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The Use of Oregon's Evidence-Based Reviews for Medicaid Pharmacy Policies: Experiences in Four States

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ABSTRACT

This issue brief describes how four state Medicaid programs used reports developed by Oregon's Drug Effectiveness Review Project (DERP) to develop pharmacy policies, based on interviews with state officials, advocacy groups, clinicians, and other stakeholders. The DERP reports have filled a void for states seeking inexpensive systematic reviews of evidence on comparative effectiveness. The influence of DERP reports on state policy was significant in all states, but varied from being the most prominent clinical evidence used in development of a preferred drug list, to being one of many clinical references used to create provider education tools. Stakeholders expressed concerns that Medicaid programs consider a wide range of evidence to promote regionally sensitive policies, and that open processes are maintained to ensure accountability.

EXECUTIVE SUMMARY

In an effort to inform pharmaceutical cost containment policies with clinical evidence, several state Medicaid programs have joined the Drug Effectiveness Review Project (DERP) to obtain information on the comparative effectiveness of pharmaceuticals within the same drug class. This research explores how four state Medicaid programs — Washington, Wyoming, Minnesota, and North Carolina — differ in their use of the DERP's systematic reviews of the literature and raises some of the key issues states may need to consider when using commonly funded reviews of the evidence for public programs. Based on 21 interviews with individuals representing 18 different organizations, including state Medicaid officials and pharmacy and therapeutics (P&T) committee members from the four case study states, the following key findings emerged:

(1) *The DERP reports' influence on the development of Medicaid drug policies ranged from being the primary evidence considered for the development of a preferred drug list (PDL) to one of several clinical references in creating provider education tools.* Washington and Wyoming reported using DERP reports as the primary basis of their clinical recommendations for their state's PDL. Minnesota combined DERP reviews with other clinical evidence such as reviews conducted by First Health Services Corporation. State officials in these three states consistently highlighted that the "robust, independent" nature of DERP reports make the development of PDLs more defensible to key stakeholders. In contrast, the North Carolina Medicaid program, which is not developing a PDL, uses DERP reviews to develop provider education tools on the use of prescription drugs.

(2) *Many interviewees encouraged Medicaid programs to consider a wider range of evidence than the clinical information included in DERP reports in order to ensure regionally sensitive policies.* States could consider several forms of additional evidence including different types of clinical studies, such as observational studies, greater public input, and state drug utilization patterns. Beneficiary advocates emphasized that the DERP reports often give minimal emphasis to the wide inter-individual variability of a medication's tolerability and effectiveness for Medicaid beneficiaries. Pharmaceutical industry representatives cautioned states against concluding that drugs are clinically equivalent when a DERP review finds that there is a lack of conclusive evidence of superiority for similar drugs in a therapeutic class. North Carolina, for example, views inconclusive evidence as a signal for additional research and the consideration of other types of clinical information, and simply gives such information to the clinician.

(3) *While there is consensus that the DERP serves as a practical model for states to obtain clinical effectiveness information for use in developing Medicaid drug policies, stakeholders expressed concerns about appropriate use of this information in the Medicaid context.* Researchers contracted by the DERP were used for technical assistance in some of the state decision-making processes we studied. However, the current DERP process explicitly leaves states to interpret DERP reviews, to consider other sources of information, and to adopt a process that is consistent with state law and norms. Medicaid does not currently offer guidance on how P&T committees should use generalized clinical effectiveness reviews and how they should be incorporated relative to local norms to protect beneficiary interests, nor are there requirements on the transparency of the PDL development process. States are ultimately responsible for both functions, and need to adopt processes that are sensitive to the special needs of low-income beneficiaries.

I. OVERVIEW AND PURPOSE

Facing a rapid rise in prescription drug expenditures and large budget shortfalls, state Medicaid programs have implemented various measures to control prescription drug spending for the Medicaid fee-for-service program over the last several years.[1] A recent survey found that 47 states implemented some form of pharmacy cost control during the 2004 fiscal year, and 43 states plan to add additional pharmacy cost control policies during the 2005 fiscal year.[2] One of the most prominent strategies used by Medicaid programs to contain drug costs is preferred drug lists (PDLs). In most cases, a PDL is a list of 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.[3]

In general, states create PDLs using both clinical and cost criteria. As states continue to develop PDLs and other strategies to control rising prescription drugs costs in Medicaid, there has been a growing interest to incorporate better clinical evidence into the policy making process. Beyond cost issues, this trend also responds to policy makers' rising regard for the principles of evidence-based medicine (EBM) to assist in the development of a range of health policies and programs, including disease management and the development of coverage and reimbursement policies. The use of EBM has been viewed as the first step to value-based purchasing for policy makers that seek to both contain costs and develop medically appropriate policies.[4]

As required by federal law, Medicaid agencies establish independent committees of physicians and pharmacists, commonly called pharmaceutical and therapeutics (P&T) committees when developing a PDL.[5] These committees usually review the clinical evidence of a given prescription drug and, without regard of the drug's costs, make recommendations as to which drugs are the most therapeutically appropriate in a class. Based on the committee's recommendations, the Medicaid agency reviews the drugs' pricing information, and normally selects the lowest priced of the recommended drugs for the list.

Within this framework, states vary in the specific processes they use to develop PDLs. While many states hire private vendors that specialize in assisting Medicaid programs build PDLs, some have elected to develop their PDLs internally or work with local universities. States also vary in the composition and degree of clinical expertise of their P&T committees, the type of clinical and cost data considered, and the decision to pursue supplemental rebates with drug manufacturers.

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[1] Between 2000 and 2002, expenditures for prescribed drugs (fee-for-service only) increased by an average of 18.8 percent per year, faster than any other major type of Medicaid covered service. Bruen B, Ghosh A. Medicaid Prescription Drug Spending and Use. Kaiser Commission on Medicaid and the Uninsured, June 2004.
[2] Smith V, Ramesh R, Gifford K, Ellis E, Rudowitz R, O'Malley M. The Continuing Medicaid Budget Challenge: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2004 and 2005, Results from a 50-State Survey. Kaiser Commission on Medicaid and the Uninsured, October 2004.
[3] As of December 2004, over 30 states have operating Medicaid PDLs. Recent Medicaid Drug Laws and Strategies 2001-2004, the web site. National Conference of State Legislatures. Available at: http://www.ncsl.org/programs/health/medicaidrx.htm. Accessed Dec. 1, 2004.
[4] Mendelson D, Carino T. Evidence-Based Medicine in the United States—De Rigueur or Dream Deferred? Health Affairs, January/February 2005.
[5] Social Security Act §1927(d)(4), 42U.S.C. §1396r-8(d)(4)

Purpose of the Issue Brief

This research focuses on state Medicaid agencies and their P&T committees' use of evidence-based reports in developing Medicaid PDLs and other pharmacy policies. The evidence-based reports are commissioned and published by the Drug Effectiveness Review Project (DERP). Currently little is known of the potential impact of the DERP reviews on participating Medicaid programs' pharmacy benefits, particularly PDLs, and the potential to influence many other non-participating organizations' pharmacy policies. The Kaiser Commission on Medicaid and the Uninsured commissioned The Health Strategies Consultancy LLC to prepare an issue brief on state Medicaid programs' use of the DERP reviews in the fall of 2004.

