

# medicaid and the uninsured

## **The Role of Clinical and Cost Information in Medicaid Pharmacy Benefit Decisions: Experience in Seven States**

**Prepared by**

**Jenny Gaffney, Marielle Kress, Caroline Pearson, and Tanisha Carino, Ph.D. of Avalere Health**

**John Connolly, Ph.D., and Robin Rudowitz of the Kaiser Family Foundation's Commission on  
Medicaid and the Uninsured**

**September 2011**

# kaiser commission medicaid and the uninsured

**The Kaiser Commission on Medicaid and the Uninsured provides information and analysis on health care coverage and access for the low-income population, with a special focus on Medicaid's role and coverage of the uninsured. Begun in 1991 and based in the Kaiser Family Foundation's Washington, DC office, the Commission is the largest operating program of the Foundation. The Commission's work is conducted by Foundation staff under the guidance of a bipartisan group of national leaders and experts in health care and public policy.**

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## EXECUTIVE SUMMARY

### *Introduction*

Now more than ever, Medicaid programs face a delicate balance in providing health care access to vulnerable individuals and being prudent with taxpayer dollars. Looking forward to fiscal year 2012, 44 states and the District of Columbia are projecting budget shortfalls totaling \$112 billion.<sup>1</sup> This comes at the same time as Medicaid enrollment is increasing due to a sluggish economy.

Over the years, states have proactively employed a variety of strategies in their Medicaid fee-for-service programs to maximize beneficiary access to beneficial prescription drugs while striving to minimize costs. The majority of states use preferred drug lists (PDLs), which generally list “preferred” medications that are found to be the least costly, therapeutically-appropriate drugs that Medicaid beneficiaries may receive without first obtaining prior authorization (PA) from the state.<sup>2</sup> States have also invested internal and external resources to augment the capacity for using clinical and cost evidence to inform pharmacy policies. Recently the federal government, through the American Recovery and Reinvestment Act (ARRA) and the Affordable Care Act (ACA), has provided significant funding for research to help Medicaid programs and others identify what treatments work best for specific patient populations.

The goal of this research is to evaluate how Medicaid programs are applying clinical evidence in their pharmaceutical policies. To answer this question, Avalere Health and the Kaiser Family Foundation Commission on Medicaid and the Uninsured conducted primary and secondary research from January to July 2011 on seven state Medicaid programs—Florida, Louisiana, Maryland, Massachusetts, Minnesota, Nevada, and Washington—and three Medicaid managed care plans—Amerigroup, Molina Healthcare, and United—operating in these markets. Our goal was to determine how states evaluate relative clinical and cost information about prescription drugs when making coverage decisions for Medicaid pharmacy benefits.

### *Key Findings from Seven Study States*

#### **State Medicaid programs in the study default to using the net price of drugs to refine PDLs due to perceived lack of compelling evidence of comparative clinical benefit.**

All of the pharmacy directors interviewed expressed interest in using clinical comparative effectiveness research (CER) to inform their PDL. However, they noted that the existing evidence base frequently lacks sufficient information to make clear decisions regarding the relative clinical effectiveness of pharmaceuticals used to treat the same condition. Therefore, many states turn to comparisons of net price to make coverage decisions.

#### **A majority of study states rely on the same pharmacy benefit manager (PBM) to help with the decision-making process for pharmacy benefits.**

Florida, Louisiana, Nevada, and Minnesota all rely on drug and therapeutic class reviews conducted by the PBM, Magellan Health Services.<sup>3</sup> Washington is the only state that uses clinical reviews from Drug Effectiveness Review Project (DERP) as the primary basis for its clinical recommendations for its PDL. Maryland combines DERP reviews with clinical reviews of drugs or drug classes conducted by Magellan.

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<sup>1</sup> McNichol E, Oliff P, Johnson, N. States Continue to Feel Recession’s Impact, Results from a 50-State Survey. Center on Budget and Policy Priorities, March 2011.

<sup>2</sup> As of April 2011, over 46 states have operating Medicaid PDLs. Recent Medicaid Drug Laws and Strategies 2001-2010, the web site. National Conference of State Legislatures. Available at: <http://www.ncsl.org/programs/health/medicaidrx.htm>. Accessed Apr. 7, 2011.

<sup>3</sup> Magellan Health Services acquired First Health Services Corp and Provider Synergies LLC. However, some states still refer to them by their former names of First Health and Provider Synergies.

The University of Massachusetts (UMass) Medical School prepares clinical reviews at Massachusetts' request. These entities, with the exception of DERP, prepare monographs of clinical *and* cost information with recommendations that are presented to state Pharmacy and Therapeutics (P&T) committees to review during their meetings to inform drug coverage and utilization management policies.

**States do not use publicly available sources of CER because of the lack of cost information, length, and timing of the analyses.**

The majority of states interviewed cited the lack of cost information in Agency for Healthcare Research and Quality (AHRQ) and DERP reports as the primary reason for why they do not consider them. Additionally, many feel that these reports are outdated at the time of PDL review or re-review and often do not include enough information on new drugs to market. States also indicated that the format of the reports, specifically their length and lack of definitive recommendations, are not easily translated into decision-making processes. Because of these limitations, states often contract out drug reviews to private organizations that cater specifically to the timing and scope of each state's PDL review.

**Relative to fee-for-service (FFS) programs, Medicaid managed care organizations (MCOs) have a closed system and fairly centralized decision-making process for developing their formulary and applying it at the state level.**

Amerigroup, Molina, and United HealthCare are three of the largest Medicaid MCOs by enrollment; 6.5, 4.7, and 10.2 percent of individuals in Medicaid MCOs were enrolled in plans sponsored by these companies in 2009.<sup>4</sup> Amerigroup and United generally manage plan formularies at the national level. If either plan chooses a preferred drug at the national level, then it will be preferred for all plans across states with only limited adjustments due to specific state regulations. Molina has a more decentralized formulary operation and permits more variation across their state markets in deciding what drugs are covered. Compared to the state Medicaid programs interviewed, the Medicaid MCOs are less transparent in how they develop their formularies. MCOs do not invite stakeholder comment at P&T committee meetings, and do not open these meetings to the public. In addition, none of the plans interviewed use public CER reports to inform their work with states. Moreover, state Medicaid program officers interviewed also claimed to exert limited influence over MCO formularies. Preliminary analysis of Medicaid MCO formularies suggests that these plans typically cover fewer drugs, particularly branded products, than do state PDLs. Since the majority of the state Medicaid programs interviewed expect enrollment in MCOs to grow, the processes and decision making of these plans will become more important in defining the type of drug coverage Medicaid beneficiaries will receive.

**While the majority of study states previously provided open access to mental health drugs, many now restrict access to drugs in these classes through the PDL.**

The Medicaid officials interviewed expressed the sensitive nature of preferring certain mental health drugs over others. Patient advocates strongly support open access to a wide variety of mental health drugs, specifically atypical antipsychotics, as patients often respond differently to each drug and its side effects. Historically, states have left atypical antipsychotics off of PDLs in order to ensure open access to these drugs. However, since atypical antipsychotics represent a large portion of state Medicaid program's drug spending and the number of available agents has grown substantially, interviewees reported growing willingness to restrict access among the branded agents in the class and add these drugs to the PDL.

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<sup>4</sup> 2010 Avalere Analysis of 2009 CMS Medicaid Managed Care Enrollment Report, MCO 2009 Annual Reports, state websites

**Some states are exploring pharmacy management tools that are tailored to individual patient needs, but find them difficult to implement.**

Some of the states interviewed emphasized the importance of generating CER that acknowledges patient heterogeneity in treatment response. At the same time, however, they recognize that the PDL and other pharmacy management tools are structured and implemented at the Medicaid population level and thus do not lend themselves to account for patient heterogeneity in treatment response. Pharmacy Directors further explained that they do not have the data infrastructure to support the added complexity of processing claims and PA requests based on many different subpopulations.

**Moving forward, states are concerned with the cost of specialty products and biologics.**

Over half of the states included in the analysis indicated that Medicaid pharmacy spending on traditional prescription drugs is under control but expressed concern with the high cost of new specialty and biologic products moving forward. Many emphasized the need for improved evidence in this space. However, they also noted that many of these products are unique and, therefore, would not have relevant comparative information available. While most states historically have not actively managed utilization of specialty products, numerous states indicated that they plan to expand their drug management to these products type of products in the future.

