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THE HENRY J. KAISER FAMILY FOUNDATION

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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 bi-partisan group of national leaders and experts in health care and public policy.

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ABSTRACT

Oregon is one of 30 states that have implemented or plan to implement a preferred drug list (PDL) to control Medicaid fee-for-service prescription drug spending. Oregon legislators and officials have worked over the past two years to distinguish Oregon's PDL, which is a voluntary program (the state does not require beneficiaries to obtain prior authorization (PA) before receiving a non-preferred drug), from other state precedents. State policymakers emphasize that PDL decisions are made based on objective reviews of clinical evidence.

Policymakers' and other Medicaid stakeholders' interest in Oregon's PDL has focused on the state's transparent decision-making process and relationship with independent researchers at the Oregon Evidence-based Practice Center (Oregon EPC). For each drug class included on the PDL, the state forms a diverse subcommittee of practitioners and patient group representatives who work with researchers at the Oregon EPC to conduct detailed, public reviews of the class. After the subcommittee completes its review and makes its recommendations, the Medicaid agency may consider the prices of drugs deemed clinically equivalent or for which there is a lack of evidence to indicate one drug's effectiveness over another. Interested stakeholders may contribute comments and testimonies throughout most of the process. This transparency combined with the state's voluntary compliance policy for prescribers allowed Oregon to proceed with broad stakeholder consensus in the early phases of its PDL implementation.

Oregon's PDL generally is more restrictive in its preferred product recommendations for most drug classes currently covered when compared to Medicaid PDLs in Michigan and Florida. Because Oregon's PDL is not enforced by PA and serves primarily as information to aid prescribers, there appears to be less concern that Medicaid beneficiaries will have problems accessing excluded medications when necessary. Oregon's research findings could take on greater significance, however, as other Medicaid programs look to incorporate the state's results into their own processes, which often rely on a PA enforcement mechanism.

Oregon's PDL development process may have a meaningful impact on emerging multi-state initiatives. Recognizing an opportunity to share the cost of clinical research, eight state Medicaid programs are already collaborating with Oregon to use the results of the state's literature reviews in their own PDL selection processes, and together sponsor future research on new drug classes. Negotiations with another nine organizations, including some outside of Medicaid, are ongoing. Medicare policymakers may also examine Oregon's experience in PDL design and development when formulating regulations to implement the new Medicare prescription drug benefit.

The present case study describes i) the PMPDP development process and ii) the state's, beneficiary advocates', manufacturers' and other stakeholders' perspectives regarding how the new policy will impact beneficiaries in Oregon and, potentially, other Medicaid program policies across the country. Below are highlights from the report, which is based on 25 interviews with individuals in 15 organizations affected by the PMPDP:

- In general, all PMPDP stakeholders appreciated Oregon's emphasis on evidence-based research, and the state's open PDL development process which allowed for beneficiary advocate, physician and manufacturer feedback. The state's PDL legislation won the support of many stakeholders by including a mandate that the program be "practitioner-managed" with a voluntary compliance policy, and an exemption for all mental health, HIV/AIDS and cancer drugs from the PDL. States may have an opportunity for greater stakeholder support for PDL and other Medicaid policies if they emphasize, like Oregon, specific patient protections and a commitment to a clinical and transparent policymaking process.
- The most significant concerns expressed by key stakeholders regarding Oregon's PMPDP process relate less to the state's beneficiaries, but rather to how Oregon's research and relatively restrictive drug selections will be applied in new markets, especially given other Medicaid programs' inclination to impose strict PA policies in conjunction with PDLs. Oregon's results may not transfer well to other Medicaid markets if collaborating states do not simultaneously consider adoption of Oregon's voluntary compliance, open processes, and efforts to engage local perspectives.
- State officials found it difficult to achieve savings targets by promoting only voluntary compliance for the PMPDP. Before legislation was passed in 2003 prohibiting Oregon from implementing a PA policy, prescribers were briefly required to obtain PA from the state when prescribing a non-preferred product. There were meaningful market share shifts and savings during the months the PMPDP was enforced with PA versus when the program was voluntary. It is too early to determine how new physician profiling, education and other alternative strategies to PA that promote PDL compliance will impact prescribing practices and beneficiaries' health, and no evaluation of the temporary PA policy's impact on beneficiaries was conducted.
- Disagreements between state officials and other stakeholders emerged about the role cost should play in PDL selections when there is an absence of clear clinical evidence for evaluating a drug's effectiveness. Relying on strict reference pricing systems to make some Medicaid PDL decisions can raise concerns about whether or not the most useful or needed products make the list, given the absence of clear evidence favoring one drug over another in many cases.

EXECUTIVE SUMMARY

Background

In the past couple of years, Medicaid preferred drug lists (PDLs) – lists of preferred prescription medications that beneficiaries generally may receive without first obtaining prior authorization (PA) from a state – have emerged as a prominent Medicaid policy to control prescription drug cost growth. Some PDLs, such as Oregon's and Mississippi's[1], are voluntary for physicians to follow and do not include a PA requirement for beneficiaries. As of December 2003, more than 30 states had implemented or announced plans to implement a Medicaid PDL. A number of factors help to explain this interest, including continued high Medicaid prescription drug spending growth rates, the Centers for Medicare and Medicaid Services' (CMS) September 2002 endorsement of PDLs as a cost containment tool,[2] and initial reports from first-mover states that PDLs can achieve immediate savings.[3]

In August 2001, former Oregon Governor John Kitzhaber signed Senate Bill (SB) 819, which authorized a PDL program for the state's Medicaid fee-for-service beneficiaries (39 percent of the approximately 390,000 Medicaid enrollees in the state).[4] Among other groups, Oregon's fee-for-service population includes beneficiaries residing in state institutions and those with certain complex medical health conditions who are exempt from the state's mandatory managed care enrollment policy. The state's PDL was intended to curb recent Medicaid prescription drug spending levels, expected to reach $885.3 million in the 2001-2003 budget cycle, a 60 percent increase from the 1999-2001 budget session.[5]

Oregon officials, with support from stakeholder groups such as AARP, worked to distinguish Oregon's PDL, known as the Practitioner-Managed Prescription Drug Plan (PMPDP), from other state policy precedents. The PMPDP emphasized the evidence-based review of drugs' clinical effectiveness that would be conducted by an independent body and would drive product selections before the state considered cost. The PDL

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[1] Mississippi's PDL is voluntary for physicians; beneficiaries pay higher co-pays for non-PDL, brand name drugs.

[2] CMS issued a letter to State Medicaid Directors in September 2002 clarifying CMS' position that state Medicaid programs may subject covered prescription drugs to PA as a means of encouraging drug manufacturers to enter into supplemental rebate agreements.

[3] Although no details on methodology have been released, Michigan claimed the state was on track to achieve $45 million in savings in its PDL's first year of operation. Bernasek, C. et al. Case Study: Michigan's Medicaid Prescription Drug Benefit. *Kaiser Commission on Medicaid and the Uninsured*, January 2003. Illinois and Washington also announced significant shifts in market share toward lower priced PDL selections soon after implementing the policy. Medicaid Pharmaceutical Cost-Containment Approaches in Four Case Study States. *The Health Strategies Consultancy LLC*, November 2002 (Unpublished Paper Prepared for the Centers for Medicare and Medicaid Services).

[4] November 2003 "First of Month" report by county for fully capitated health plans, fee-for-service, and primary care case managers. *State of Oregon, Office of Medical Assistance Programs,* Available at: http://www.dhs.state.or.us/healthplan/data_pubs/enrollment/1103/fchp_1103.pdf Accessed December 11, 2003.