The purpose of this issue brief is to: (1) describe how different state Medicaid programs are using the DERP reports; (2) describe the views of different Medicaid stakeholders on how states are using the DERP reports and some of the perceived benefits or concerns; and (3) raise some of the key issues that public programs need to consider when using commonly funded evidence-based reports for public policy. This research does not entail an evaluation of the DERP and its processes, but rather provides information on the processes through which state Medicaid programs are using its evidence-based reports and the reactions of stakeholders to these uses.

Background

In 2001, the state of Oregon began pursuing a model for developing a Medicaid PDL that gained national attention. Oregon's PDL—called the Practitioner-Managed Prescription Drug Plan—distinguished itself from other state PDLs by emphasizing that preferred products are selected according to evidence-based reviews of the clinical effectiveness of drugs in the same therapeutic class.[6] The state worked with researchers from the Oregon Evidence-based Practice Center (Oregon EPC) to conduct literature reviews of the evidence for drugs in the same class.[7] The Oregon EPC is also contracted by the federal Agency for Healthcare Research and Quality (AHRQ) to develop evidence-based reports and technology assessments on topics especially relevant for Medicare and Medicaid populations. The Oregon Medicaid agency reported that it only considers drug prices after the literature review is completed by the Oregon EPC and a subcommittee of local practitioners prepares recommendations regarding products' comparative effectiveness.[8]

In 2003, as states became keenly interested in Oregon's evidence-based reviews, former Oregon state policy officials initiated a project at the Oregon Health & Science University's Center for Evidence-based Policy (OHSU Center) to enable other states to collaborate with Oregon and co-fund the research. Led by former Oregon governor John Kitzhaber, MD, the OHSU Center's Drug Effectiveness Review Project (DERP) provides other states and organizations the clinical reviews conducted for Oregon's Medicaid PDL and together sponsors

[6] Oregon Practitioner-Managed Prescription Drug Plan, the website. Governor's Letter to Provider Leaders, April 2002. Available at: http://www.oregon.gov/DAS/OHPPR/ORRX/HRC/history.shtml. Accessed Dec. 1, 2004.
[7] Oregon EPC is a collaboration of the Oregon Health & Science University, Kaiser Permanente Center for Health Care Research, and the Portland VA Medical Center.
[8] Bernasek C, Mendelson D, Padrez R, Harrington C. Oregon's Medicaid PDL: Will an Evidence-Based Formulary with Voluntary Compliance Set a Precedent for Medicaid? Kaiser Commission on Medicaid and the Uninsured, January 2004.

new evidence-based reviews for additional drug classes. The stated goal of the DERP is to provide a way for states and other organizations to obtain evidence on the comparative effectiveness and safety between drugs to apply to public policies, such as developing PDLs.[9]

As of December 2004, the DERP had 15 member participants, including 13 states and two other organizations (i.e., the California HealthCare Foundation and Canadian Coordinating Office for Health Technology Assessment), with a majority being state Medicaid programs (see Figure 2). The DERP plans to complete systematic reviews for 25 drug classes, as selected by its member participants, over its three-year timeline. The DERP has completed final reviews for 18 drug classes, and each review will be updated at a minimum every 12 months for new evidence and drug products (see Figure 1).

Figure 1: Drug Classes Reviewed or Scheduled for Review by the DERP[10]

Drug Class Reviewed	**Report Date**
ACE Inhibitors	June 2004
Angiotensin II Receptor Antagonists	September 2004
Antidepressants, 2nd Generation	November 2004
Antihistamines, 2nd Generation	November 2004
Beta Adrenergic Blockers	September 2004
Calcium Channel Blocker	June 2004
Estrogens	July 2004
Non-Steroidal Anti-Inflammatory Drugs	May 2004
Opioids, Long Acting	April 2004
Oral Hypoglycemics	February 2004
Proton Pump Inhibitors	April 2004
Skeletal Muscle Relaxants	January 2004
Statins	June 2004
Triptans	September 2004
Urinary Incontinence Drugs	January 2004
Drug Classes Scheduled for Review	**Report Expected**
Alzheimer's Disease Drugs	April 2005
Anti-Epileptic Drugs	December 2004
Anti-Platelets	May 2005
Attention Deficit Hyperactivity Disorder Drugs	June 2005
Atypical Antipsychotics	February 2005
Inhaled Corticosteroids	January 2005
Thiazolidinedione Antidiabetic Agents (TZD)	October 2005
$5HT_3$ Antagonists	TBA
Anti-TNF (tumor necrosis factor alpha)	TBA

The DERP reports do not include any mention of drug costs and do not recommend any given purchasing policy. DERP officials publicly emphasize that the goal of the project is to "globalize the evidence, and localize the decision"—i.e., while gaining access to the same information, each member participant is able to let local decision-making processes decide how to interpret and use the information. The DERP also provides its participants with equal access to researchers from the project's contracted EPCs for technical assistance when reviewing the findings in the evidence-based reports. Participants are able to purchase additional technical support if needed. Most Medicaid program participants are using the reports in their PDL

[9] Drug Effectiveness Review Project, the website. Available at: http://www.ohsu.edu/drugeffectiveness/index.htm. Accessed Dec. 1, 2004.
[10] Ibid.

development processes by distributing the reports to P&T committees to review when making clinical recommendations to the Medicaid agency.[11]

The use of the DERP's reviews may also extend beyond the project's 15 member participants since the project posts its final reports on its website for anyone to download and review (www.ohsu.edu/drugeffectiveness/). While paying participants are important to the long-term fiscal health of the initiative – participating groups pay $96,000 per year[12] – OHSU Center officials administering the DERP commonly report their commitment to ensuring the information is publicly available and widely disseminated. As a result, groups such as the AARP and the Consumers Union have created consumer-oriented summaries of the reviews and have posted links to the DERP reports on their external websites to further publicize the information to non-paying participants and consumers. (A list of internet links to the final DERP reports and websites with evidence summaries that reference the DERP reviews is included in the Appendix.)

The DERP Review Process

As its core service, the DERP provides member participants a series of systematic reviews of the clinical evidence for drug classes. The clinical reviews are conducted by researchers at contracted Evidence-based Practice Centers (EPCs) in Oregon, southern California, and North Carolina, with the Oregon EPC coordinating the process. Member participants govern the review process by selecting the therapeutic classes and developing the key review questions through a voting process, where each member participant is allowed one vote. These key questions guide the systematic reviews by specifying the clinical conditions and defining the populations, interventions, and outcomes of interest. Generally, the questions cover three broad topic areas: (1) how drugs in a defined class compare in overall effectiveness; (2) how drugs compare in terms of safety and adverse events; and (3) how drugs' effectiveness and safety profiles may differ for specific subpopulations.