*Issues Looking Forward*

This project analyzes how states, in times of grave economic pressures, use information to inform pharmacy coverage decisions. There are many questions about the usefulness and robustness of the existing comparative effectiveness information available to state decision-makers. Medicaid FFS programs and Medicaid MCOs seek comparative information to establish their pharmacy policies, but those interviewed rarely use CER reports from public sources, such as AHRQ and DERP. Instead, they turn to resources that produce information customized to their individual needs and are timely, concise, and include cost information. In addition, although they serve the same patient population, there is significant variation among state Medicaid FFS and Medicaid MCOs in coverage decisions and the formulary development process. Looking forward, these findings may lead to the following implications for policymakers and CER organizations:

- There is a need for public CER organizations to better fill key evidence gaps identified by Medicaid PDs in order to inform drug coverage decision making.
- Research organizations can provide important assistance to Medicaid decision makers by generating, translating, and disseminating CER in a way that is timely, targeted and includes cost information.
- It will be important to better understand the effect of differences between fee-for-service and managed care pharmacy benefits decisions, including the transparency and opportunities for public engagement in these decisions.

## I. OVERVIEW AND PURPOSE

States have faced significant budget crises over the past three years, and many will still run deficits in the near future. In FY 2012, 44 states and the District of Columbia will experience a budget shortfall, and deficits in 26 of those states are projected to exceed 10 percent of their fiscal year 2011 budgets.<sup>5</sup>

State Medicaid programs have always had a two-pronged mandate: to provide beneficiaries with the highest quality care at the lowest cost to state and federal taxpayers. The current economic crisis and resulting entrance of approximately 7.6 million new Medicaid beneficiaries during the recession compound the challenge of meeting both mandates.<sup>6</sup> Moreover, states must prepare for mandated Medicaid expansions authorized in the Affordable Care Act (ACA) that go into effect in 2014.<sup>7</sup> An additional 16 million people are expected to enroll in Medicaid as a result of these expansions by 2019.

Over the years, states have employed a variety of strategies in the Medicaid fee-for-service (FFS) program to maximize beneficiary access to prescription drugs while limiting costs, such as generic substitution, prior authorization (PA), and bulk-purchasing pools. Preferred drugs lists (PDLs) are one of the most predominant strategies used by Medicaid programs to contain costs. Forty-seven states currently operate PDLs, which generally identify “preferred” medications that are found to be the least costly, therapeutically-appropriate drugs that Medicaid beneficiaries may receive without first obtaining PA from the state.<sup>8</sup>

As required by federal statute, Medicaid agencies must establish committees of physicians and pharmacists, usually called pharmaceutical and therapeutics (P&T) committees, to inform the development of a PDL.<sup>9</sup> These committees generally review the available clinical evidence as well as the net cost of the drugs in a given class, and then make recommendations based on both pieces of evidence. Although most states generally follow this process, there is significant variation in the type of clinical and cost evidence considered, the extent to which cost information is factored in, whether private vendors are used to negotiate supplemental rebates with drug manufacturers, and the composition of the P&T committees. Exhibit 1 provides more information on the composition of the P&T committees evaluated in this paper.

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<sup>5</sup> McNichol, E, Oliff P, N Johnson. States Continue to Feel Recession’s Impact, Results from a 50-State Survey, Center on Budget and Policy Priorities, March 2011.

<sup>6</sup> Kaiser Family Foundation. Medicaid Enrollment: June 2010 Data Snapshot. February 2011.

<sup>7</sup> CBO March 2011 Estimate of the Effects of the Insurance Coverage Provisions Contained in the Patient Protection and Affordable Care Act (Public Law 111-148) and the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152)

<sup>8</sup> Avalere tracking analysis of publicly available Medicaid policy data, Medicaid program websites, updated, 2011.

<sup>9</sup> Social Security Act §1927(d)(4), 42U.S.C. §1396r-8(d)(4)

**Exhibit 1: Information on P&T Committees for States Developing PDLs**

State	Composition
<b>Florida</b> <i>P&amp;T Committee</i>	11 members <ul style="list-style-type: none"> <li>4 physicians (at least 1 psychiatrist)</li> <li>5 pharmacists (at least 1 with expertise with mental health drugs)</li> <li>1 consumer representative</li> <li>At least one member must represent the interests of pharmaceutical manufacturers</li> </ul>
<b>Louisiana</b> <i>P&amp;T Committee</i>	21 members <ul style="list-style-type: none"> <li>12 physicians (variety of specialists must be included, such as at least 1 psychiatrist and 1 pediatric oncologist)*</li> <li>4 pharmacists</li> <li>3 legislative officials</li> <li>1 Medicaid recipient</li> <li>Medicaid program director</li> </ul>
<b>Maryland</b> <i>P&amp;T Committee</i>	12 members <ul style="list-style-type: none"> <li>5 physicians</li> <li>5 pharmacists</li> <li>2 consumer representatives</li> </ul>
<b>Massachusetts</b> <i>Pharmacy Policy Committee (PPC)**</i>	16 members: <ul style="list-style-type: none"> <li>2 physicians</li> <li>12 pharmacists</li> <li>2 analysts</li> </ul>
<b>Minnesota</b> <i>Drug Formulary Committee</i>	9 members <ul style="list-style-type: none"> <li>4 physicians (1 must be actively engaged in the treatment of persons with mental illness)</li> <li>4 pharmacists</li> <li>1 consumer representative</li> </ul>
<b>Nevada</b> <i>P&amp;T Committee</i>	9 - 11 members <ul style="list-style-type: none"> <li>At least 1/3 must be physicians, but not more than 51 percent</li> <li>At least 1/3 must be pharmacists or persons with doctoral degrees in pharmacy, but not more than 51 percent</li> <li>1 psychiatrist</li> </ul>
<b>Washington</b> <i>P&amp;T Committee/ DUR Review Board</i>	10 members <ul style="list-style-type: none"> <li>4 physicians</li> <li>4 pharmacists</li> <li>1 physician’s assistant</li> <li>1 nurse practitioner</li> </ul>

\*Complete description of Louisiana P&T committee composition as required by bylaws available [here](#).

\*\*Note the Massachusetts Pharmacy Policy Committee is a staff committee.

In general, states develop PDLs using both clinical and cost information. As states continue to refine their PDLs to ensure they deliver the highest quality for the best price, there has been a growing interest to incorporate better evidence into their policy making process. In this vein, states have invested in internal and external resources to augment their capacity to conduct clinical and cost reviews of drug classes to inform development of their PDLs and pharmacy policies.

Increasingly, state Medicaid programs are shifting beneficiaries to managed care plans to gain more predictability over Medicaid spending. Typically, states pay managed care organizations (MCOs) a capitated amount per enrollee to provide all or a defined set of health services. Moreover, MCOs offer opportunities for improved care coordination as proponents of managed care say that MCOs link enrollees with a primary care provider and can also be designed to encourage prevention and early detection of health conditions.<sup>10</sup> Thirty-five states currently contract with fully-capitated MCOs to provide services to almost half of Medicaid beneficiaries.<sup>11</sup> Only 43 percent of individuals in Medicaid currently receive their drugs from MCOs due to drug carve-outs; 11 states currently carve drugs out of Medicaid MCO contracts.<sup>12,13</sup> As a result of the ACA, states can now collect mandatory Medicaid rebates from drug manufacturers for enrollees in managed care plans so states that had carved drugs out may consider including drugs in the MCO capitation. As of October 2011, New York and Ohio, two large states that previously carved drugs out of MCO contracts, will carve the drug benefit back into Medicaid managed care contracts—shifting drug benefits for 4.3 million beneficiaries from fee-for-service to MCOs.<sup>14,15</sup> Additionally, the percentage of total lives in Medicaid MCOs will grow by an estimated 9.5 million individuals over the next few years due to states expanding enrollment in MCOs, representing an increase of lives in MCOs of approximately 19 percentage points.<sup>16</sup>

At the same time, there is growing interest among public and private sector organizations to assist states in identifying the highest value drugs by providing information states need to establish these policies. A number of state Medicaid programs have joined Oregon’s Drug Effectiveness Review Project (DERP) to obtain information on the comparative effectiveness of pharmaceuticals within the same drug class to inform pharmacy benefit policies.<sup>17</sup> The DERP conducts systematic reviews of the clinical evidence of drug classes selected by its member states. In 2005, Avalere and the Kaiser Family

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<sup>10</sup> Medicaid and CHIP Payment and Access Commission. Report to the Congress: The Evolution of Managed Care in Medicaid. June 2011.