[5] Gold, R. "Oregon's New Track on Drug Prices," *The Wall Street Journal*, August 1, 2001.

authorizing legislation also mandated that physicians be allowed to prescribe non-preferred products, by indicating on a script that a drug is medically necessary for a beneficiary.

Oregon's PDL selections rely on a multi-step review process that allows for public participation and comment. (This process is illustrated in Appendix D.) For each drug class included on the PDL, the state first forms a subcommittee of physicians, pharmacists, and other healthcare or beneficiary specialists, who work with independent researchers from the Oregon Evidence-based Practice Center[6] (Oregon EPC) to conduct detailed literature reviews on the class. Only after the clinical review process is complete and recommendations regarding products' comparative effectiveness are prepared will the Medicaid agency consider the prices of drugs deemed to be clinically equivalent or for which there is a lack of evidence to indicate one drug's effectiveness over another. Interested parties may contribute testimony throughout most of the process and the state posts all clinical reports supporting its PDL selections on a state-run website (www.oregonrx.com).

Several beneficiary protections included in SB 819 minimized the resistance of important Medicaid stakeholders when the PMPDP was initially launched. The program began in August 2002 as a voluntary list from which a physician could still prescribe any Medicaid drug without prior approval. State officials emphasized that the program would be "practitioner-managed." The legislation also protected all mental health, HIV/AIDS, and cancer prescription drugs from PA or any other limitation that the state incorporated into the PMPDP program.

Given the difficulty of achieving physician adoption and savings goals with a voluntary PDL, the Oregon Department of Human Services added a PA requirement to the PMPDP through administrative rule in May 2003. Physicians had to first contact the state for approval before prescribing non-preferred products. Although providers still retained full authority to make final prescribing decisions when contacting the state, the passage of House Bill (HB) 3624 in August 2003 statutorily prohibited officials from using any type of PA as a compliance mechanism. Oregon officials have now developed an educational physician-profiling program to promote the PMPDP.

Other state Medicaid officials, and beneficiary and manufacturer groups have expressed interest in and/or raised questions about Oregon's PMPDP development process as a potential precedent for future Medicaid PDLs. Eight states have already contracted to collaborate with Oregon to use the state's prescription drug research in their own PDL selection processes. In response, in the spring of 2003, the Kaiser Commission on Medicaid and the Uninsured asked The Health Strategies Consultancy LLC to prepare a case study of Oregon's experience with its new prescription drug policy.

[6] The Oregon EPC, which is also contracted by the federal Agency for Healthcare Research and Quality, is a collaboration of the Oregon Health & Science University, Kaiser Permanente Center for Health Research, and Portland VA Medical Center.

Based on 25 interviews with individuals from 15 organizations involved with or affected by the Medicaid fee-for-service pharmacy program in Oregon, this Report (1) describes the PMPDP and Oregon's clinical review process, and assesses the results relative to other state PDLs; (2) gathers key Medicaid stakeholder perspectives on the new policy and implementation of the program; and (3) describes stakeholder views regarding how the pharmacy changes in Oregon have impacted or may impact the health of Medicaid beneficiaries in Oregon and other states.

While interviews for this report were conducted prior to passage of the latest Medicare law, efforts to implement the new Medicare prescription drug benefit will potentially increase the importance of and focus on state Medicaid PDLs. When writing implementing regulations for the new drug benefit, CMS officials may seek information regarding Oregon's PMPDP and other states' efforts to incorporate drug utilization management strategies into public programs. As a result, Oregon's decisions around PDL category and drug selections, and stakeholder engagement described in this Report, and its experience implementing utilization controls that in part affect a dual eligible population, are likely to be studied by an even broader audience.

Summary of Key Stakeholder Perspectives

All stakeholders endorsed language included in SB 819 emphasizing evidence-based research, drug exemptions, voluntary compliance, and an open PDL process as useful precedents for other state Medicaid programs. Beneficiary protections included in SB 819 (Appendix C) helped to minimize manufacturer and beneficiary lobbying against the PMPDP. Patient and manufacturer representatives especially highlighted the state's voluntary compliance policy and physicians' ultimate authority in making prescribing decisions to explain their initial support of the program. Opposition mounted during the months when the state instituted its new PA policy, which was ultimately revoked by the legislature.

According to state Medicaid officials and some patient and provider groups, Oregon's reliance on independent researchers at the Oregon EPC to conduct clinical reviews enhances the credibility of the PMPDP process. Interviewees from Oregon, other states, and some beneficiary and provider groups emphasized the importance of having independent researchers immune from "special interests" conduct the clinical reviews for the PMPDP. The state has relied on its relationship with the Oregon EPC to help build the program's reputation as a more "clinically focused" PDL. AARP in particular has supported efforts to market Oregon's research nationally as an objective tool useful to all prescription drug consumers and prescribers. AARP has published all of Oregon's evidence-based research on an AARP Oregon Rx website.

Process transparency and stakeholder involvement was important to obtaining public support for the new policy. Consistent with health policy decisions in the past, Oregon afforded the public the opportunity to understand and contribute to the development of the PMPDP. Policymakers expressed a desire to guard against misperceptions that the state was making drug selections according to special interests,

"behind closed doors." Physicians interviewed especially appreciated the state's general efforts to include physicians as participants on the reviewing subcommittees and in conducting the evidence-based reviews.

Manufacturer and state representatives disagreed about the role cost should play in PDL decisions when there is an absence of clear clinical evidence indicating one drug's effectiveness versus another. Many of the subcommittee reports submitted to the state indicated that there was insufficient evidence to draw clear conclusions about drugs' comparative clinical effectiveness or safety within a therapeutic class. When such evidence was lacking, Medicaid officials proceeded to select preferred drugs based on price, emphasizing the need for more comparative clinical studies in the future. Manufacturer representatives held fast to the position that in the absence of clear clinical evidence indicating one drug's effectiveness versus another, *all* products in the category should be included on the PDL.

Some manufacturer representatives and providers challenged the Oregon EPC's stringent literature reviews and the lack of specialist perspective in some of the HRC committee processes. Some manufacturer representatives were not content that the Oregon EPC only considered randomized controlled trial information when assessing products' clinical effectiveness. Especially in classes in which such information is inadequate, disease registries and other patient claims databases, and specialist experience and consensus treatment guidelines may enhance the understanding of how different patients react to different products. At one HRC subcommittee meeting, an Oregon rheumatologist challenged the state's decision to exclude COX-2 inhibitors from the NSAID class because it contradicted consensus guidelines endorsed by several physician societies.

The challenge of promoting voluntary compliance with the PMPDP led state officials to implement a new PA requirement in May 2003. After less than a year of operating the PMPDP on a voluntary basis, state officials determined that a new PA policy was necessary to achieve savings targets. The state lacked the resources to run the larger, more targeted physician outreach and education efforts deemed necessary to promote voluntary compliance. It also proved difficult for the state to counter manufacturers' campaigns encouraging physicians to write "dispense as written" when prescribing non-preferred products.