Using the defined key questions as a guide, EPC researchers rely on electronic databases such as Cochrane, MEDLINE, and EMBASE, to identify studies of the drugs in the particular therapeutic class. Researchers also review citations submitted by content experts or pharmaceutical manufacturers. However, EPC researchers only include in the final reviews studies that manufacturers are willing to have made public, that provide relevant evidence to answer the key questions, and that meet internal quality criteria such as ensuring the methods used in a study to enroll patients or assess outcomes minimize bias. After evaluating the studies, EPC researchers synthesize the data into written reports that describe the available evidence and their assessment of the quality of evidence to answer the key questions. Draft reports are peer reviewed by topic experts selected by the EPC and before making the reports final, DERP officials post drafts on the OHSU Center's website for two weeks of public comment.[13]

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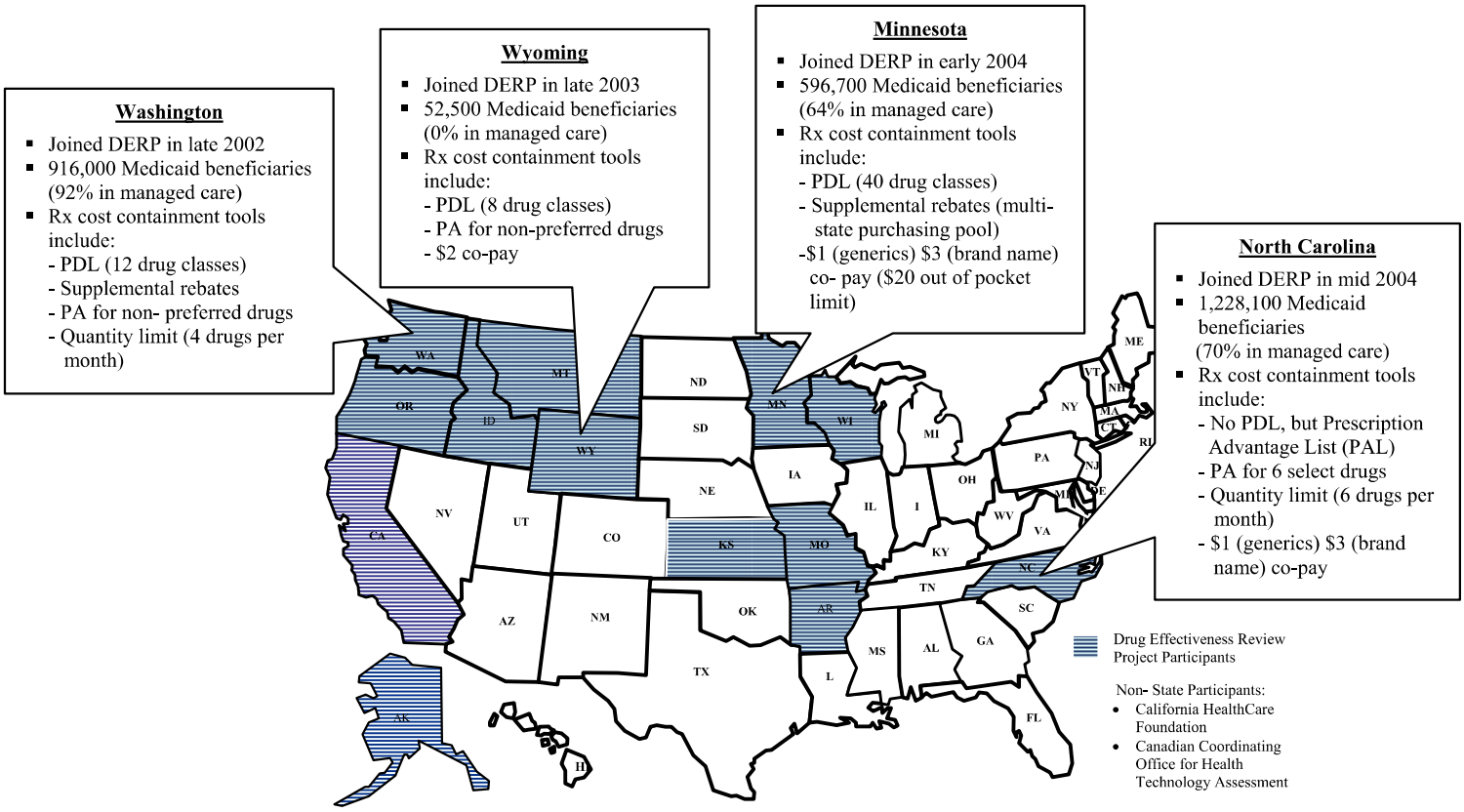
[11] Fox D. Evidence of Evidence-Based Health Policy: The Politics of Systematic Reviews in Coverage Decisions. Health Affairs, January/February 2005.
[12] Silow-Carrol S, Alteras T. Stretching State Health Care Dollars: Pooled and Evidence-Based Pharmaceutical Purchasing. The Commonwealth Fund, October 2004.
[13] More information on the project's methods and review processes found at Drug Effectiveness Review Project, the website. Available at: http://www.ohsu.edu/drugeffectiveness/index.htm. Accessed Dec. 1, 2004.

II. STUDY APPROACH

The perspectives contained in this issue paper are based on case studies of four states participating in the DERP as of December 2004. This research provides descriptions of a cross-section of states that are participant members, which influence the selection of therapeutic classes and define the key questions for the DERP reviews. Figure 2 provides more background on the states selected for case studies.

Figure 2: Drug Effectiveness Review Project Participants[14]



In general, member states participating in the DERP fell into two groups—those who joined the DERP prior to the development of a PDL and those who had implemented or were in the processes of implementing a PDL prior to participation with the DERP. We chose two states for case studies from each group—Washington and Minnesota from the group of states who were in the process of implementing a PDL and Wyoming and North Carolina from the group of states that had not started developing a PDL prior to joining the DERP. These states were also selected for various unique attributes, including geographical location, variation in cost containment strategies, and state officials' willingness to participate and availability (states could not be

[14] Medicaid Enrollment, State Health Facts. The Henry J. Kaiser Family Foundation. Available at: www.statehealthfacts.kff.org. Accessed December 2004. Note: Total Medicaid enrollment estimates are for the 2000 fiscal year and estimates of percentage of Medicaid beneficiaries in managed care are for 2003.

included due to key state officials' unavailability or reluctance to return phone calls during the research period). The selection of these four states should not be considered a random selection, but the methodology still provides a diversity of experiences and perspectives.

After selecting the states, we conducted in-depth interviews or focus groups with 21 individuals that represent 18 different organizations. For all four case studies, we spoke to state officials who had the most knowledge of the OHSU Center's DERP and how the state uses the DERP reviews. We also included one representative from each state's P&T or pharmacy committee. Finally, we obtained the perspectives of key stakeholders through 12 interviews with representative organizations, individual manufacturers, and patient groups. All sections pertaining to a state Medicaid program's use of the DERP reports was reviewed and approved by at least one state official. Factual statements made by interviewees were also reviewed to ensure that their accounts and opinions were accurately represented. All interviewees were guaranteed confidentiality.

This research illustrates only some of the ways states may be using the reviews to develop PDLs or other types of pharmacy policies. It does not reflect the views and perspectives of state Medicaid programs that use the DERP reports but do not directly participate with the OHSU Center's initiative or states that may be developing a PDL or other cost containment tools without using DERP reports in their analysis at all. For example, at the time of our research larger Medicaid programs in states such as Florida, New York, and Texas did not participate in the DERP; however, it cannot be inferred that these states do not conduct systematic reviews of clinical evidence when developing pharmaceutical policies or use the DERP reports. This research also does not look at how PDL drug selections vary across the case study states or draw causations between final PDL selections and the influence of the DERP. That analysis would involve looking at the state's entire PDL development process to explore reasons to account for potential differences in drug selection, such as different drug pricing or supplemental rebate policies. Instead, this research focuses on the variety of ways states, in particular their Medicaid P&T committees, use DERP reports in their development of recommendations for a state's PDL.