<sup>11</sup> CMS Medicaid Managed Care Enrollment Report, June 2009; Avalere Tracking and Analysis.

<sup>12</sup> CMS Medicaid Managed Care Enrollment Report, June 2009; Avalere Tracking and Analysis of publicly available news sources and state Medicaid websites. Updated 2011.

<sup>13</sup> The following states carve drugs out of MCO contracts: CT, DE, IL, IN, MO, NE, TN, TX, UT, WV, and WI. In 2006, the Office of Vermont Health Access (OVHA), contracted with the state to serve as a publicly sponsored MCO. The authors consider this arrangement to be a publicly administered program (not a traditional capitated MCO) and regard the pharmacy benefit to still be managed by the state. Illinois recently enrolled approximately 40,000 aged, blind, and disabled beneficiaries in MCOs, and the MCOs in this program manage the drug benefit. However, the state still carves out drugs from MCO contracts for families and children, the majority of beneficiaries enrolled in MCOs in Illinois. As of 2009, CMS reports that Utah did not have any beneficiaries enrolled in fully capitated MCOs. However, since the data’s publication, the state has begun enrolling beneficiaries in fully capitated plans, and carves drugs out of these contracts.

<sup>14</sup> CMS Medicaid Managed Care Enrollment Report, June 2009; Avalere Tracking and Analysis of publicly available news sources and state Medicaid websites. Updated 2011.

<sup>15</sup> Texas is also planning a reversal of its drug carve out, but will require MCOs to adhere to the state’s PDL, including utilization requirements, until 2013. Therefore, we consider the state to retain control of the drug benefit.

<sup>16</sup> CMS Medicaid Managed Care Enrollment Report, June 2009; Avalere Tracking and Analysis of publicly available news sources and state Medicaid websites. Updated September 1, 2011.

<sup>17</sup> Currently 10 states participating in the DERP program: Arkansas, Idaho, Oregon, Maryland, Missouri, Montana, New York, Washington, Wisconsin, and Wyoming. Drug Effectiveness Review Project, the website. Available at: <http://www.ohsu.edu/drugeffectiveness/index.htm>. Accessed June. 27, 2011.

Foundation (KFF) Commission on Medicaid and the Uninsured published a report that analyzed how four state Medicaid programs used DERP reviews to develop pharmacy policies. The report found that the influence of the DERP reports varied from being the principal source of clinical evidence used in the development of a PDL, to not being a significant input in a state's pharmacy decision making.

Since the report's publication, the federal government has increased its funding of CER to support decision-makers, like state Medicaid programs, who must balance patient access to pharmaceuticals with mounting budget pressures. In 2005, the Agency for Healthcare Research and Quality (AHRQ) developed the Medicaid Care Management Learning Network to facilitate cross-collaboration among state Medicaid programs in determining best practices for delivering high-quality care to their beneficiaries.<sup>18</sup> Moreover, as mandated by the Medicare Modernization Act of 2003, AHRQ launched the Effective Health Care Program in 2005 to develop systematic reviews and fill evidence gaps on the relative effectiveness of alternative clinical interventions and translate them into usable formats for a range of clinical decision-makers.<sup>19</sup> In 2009, the American Recovery and Reinvestment Act (ARRA) invested \$1.1 billion to fund CER over two years. Finally, in 2010 with the passage of ACA, the federal government established the Patient-Centered Outcomes Research Institute (PCORI), which will receive roughly \$6 billion over the next 10 years to generate CER to assist a wide range of decision makers, including the Medicaid programs, to identify what treatments work best for specific patient populations compared with alternative therapies.

The goal of this research is to examine how Medicaid programs are applying clinical evidence in their pharmaceutical policies in light of new state fiscal pressures and new investments in CER. We sought to address:

- Whom do states turn to for assistance in evaluating evidence when defining their drug benefits?
- How do states view the relevance and usefulness of publicly available CER?
- What are the key similarities and differences in how states and managed care plans define benefits?
- What challenges and opportunities do states anticipate for the future?

To answer these questions, Avalere Health and the KFF Commission on Medicaid and the Uninsured (the Commission) conducted primary and secondary research on seven state Medicaid programs.

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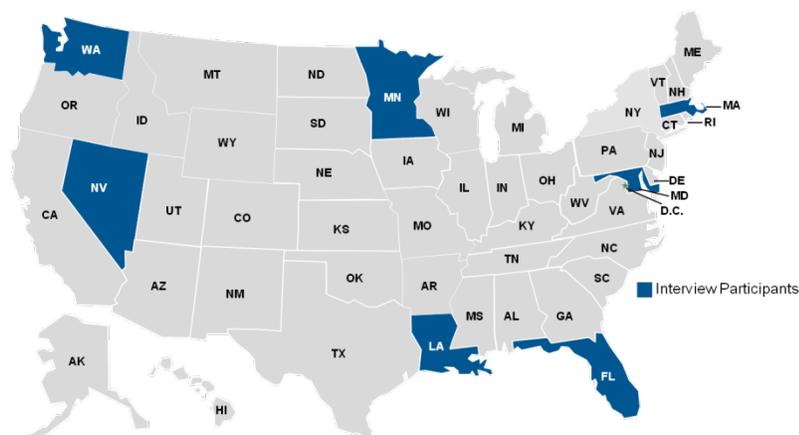
<sup>18</sup> The Lewin Group. Designing and Implementing Medicaid Disease and Care Management Programs: A User's Guide. March 2008.

<sup>19</sup> AHRQ EHCP, the website. <http://www.effectivehealthcare.ahrq.gov/>. Accessed June 27, 2011.

## II. METHODOLOGY

From January to June of 2011, Avalere and the Commission conducted primary and secondary research on seven state Medicaid programs: Florida, Louisiana, Maryland, Massachusetts, Minnesota, Nevada, and Washington. We chose these states based on a number of factors to ensure an appropriate cross-section of states in our analysis. We aimed to select states that were geographically diverse and had different levels of Medicaid managed care penetration. We also selected states based on a number of other factors, including projected FY 2012 budget shortfall, membership in the DERP, participation in a bulk purchasing program, and use of private pharmacy benefit manager (PBM) to support the PDL development process. Exhibit 2 provides more background on the states selected for case studies.

**Exhibit 2: Profiles of States Included in the Analysis**<sup>20,21,22,23</sup>



State	MC Enrollment	Percent in Medicaid MC Pharmacy	FY 2012 Budget Shortfall	Mandates Generic Substitution	Carve Outs	Purchasing Pool	DERP Participant
Florida	1,881,100	49%	\$3.6B	Yes*	No	No	No
Louisiana	884,600	0%^	\$1.6B	No	No	TOP\$	No
Maryland	639,200	92%	\$1.4B	Yes*	Mental Health and HIV Drugs	TOP\$	Yes
Massachusetts	993,900	44%	\$1.8B	Yes*	No	No	No
Minnesota	558,700	67%	\$3.8	Yes*	No	NMPI	No
Nevada	181,118	59%	\$1.5B	Yes	No	NMPI	No
Washington	967,100	60%	\$2.5B	Yes*, Therapeutic Interchange Program**	HIV Drugs (Protease Inhibitors Only)	NPDC	Yes

\* Unless overridden by a doctor

\*\*Program allows physicians and other prescribers to endorse the PDL. For these providers, pharmacists must automatically substitute the preferred drug for non-preferred drugs unless the prescription is for a refill of an antipsychotic, antidepressant, chemotherapy, ARV, or immunosuppressive.

^Louisiana is planning to launch a Medicaid managed care program in early 2012. (Kaiser Health News, April 26, 2011)

NMPI: National Medicaid Pooling Initiative; TOP\$: Top Dollar Program; NPDC: Northwest Prescription Drug Consortium

<sup>20</sup> Participating Organizations. Drug Effectiveness Review Project. <http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/derp/participating-organizations.cfm> (accessed May 9, 2011).