Stakeholder support for the PMPDP declined when officials instituted a PA policy; the requirement, which was ultimately revoked, enabled the state to achieve more significant market share shifts. Most beneficiary and manufacturer advocates challenged the Medicaid agency's authority to add PA to the PMPDP due to SB 819's specific mandate that physicians must be able to prescribe any medically necessary drug for beneficiaries. Physicians also complained that any type of authorization, no matter how easy it is to obtain, presents an administrative burden on practices and detracts from patient care. Opponents ultimately succeeded in pushing for the passage of HB 3624, which voided the Department's PA rule. During the months when the PA policy was in effect, however, the state did achieve more significant market share shifts through the

PMPDP. For example, two months after PA was added, market share for preferred statin drugs rose by more than 250 percent (from 23 percent to 81 percent market share), while share for non-preferred statins declined by 75 percent (from 77 percent to 19 percent market share).[7]

Summary Observations

Oregon's original efforts to design a PDL program with clear beneficiary protections and a commitment to run an open policymaking process were embraced by a range of stakeholders. Medicaid stakeholder interviewees in Oregon expressed less resistance to and concern about the state's original PDL design. States may have the opportunity for greater stakeholder support for a PDL policy if they include, like Oregon, patient protections in the authorizing legislation and commit to clinical and transparent policymaking processes.

Oregon's eventual institution of the PA requirement highlighted the challenge of changing provider prescribing patterns without some type of enforcement mechanism. The additional educational campaigns needed to change physician-prescribing behaviors when the PMPDP was voluntary were too expensive given the state's tight budget. Oregon's significant market share shifts experienced during its trial with PA demonstrated the potential for this enforcement mechanism to generate savings for the state; however, no evaluation of patient experience and outcomes was conducted during this time.

Oregon's evaluation of the PMPDP should address the state's ability to achieve savings goals and promote safe and effective prescribing practices in the absence of a strong enforcement mechanism. Given the current prohibition against PA, Oregon will have to rely on new physician profiling, education and other strategies to promote PDL compliance. SB 819 included specific mandates for the state to evaluate its experience with the PMPDP, which should help to inform other states and policymakers seeking to understand PA alternatives. In the first nine months of the voluntary PMPDP, the state's approach did generate some savings resulting from altered prescribing patterns. Future evaluations will be important to assess any impact that the state's evidence-based research has on prescriber practices and Medicaid beneficiaries' health.

Conflicting perspectives from manufacturers and beneficiaries, and the state exposed a fundamental dilemma regarding the interpretation of existing prescription drug research studies. Oregon used price to select preferred drugs when there was insignificant clinical evidence to distinguish products in a class. Interviewees consistently discussed the dilemma that emerges when comparing and selecting products according to available clinical research: in the absence of data comparing drugs' effectiveness and safety, and acknowledging the unique challenges in serving Medicaid populations, should all products be included on a PDL? The situation also raises the question of whether Medicaid programs should be held to a higher standard of

[7] Market share date based on internal state documents.

inclusiveness than private sector payors, given the poor, more vulnerable populations they serve.

Relying on strict reference pricing systems to make some Medicaid PDL decisions can raise concerns about beneficiary access, given the general lack of clear evidence regarding drugs' relative effectiveness. Oregon's reference pricing system in which only products within five percent of the benchmark product's average wholesale price are included on the PDL, may not afford enough flexibility to include certain higher priced products and alternative drug forms that can have a meaningful benefit for certain beneficiaries. For example, the decision to exclude topical estrogen products from the PDL (only oral estrogen products are preferred) appears to be a more restrictive recommendation versus certain other Medicaid PDLs and private sector formularies.

Oregon's clinical review process led to a more restrictive list of preferred products when compared to some other Medicaid PDLs. An analysis of Oregon's clinical review process outcomes versus PDLs in Michigan and Florida, indicates that the Oregon list is more exclusive than the other state lists in most classes. (The analysis is included in Appendix G.) Specifically, Oregon's PDL lists fewer preferred products than Michigan and Florida in seven of nine drug classes evaluated. However, Oregon's limited preferred drug selections may not restrict access to drugs for beneficiaries as much as other Medicaid PDLs, given the state's voluntary compliance policy. Oregon's relative restrictiveness becomes more important as other markets look to leverage the state's research results in their own PDL processes relying on strict PA enforcement mechanisms.

Oregon's PMPDP development process may have a significant impact on emerging multi-state initiatives. Recognizing an opportunity to share the cost of clinical research, eight states have already begun to collaborate with Oregon to use the results of the state's literature reviews in their own PDL selection processes, and together sponsor new research. Negotiations with nine other organizations, including some outside of Medicaid, are ongoing. Some interviewees expressed concern about exactly how Oregon's research results get applied in new markets, especially given the state's more restrictive product selections, and other Medicaid programs' inclination to impose strict PA policies on beneficiaries. Support for Oregon's results also may not transfer to other markets if collaborating states do not simultaneously consider adoption of Oregon's open policymaking process and efforts to engage local stakeholders.

I. INTRODUCTION

Working amidst severe budget shortfalls and mandated Medicaid cuts, state policymakers around the country increasingly are applying new cost controls to their Medicaid prescription drug benefit. While prescription drug costs account for only nine percent of the total Medicaid budget,[8] growth in this category has significantly outpaced other program spending. In fiscal year 2001, Medicaid fee-for-service prescription drug costs were $24.7 billion (combined federal and state), and in 2003 the Centers for Medicare and Medicaid Services (CMS) projected costs to grow by approximately 24 percent to $32.5 billion.[9] Current cost containment efforts to curb these trends include implementing quantity limits on the number of prescriptions or refills a beneficiary may fill, mandating the use of generic drugs, requiring prior authorization for select medications, and developing preferred drug lists (PDLs).

In the past couple of years, PDLs – in most cases, lists of preferred prescription medications that beneficiaries may receive without first obtaining prior authorization (PA) from the state – have emerged as a prominent Medicaid policy. Some PDLs, such as Oregon's and Mississippi's[10], are voluntary for physicians to follow and do not include a PA requirement for beneficiaries. As of December 2003, more than 30 states had implemented or had announced plans to implement Medicaid PDLs. A number of factors help to explain this interest, including CMS' September 2002 endorsement of the strategy,[11] and initial reports from states that PDLs with PA can achieve significant savings within the first year of operation.[12]

To date, no two state Medicaid PDLs look exactly alike, differing in the processes by which they were developed, scope of drug categories covered, number of Medicaid beneficiaries affected, and strategies by which the lists are enforced among physicians. State legislators and Medicaid agency officials also have made varying decisions regarding the use of outside vendors to recommend preferred products and manage PA phone banks, exemption policies for the most vulnerable beneficiaries or classes of drugs

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[8] Weil, A. "There's Something About Medicaid," *Health Affairs*, Vol. 22. No 1., January/February 2003.
[9] Fiscal year 2002 mid-session review of Medicaid spending projections. Office of the Actuary, Centers for Medicare and Medicaid Services.
[10] Mississippi's PDL is voluntary for physicians; beneficiaries pay higher co-pays for non-PDL brand name drugs.
[11] CMS issued a letter to State Medicaid Directors in September 2002 clarifying CMS' position that state Medicaid programs may subject covered prescription drugs to PA as a means of encouraging drug manufacturers to enter into supplemental rebate agreements.
[12] Although no details on methodology have been released, Michigan claimed the state was on track to achieve $45 million in savings in its PDL's first year of operation. Bernasek, C. et al. Case Study: Michigan's Medicaid Prescription Drug Benefit. *Kaiser Commission on Medicaid and the Uninsured*, January 2003. Illinois and Washington also announced significant shifts in market share toward lower priced PDL selections soon after implementing the policy. Medicaid Pharmaceutical Cost-Containment Approaches in Four Case Study States. *The Health Strategies Consultancy* LLC, November 2002 (Unpublished Paper Prepared for the Centers for Medicare and Medicaid Services).

that serve some of these individuals, supplemental rebate strategies, and the documentation burden imposed on physicians seeking to prescribe a non-PDL product.[13]

In 2001, the state of Oregon announced plans to pursue a somewhat different model for a Medicaid PDL that gained national attention. As elsewhere, Oregon's growing prescription drug spending captured legislators' attention. State officials projected $885.3 million in prescription drug spending in the 2001-2003 budget cycle, a 60 percent increase from the 1999-2001 budget session.[14] In response to these trends, state legislators in 2001 approved Senate Bill (SB) 819, which authorized the implementation of a PDL for the Medicaid fee-for-service program.