We present the results of the interviews for these case studies in three sections. In the first section, we explain how each of the four states uses the DERP reviews and some factors that drove the state to participate in the project as described by interviewed state officials. Next, in the key findings section, we portray the major trends observed in interviews with state officials and other stakeholders across the four states, including the perceived benefits and challenges of using the DERP reviews for Medicaid prescription drug policies. Finally, we provide summary observations about the DERP and raise some key issues states or other organizations should consider when using these or other common evidence-base reports in the development of public policy.

III. CASE STUDIES

Of the four case studies, three states, Washington, Wyoming, and Minnesota, are developing PDLs to contain prescription drug costs in their Medicaid program. Figure 3 provides more information on each state's P&T committee. North Carolina is not included in the Figure because the state is not currently developing a PDL.

Figure 3: Information on P&T Committees for States Developing PDLs

	Composition	Meetings Open to Public?	Oregon EPC researchers present at meetings
Washington: *Pharmacy and Therapeutics (P&T) Committee*	10 members ➢ 4 physicians ➢ 4 pharmacists ➢ 1 physician's assistant ➢ 1 nurse practitioner	Yes	Yes
Wyoming: *Preferred Drug List Advisory Committee*	9 members ➢ 4 physicians ➢ 3 pharmacists ➢ 1 insurance company representative ➢ 1 consumer representative	Yes	Yes
Minnesota: *Drug Formulary Committee*	9 members ➢ 4 physicians ➢ 4 pharmacists ➢ 1 consumer representative	Yes	No

Washington – DERP's First Member Participant

As the first state to join the DERP and collaborate with the state of Oregon, Washington relies heavily on the DERP in its PDL development process. The Agency 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 report for that particular class.

Prior to joining the DERP, the state Medicaid program faced pressure from the governor and the state legislature to contain prescription drug costs and develop a PDL.[15] After beginning the process of evaluating prescription drug information in collaboration with a local university, state officials decided to participate in the DERP because it offered more comprehensive and defensible clinical reviews of the evidence. State officials believed that using reviews conducted by an EPC affiliated with AHRQ would encourage broader stakeholder acceptance of the evidence and ensure the state's Medicaid prescription drug policies, such as the PDL, are based on both quality and cost. Finally, state officials saw the DERP as a valuable opportunity to work with other states and experts across the country to establish a more extensive clinical review process, incorporating the views of all member participants.

Legislation was passed shortly after the state joined the DERP directing the Medicaid program to identify preferred drugs through an evidence-based review process.[16] As a result, the P&T committee uses the DERP reports as the only body of evidence for its clinical review when making PDL recommendations to the state. During each public meeting, P&T committee members review the DERP reports and without looking at the cost of the drugs, make recommendations to the state regarding the efficacy, effectiveness, and safety of different drugs within the therapeutic class. Although DERP's stated position is to allow local decision making, Washington requests from the DERP that a researcher from the Oregon EPC be present either in

[15] In April 2001, Gov. Gary Locke initiated the Prescription Drug Project to manage prescription drug costs in the state by developing a single PDL and coordinating prescription drug purchasing across three state agencies, Medical Assistance Administration (Medicaid), Health Care Authority, and Department of Labor & Industries.
[16] Senate Bill 6088 enacted during the 2003 Legislative session; Revised Code of Washington (RCW) 70.14, Washington Administrative Code (WAC) 182-50.

person or via telephone at each of the P&T committee's meetings to present key findings in the DERP reports and be available to answer P&T committee members' questions. The state also permits a limited time for public comment to the P&T committee. State officials report that pharmaceutical manufacturer representatives make most comments, and stakeholders cannot present new evidence to the P&T committee without first having it reviewed by one of the DERP's contracted EPCs. Then, based on the P&T 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.

Wyoming – DERP Drives PDL Timeline

Similar to Washington, Wyoming's Medicaid agency also uses the DERP reviews as the main source of clinical evidence in its PDL development process and utilizes the DERP timeline for its review of drug classes.

Wyoming state officials decided to join the DERP in October 2003 in response to a legislative mandate, including dedicated resources, to increase cost containment efforts to control rising Medicaid prescription drug costs. First, the state implemented prior authorization (PA) policies for select drugs. While the PA policies were successful at reducing costs, the state faced strong opposition from pharmaceutical manufacturers, physicians, and other local stakeholders. Relative to other states, Wyoming has a small managed care presence, and some state officials believed that part of the opposition stemmed from local providers' and beneficiaries' inexperience with private-sector approaches to cost containment, such as PA.[17] State officials believed that to fulfill their mandate from the legislature to develop additional cost containment policies such as a PDL, they had to minimize expected opposition, namely by demonstrating that Wyoming's policies would be created using what they consider to be the best possible clinical evidence and not simply based on costs. State officials saw the DERP as the best source of clinical evidence available and contracted with the DERP to form a solid foundation for the PDL process through evidence-based research.

The Wyoming Medicaid agency uses a P&T committee, the Preferred Drug List Advisory Committee (PDLAC), to assist the state in developing a PDL. The PDLAC reviews the DERP reports during public meetings and determines whether the evidence demonstrates that certain drugs are clinically superior or if all drugs in the class are therapeutically equivalent.[18] Like Washington, the Medicaid agency invites researchers from the Oregon EPC to present the DERP report's findings and to be available for questions from PDLAC members. The PDLAC does not review drug cost information and has historically reviewed very little clinical information outside of the DERP reports. The state does permit time for the public to make comments to the PDLAC. However, similar to Washington, state officials report that pharmaceutical

[17] As of December 2003, no Medicaid beneficiaries in Wyoming were enrolled in managed care. Medicaid Managed Care Penetration Rates by State, December 31, 2003. Centers for Medicare and Medicaid Services, US Department of Health and Human Services. Available at: http://www.cms.hhs.gov/medicaid/managedcare/mmcpr03.pdf. Accessed Dec. 1, 2004.

[18] Information on the Wyoming Department of Health Preferred Drug List Advisory Committee available at: http://wdh.state.wy.us/pharmacy/PDL.asp. Accessed Dec. 1, 2004.

manufacturer representatives have made nearly all of the public comments.[19] Based on the PDLAC's recommendations, the Medicaid agency reviews information on cost and other characteristics of the drug, such as dosing differences and drug utilization patterns by Medicaid beneficiaries in the state, to make final selections for the PDL.

Minnesota – Participates with DERP in Conjunction with a Multi-State Purchasing Pool

Minnesota also uses the DERP reports when reviewing the clinical evidence during its PDL development processes. However, unlike Washington and Wyoming, Minnesota also relies on other sources of clinical evidence. In addition to the DERP, Minnesota works with the First Health Services Corporation (First Health) to develop a PDL. First Health provides additional clinical reviews and enables the state to participate in a multi-state purchasing pool with six other Medicaid programs in an attempt to obtain larger supplemental rebates.[20]

Similar to the other states reviewed, the Minnesota Medicaid agency decided to join the DERP after receiving legislative pressure to contain prescription drug costs and develop a PDL. However, when joining the DERP, Minnesota had already begun developing a PDL. Despite its legislative directive, Minnesota officials anticipated opposition from beneficiary advocate organizations and the pharmaceutical industry, which argue that Medicaid programs are developing PDLs solely based on costs. To fulfill its mandate to implement quickly a PDL for multiple drug classes and to respond to stakeholder pressure to consider quality, Minnesota elected to sign a contract with First Health for assistance and to join the DERP.