<sup>21</sup> Percent of non-dual lives covered by Medicaid managed care pharmacy. 2009 CMS Medicaid Managed Care Enrollment report. June 2009. Managed care numbers only include fully-capitated plans.

<sup>22</sup> McNichol, E, Oliff P, N Johnson. States Continue to Feel Recession's Impact, Results from a 50-State Survey, Center on Budget and Policy Priorities, March 2011.

<sup>23</sup> Generic substitution laws. National Association of Boards of Pharmacy. Survey of pharmacy law [CD-ROM]. Mount Prospect (IL): The Association; 2008.

After selecting these states, Avalere Health and the Commission conducted in-depth interviews with the Pharmacy Directors (PDs) of each program. In each interview, we asked the PD to describe the composition of its P&T committee; its PDL development process; and how it makes decisions related to the coverage and utilization management of pharmaceuticals, including the steps in this process, the individuals involved at each step, and the type of information considered. We also probed about differences in the way each program manages distinct drug classes, such as those to treat type II diabetes and atypical antipsychotics. We chose these two drug classes as the existing evidence base strongly supports metformin for first-line therapy of type II diabetes patients, whereas the evidence base for atypical antipsychotics is less conclusive given the considerable variation in treatment response to these agents among mental health patients.

To supplement these interviews, we conducted secondary research on statutes, policies, and regulations governing each state's Medicaid P&T committee and PDL development processes. We also interviewed three Medicaid managed care plans operating in these states – Amerigroup, Molina Healthcare, and United. Finally, we interviewed Magellan Medicaid Administration (Magellan) and the University of Massachusetts Medical School (UMMS), each of which supports state Medicaid programs with PDL development. We have included a profile of each of the seven states and additional background information in the Appendix.

### III. KEY FINDINGS

Our research revealed that states in this study are in a significant period of transition. They are turning to a variety of resources to help them make more informed choices in establishing their pharmacy policies and continue to struggle with the information they have versus the information they need to guide their decisions. Our findings are summarized below:

#### **1. State Medicaid programs in this study default to using net the price of drugs to refine their PDLs due to perceived lack of compelling evidence of comparative clinical benefit.**

Most Pharmacy Directors (PDs) agreed that medical literature often lacks sufficient evidence to make clear distinctions regarding the therapeutic equivalence or clinical superiority of drugs in the same class. Although they all indicated that they prioritize clinical evidence in the PDL decision-making process, they acknowledged that, given the dearth of comparative clinical effectiveness information, they often turn to comparisons of net price to make the ultimate coverage decision.

With the exception of state officials from Washington, all of the PDs explained that their P&T committee considers *both* the clinical and cost information of a drug in making a PDL recommendation. In fact, Florida and Maryland's respective statutes assert that the P&T committee must develop its PDL recommendations by considering the clinical efficacy, safety and cost-effectiveness of a product.<sup>24,25</sup>

While all of the PDs emphasized that the clinical merits of a product are of primary consideration, they stated that cost figures prominently in the committee's recommendation. One PD emphasized that, as a result of the lack of comparative data available on most classes, it is vital to review cost and clinical efficacy together. This particular PD contended that the P&T committee must often "line up the drugs and choose what drug to prefer based on cost alone," because there are no head-to-head clinical trials to provide the committee with adequate comparative data.

Prior to each P&T Committee meeting, Florida, Louisiana, Maryland, and Minnesota all receive reports from Magellan that synthesize the clinical evidence and provide a cost evaluation of the drug or therapeutic class under consideration. In addition, Magellan's reports include specific PDL recommendations for the state. Magellan representatives explained that these recommendations marry a clinical analysis of the evidence with a financial analysis based on the net price negotiated with the manufacturer. If the clinical analysis concludes that the drugs are fairly similar, then the recommendation is based on the net price.

Massachusetts' Pharmacy Policy Committee (PPC) contracts with the University of Massachusetts Medical School (UMMS) to prepare similar drug reviews with coverage recommendations to inform its decision-making. A representative from UMMS explained that they prioritize head-to-head trials in their reviews. As an example, he described how for newer atypical antipsychotic agents, UMMS recommended that the drugs be prior authorized until there is a head-to-head trial that shows clinical equivalence against existing atypical agents.

Nevada statute prohibits the P&T committee from explicitly considering cost information in its decision-making. Though the P&T committee does not directly assess cost information, it does receive coverage

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<sup>24</sup> Fla. Stat. § 409.91195(9)

<sup>25</sup> MD. Stat. § 10.09.03 <http://www.dsd.state.md.us/comar/comarhtml/10/10.09.03.12.htm>

recommendations from Magellan that are partially based on cost data. These recommendations are presented to the P&T committee along with a report of the clinical evidence produced by Magellan. These two inputs inform the P&T committee’s binding PDL recommendation.

Bucking the trend of evaluating cost information at the same time as clinical information, Washington’s P&T committee’s discussion is limited to a review of clinical evidence. The state’s statute also prohibits the committee from considering cost in its PDL decision-making.<sup>26</sup> However, unlike Nevada, only after the P&T committee’s recommendations does the state Medicaid agency review cost information for the recommended drugs, including supplemental rebates offered by drug manufacturers, and select the recommended drugs with the lowest costs for the PDL.

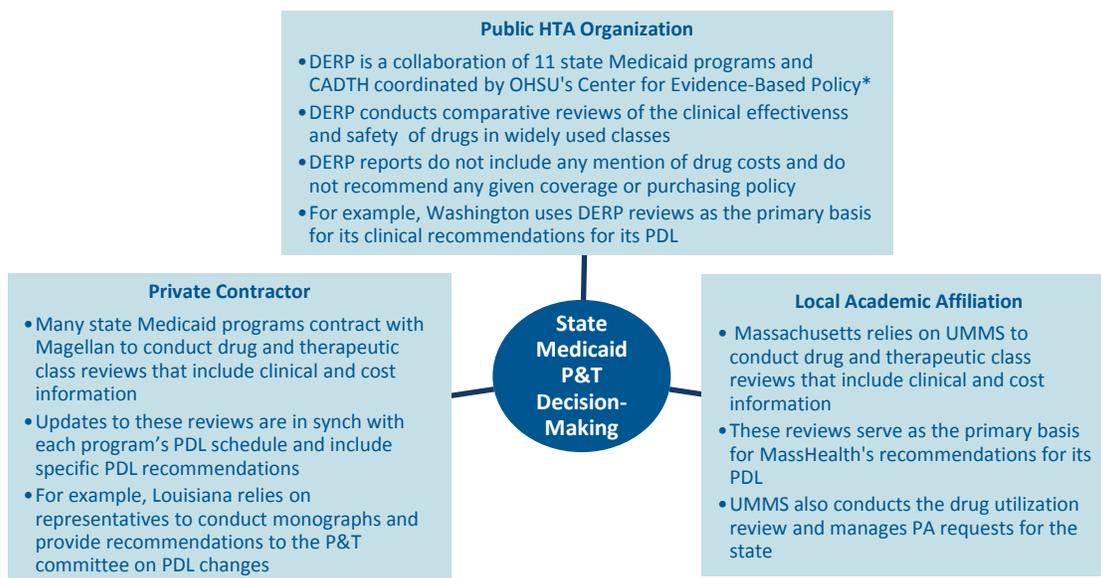
As states continue to face fiscal pressure, cost will likely play more of a role in state decision-making around what interventions should be preferred and for which populations. It will be important to reconcile the economic pressures states are facing with public concerns that a more explicit inclusion of cost in payer decision-making will lead to rationing and reductions in access to care.

**2. A majority of states rely on the same pharmacy benefit manager (PBM) to help with the decision-making process for pharmacy benefits.**

Exhibit 3 provides an overview of the distinct sources of information considered by each state in their decision-making process: (1) private contractor; (2) public health technology assessment organization; and (3) local academic institution.