Approximately 39 percent, or just above 150,000 of Oregon's 390,000 Medicaid enrollees receive prescription drugs through the fee-for-service benefit.[15] Among other populations, Oregon's fee-for-service program is comprised of beneficiaries who reside in a state institution or in a county without an operating MCO, and those with certain complex health needs who are exempt from the state's mandatory managed care enrollment policy.[16]

Oregon's PDL – called the Practitioner-Managed Prescription Drug Plan (PMPDP) – distinguishes itself from other state PDLs by emphasizing that preferred products are selected according to evidence-based reviews of drugs' clinical effectiveness in conjunction with cost analyses. Independent scientists from the Oregon Evidence-based Practice Center (Oregon EPC) rely on peer-reviewed literature to evaluate selected classes of drugs, and all results from these reviews are public. Only after clinical reviews are complete do state Medicaid officials consider a product's cost effectiveness.

Several state Medicaid programs, encouraged by AARP, have become keenly interested in leveraging the PMPDP's clinical, evidence-based review process. Among other states, Washington, Idaho, Wisconsin, and Wyoming have begun to collaborate with Oregon to use the state's prescription drug research and literature reviews in their own PDL selection processes, and together sponsor future research on new drug classes. As Medicaid officials increasingly look to learn from other states' experiences in prescription drug management, and as CMS officials plan to implement the new

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[13] Bernasek, C. "Preferred Drug Lists: Summary of State Activity and Lessons Learned," *Written Statement Submitted to the West Virginia Oversight Committee on Health and Human Resources*, July 13 2003.

[14] Gold, R. "Oregon's New Track on Drug Prices," *The Wall Street Journal*, August 1, 2001.

[15] November 2003 "First of Month" report by county for fully capitated health plans, fee-for-service, and primary care case managers. *State of Oregon, Office of Medical Assistance Programs*. Available at: http://www.dhs.state.or.us/healthplan/data_pubs/enrollment/1103/fchp_1103.pdf Accessed December 11, 2003.

[16] According to OHP rule 410-141-0060, some populations exempted from mandatory enrollment in managed care include: women in third trimester of pregnancy under the care of a provider not in one of the available plans, beneficiaries who need continuity of care for a current health condition from a provider not in one of the available plans, beneficiaries eligible to receive benefits through the Indian Health Services facility, beneficiaries diagnosed with ESRD, beneficiaries hospitalized at the time of enrollment, and women eligible for the breast and cervical cancer medical program.

Medicare drug benefit, Oregon's PMPDP processes could have meaningful effects on Medicaid beneficiaries nationwide.

Purpose of the Case Study

Given the potential impact of Oregon's plan on Medicaid policy and benefits, in the spring of 2003 the Kaiser Commission on Medicaid and the Uninsured commissioned The Health Strategies Consultancy LLC to prepare a case study of the PMPDP. The purpose of the case study is to (1) describe the PMPDP and Oregon's clinical review process, (2) gather key stakeholder perspectives on the new policy and implementation of the program, and (3) describe the views of Medicaid stakeholders about how the pharmacy changes in Oregon have impacted or may impact the health of Medicaid beneficiaries in Oregon and other states.

Study Methodology

This Report is based on a combination of primary and secondary data sources. We reviewed relevant legislation, news articles, state reports, and other information on the state's Medicaid pharmacy program. These sources provided basic background about the state's development and implementation of the PMPDP. (A complete bibliography is included in Appendix A.)

The majority of information presented in this Report comes from primary information sources. We conducted 25 interviews with representatives from 15 different organizations. To gain a broad mix of perspectives, we interviewed representatives from a range of institutions and organizations in Oregon, including beneficiary groups, physician groups, pharmacist groups, pharmaceutical manufacturer representatives, state Medicaid officials, and others knowledgeable about the program. (A list of interviewees is located in Appendix B.) The majority of the interviews were conducted between May and August of 2003; an update on the multi-state initiative was obtained in December 2003. Interviewees were given the opportunity to review sections of the Report covering their perspectives to ensure that their views and opinions were accurately represented, and all interviewees were guaranteed confidentiality.

Organization of the Case Study

The Report is organized into five sections:

- **BACKGROUND ON MEDICAID IN OREGON** Describes Oregon's Medicaid program, The Oregon Health Plan, and provides relevant background on the increase in Medicaid prescription drug spending.

- **AUTHORIZATION OF OREGON'S PREFERRED DRUG LIST** Describes the political environment and activities surrounding the passage of SB 819.

- **OREGON'S PRACTITIONER-MANAGED PRESCRIPTION DRUG PLAN** Explains key elements of the PMPDP, including the process for selecting drugs and the state's implementation experience to date. This section also highlights emerging efforts of other state Medicaid programs to collaborate with Oregon in their PDL development efforts.

- **PERSPECTIVES ON THE PRACTITIONER-MANAGED PRESCRIPTION DRUG PLAN** Describes stakeholder perspectives regarding the PMPDP and its potential impact on beneficiary health.

- **CONCLUDING OBSERVATIONS** Provides final observations about Oregon's experience with the PMPDP, and its future impact on Medicaid stakeholders.

II. BACKGROUND ON MEDICAID IN OREGON

Oregon's historical focus on broad health coverage initiatives and open policymaking processes provides important context for the state's recent PMPDP launch. Oregon has been recognized as a leader in health reform,[17] pursuing several programs that reduced the number of individuals without insurance in the state from 16.4 percent in 1990 to 12.3 percent in 2000.[18]

In 1994, Oregon implemented the Oregon Health Plan (OHP), a program that uses federal Medicaid and State Children's Health Insurance Program funds to cover Medicaid eligibles and other uninsured state residents. Within OHP, the state considers public input to develop and prioritize a list of services that are covered by the program. The legislature has the authority to adjust the coverage level up or down on this list based on available budget resources. As of November 1, 2003, 389,154 Medicaid beneficiaries were enrolled in OHP, 61 percent of whom received coverage through fully capitated managed care plans.[19]

The process by which OHP was formed reflects Oregon's philosophy, as described by state interviewees, that all health policy decisions should emanate from open, public processes. It was believed that in order for the OHP to be accepted, the public should be involved in the state's decision to expand health coverage to the poor. The state held 47

[17] Silow-Carroll, S., et al. Assessing State Strategies For Health Coverage Expansion: Case Studies of Oregon, Rhode Island, New Jersey, and Georgia. *The Commonwealth Fund*, November 2002.
[18] Ibid. Examples of public-private partnership initiatives that have helped Oregon to reduce the number of uninsured in the state include: The Family Health Insurance Assistance Program, a subsidy program that helps low income residents to purchase private or employer-based coverage; The Oregon Medical Insurance Pool, a program within OHP that helps high-risk residents who are unable to obtain health coverage due to medical conditions; and The Insurance Pool Governing Board, which helps small businesses and self-employed residents obtain health coverage for themselves and/or their dependents.
[19] November 2003 "First of Month" report by county for fully capitated health plans, fee-for-service, and primary care case managers. *State of Oregon, Office of Medical Assistance Programs.* Available at: http://www.dhs.state.or.us/healthplan/data_pubs/enrollment/1103/fchp_1103.pdf Accessed December 11, 2003.

public meetings to help officials decide which services should be covered under OHP and how these services should be prioritized.[20] By law, major changes to the OHP benefit must be presented for community input. The development of Oregon's PMPDP described in detail below, places similar emphasis on public participation and transparency.