In interviews, state officials cited three main factors that drove Minnesota to join the DERP rather than rely solely on First Health to assist them in their development of a PDL:

- The DERP offered an opportunity to base Minnesota's PDL program on a strong clinical foundation and signal the state's interest in considering quality over cost;
- The DERP reports represented the most robust review of the clinical evidence available; previous attempts to conduct internal systematic reviews of the evidence proved to be time consuming and difficult; and
- Minnesota wanted to offer financial support to the DERP, which officials believe to be a social good.

The Minnesota Medicaid agency, like other states, uses a P&T committee, the Drug Formulary Committee (DFC), to review the available evidence and make recommendations to the state for drugs to include on the PDL. DFC members base their recommendations on the DERP reports when available, clinical reviews generated by First Health, testimony and evidence presented by stakeholders during public meetings, and their personal clinical experiences. In contrast to Washington and Wyoming, Minnesota does not invite researchers from the Oregon EPC to review the DERP reports' findings during the DFC's public meetings. State officials instead

[19] Nearly all public comments recorded in meeting notes for the Oct. 30, 2003 and April 15, 2004 PDLAC meetings were from representatives sponsored by or affiliated with the pharmaceutical industry. Meeting notes available at: http://uwacadweb.uwyo.edu/PDL/Past%20Meeting%20Information.asp. Accessed Dec. 1, 2004.

[20] As of December 2004, the Centers for Medicare and Medicaid Services (CMS) has approved state plan amendments for seven states to participate in a multi-state purchasing pool facilitated by First Health. Participating states include: Alaska, Hawaii, Michigan, Minnesota, Nevada, New Hampshire, and Vermont.

emphasize that many of Minnesota's DFC members have experience on other organization's P&T committees and are well acquainted with the principles of evidence-based medicine to understand the DERP reports. However, a representative from First Health attends each meeting. Unlike Washington and Wyoming, the DFC considers and makes recommendations for therapeutic classes not yet reviewed by the DERP given the agency's strong pressure to establish a PDL quickly. Finally, based on the DFC's recommendations, the Medicaid agency works with First Health to obtain supplemental rebates from pharmaceutical manufacturers and select the lowest cost drugs among recommended products for the PDL.

North Carolina- Uses DERP Information for Provider Education

In contrast to other states, North Carolina uses the DERP reports to assist the state in developing non-regulatory and targeted provider education products. As of December 2004, the state has no plans to develop a PDL for its Medicaid program. Instead, the state uses the DERP reports to help create a variety of tools to influence providers' prescribing habits, encouraging them to use more effective, safer, and lower cost drugs for their patients.

When electing to join the DERP, the state was conscious of controlling prescription drug expenditures. However, unlike the other case study states, North Carolina's legislature has a preference for first pursuing non-regulatory approaches and has favored partnering on alternative approaches to managing costs with its close-knit provider community, a byproduct of a large managed care market.[21] The Medicaid managed care program creates provider networks that foster strong communication and collaboration among physicians. These factors drive state officials' belief that alternatives to regulatory policies such as PDLs may be just as effective to encourage the appropriate use of medications and contain costs.

Nonetheless, interviewed state officials recognize the value in having access to the DERP reports and cite the importance of participating in the DERP research process to help define the key research questions and involve local providers in the process. State officials believe incorporating local providers in the research processes will lead to greater buy-in from the provider community for the evidence-based reports and the educational tools. Finally, as in Minnesota, a state official expressed the importance of providing financial support to the DERP with public funds.

One way the state utilizes information in the DERP reports is to help develop a provider education tool called the Community Care of North Carolina Prescription Advantage List (PAL). Developed in 2003, the PAL provides physicians relative cost information for different drugs within the ten most expensive therapeutic classes in the Medicaid program.[22] State officials use evidence tables in the DERP reports to help develop comparable formulations of drugs in a therapeutic class to objectively rank the relative costs on the PAL. The state chose this approach

[21] The Medicaid program developed Community Care of North Carolina—a voluntary regional provider network that implements local quality and cost containment initiatives. To date, there are 13 networks involving more than 3,000 physicians and other healthcare providers covering 543,574 Medicaid recipients. Dobson A. Progress Since 2000 in North Carolina Medicaid Pharmacy Program. Annals of Family Medicine. Electronic Letter, Oct. 10, 2004. Available at: http://annalsfm.highwire.org/cgi/eletters/2/5/488. Accessed Dec. 1, 2004.

[22] Community Care of North Carolina Prescription Advantage List. Available at: http://www.dhhs.state.nc.us/dma/pal/pal.pdf. Accessed Dec. 1, 2004.

based on its non-regulatory philosophy maintaining that physicians are capable of incorporating information, such as the relative cost of drugs and available evidence for comparative effectiveness, into prescribing habits without directives. The state believes that these non-regulatory approaches have already produced savings and an evaluation of their policies is forthcoming.[23]

Along with the PAL, the state uses clinical information in the DERP reports in three additional ways. First, the state is in the process of developing "clinical pearls" that synthesize the evidence in the DERP reviews into much shorter documents to more easily disseminate the information to physicians. The state also references the reports, when available, to develop criteria for its limited PA program.[24] Finally, outside of the Medicaid program, the information is used by North Carolina Area Health Education Centers (AHEC) to develop teaching tools for medical students and for posting on websites for physicians, and other health care providers across the state to reference.[25]

IV. KEY FINDINGS

Several key findings emerge from these case studies including the major motivations to join the DERP and perceived benefits and challenges to using the DERP reports for Medicaid pharmacy policies. Figure 4 organizes some of the key findings into three themes.

Figure 4: Major Themes in Case Study States

States' Use of the DERP Reports	Expressed Motivations to Join DERP	Expressed Challenges of Using DERP Reports
• Prominence of the DERP reports varies in states' PDL development processes	• Meet legislative mandates for Rx cost containment policies • Broad acceptance and high regard for DERP reports and ability to help to diffuse stakeholder criticism of PDL efforts • Value participating in the research process	• Training in evidence-based medicine or explanations by EPC researchers sometimes necessary to fully understand reports • Making recommendations when there is limited evidence available for key questions • Filtering evidence through personal clinical experience • Lack of observational studies in reports

States' Use of the DERP Reports

States vary in the prominence of the DERP in PDL development processes. Both Washington and Wyoming rely heavily on the DERP. They use its reports as the main source of clinical evidence and neither state currently reviews a therapeutic drug class for the PDL without

[23] The state reportedly saved $80 million in 2003 with policies focused on increasing the use generic drugs and estimates to save $25 million in FY2004 with its Prescription Advantage List. Dobson A. Progress Since 2000 in North Carolina's Medicaid Pharmacy Program. Annals of Family Medicine. Electronic Letter, Oct. 10, 2004. Available at: http://annalsfm.highwire.org/cgi/eletters/2/5/488. Accessed Dec 1, 2004.
[24] North Carolina Medicaid program requires PA for select drugs including Aranesp, Procrit/Epogen, Neupogen, OxyContin, Provigil, Celebrex, Bextra, Enbrel, Botox, Myobloc, and growth hormones. One state official explained a DERP report was used to help develop the PA criteria for Celebrex and Bextra.
[25] North Carolina Area Health Education Centers (AHEC) provide educational programs for the state's health workforce by partnering with academic institutions, healthcare agencies, and other organizations committed to improving the health of people in North Carolina. North Carolina AHEC, the web site. Available at: http://www.med.unc.edu/ahec/welcome.htm. Accessed Dec. 1, 2004.

a final DERP report. In addition, both states request Oregon EPC researchers to be present or be available via telephone during P&T committee meetings and ask that all evidence submitted by stakeholders first be reviewed by DERP contracted EPCs. In contrast, due to the presence of First Health and pressure to implement a PDL quickly, Minnesota views the DERP reports more as supplemental information when available, rather than the foundation of Minnesota's PDL development process. One Minnesota official acknowledged that the DERP has reviewed the most relevant drug classes for a Medicaid PDL, but the state expects to establish a PDL faster than the DERP is releasing the reports and for more drug classes than the DERP is intended to review.