**Exhibit 3. Sources of Clinical and Cost Information Considered by State Medicaid Programs**

\*Oregon’s Evidence-Based Practice Center, which is part of the AHRQ Effective Health Care Program, conducts the drug class review



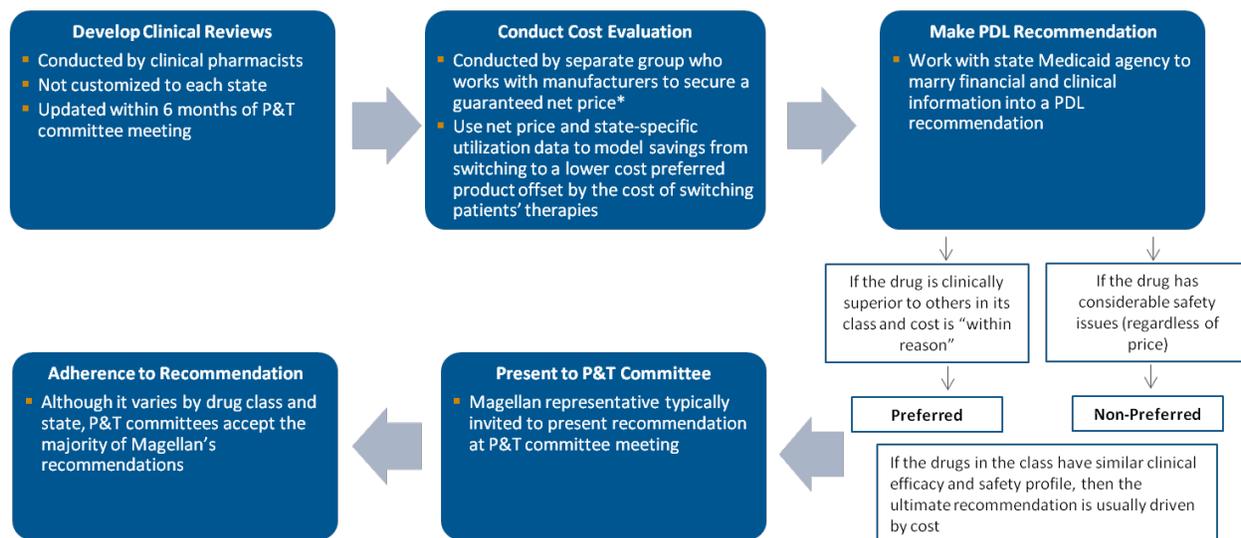
CADTH: Canadian Agency for Drugs and Technologies in Health; OHSU: Oregon Health and Science University; UMMS: University of Massachusetts Medical School

<sup>26</sup> WA Stat. RCW 70.14.050 <http://www.rx.wa.gov/ptplanofops.html>

Each source develops evidence reports that figure prominently into the P&T committee’s PDL recommendation. However, the process used by each to develop these reports is very different. Unlike reviews developed by the PBM, Magellan, and UMMS, DERP reviews do not include cost information and are developed through a relatively transparent process with opportunities for public comment. Moreover, DERP reviews do not conclude with specific PDL recommendations, like the reports prepared by Magellan and UMMS. In contrast to Magellan and DERP, who produce national class reviews, UMMS’ reviews are developed at a local level and for Massachusetts.

While the relationship between state Medicaid programs and PBMs is not new, the extent to which states rely on PBMs has grown significantly in the past ten years. At first, states primarily contracted with a PBM for administrative support, such as claims processing. Now, largely due to resource limitations, states are also using PBMs to negotiate supplemental rebates and conduct clinical drug class reviews that inform PDL decision-making. Currently, 37 states rely on PBMs to negotiate supplemental rebates and provide PDL support.<sup>27</sup> Florida, Louisiana, Maryland, Nevada, and Minnesota all rely on drug class reviews conducted by the PBM, Magellan, to inform their PDL decision-making.<sup>28,29</sup> The PDs from these five states explained that these reviews provide their P&T committees with a consolidated, up-to-date resource of the relevant clinical and cost information for a specific drug or class. Moreover, they conclude with specific PDL recommendations. In most cases, the PD explained that a Magellan representative presents the review and recommendations at the P&T committee meeting, and then the committee’s discussions are centered on accepting or rejecting these recommendations.

#### Exhibit 4: Magellan’s Process for Developing State-Specific PDL Recommendations



\*Net price amount defined as the pharmacy reimbursement minus the respective federal and supplemental rebates

<sup>27</sup> Avalere Research, state Medicaid websites, 2011.

<sup>28</sup> Nevada will switch to contracting with SXC following a contract rebid.

<sup>29</sup> Maryland is also a member of the DERP, and it uses these reviews to complement those developed by Magellan.

In addition to providing states with evidence reviews to inform PDL decision making, Magellan enables states to participate in one of two multi-state purchasing pooling programs the company administers—the National Medicaid Pooling Initiative and the TOP\$ pool. In these programs, Magellan pools the purchasing power of participating state Medicaid programs to obtain greater supplemental rebates, price concessions negotiated with manufacturers to ensure preferential placement of drugs on PDLs. Louisiana, Maryland, Minnesota, and Nevada are all members of one of the two multi-state purchasing pools managed by Magellan. Therefore, for these states, Magellan provides an integrated platform upon which the Medicaid program can manage its PDL.

Massachusetts is unique in that it works with an academic center—UMMS— to prepare drug and therapeutic class reviews to inform the Pharmacy Policy Committee’s (PPC) decisions. UMMS explained how its roots in Massachusetts allow it to have connections with key providers and community-based advocacy groups that it can tap into when it has questions about specific drugs or classes. Following completion of the review, UMMS pharmacists present the key findings and make benefit recommendations to the MassHealth PPC. UMMS also helps to administer the state’s PDL by managing PA requests.

Consistent with our 2005 report’s conclusions, Washington is the only state that uses clinical reviews from DERP as the only body of evidence for its clinical review when making PDL recommendations to the state.<sup>30</sup> Washington statute requires that all preferred drugs be identified through an evidence-based process.<sup>31</sup> Although the statute allows the agency to contract with either DERP or “another similar entity” to conduct evidence-based reviews, Washington’s P&T committee uses the DERP reports as the sole body of evidence for its clinical review when making PDL recommendations. In fact, Washington does not review a therapeutic class for inclusion on its PDL unless the DERP has released a final evidence-based report for that class. A DERP representative attends each P&T committee meeting to present the key findings from the report. Moreover, stakeholders cannot present new evidence during the public comment period of the P&T committee without first having it reviewed by DERP.

### **3. States do not use publicly available sources of CER because of the lack of cost information, length, and timing of the analyses.**

The majority of states interviewed cited the lack of cost information in AHRQ and DERP reports as the primary reason why they are not often incorporated in the decision-making process. Since all of the interviewed PDs, with the exception of Washington, consider clinical and cost information in their PDL decision-making, they prefer having a resource that includes both pieces of information. Moreover, those interviewed said that the length of the DERP reports, which can exceed 100 pages, was not as easily translated into targeted PDL recommendations. Similarly, as a member of DERP and a client of Magellan, Maryland emphasized that while the state considers DERP’s analyses and recognizes that DERP’s mission is to focus only on the clinical evidence, cost is something they cannot ignore in their decision-making. Maryland also explained that DERP reports are sometimes outdated at the time of PDL review, and thus do not include information on new drugs to market.

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<sup>30</sup> Padrez, R et al. The Use of Oregon’s Evidence-Based Reviews for Medicaid Pharmacy Policies: Experiences in Four States. May 2005.

<sup>31</sup> Senate Bill 6088 enacted during the 2003 Legislative session; Revised Code of Washington (RCW) 70.14, Washington Administrative Code (WAC) 182-50.

Because of these limitations, states often contract out their drug reviews to private organizations, like Magellan, that cater specifically to the timing and scope of each state's PDL review. Magellan specifically tailors their reports to meet the needs of state Medicaid programs: the development and updating of reports are synched with each state's PDL review; reports are generally kept to between eight and ten pages and include recommendations specific to each state's PDL. Further, Magellan can provide states with both clinical and cost information.

Interviewee's stated preference of Magellan's reports over DERP's reviews highlights the importance of effectively translating research findings in a way that is useful to the end user. Despite the public availability of DERP and AHRQ reports, states find the lag time between updates to reports, lengthy format, and lack of cost information all barriers to using them in decision-making. Ideally, from the states' perspectives, they would have a resource at their disposal that was timely, concise and included cost considerations. Magellan's reports include all three of these factors, which is why states rely so heavily on them.