Current Medicaid Budget Situation

Like most states, Oregon has encountered significant fiscal challenges, which has made it difficult for the state to continue to operate OHP in its current form. Oregon has no sales tax and the legislature is bound by law to return any additional revenue above two percent to taxpayers at the end of each fiscal year. Within OHP, enrollment and service utilization has exceeded projections, and Medicaid fee-for-service spending continues to climb as low reimbursement rates force many Medicaid managed care organizations to pull out of the program.

In this environment, Oregon's Medicaid cost containment efforts have begun to focus on the prescription drug benefit. Prescription drug spending accounted for 62 percent of the increase in OHP costs during the past decade[21] and in 2001, prescription drugs accounted for 26.5 percent of the OHP budget.[22] State officials expected that between the 1999-2001 budget cycle and the 2001-2003 budget cycle, drug expenditures for the Medicaid program would increase by 60 percent.[23] To address this issue, the state turned to a PDL strategy for OHP in 2001.

III. AUTHORIZATION OF OREGON'S PREFERRED DRUG LIST

The campaign to create a PDL for the OHP fee-for-service population was driven largely by the OHP champion and former state governor, John Kitzhaber, MD. Governor Kitzhaber wanted to address the rise in prescription drug costs by creating a marketplace where drug manufacturers would compete on price for clinically equivalent drugs. As a physician, Governor Kitzhaber argued that pharmaceutical manufacturer direct-to-consumer advertising campaigns created market demand for high priced drugs that lacked adequate clinical grounding.[24] He won support for his PMPDP model as he emphasized that the program would be voluntary for physicians and that it would exempt several controversial categories of drugs.

The voluntary nature of the PDL proved important in gaining the legislative authority to implement the new policy. An initial PDL bill, House Bill (HB) 3300, died in the House after patient and manufacturer groups lobbied heavily against the idea of creating a more

[20] Silow-Carroll, S., et al. Assessing State Strategies For Health Coverage Expansion: Case Studies of Oregon, Rhode Island, New Jersey, and Georgia. *The Commonwealth Fund*, November 2002.
[21] "State Draws up First Prescription Drug List," *Associated Press Newswires*, June 15, 2002.
[22] Oregon Department of Human Services, Finance and Policy Analysis, Office of Rate Setting.
[23] Gold, R. "Oregon's New Track on Drug Prices," *The Wall Street Journal*, August 1, 2001.
[24] PBS Web site. PBS Frontline, The Other Drug War: The Battlefield in the States. Available at: http://www.pbs.org/wgbh/pages/frontline/shows/other/etc/states.html. Accessed June 23, 2003.

restrictive formulary for OHP. According to Kitzhaber, pharmaceutical manufacturers had more than one lobbyist for every four legislators and worked hard to prevent the bill from ever leaving the committee.[25]

This experience prompted Governor Kitzhaber to work closely with legislative leaders at the end of the 2001 session to draft favorable PDL language that could win bipartisan support. The governor campaigned aggressively for a new bill, SB 819, estimating $7 million in savings for 2002, its first year in operation, and $17.5 million in savings during the 2003 to 2005 biennium budget cycle.[26] The governor further threatened to veto the Department of Human Services' budget if the PDL language was not passed. SB 819, which authorized the PMPDP, passed the legislature by a comfortable margin on the last day of session and was signed into law in August 2001.

After SB 819 was signed into law, there were some unsuccessful attempts to halt the implementation of the PMPDP. One month before the new program went into effect, the Joint Commission on Health Care Costs and Trends, a panel of nine legislators that oversees health policy, asked to delay the program's launch due to concerns regarding the state's PDL decision-making process. These legislators, who some interviewees speculated were under pressure from pharmaceutical lobbyists, were concerned that in the absence of clear evidence regarding drugs' comparative effectiveness, the state was creating a predominantly price-driven list. Such delay tactics failed, however, since the legislators ultimately did not have the authority to stop the program.

The PDL authorization language contained in SB 819 differs from other state precedents on many fronts; some interviewees referred to these differences to help explain the initial absence of heavy lobbying against the program. (Appendix C contains the PDL mandate included in SB 819.) Most importantly, the PMPDP was to be practitioner managed—physicians, not state-hired pharmacists, were to have the final say regarding a patient's need for a particular drug. Writing "dispense as written" (DAW) or similar notations on a prescription was to ensure that a patient obtained a non-PDL product without delay.[27] This language, which in effect made the initial PDL voluntary, won the support of many strong activists in the state, including AARP. Beneficiary advocates and manufacturers also supported the mandates that all PDL drug selections must be made according to evidence-based research, and that patients must retain open access to all mental health, HIV/AIDS and cancer products.

[25] Ibid.
[26] Cook, R. "Bill Intended to Cut Prescription Costs: Legislature 2000," *The Seattle Times*, January 22, 2002.
[27] SB 819 (2001) SECTION 3. The language, "…a practitioner may prescribe any drug that the practitioner indicates is medically necessary," was presented to approving legislators to mean that a physician may write "do not substitute" or other similar phrases on the prescription to indicate medical necessity.

Select Language From SB 819

SECTION 2. It is the policy of the State of Oregon that a Practitioner-managed Prescription Drug Plan will ensure that:
(1) Oregonians have access to the most effective prescription drugs appropriate for their clinical conditions;
(2) Decisions concerning the clinical effectiveness of prescription drugs are made by licensed health practitioners, are informed by the latest peer-reviewed research and consider the health condition of a patient or characteristics of a patient,
including the patient's gender, race or ethnicity; and
(3) The cost of prescription drugs in the Oregon Health Plan is managed through market competition among pharmaceutical manufacturers by publicly considering, first, the effectiveness of a given drug and, second, its relative cost.

SECTION 3. (1) The Department of Human Services shall adopt a Practitioner-managed Prescription Drug Plan for the Oregon Health Plan. The purpose of the plan is to ensure that enrollees of the Oregon Health Plan receive the most effective prescription drug available at the best possible price.
(2) Before adopting the plan, the department shall conduct public meetings and consult with the Health Resources Commission.
(3) The department shall consult with representatives of the regulatory boards and associations representing practitioners who are prescribers under the Oregon Health Plan and ensure that practitioners receive educational materials and have access to training on the Practitioner-managed Prescription Drug Plan.
(4) Notwithstanding the Practitioner-managed Prescription Drug Plan adopted by the department, a practitioner may prescribe any drug that the practitioner indicates is medically necessary for an enrollee as being the most effective available.
(5) An enrollee may appeal to the department a decision of a practitioner or the department to not provide a prescription drug requested by the enrollee.
(6) This section does not limit the decision of a practitioner as to the scope and duration of treatment of chronic conditions, including but not limited to arthritis, diabetes and asthma.

SECTION 5. …(6)Notwithstanding subsection (3) of this section, the department may not limit legend drugs when used as approved by the federal Food and Drug Administration to treat mental illness, HIV and AIDS, and cancer.