Expressed Motivations to Join the DERP

Medicaid budgetary restrictions are a motivation for states to develop a PDL and consequently join the DERP. Of the case study states that currently have a PDL (Minnesota, Washington, and Wyoming), interviewees in each of the Medicaid agencies explicitly stated that they made decisions to develop a PDL mainly due to budgetary pressure from state legislators. That is, the evidence presented in the DERP reports did not drive state Medicaid programs to develop a PDL; rather, these states were under pressure to implement a PDL prior to joining the DERP.

Many state officials reported that the DERP offered a well-accepted tool to assist the state Medicaid agencies in reviewing the clinical evidence when tasked with developing a PDL, especially when they faced a shortage in resources, expertise, or time. For example, prior to joining the DERP, both the Minnesota and Washington Medicaid agencies began conducting their own assessment or contracted with a local university to develop literature reviews of the evidence. Even when the DERP was in its infancy, Washington saw the DERP as offering a more credible and defensible alternative than continuing with local efforts. Interviewed officials in Wyoming recognized from the start that they could not internally review the evidence with the same rigor as the OHSU Center's contracted EPCs and believed the DERP was the best option available.

States value being a member of the DERP and participating in its research process. When asked why states had elected to become active participants in the DERP, rather than accessing the reports for free over the Internet, all stated the importance of being able to influence the selection of therapeutic categories to be reviewed and the shaping of research questions. Interviewees stated that they are pleased with the DERP's voting process used to select the drug classes and key questions. State officials explained that the process works well in part because most Medicaid programs agree on the drug classes they believe are most relevant for inclusion on a PDL. While the DERP recently began posting drafts of the key questions on the project's web site for a brief public comment period, participating members have the main responsibility of defining the questions. Officials from participating states emphasize the value in being able to share drafts of the key questions with P&T committee members or other local experts to ensure the DERP reviews address what local constituents believe to be the most appropriate issues.

Some representatives from the pharmaceutical industry expressed frustration that until most recently only member participants were able to define the research questions. Many of the interviewees believe it is important for the transparency and credibility of the project that other

stakeholders be meaningfully involved. While no specifics were raised as to key questions the DERP should have considered in its completed systematic reviews, industry representatives emphasized that their clinical expertise should help define what clinical outcomes should be considered. In addition, certain interviewees raised the concern that the process may introduce a cost containment bias into the process given that the key questions are defined by many state officials motivated to contain drug costs.

The DERP reports help to diffuse criticism when developing a PDL. Representatives from all states interviewed characterized the DERP's reputation as highly regarded and widely accepted. Many interviewees described the reports as the most rigorous approach available to systematically organize the current evidence on drug effectiveness for PDL development. One Washington state official stated that the DERP reports helped to "infuse credibility into the state's prescription drug cost containment efforts." The same official in Washington and another in Wyoming credited the reputation of the DERP reports for subduing the criticism of the state's PDL efforts from the pharmaceutical industry and other beneficiary stakeholders. One member of the DFC in Minnesota acknowledged that when clinical reviews are available from both the DERP and First Health, the committee's discussions focus more on the DERP reports due to their ability to better synthesize the information and present it in a more comprehensive manner.

Even stakeholders that expressed concerns regarding states' interpretation and use of the reports in developing PDLs, characterized DERP reports as being "rigorous" reviews of the literature. Representatives interviewed from the pharmaceutical industry acknowledged the value of the systematic review process and that the DERP reports are often high quality evaluations of the studies the project elects to include in their reviews. However, interviewees carefully clarified that the DERP reviews often omit many studies and that the evidence from a systematic review process is necessary but not sufficient to adequately inform health care decision-makers designing a PDL.

Expressed Challenges of Using DERP Reports

Distinctions are made between the quality of the DERP reports and P&T committee members' ability to effectively use them when developing recommendations for a state's Medicaid prescription drug policies. All interviewed DERP participants reported being highly satisfied with the reports for their comprehensiveness and rigorous assessment of the literature. However, the degree of training of the P&T committee members in the principles of evidence-based medicine appears to play a large role in determining how well the reports can be fully understood and used for making PDL recommendations. Interviewed state officials and beneficiary advocate groups expressed concerns that some P&T committee members are not sufficiently familiar with the principles of evidence-based medicine to understand the critical clinical issues presented in the DERP reports.

Acknowledging these concerns, states cited one benefit to joining the DERP was having access to Oregon EPC researchers to facilitate understanding of the reports. One state official explained that Oregon EPC researchers provided training to P&T committee members and state officials on the principles of evidence-based medicine. In addition, the presence of Oregon EPC researchers during P&T committee meetings to review the reports' findings and answer committee members'

questions was particularly valued to help address questions regarding the evidence or literature review methodology raised by stakeholders' public comments. Interviewees acknowledged that some P&T committee members only fully understand the DERP report after the Oregon EPC researchers' explanations due to the length of the reports, complexity of the issues, and some committee members' minimal background in clinical evidence-based reviews. One P&T committee member stated that discussions were often short when first reviewing the DERP reports, but as members became more familiar with evidence-based medicine principles and with each other, there were much longer deliberations about the reports before reaching a consensus on their recommendations.

Disagreements emerge about whether the lack of conclusive evidence of superiority in the DERP reviews indicates that the drugs are clinically equivalent. Medicaid officials from Washington and Wyoming affirmed that the systematic reviews that DERP conducts are thorough and establish that if there is evidence available to determine differences between products regarding safety, efficacy, and effectiveness, the DERP will find it. During times when the DERP reviews find that there is no quality evidence to support that one drug is more effective or safe than the other, some states automatically determine that the drugs are clinically equivalent. Such a determination gives the states what they believe to be defensible grounds to choose the least expensive drug for the PDL.

Some states believe that the reports' inconclusive findings for many of the key questions underscore the need for more research. One official in North Carolina stated that the DERP reports are particularly helpful in highlighting when there is no quality evidence because of the lack of head-to-head trials that would address side effects or adherence rates of populations especially important to the Medicaid program. In such cases, the state does not automatically determine that the lack of evidence means the drugs are clinically equivalent. Rather, the state provides the available information to physicians as one tool along with information on relative cost so that both can be incorporated into evidence-based decisions for individual patients.

Stakeholders, especially representatives from the drug industry, stated that when the DERP reports conclude that there is no evidence to demonstrate that one drug is more effective than the other, it is wrong and "dangerous" for states to assume all drugs in the class are clinically equivalent and only allow unrestricted access to one drug based on price. Beneficiary advocates often urge state officials and P&T committee members to consider additional sources of information before deciding when drugs in a class are therapeutically equivalent. These interviewees acknowledged that although they believed the reports reflect a comprehensive and systematic review of clinical trials considered by the DERP, a truly complete review of the evidence should include additional information such as observational studies, drug utilization patterns, and studies of the implications of restricting access on adherence rates. This additional information could highlight important clinical concerns such as the non-interchangeability of medications for individuals—the idea that each individual or a small sub-population may react uniquely to each medication within the same therapeutic class.