**4. Relative to states' fee-for-service (FFS) programs, Medicaid managed care organizations (MCOs) have a closed system and fairly centralized decision-making process for developing their formulary and applying it at the state level.**

Although a majority of Medicaid beneficiaries (57%) currently receive their drugs from FFS programs, states are increasingly moving towards enrolling more Medicaid beneficiaries in managed care, and fewer beneficiaries are receiving drugs from the state's PDL.<sup>32</sup> However, every state PD we interviewed stated that they exercise limited oversight of the formularies or formulary development processes for MCOs operating in the states. The three MCO PDs included in the study (Amerigroup, Molina, and United) also agreed that states exerted minimal supervision over the decisions being made regarding the MCO formulary. While most states have specific requirements written into MCO contracts that dictate the level of similarity that the MCO formulary must have to the PDL, none of these requirements specify PA criteria or preferred placement for one product versus another. Some states require MCOs to cover all drugs on the state's PDL (Florida and five other states), while some require the MCO to cover a therapeutic equivalent to all classes on the PDL (Washington and five other states), and some states have no requirements at all (New Mexico and eight other states).<sup>33</sup> Though some states, such as Maryland, require MCOs to submit changes to formularies for approval, other states take a much more hands-off approach to MCO formulary decision-making. One MCO PD explained that "most states have very vague language around what [Medicaid MCOs] can and cannot do," and so the oversight remains minimal. More specifically, the language does not require the MCO to prefer drugs that the state prefers on the PDL, nor do the MCOs have to adhere to utilization management requirements that the state imposes on drugs on the PDL.

In addition to limited oversight from the state, the PDL development process for all three MCOs is less transparent than that of the states' FFS programs, where there are explicit public engagement opportunities for advocates, local physicians, and drug manufacturers. Six out of the seven states interviewed allow stakeholders to attend P&T committees and testify on behalf of products or classes of products. However, none of the MCOs interviewed conduct open P&T committee meetings. While the

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<sup>32</sup> CMS Medicaid Managed Care Enrollment Report, June 2009; Avalere Tracking and Analysis of publicly available news sources and state Medicaid websites. Updated 2011.

<sup>33</sup> Avalere analysis of publicly available information on state Medicaid policies, 2009.

plans do accept information in writing from pharmaceutical manufacturers and evaluate manufacturer-sponsored clinical studies, they are not invited to comment at the committee meetings.

Despite the more closed approach, based on our interviews with the MCO PDs, the MCO formulary development process closely mirrors that of FFS. All three of the MCO PDs detailed a process in which they evaluate the best available clinical information and marry that analysis with relative cost information. Each MCO employs a staff of pharmacists to evaluate the best available clinical information and prepare comparative reviews for classes of drugs. The MCOs also negotiate additional rebates from manufacturers and evaluate those cost considerations against the available clinical evidence. One major difference between the evidence evaluation process that states employ versus the MCOs is that the MCO's processes for synthesizing clinical information is mostly internal. Unlike the states, the MCOs we interviewed are not contracting with private PBMs to conduct clinical class reviews. While a couple of the MCOs use PBMs to negotiate supplemental rebates, they conduct the evidence reviews in-house. Nonetheless, despite having similar evidence review processes, an analysis of drug coverage among several top Medicaid therapeutic classes revealed that formularies for the largest MCOs in each state typically covered fewer drugs than do state PDLs. Branded products are particularly less well covered on MCO formularies than on many state's PDLs. Thus, as more enrollees move into managed care, access to and utilization of branded drugs could diminish among Medicaid enrollees.

#### **5. While the majority of study states previously provided open access to mental health drugs, some now restrict access to drugs in these classes through the PDL.**

Historically, state Medicaid programs have left mental health drugs off of the PDL due to strong advocacy surrounding open access to these agents. Patient advocacy groups and providers support open access to a wide variety of mental health drugs, specifically atypical antipsychotics, as there is substantial variability in the response of individuals to these treatments.<sup>34</sup> However, the state PDs we interviewed expressed a shift toward including these drugs on PDLs, thereby imposing controls on them, for a number of reasons.

Recent state budgetary deficits have driven states to restrict access to mental health classes of drugs through their PDLs. The state PDs we spoke to explained that mental health drugs, and very specifically atypical antipsychotics, make up a substantial proportion of the drug spending in the Medicaid program in their states and thus, represent an area of great potential savings. By leaving the atypical antipsychotics off of the PDL, the PDs said that they were losing supplemental rebate dollars. This is due to the fact that pharmaceutical manufacturers offer states supplemental rebates in return for favorable placement on PDLs; by leaving these drugs off of PDLs, states could not negotiate for additional rebates for drugs in this class. They also highlighted the lack of comparative trial data demonstrating the superiority of certain agents over others, particularly in the atypical antipsychotic class where newer and more expensive agents continue to enter the market. Therefore, in the face of tightening budgets, it has become difficult for states not to consider the cost of these drugs in order to better manage this class.

At the same time, however, the Medicaid PDs we spoke with recognize the sensitive nature of selecting preferred agents in this class due to patients' specific responses to the drugs, as well as the strong advocacy efforts surrounding mental health disorders. Given the concerns of mental health advocacy

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<sup>34</sup> National Alliance on Mental Illness (NAMI). The Role of Psychiatric Medications. 2008. [http://www.nami.org/Template.cfm?Section=Access\\_to\\_Medications&Template=/ContentManagement/ContentDisplay.cfm&ContentID=63435](http://www.nami.org/Template.cfm?Section=Access_to_Medications&Template=/ContentManagement/ContentDisplay.cfm&ContentID=63435)

groups and the sensitivity of mental health issues, the PDs stated how important it was to include these groups in the discussions to put atypicals on the PDL. Maryland worked with mental health advocates to include atypical antipsychotics on the PDL in 2007. When the state faced a budget shortfall, the Medicaid agency engaged the mental health advocates for input and support and got the state law barring mental health drugs from being on the PDL repealed. Similarly, Louisiana worked with mental health stakeholders and advocacy groups to include mental health drugs on the PDL in 2005. Florida also added these drugs to the PDL in 2005. All states interviewed for this study currently include atypical antipsychotics on the PDLs.

Despite placement on the vast majority of PDLs, state mental health programs are still very involved in the management of mental health drugs. In Massachusetts, for all other classes of drugs, the state Medicaid program has the final say in the coverage and PA policies related to the PDL. Conversely, for mental health drugs, the mental health commissioner has the final say on all coverage and utilization management decisions. In Minnesota, the state Medicaid program is limited by statute to not use PA for atypical antipsychotics.

In sum, study states indicate that they are increasingly willing to place mental health drugs on PDLs in order to reap cost savings for this very expensive class. Further management of this class is also likely, due to the Medicaid expansions authorized in the ACA. Many new Medicaid beneficiaries will be young males, and this particular population has a high incidence of mental illness.<sup>35</sup> Thus, these beneficiaries will likely drive up the utilization of atypical antipsychotics in state Medicaid programs. Therefore, states, in persisting budget difficulties, will continue to scrutinize this class in order to realize additional cost savings and efficiencies.

## **6. Some states are exploring pharmacy management tools that are tailored to individual patient needs, but are finding them difficult to implement.**

Each state Medicaid program serves a variety of distinct subpopulations, from children, adults, the aged (65+), individuals with disabilities, and numerous ethnic and racial groups. The states interviewed acknowledged that the PDL is a blunt tool that is not conducive for translating subpopulation-specific evidence into targeted coverage policies. With the exception of Massachusetts, the PDs explained that they do not have the data infrastructure to support the added complexity of processing claims and PA requests based on many different subpopulations. Therefore, coverage decisions for specific drugs or therapeutic classes are generally made at the population level. Minnesota, for example, imposes no restrictions at the subpopulation level. Overall, the most granular the PDL gets is to break out the coverage policy for a drug class by adults and children. For example, Florida imposes age limits for all atypical antipsychotics it places on the PDL.

Relative to the other states, Massachusetts has a more targeted PDL, which refines PA approval to a greater level of clinical and demographic detail. Many drugs have PA requirements placed on them for children under 18 or 21 based on clinical criteria. All PA requests must include clinical diagnosis, drug name, dose, and frequency, and the system may allow the state to fast-track a PA if a particular diagnosis is recorded or an individual has already been taking a drug. This process is called SMART PA, which is based on a set of algorithms that automate PA or override it based upon clinical information and utilization history. The algorithms are set by the clinical pharmacists that work for Massachusetts

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<sup>35</sup> Robert Wood Johnson Foundation and the Urban Institute, *The Health Status of New Medicaid Enrollees Under Health Reform*, August 2010.