Source: Oregon Senate Bill 819 (2001).

IV. OREGON'S PRACTITIONER-MANAGED PRESCRIPTION DRUG PLAN

When compared to other Medicaid PDLs, Oregon's PMPDP is distinctive in part due to the process by which the state selects preferred products. Final PDL selections are based on a multi-step process, which subscribes to the stated Oregon ethic of public and transparent health policy decisions, and which considers both a drug's effectiveness and cost. From the beginning, the state has marketed its PMPDP as taking a more evidence-based approach to Medicaid PDL decision-making.

This next section of the Report includes state officials' description of the steps Oregon takes to select preferred products for the PMPDP, and also perspectives on the state's implementation experience to date.

Drug Selection Process

The Players
In developing its PMPDP, Oregon Medicaid officials rely on input from many different organizations and government bodies. Below is a brief description of the key players who have a prominent role in the drug selection process.

- The Health Resources Commission (HRC)

SB 819 mandated that the PDL be established in an open, public process conducted by the HRC. The HRC was created in 1991 as a component of the OHP to conduct analysis and disseminate information regarding the effectiveness and cost of medical technologies.

In its role as coordinator of the PDL's development, the HRC appoints a subcommittee for each class of drugs under review. The HRC subcommittee members include physicians, pharmacists, nurse practitioners, other healthcare professionals, consumers, and patient advocates who volunteer their time to the effort. Each HRC subcommittee is responsible for developing a brief report for the Office of Medical Assistance Programs (OMAP); reports draw clinical conclusions in each drug class based on evidence-based reviews and public testimonies.

- Office of Medical Assistance Programs (OMAP)

OMAP, the office that administers OHP, is ultimately responsible for creating the list of preferred drugs based on clinical effectiveness conclusions contained in the HRC subcommittee reports and product costs. OMAP's goal is to create a list of preferred drugs that are the most clinically effective with the lowest costs. OMAP follows an administrative rule that all clinically equivalent drugs within 5 percent of the average wholesale price of the lowest costing drug in the class must be placed on the PDL.

- Oregon Evidence-based Practice Center (Oregon EPC)

OMAP contracts with the Oregon EPC to assist in the development of the state's PDL. Specifically, the HRC subcommittees rely on the Oregon EPC to search and review medical literature and answer a set of pertinent clinical questions the subcommittee develops for each drug class. The Oregon EPC, which is also contracted by the federal Agency for Healthcare Research and Quality (AHRQ) for certain research tasks, is a collaboration of the Oregon Health & Science University, Kaiser Permanente Center for Health Research, and the Portland VA Medical Center.

Using standardized methods, the Oregon EPC systematically reviews databases, peer-reviewed medial literature and dossiers submitted by pharmaceutical manufacturers. Evidence is specifically sought for subgroups of patients based on race, ethnicity and age, demographics, other medications and co-morbidities. The Oregon EPC submits a report to the HRC detailing evidence from the literature reviews; the report and the center's work focus solely on clinical and technical evaluations of the drugs.

- Stakeholders

After evaluating the literature reviews submitted by the Oregon EPC, HRC subcommittees listen to public comments and review materials submitted by any interested party during a series of public meetings. Meetings specifically allot time for public comment, questions, and testimony.

The Process
Soon after SB 819 was passed in 2001, Oregon Medicaid officials within OMAP selected twelve drug classes to be reviewed in the first year of the PMPDP's operations. To date, nine class reviews have been completed according to the following process. (This process is illustrated in Appendix D.)

- Step 1: HRC Forms a Subcommittee

For each drug class review, the HRC convenes a volunteer subcommittee of six to fifteen members, which may include experts and specialists familiar with the particular class, primary care physicians, specialty physicians, retail pharmacists, institutional pharmacists, nurse practitioners, attorneys, and consumer or patient advocates. The HRC subcommittee's role is to facilitate the evidence-based reviews, listen and weigh public testimonies, and advise OMAP on what the evidence shows regarding drugs in a class.

Different organizations throughout the state such as the Oregon Medical Association, the Oregon State Pharmacists Association, and AARP may make subcommittee member recommendations to the Governor, who approves all final appointees. All potential appointees are screened for conflicts of interest; individuals currently conducting any research for a manufacturer cannot participate on a subcommittee.

- Step 2: HRC Subcommittee Develops Key Questions

The HRC subcommittee consults with members of the Oregon EPC in public meetings to develop a list of the key questions that direct the drug class reviews. These questions cover three broad topic areas: (1) How do the drugs in the class compare in overall effectiveness? (2) How do the drugs compare in terms of safety and adverse effects? (3) Are there any subpopulations for which the safety and profile of the drug differ? Also at this time, the group determines which drugs will be included in the class and which health outcomes will be considered to determine a drug's effectiveness.

For example, the HRC non-steroidal anti-inflammatory drugs (NSAID) subcommittee decided to include COX-2 inhibitors and non-selective NSAIDs (ibuprofen) in the same therapeutic class. The HRC statins subcommittee determined that a product's effectiveness could best be estimated from evidence that a drug lowers the overall rate of heart attacks rather than just the ability to lower cholesterol levels. While input from the Oregon EPC is considered, the HRC subcommittee ultimately is responsible for making final decisions regarding the question list and category composition.

- Step 3: Oregon EPC Conducts Literature Reviews

Following the HRC subcommittee's determination of the key questions to be considered for a therapeutic class, researchers at the Oregon EPC conduct a series of medical literature reviews. Researchers rely on major medical databases including the Cochrane Library, MEDLINE, and EMBASE, to identify peer-reviewed literature for specific drugs in the class under review. Pharmaceutical manufacturers also can submit product dossiers, containing clinical and economic evaluation data, to the Oregon EPC. Each study is graded by the Oregon EPC with a "poor," "fair," or "good" ranking based on criteria developed by the researchers at the Center. Poor studies – for example a study in which the control group had characteristics that skewed the results – are not considered in the review. The researchers then form a matrix comparing the evidence reports with the key questions laid out by the HRC subcommittee. After the research is complete, the Oregon EPC delivers a detailed report to the HRC subcommittee detailing its research and findings.

- Step 4: HRC Subcommittee Evaluates the Oregon EPC Report

The HRC subcommittee then holds a series of public meetings to discuss the findings in the Oregon EPC report. Specifically designated meetings allot time for public comment, questions, and testimony. The HRC subcommittee assembles a shorter report based on the Oregon EPC review and subsequent verbal testimony and materials submission, which gets submitted to the full HRC for final approval. These documents focus solely on clinical conclusions about each drug class and do not address cost issues.

- Step 5: OMAP Conducts Cost Evaluations and Selects Preferred Drugs

The HRC submits approved reports to OMAP, which has the ultimate legislative responsibility for establishing and developing the PMPDP. OMAP reviews cost information in conjunction with the HRC's clinical recommendations. The cost analysis focuses first on the public average wholesale price (AWP) of each drug in the class under review. The lowest listed AWP among the drugs that satisfy important clinical considerations such as effectiveness, safety and prescribing ease, becomes the benchmark price for products in the class.[28] Next, OMAP determines the actual net cost of all other drugs deemed clinically comparable by the HRC. (The net cost considers maximum allowable costs, federal upper payment limits, federal Medicaid rebates, and any other discount given to the state.) In accordance with an administrative rule and a stated effort to achieve an inclusive PDL, OMAP includes on the list any drug that has a net price within five percent of the benchmark drug.