A number of P&T committee members, beneficiary advocates, and members of the pharmaceutical industry believe that the DERP should integrate more observational studies in their reviews of the evidence. While commonly recognized as being a thorough and useful analysis of the available evidence, multiple interviewees suggest that the DERP could

strengthen its reports by including evaluations of more observational or retrospective studies in order to provide more insight of a drug's real-world effectiveness.[26] Observational studies are typically studies that address a clinical question by retrospectively analyzing databases of patient information that can be collected for a variety of purposes. For example, a P&T committee member explained that more information in the DERP report from observational studies might have helped when it reviewed the evidence for COX-II inhibitors (cyclooxygenase-2 inhibitors). During the meeting, a number of committee members raised that the DERP report reviewed for this class did not fully address the safety concerns of certain COX-II inhibitors, based upon their own clinical experience and knowledge of other observational studies. Such experiences were not captured in reviews of the randomized, controlled trials that the DERP reports review. These concerns drove the committee to table the discussion until more data could become available.

Representatives from the pharmaceutical industry also question the DERP's rigid inclusion criteria for studies and the lack of key observational studies in the reports. National beneficiary groups raised concerns that the DERP's inclusion criteria may cause its reports to ignore other research data recognized as providing valuable information about a drug's therapeutic benefits and adverse events on different subgroups. However, these groups did acknowledge that such observational studies should not receive the same clinical weight as randomized control trials in the reports.

P&T committee members stress the importance and challenge of balancing evidence in the DERP reports alongside personal experiences and acknowledged forms of less rigorous clinical evidence. One state's P&T committee member stated that although the DERP reports are an outstanding resource, it is just as important that a committee of practicing physicians and other providers filter the evidence through real clinical experiences. Some interviewed P&T committee members acknowledged that the DERP reports' omission of many observational studies from their literature reviews leads some members to believe that there is room for their personal observations and knowledge of these types of clinical studies, despite acknowledging that personal observations are considered less rigorous. Beneficiary groups supported this perspective by explaining that the DERP reports should just be one facet of information states need to consider for real evidence-based policy making. However, some committee members explained the challenge in weighing personal clinical experience when it contradicts evidence presented in the DERP reports or when there is little high quality evidence available to answer a key question.

Many beneficiary stakeholder groups do not track or do not engage with states on their use of the DERP reports to develop their Medicaid prescription drug utilization management policies. Apart from AARP and the advocacy or disease groups that concentrate on beneficiaries with mental illnesses, it was difficult to identify other groups that track the use of DERP reports on a state specific level or engage with states regarding their use of the DERP reports. While many beneficiary advocacy groups have historically been active at challenging a state's decision to develop a PDL or other polices that restrict a beneficiary's access to medications, few appear to focus on states' use of the DERP reports, and few organizations make comments during PDL P&T committee meetings. Many of the contacted beneficiary groups cite a lack of resources as

[26] Since completing interviews for this research, some interviewees acknowledged that officials administering the DERP have stated they will begin to include reviews of more observational studies in future DERP reports.

the primary reason for their inability to examine the DERP reports and engage with states. AARP and the pharmaceutical industry were among the few stakeholder groups found to be closely monitoring the DERP from the beginning and pharmaceutical industry representatives are one of the few groups actively making comments on the reports at P&T committee meetings in different states. However, unlike most pharmaceutical industry representatives, AARP supports the DERP's evidence-based reports and encourages both the public and private sectors to use them as the basis for respective cost containment measures.[27]

Public input during P&T committee meetings was regarded as an ineffective method of influencing PDL recommendations. State officials, P&T committee members, beneficiary advocates, and representatives from the industry believe that historically stakeholder input during state public meetings usually does not provide additional information that is considered by P&T committee members when developing recommendations for the state's Medicaid PDL. Instead, stakeholders often view public comment periods as simply a formality. While most state P&T committee meetings are open to the public and allow public comments, many stakeholders agree that the length and form of the current comment periods are not sufficient to raise all of the key clinical concerns that may not be addressed in the DERP reports.

V. DISCUSSION AND CONCLUSIONS

Nearly all stakeholders interviewed for this issue brief recognized the value of the DERP's review process and its aim to provide a systematic review of the clinical evidence on the comparative effectiveness of drugs in the same therapeutic class. However, given the potential variation in interpretations of the evidence and lack of guidance from the DERP, it is important to consider ways this evidence-based information can be used to develop effective pharmacy policies for containing costs while ensuring that beneficiary health is not compromised. The research findings from the four case studies raised several important observations and questions for those who are using or are interested in using common systematic literature reviews, such as from the DERP, for establishing pharmacy coverage and payment policies.

DERP offers a unique and practical model for states to work together to obtain common clinical evidence on drugs' comparative effectiveness; however, further research is needed. Given many states' need to provide clinical evidence to P&T committees and the time and resources it takes to individually conduct rigorous systematic reviews of the volumes of literature, it makes sense for states to have a desire to work together and rely on experts to review and obtain this information. By collaborating and sharing resources, states are able to fund comprehensive reviews for more drug classes than they would be able to on their own.

State officials are pleased with the first drug classes and key questions the DERP commun ally has selected for its literature reviews, and they especially value the fact that the project conducts its reviews with researchers at the same EPCs that work with AHRQ. State officials accredit the project's reviews for bringing creditability to and helping to diffuse criticism of their decision-making processes. However, further research is warranted to compare the DERP reports to other

[27] AARP, the website. AARP Building a Functioning Market for Prescription Drugs. Available at: http://www.aarp.org/legislative/prescriptiondrugs/rxprices/Articles/a2004-06-29-buildingmarket.html. Accessed on Dec. 10, 2004.

existing efforts to systematically synthesize evidence for the purpose of developing pharmaceutical policies, such as evidence reports and processes developed by pharmaceutical benefits managers and managed care plans. Such evaluations will become increasingly more important as dual-eligible beneficiaries move from the Medicaid program to Medicare prescription drug plans, which will likely use different evidence reviews for establishing their formularies.

Sufficient clinical evidence is often lacking in the medical literature to make clear decisions regarding drugs' comparative effectiveness. Most interviewees agreed that many of the DERP reports demonstrate there are often few studies deemed high quality found in systematic reviews of the literature for making clear distinctions on therapeutic equivalency or superiority for drugs in the same class. One P&T committee member acknowledged the disappointment that there is so little quality evidence produced by the drug industry to address many of the key questions, making it difficult to decidedly determine the comparative effectiveness between two drugs in the same class. Interviewed beneficiary advocates specifically pointed out that many questions remain unanswered in the DERP reports regarding the effectiveness or varying side effects of the drugs on different clinical populations or subgroups, which may be an important consideration when developing policies for the Medicaid program. Many state policy makers hope that initiatives such as the DERP will increase the demand for more clinical evidence and that the industry or other research centers will respond with more quality head-to-head trials that can begin to answer with more certainty many of the DERP reports' key questions.

When meaningful uncertainty exists regarding a drug's comparative effectiveness and/or safety for some population subgroups, states may want to consider erring on the side of fewer restrictions or more grandfather policies until more information becomes available to gain broad stakeholder support. Mental health advocacy groups especially emphasized this point: the DERP's release of reports on antidepressants and atypical antipsychotics may prompt states with current exemptions for many mental health drug classes to begin to reconsider addressing these classes on their PDLs. These advocates worry that states are going to read the DERP reports, assume the lack of conclusive evidence found in randomized, controlled trials means that there are no clinical differences between the drugs, and place restrictions on vulnerable beneficiaries' access to select medications. Finally, the constant availability of new information raises the question as to whether updates of the DERP reports will be sufficient to ensure patient access to medications newly proven to be effective or discontinue use of medications that have new discovered risks.