Medicaid. For example, for patients taking certain antipsychotics, claims will usually process at the pharmacy without a PA request, if the patient has a history of pharmacy claims of the requested agent for a specific period of time in the last several months. Nevada also uses a SMART PA system, but only for pediatric indications. Few other states have processes as sophisticated as Massachusetts' that take into account individual's treatment response and prior medication history.

In addition to needing a more robust infrastructure to support a more tailored PDL, PDs from FFS and MC also cited a dearth of subpopulation evidence to support more targeted benefit design. PDs stated that existing research on drugs rarely includes Medicaid populations, specifically children, individuals with disabilities, the elderly, pregnant women, those with multiple chronic conditions, and people with serious mental illness, due to underrepresentation in the population and ethical issues. Lack of such research makes it hard for them to effectively make coverage decisions that are tailored to the needs of these populations. The two issues of insufficient infrastructure and subpopulation data are inextricably linked; the more granular tool is not valuable if the information does not exist.

## **7. Moving forward, states in the study expressed concern with the cost of specialty products and biologics.**

Around half of the study states included in the analysis mentioned the management of specialty products and biologics as the most challenging issue facing Medicaid pharmacy programs in the near future. Most states that we spoke to indicated that their spending related to traditional prescription drugs has remained flat for the past few years, and is therefore under control. However, the PDs in Florida, Maryland, Minnesota, and Washington all expressed concern with new high-cost specialty and biologic products moving forward. These PDs expressed particular concern over the cost of specialty and biologic products usually used to treat multiple sclerosis, cancer, hepatitis c, and other complicated and chronic diseases.

These decision-makers emphasized the need for improved comparative clinical evidence in this space. They acknowledge that the characteristics of these products and their unique formulations and heterogeneity in treatment response make it difficult to conduct comparative evaluations. However, they emphasized the need for more evidence to manage rising utilization of these products. Historically, while most states have not actively managed utilization of specialty products, the majority of states in our analysis plan to expand their drug management to these products by adding them to the PDL or through the use of specialty pharmacies.

## IV. Issues Looking Forward

Medicaid FFS programs and Medicaid MCOs seek comparative information to establish their pharmacy policies, but those interviewed rarely use CER reports from public sources, such as AHRQ and DERP. Instead, they turn to resources that produce information customized to their individual needs and are timely, concise, and include cost information. In addition, although they serve the same patient population, there is significant variation among state Medicaid FFS and Medicaid MCOs in coverage decisions and the formulary development process. Looking forward, these findings may lead to the following implications for policymakers and CER organizations:

**There is a need for public CER organizations to better fill key evidence gaps identified by Medicaid PDs in order to inform drug coverage decision-making.** PDs from both state Medicaid programs and managed care plans are supportive of continued public funding for CER, but emphasize that these efforts will be most valuable if the research focuses on therapeutic areas where treatment costs are highest, prevalence is greatest, and where there are many treatment alternatives. They specifically identified the need for CER to inform their decisions related to biologics, atypical antipsychotics, hepatitis C, and multiple sclerosis. In addition, there was interest in research that evaluates the effectiveness of drugs for the variety of subpopulations in the Medicaid program, specifically children, people with disabilities, the elderly, pregnant women, those with multiple chronic conditions, and people with serious mental illness. However, in order to effectively translate subpopulation data into practice, interviewees noted that states will need to invest in more robust data infrastructures so that they can administer more tailored pharmacy benefits.

**Research organizations can provide important assistance to Medicaid decision makers by generating, translating, and disseminating CER in a way that is timely, targeted and includes cost information.** As the newly-established, federal CER entity—the Patient-Centered Outcomes Research Institute—begins to define its role in the research community, it will be pivotal to fill the research gaps identified by the PDs as well as work to better translate this research and the research that already exists in a way that meets the needs of Medicaid decision-makers. The creation of communication systems linking state Medicaid programs, researchers, and those that translate this research to the payer community are vital to ensure the research is timely and relevant. The AHRQ’s Medicaid Medical Directors Learning Network (MMDLN) links researchers and state Medicaid Medical Directors to make CER more relevant to Medicaid programs. Perhaps a similar network could be created for state Medicaid PDs and could extend its focus to also discuss how to translate and disseminate the CER findings. An emerging example of such an effort is the Regional Adaptation for Payer Policy Decisions (RAPiD) initiative. Launched by the Institute for Clinical and Economic Review, the policy goal of the RAPiD initiative is to establish a robust and transparent process for translating federal evidence reviews into a format that better informs coverage and reimbursement decisions at the regional level.

**It will be important to better understand the effect of differences between fee-for-service and managed care pharmacy benefits decisions, including the transparency and opportunities for public engagement in these decisions.** Currently, there is a significant amount of variation among formularies for state Medicaid programs and Medicaid managed care plans, as well as in the degree to which the public can engage in the formulary development process and the level of transparency for this process. More research is needed to determine whether differences between MCO formularies and state PDLs result in differences in beneficiaries’ clinical outcomes. The Medicaid and CHIP Payment and Access Commission (MACPAC) calls for research that tracks the clinical outcomes of patients in FFS and MCOs and monitors the rate at which denials are overturned on appeals to ensure comparable access to high-

quality care.<sup>36</sup> This research will be especially important now that states are beginning to enroll more aged, blind, and disabled Medicaid beneficiaries in MCOs and as states enroll many newly eligible Medicaid beneficiaries in managed care plans starting in 2014 due to health reform.

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<sup>36</sup> Medicaid and CHIP Payment and Access Commission. Report to the Congress: The Evolution of Managed Care in Medicaid. June 2011.

## **V. APPENDIX**

### ***State Profiles***

#### **Florida:**

Florida's P&T committee meets quarterly to discuss changes to its PDL. The committee consists of physicians and pharmacists, and statutorily must include at least one pharmaceutical manufacturer representative and one consumer representative. Florida contracts with Provider Synergies to conduct the clinical reviews of the drugs or drug classes and to negotiate the supplemental rebates for the state. As a general standard, new drugs must be on the market for 90 days before they can be reviewed by the P&T committee. During this time, they are not on the PDL and subject to prior authorization. The clinical reviews, rebate information, and the net cost of adding the drug to the PDL are shared with the committee prior to the meeting. P&T committee meetings are open to the public and include a representative from Provider Synergies, who presents the clinical evidence. All interested parties, including manufacturers, have the opportunity to provide public testimony at the meeting. Florida's public documents and our interview proceedings indicate that clinical efficacy, safety, and cost-effectiveness are considered equally by the committee when developing its PDL recommendations. While these recommendations are only advisory and can be overturned by Florida's Secretary of Health, they are rarely overturned.

#### **Louisiana**

Louisiana's P&T committee meets twice a year to discuss changes to its PDL. The committee is comprised of 21 members, including pharmacists, physicians, a Medicaid beneficiary, and officials representing the state legislature. However, only 11 members have to be present for a P&T committee meeting to take place; there must be at least 5 physicians and 1 pharmacist in this quorum. The committee reviews half of the classes of drugs on the PDL every six months, so that all classes of drugs are reviewed every year. Once a drug comes to market, it is included on the PDL until it is reviewed by the P&T committee. In 2007, Louisiana expanded its PDL to include antipsychotics and hepatitis C drugs, which were formerly carved out. Louisiana contracts with Provider Synergies to conduct clinical reviews of the drugs or drug classes up for review, to negotiate the supplemental rebates for the state, and to evaluate the cost of adding drugs to the PDL. The committee meetings are open to the public, and stakeholders may provide testimony on the classes being reviewed. At the P&T committee meetings, Provider Synergies makes coverage recommendations based on their clinical and cost reviews. Most of the time, the members of the P&T committee agree with Provider Synergies' coverage recommendation.