- Step 6: State Posts PDL Selections along with Supporting Evidence on State Website

[28] For example, in the long-acting opioid analgesics drug class the three cheapest drugs based on AWP, Methadose, methadone, and levorphanol, were not chosen as benchmark drugs due to their dosing requirements or associated stigmas given their use in addiction treatment. Instead, long-acting morphine sulfate was selected as the benchmark drug.

To maintain maximum transparency, the Office for Oregon Health Policy and Research (OHPR), which presides over the HRC, posts all of the results from the process on a state-run website, www.oregonrx.com. The website includes not only the final preferred product list, but also the HRC subcommittee reports and Oregon EPC reports for each drug class for all consumers to review. The website also provides updates to classes currently under review for the PMPDP and the times and locations for HRC subcommittee meetings for particular drug classes.

- Step 7: HRC Subcommittees Reevaluate Drug Classes

One of the PMPDP goals is to ensure that drug selections reflect the most recent clinical evidence available. The HRC subcommittees meet every six months to re-evaluate each drug class and update or modify conclusions as appropriate. The OHPR is responsible for monitoring new medial literature that may contradict or lead to changes in the drug class, and for bringing any new evidence to the attention of the HRC subcommittee.

PMPDP Implementation

Oregon began rolling out the list of preferred drugs in August 2002. The state first reviewed proton pump inhibitors (PPIs), long-acting opioid analgesics, statins, and NSAIDs; a review of the estrogen class followed soon thereafter. In November 2003, triptans, skeletal muscle relaxants, oral hypoglycemics, and urinary incontinence drugs were added to the list. HRC subcommittees are currently reviewing calcium channel blockers, ACE inhibitors, and beta-blockers, which the state plans to add to the PMPDP at the beginning of 2004, bringing the total number of classes covered to twelve. (A list of preferred drugs and therapeutic categories covered by the PMPDP is included in Appendix E.)

For three of the first four classes reviewed—the long acting opioid, proton pump inhibitor, and NSAID categories—HRC subcommittee officials concluded that there was insufficient evidence in both the Oregon EPC literature reviews as well as verbal stakeholder testimonies to rate one drug clinically more effective or safer than another. For example, the HRC subcommittee for the long-acting opioid category stated in its final report that there was "insufficient evidence to draw any conclusions about the comparative effectiveness" for drugs in the class. In such cases, OMAP analyzed prices to make its product selections.

As mentioned briefly above, Oregon initially did not enforce the PMPDP as a mandatory Medicaid policy. Physicians had the option of writing "dispense as written," "DAW," "medically necessary," or "do not substitute" to ensure a non-preferred product would get dispensed to a patient. Pharmacists could also call prescribing physicians and accept a verbal "dispense as written" in the event that they received a prescription for a non-preferred drug without an explicit physician directive.

Governor Kitzhaber and others in the state worked to educate prescribers about the voluntary PMPDP, which resulted in some market share shifts to lower priced, preferred

products. For example, market share for preferred PPIs rose by 12.5 percent in the first two months (from 64 percent market share to 72 percent market share). Market share for non-preferred PPIs declined by 22.2 percent during the same time period (36 percent to 28 percent). In the NSAID category, market share for preferred drugs rose by 20.9 percent (43 percent to 52 percent), while non-preferred products' share declined by 15.8 percent (57 percent to 48 percent).[29]

Despite some market share shifts, allowing voluntary compliance with the PDL ultimately prevented the state from achieving savings targets critical in its current budget environment. The state had hoped to generate $7 million in savings during the 2002 fiscal year.[30] Oregon, however, was only able to save an estimated $3 to $5 million and achieve market share shifts of 20 to 25 percent during this time period.[31]

In response to this shortfall, on May 1, 2003, Oregon passed an administrative rule for the PMPDP mandating that, "the prescribing practitioner must call the Managed Access Program Help Desk to request an exception for medically appropriate drugs not listed in the PDL categories."[32] (Full text of the May 2003 administrative rule is included in Appendix F.) OMAP contracted with First Health Services Corporation (First Health), the state's claims administrator, to operate the new PA program in the state.

Oregon's PA process was less stringent than other state Medicaid PA precedents. Specifically, the state required doctors to call or send a fax to a pharmacy representative at First Health to seek approval to prescribe non-preferred drugs. Physicians (or other practitioners calling on behalf of the physicians) were only required to listen to or read an educational message regarding the PMPDP research and rationale for preferred drug utilization. First Health did not apply criteria nor did it have the authority to deny a doctor's request for PA, except for drugs treating diagnoses not covered in the OHP. State officials estimated that the new PA process could have allowed the state to save an additional $12 million during the 2003 to 2005 biennium.[33]

After adding what was considered to be only a "soft" PA requirement to the program, the state immediately experienced more dramatic market share shifts compared to when PMPDP compliance was voluntary. As illustrated in the table below for example, two months after the new policy was implemented, market share for preferred statin drugs rose by more than 250 percent (23 percent market share to 81 percent market share), while market share for non-preferred statins declined by 75.3 percent (77 percent to 19 percent).

[29] Market share calculations are based on internal state documents.
[30] Gold, R. "Oregon's New Track on Drug Prices," *The Wall Street Journal*, August 1, 2001
[31] Interview with a state representative.
[32] OAR 410-121-0030, (6)(a). May 2003.
[33] Cain, B. "Physicians not Supporting Cost-Saving Rule," *The Register-Guard*, July, 14, 2003.
[34] Market share calculations based on internal state documents.

Figure 1[34]

Market Share Shifts

Drug Class	2 Months After Implementing PMPDP: market share 7/02	2 Months After Implementing PMPDP: market share 9/02	2 Months After Implementing PMPDP: % change	2 Months After Adding PA: market share 4/03	2 Months After Adding PA: market share 6/03	2 Months After Adding PA: % change
PPI						
PDL drugs	64%	72%	12.5%	72%	79%	9.7%
Non PDL drugs	36%	28%	-22.2%	28%	21%	-2.5%
LA Opioid						
PDL drugs	58%	61%	5.2%	64%	82%	28.1%
Non PDL drugs	42%	39%	-7.2%	36%	18%	-50.0%
NSAID						
PDL drugs	43%	52%	20.9%	55%	79%	43.6%
Non PDL drugs	57%	48%	-15.8%	45%	21%	-53.3%
Statin						
PDL drugs	11%	12%	9.1%	23%	81%	252.2%
Non PDL drugs	89%	88%	-1.1%	77%	19%	-75.3%

Challenges to the PMPDP

In September 2002, Purdue Pharma filed a lawsuit against Oregon objecting to the state's decision to omit the company's long acting opioid, OxyContin, from the PDL.[35] The lawsuit, which is still pending, specifically challenges OMAP's consideration of costs when selecting products.

Beginning in May 2003, OMAP's authority to enforce the PMPDP with a new PA requirement was challenged. Opponents emphasized the SB 819 mandate that "a practitioner may prescribe any drug that the practitioner indicates is medically necessary,"[36] and pressured legislators to add language to a new bill, HB 3624, which explicitly prohibits OMAP from continuing with the PA policy. The bill passed at the end of the 2003 legislative session with the following mandate:

> "The Department of Human Services may not adopt or amend any rule that requires a prescribing practitioner to contact the department to request an exception for a medically appropriate or medically necessary drug that is not listed on the Practitioner-Managed Prescription Drug Plan drug list for that class of drugs adopted under ORS 414.334, unless otherwise authorized by enabling legislation setting forth the requirement for prior authorization."[37]

In response to HB 3624, OMAP revoked the PA requirement in November 2003, and will instead focus on its new Prescription Change Form Process to promote PDL compliance. Through this process, Oregon will analyze prescription drug claims data to identify

[35] Appleby, J. "Oregon's List of Preferred Drugs Skips Some Big Names," *USA Today*, October 10, 2002.
[36] Oregon Senate Bill 819 (2001) SECTION 3, subsection 4.
[37] House Bill 3624 (2003) Enrolled.

physicians who are prescribing non-preferred products. The state will mail letters to physicians explaining why a particular drug is not preferred, providing cost savings information on the preferred alternative. The mailing will also include a form that can be faxed to a pharmacy to switch a patient to a preferred product. Oregon State University's College of Pharmacy is helping the state to develop and run the program.