Reviews of utilization trends and other clinical factors that may affect beneficiaries' health are outside of the scope of the DERP literature review process. Given the lack of randomized controlled trials or other studies that involve Medicaid beneficiaries reviewed in the DERP reports, there are important questions states should consider outside of the DERP before implementing restrictive pharmacy policies. In addition, several stakeholder interviewees point out that randomized controlled trials generally offer limited relevance to real world clinical practice because of their need to include populations and outcomes that can be easily measured, rather than including the patients with complex diseases commonly enrolled in Medicaid programs.

Some stakeholder interviewees urge officials administering the DERP to include an explicit section in each report that discusses the limitations of the evidence for making restrictive Medicaid policies. This additional section would remind states to consider other information in their decision making process, such as the current prescribing and drug utilization patterns in the states. For example, states should explore questions such as how many beneficiaries are using a certain drug and for what conditions, in what settings are beneficiaries obtaining the drug, or are beneficiaries using higher or lower doses than recommended. Without Medicaid beneficiaries' drug utilization information, P&T committee members may not be aware of the potential implication of their recommendations on beneficiaries' access and use of needed medications, and states may have no way of evaluating the success or failure of PDL policies.

Individual preferences and adherence rates are also important factors states may need to consider further in conjunction with the clinical evidence in the DERP reports. Interviewed beneficiary advocates explained that the studies reviewed in the DERP reports give minimal emphasis to the wide inter-individual variability in terms of medication tolerability and effectiveness, such as not addressing the reality that particular drug characteristics affect the health outcomes of patients outside of the randomized, controlled environment. For example, when the systematic reviews identify two drugs as clinically equivalent for a group of patients, the willingness of an individual patient in a community to adhere to one drug therapy over another due to dosage form, drug-to-drug interactions, or other personal factors is important to consider. Medicaid officials may need to look beyond drug costs and likely savings to consider the consequences of changing medications for beneficiaries and the potential that medication switches and increases in non-compliance with drug regimens could be more detrimental to overall program costs by causing an increase in emergency room visits or hospitalizations.

States or other entities that use the DERP reports will need to address demands for accountability from beneficiary groups, industry representatives, or other stakeholders. While supporting the concept of systematic reviews of the evidence, many stakeholders raise strong concerns in the way state Medicaid programs use the DERP reports, especially for those states not directly participating in the DERP and still using the reports in their policy making processes. Many representatives from the pharmaceutical industry feel the DERP "creates a veil behind which government officials and some managed-care organizations justify restrictions on patients' access to health care in order to reduce short-term drug costs."[28] Some disease and beneficiary groups also expressed similar concerns regarding states developing PDLs with the DERP reports being too focused on reducing costs rather than improving quality. The burden is on each state to develop a transparent process that enables meaningful input from all stakeholders, including beneficiary groups, to determine how to interpret and use the information for Medicaid pharmacy policies. States may want to include additional avenues for permitting stakeholder input outside of the P&T committee meetings to ensure policy decisions incorporate other perspectives.

Given that questions remain regarding how states should appropriately use the information in the DERP reports when making policy decisions, a tension has developed around whether or not OHSU officials administering the DERP have a greater responsibility to provide information on

[28] Holmer A. Patients' Medical Needs Decided by Bureaucrats. The Wall Street Journal, December 13, 2004. (Alan Holmer wrote this letter when president and CEO of Pharmaceutical Research and Manufacturers of America.)

their reports' limitations and specific recommendations on their utility. Officials administering the DERP state that the goal is only to collect, evaluate, and distribute the best available evidence, but defer to the participants' local processes to decide how to use and interpret the information. This belief leaves the full responsibility to states to decide what other evidence and perspectives are necessary to develop appropriate pharmacy policies. However, as more states and others such as pharmacy benefit managers (PBMs), private sector insurers, and consumers begin relying on information presented in the DERP reports, the tension on where public accountability lies will increase. It is also possible that the federal government may begin to play a greater role in determining proper accountability when using similar evidence for policy making since AHRQ is initiating research for federally funded programs on the comparative clinical effectiveness of pharmaceuticals as directed under Sec. 1013 in the 2003 Medicare Modernization Act.

This short descriptive study only begins to highlight the implications of state Medicaid agencies' use of DERP reports to develop PDLs. Many questions still need to be addressed to asses the full impact of the DERP's reports and to continue to illustrate issues policy makers may need to consider when relying upon this type of clinical evidence. For example, further research is needed to better understand how non-participant members, including other state Medicaid programs, are using the DERP's evidence-based reviews and what impacts the reports have on their pharmacy benefits. It will also be valuable to assess if and how plans that expect to participate in the new Medicare Part D benefit in 2006 will begin to reference information in the DERP reports when designing their PDLs or formularies. While it is advantageous that many states and other entities have begun to recognize the importance in pursing the development of policies and programs based on unbiased evidence-based research, it will be important that future research considers what other sources of information and evaluations are necessary to ensure patient care is protected. Research should further examine the process of developing the DERP reports, and how greater transparency and openness to stakeholder input affects the development of PDLs and beneficiary outcomes. Finally, if an increasing number of states join the DERP or rely prominently on its reports, federal officials need to consider whether the DERP evolves into a de facto federal advisory committee subject to the same rules of public involvement and transparency as other federal advisory groups.

States should be supported in their desire and efforts to move past considerations of only costs when developing pharmaceutical utilization policies. For the states interviewed, the DERP offers an efficient process and well-recognized credible source of information. Policies based on this information and best practices around how to incorporate the reports into public processes should continue to be developed and monitored.

APPENDIX

Internet links to the full DERP evidence-based reports and samples of other evidence summaries available to the public that reference the DERP reviews:

1. **Oregon Health & Science University Center for Evidence-based Policy**

   http://www.ohsu.edu/drugeffectiveness/

   This is the official website for the Drug Effectiveness Review Project. The web page provides internet links to all final DERP reports and more information on the project.

2. **Washington State Government—Rx Washington**

   http://rx.wa.gov/

   This website provides a description of the DERP and links to the full DERP reports.

3. **Oregon State Government—Office for Oregon Health Policy and Research**

   http://www.oregon.gov/DAS/OHPPR/ORRX/HRC/evidence_based_reports.shtml

   This website provides internet links to one-page consumer reports based on the Oregon Health Resources Commission's review of the DERP reports and other information for 13 therapeutic classes. The website also provides internet links to the full DERP reports.

4. **AARP**

   http://www.aarp.org/ResearchRx

   This website provides consumer and provider oriented summaries of evidence related to the effectiveness and safety prescription drugs in nine therapeutic classes. The website notes the conclusions of the summaries are based on the DERP reviews and provides internet link to full DERP reports.

5. **Consumers Union Consumer Reports Best Buy Drugs**

   http://www.crbestbuydrugs.org/

   This website compares and contrasts effectiveness, safety, and cost of prescription drugs in four therapeutic classes in consumer-oriented summaries. The website notes the Consumer Reports Best Buy Drugs is designed, in part, to help bring the DERP findings to the public. The website provides internet links to the full DERP reports.

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