#### **Maryland**

Maryland's P&T committee meets semi-annually, but can meet more often if there are new drugs that come to market. The committee consists of 12 members; five pharmacists, five physicians, and two customer representatives, each with three year terms. The P&T committee reviews half of the classes of drugs on the PDL every six months, so that all classes of drugs are reviewed every year. Maryland contracts with Provider Synergies to conduct the clinical reviews of the drugs or drug classes and to negotiate the supplemental rebates for the state. The clinical reviews and rebate information are shared with the committee during the meeting, as well as Provider Synergies' coverage recommendations. P&T committee meetings are open to the public. The state allows 15 speakers to provide public testimony before the meeting. The speaking slots are awarded through a lottery. The P&T committee makes coverage recommendations to the Maryland Department of Health and Mental Hygiene, which makes the ultimate coverage decision. Maryland's public documents and our interview proceedings indicate that the P&T committee develops PDL recommendations based on the clinical

efficacy of the drug, the cost effectiveness of the drug, including any supplemental rebates from manufacturers; and the needs of program recipients, such as the ease of drug therapy administration, rate of compliance with drug therapy instructions, and frequency of prior authorization. Although the state is a member of DERP, they rely more on the information provided by Provider Synergies, as it includes information on net cost.

### **Massachusetts**

Massachusetts' P&T committee, called the Pharmacy Policy Committee (PPC), meets once a week to review new drugs and discuss changes to its PDL, called the MassHealth Drug List (MHDL). The PPC consists of 16 members, two physicians, 12 pharmacists, and two analysts, all appointed by the pharmacy director. The PPC is a staff committee, meaning that the individuals on the committee are all employed by MassHealth, and are not affiliated with outside contractors, or community physicians or pharmacists. In order to determine drugs that are on the market or are coming to market, Massachusetts contracts with ACS, which provides the state with this information. After determining new drugs to market, the University of Massachusetts Medical School (UMMS) conducts a monograph of clinical and cost information on these drugs. The UMMS pharmacists then come to the PPC meeting to present the findings and make a coverage recommendation. The activities of the PPC are guided by a formal public/external, appointed Drug Use Review Board and various standing or ad hoc interdisciplinary professional advisory committees. The PPC then makes its own coverage recommendation, however, the ultimate decision-making power is held by the pharmacy director. The PPC meetings are closed to the public.

### **Minnesota**

Minnesota's P&T committee is called the Drug Formulary Committee (DFC). The DFC meets at least twice per year, but the commissioner can require more frequent meetings as needed. The committee consists of four physicians, four pharmacists, and one consumer representative. An employee of the Minnesota Department of Human Services also sits on the committee, as well as the Department's medical director, but both of these individuals are ex officio, nonvoting members. Minnesota contracts with First Health to negotiate supplemental rebates and gain access to clinical information, but DHS staff prepares clinical class reviews. The state can put a drug on prior authorization for up to 180 days before it is reviewed for inclusion on the PDL. Once the drug is up for review, DHS brings the clinical information to the DFC. The DFC evaluates the clinical and cost information and makes a recommendation back to DHS about whether the drug should remain on prior authorization and the parameters of the prior authorization. The DFC then has another public meeting and a public comment period in which anyone and can speak on behalf of a product. The DFC then makes a decision on whether to continue the prior authorization. The committee also makes a decision on whether the drug should have preferred or non-preferred status; a decision that is based more on cost information. The final decision on prior authorization and preferred status is left to the commissioner of DHS.

### **Nevada**

Nevada's P&T committee meets quarterly to discuss changes to its PDL, but can meet more often if called upon by the chair of the committee. The committee is comprised of no less than nine members, but no more than eleven. Currently, the committee is made up of 10 members, five of whom are physicians, and five are pharmacists. All P&T members are appointed by the governor, and generally sit on the P&T committee for a two-year term. At each meeting, the committee reviews new drugs, drugs that recipients or physicians have requested to be reviewed, or if there is significant new clinical evidence that may change coverage in a class. Members of the P&T committee can also suggest class reviews due to changes in patent status or new indications. The P&T also uses one of the quarterly

meetings, usually in June, to re-review the entire PDL. Nevada contracts with Magellan to conduct clinical reviews of the drugs or drug classes up for review, to negotiate the supplemental rebates for the state, and to evaluate the cost of adding drugs to the PDL. However, the state re-bid the contract, and SXC will take over these responsibilities starting in 2012. The committee meetings are open to the public, and stakeholders may provide testimony of five minutes on the classes being reviewed, which are posted 45 days before the meeting. At the P&T committee meetings, Magellan makes coverage recommendations based on their clinical and cost reviews; however, members of the P&T committee are prohibited from hearing the cost information. If cost is mentioned in the meeting, the session comes to a halt, and a coverage recommendation will not be made. The P&T committee then makes coverage decisions based on the vendor's information, and these decisions are binding. This differs from other states, where the PD or Medicaid director in the state has the final decision-making authority.

### **Washington**

Washington's P&T committee meets every other month to discuss updates to the PDL. The P&T is made up of physicians and pharmacists, and its meetings are open to the public. There are approximately 30 classes of drugs on the PDL. Washington uses the DERP reviews as the central body of clinical evidence and does not review a therapeutic class for inclusion on its PDL unless the DERP has released a final evidence-based review for that particular class. The P&T committee's recommendations are based on the safety and efficacy of the drug. Then, based on the committee's recommendations, the state Medicaid agency reviews the cost information for the recommended drugs, including supplemental rebates offered by drug manufacturers, and selects the recommended drugs with the lowest costs for the PDL. The state also manages a separate PA program, whose meetings are not open to the public. New drugs coming on to the market are automatically placed on PA, and when the drug's utilization increases, a drug utilization review board scores the drug for safety, potential for abuse, and cost. The scores determine the type of controls the state imposes on the drug. The state can cover the drug without limits, cover the drug with limits, cover the drug with prior authorization, or other arrangements. When a DERP report becomes available for the drug class in question, the P&T committee will then review the drug for inclusion on the PDL.

## **Glossary**

**Agency for Healthcare Research and Quality (AHRQ):** The health services research arm of the U.S. Department of Health and Human Services (HHS). The agency sponsors and conducts research that provides evidence-based information on health care outcomes; quality; and cost, use, and access.

**Comparative effectiveness research (CER):** The conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.<sup>37</sup>

**Drug Effectiveness Review Project (DERP):** A collaboration of 11 state Medicaid programs and the Canadian Agency for Drugs and Technologies in Health coordinated by Oregon Health and Science University’s Center for Evidence-Based Policy that produces systematic, evidence-based reviews of the comparative effectiveness and safety of drugs in widely used classes to inform public policy and related activities.

**Medicaid Managed Care Organizations (Medicaid MCOs):** Organizations that deliver Medicaid health benefits and additional services through an arrangement with the state Medicaid agency.

**Multi-State Prescription Purchasing Pool:** Groups of states that aggregate or consolidate their purchasing of pharmaceuticals to negotiate a lower price for all those included. Examples include:

- National Medicaid Pooling Initiative (NMPI): Started in 2003 and serves Alaska, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New York, North Carolina, Rhode Island, South Carolina, and D.C.
- Top Dollar Program (TOP\$): Started by Provider Synergies and serves Delaware, Idaho, Louisiana, Maryland, Nebraska, Pennsylvania, and Wisconsin
- Northwest Prescription Drug Consortium (NPDC): Started in 2007 and combines non-Medicaid state pharmaceutical programs in Oregon and Washington

**Pharmacy Benefit Managers:** Independent organizations and subsidiaries of drug companies or insurance companies that specialize in reducing the cost of pharmaceuticals, typically in support of self-insured employers, government entities, private insurers, third party administrators, HMOs, hospital systems, etc. Typically PBMs set up pharmacy benefits (formularies), negotiate rates with drug companies, administer rebates, set up pharmacy networks and/or mail order systems, and process claims.

**Prior Authorization (PA):** Under a system of utilization review, a requirement imposed by a health plan or third party administrator that a provider justify the need for delivering a particular service in order for a patient to receive it.

**Preferred Drug List (PDL):** A list of covered drugs that a state Medicaid program agrees to provide without prior authorization. All other medically necessary drugs require prior authorization.

**Supplemental Rebate:** Additional payments by pharmaceutical manufacturers to states and negotiated directly with individual states. Manufacturers offer supplemental rebates in exchange for having their products receive preferred status on the state’s PDL.

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<sup>37</sup> Federal Coordinating Council on CER Definition: <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>

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