advance approval for prescribing/dispensing of a drug, in order to qualify for reimbursement. Prior authorization may be required for clinical reasons, to assure

appropriate use, or based on a product's "non-preferred" status on a PDL. Prior authorization requires adequate medical justification for the use of a non-preferred drug.

**Provider.** Any supplier of medical or health care-related services, such as a physician, pharmacist, or case management firm.

**Rebate.** Medicaid drug rebates are mandated under federal law, and shared by the federal and state governments. The statutory rebate is the same across state fee-for-service Medicaid programs. Many states negotiate additional, or supplemental, rebates with drug manufacturers.

**Single-source Brand.** A drug under patent protection that is sold under a brand name and is thus available from only one manufacturer (or occasionally from other manufacturers under license from the patent holder). No generic version is available.

**Specialty Drug.** Specialty drugs are produced through DNA technology or biological processes to treat chronic and complex diseases. Inhaled, infused, or injected, these drugs have unique administration requirements and require a customized medication management program that includes medication use review, patient training, coordination of care, and adherence management for successful treatment.

**Specialty Pharmacy Vendor.** A pharmacy that dispenses generally low-volume and high-cost medicinal preparations to patients who are undergoing intensive therapies for illnesses that are generally chronic, complex, and potentially life-threatening (e.g., rheumatoid arthritis, multiple sclerosis, hemophilia). These therapies often require specialized delivery and administration.

**Stakeholder.** A party of interest. With respect to prescription drugs, stakeholders include but are not limited to purchasers, group purchasing organizations, wholesalers, pharmaceutical manufacturers, providers, and patients.

**Step Therapy.** A medication management strategy imposed by a health plan or pharmacy benefit manager that requires a beneficiary to try one drug, often a generic, before the plan will pay for another, usually a brand-name one. A principal purpose of step therapy is to reduce the average cost of treating a given condition (e.g., hypertension, heartburn, or depression) by requiring a trial, by beneficiaries, of an equally effective, lower-cost drug before a higher-cost, second-line drug will be covered. The health plan or other payer may require evidence of therapeutic failure (e.g., intolerance due to side effects) before coverage of the second-line drug.

**Supplemental Rebate.** In addition to federally mandated rebates, some states choose to pursue supplemental rebates, additional payments by pharmaceutical manufacturers negotiated directly with individual states. Manufacturers offer supplemental rebates in exchange for having their products receive preferred status on the state's PDL.

**Therapeutically Equivalent Product.** Drug products containing different chemical entities that should provide the same pharmacological action or chemical effect, and similar treatment effects, when administered to patients in therapeutically equivalent doses. Per *Approved Drug Products with Therapeutic Equivalents* (also known as the *Orange Book*), drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

**Therapeutic Substitution.** Dispensing by a pharmacist of a product different from that prescribed but deemed to be therapeutically equivalent. This practice requires the prescribing physician's authorization before the substitution may occur. A P&T Committee most often approves the rationale for therapeutic equivalency prior to the substitution being made.

**Third-party Payer.** A public or private organization (such as Blue Cross and Blue Shield, Medicare, Medicaid, or a commercial insurer, self-insured employer, Taft-Hartley Trust, or Multiple Employer Trust) that pays for or underwrites coverage for health care expenses for an individual or group. The individual enrollee generally pays a premium for coverage in all private and some public health insurance programs, and the organization pays claims on the patient's behalf.

**Usual and Customary Price.** The price for a given drug or service that a pharmacy or other provider would charge a cash-paying customer without the benefit of insurance provided through a payer or intermediary with a contract with the provider.

**Wholesale Acquisition Cost.** The list price of a pharmaceutical sold by a manufacturer to a wholesaler.

**Wholesaler.** A firm involved in logistical functions (assembling, sorting, and redistributing) in the distribution chain for pharmaceuticals. Wholesalers purchase goods from manufacturers and redistribute them to purchasers, who may be pharmacies, physicians, or other types of providers.



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