Emerging Initiatives

Oregon's PMPDP development process has captured the interest of other state Medicaid programs and many consumer groups. One of the most vocal supporters of the state's efforts has been AARP. AARP has collaborated with Oregon to help publicize the PMPDP's clinical reviews, conducting educational presentations around the state and posting consumer guides and links to the official research reports on an increasingly popular AARP Oregon Rx web site.[38] AARP's stated goal is to encourage all individuals to reference Oregon's objective prescription drug research and to become more informed healthcare consumers. The organization also has been active in encouraging other state Medicaid programs to follow Oregon's approach when developing their own PDLs.

Many Medicaid directors and state legislators perceive an opportunity to leverage Oregon's extensive efforts to design a clinically based PDL that can potentially win greater support among Medicaid stakeholders. In response, a group of former Oregon officials have been working to form a multi-state consortium to enable states to pool resources to sponsor ongoing, evidence-based prescription drug research. Specifically, the new OHSU Center for Evidence-based Policy is serving as a coordinator of the effort, and plans to work with the Oregon EPC and other evidence-based practice centers around the country to conduct therapeutic class research for consortium subscribers. Member states have a voice in selecting the drug classes to be reviewed by the centers and the key questions to drive the research.

Organizers of this multi-state effort emphasized that while members of the consortium will leverage the same body of prescription drug research, each state will maintain total control over how this information translates into PDL selections. Organizers explained their goal to "globalize the evidence, and localize the decision"—i.e., while gaining access to the same evidence, each state may still have its own committee of physicians, pharmacists, and other specialists to interpret the evidence based on local practice habits. Actual PDL implementation decisions (e.g., prior authorization requirements, supplemental rebate strategies, process to incorporate public feedback) will also vary by state.

Washington, one of the participating states, provides an example of how two Medicaid programs can act upon the same information differently. The Washington Drug Utilization and Education Council, the committee of specialists reviewing the evidence, concluded that superiority of a triptan drug with respect to one short-term outcome made it the best in its class, whereas Oregon's HRC subcommittee decided that unless a drug

[38] According to AARP, the website, http://www.aarp.org/wiseuse/oregon-research.html, received 18,000 hits within the first six weeks of its posting.

demonstrated superiority for a long-term outcome measure, it was not the best triptan. Washington is also using a slightly different cost evaluation process that may result in fewer drugs per class on the preferred list when compared to Oregon's.

To date, eight states along with the California HealthCare Foundation/California Public Employees' Retirement System (CalPERS) and a nonprofit technology assessment group funded by the Canadian government have contracted to join the multi-state effort. Negotiations with another nine organizations are ongoing. The group will inherit the twelve prescription drug class reviews completed or in the process of being completed by the Oregon EPC. Participants are now focusing efforts on reviews for angiotensin receptor blockers and second generation anti-depressants, including selective serotonin re-uptake inhibitors.

V. PERSPECTIVES ON OREGON'S PRACTITIONER-MANAGED PRESCRIPTION DRUG PLAN

The interview sample for this Report included representatives from each of the key Medicaid stakeholder groups involved in and/or affected by the state's new PMPDP. The following chart includes interviewees' general impressions about the initiative.

Represented Groups/Organizations	Views Expressed in Interviews
Oregon Department of Human Services[39]	• Oregon EPC's distance from commercial influences enhances the PMPDP process. • Process transparency was critical to gaining stakeholder support for the program. • Maintaining a voluntary compliance policy was not possible given education challenges and current budget environment. • PMPDP process highlights need for higher quality research on drugs' comparative clinical effectiveness.
Beneficiary Advocates	• PDL mandates included in SB 819 – evidence-based research, drug exemptions, voluntary compliance, and open process – create useful model for other state Medicaid programs. • Evidence-based research processes generally can benefit all consumers and prescribers. • While the process was transparent, the state did not always value public participation. • PA processes restrict beneficiary access to necessary drugs; physician profiling and education efforts should replace any attempts at a PA policy.
Pharmaceutical Manufacturers	• Oregon's PA policy did not comply with the legislative mandate contained in SB 819.

[39] Interviewees included past and current officials within OMAP, OHPR, the HRC, and the Governor's office.

Pharmaceutical Manufacturers, continued	• The absence of clinical data to differentiate products does not give Oregon Medicaid license to select preferred products on the basis of cost. • Important patient data sometimes were not considered given the Oregon EPC's stringent literature reviews and absence of specialists' perspectives in some therapeutic category review processes. • Other state Medicaid programs should not develop PDLs with strict PA based solely on the Oregon EPC's literature reviews.
Physicians	• It is critical to include providers in the PMPDP development process and include specialists' perspectives and consensus guidelines in final recommendations. • Support for the PMPDP waned somewhat when the PA requirement was temporarily added. Any PA requirement can detract from patient care and burden a practice. • While the PMPDP process generates valuable research, providers have not been adequately educated on the effort.
Pharmacists	• PDLs can help to lower prescription drug spending and deflect attention from pharmacy reimbursement rates. • Additional communication with pharmacies regarding the "dispense as written" exemption was necessary when the PMPDP was launched.

State Perspectives

The state argued that the Oregon EPC's distance from commercial influences enhances the PMPDP process.

Oregon's goal in launching the new PMPDP was to create a "Consumer Reports"-style PDL; doctors should be confident that the list includes effective drugs according to the most recent evidence-based research. State interviewees emphasized the importance of having an independent and well-respected entity conduct clinical research for the PMPDP. The Oregon EPC is one of thirteen institutions across the country selected to serve as a federal Agency for Healthcare Research and Quality Evidence-based Practice Center. According to the state, this affiliation endorses the legitimacy and comprehensiveness of the Center's research methods, making it more difficult for manufacturers and other outside groups to challenge the research basis of the state's process. Researchers at the Center also can operate independent of special interests, which is important to the state's efforts to maintain the PMPDP's reputation as a "clinically-focused" PDL. Interviews with a representative from Washington state pointed to the Oregon EPC affiliation as an important driver in Washington's decision to leverage Oregon's prescription drug research.

Process transparency is critical to obtaining public support for new policies; according to Oregon officials, the open PMPDP process has not compromised the quality of the state's PDL decisions.
Interviewees referenced Oregon's history of pursuing open, public processes when developing and implementing new policies. According to one individual, "openness is an Oregon ethic that transcends all health policies" and was important to gaining public support for the PMPDP. Specifically, policymakers wanted to guard against any misperceptions that the state was making drug selections according to special interests, "behind closed doors."

Oregon's open process prevented some manufacturers from submitting what they considered to be confidential clinical information about their products. In program guidance sent to manufacturers, the state indicated that, "it is the submitter's responsibility to limit dossier information submitted [to the state to only] data and information that may be publicly disclosed."[40]

State officials did not share the concern of some manufacturer interviewees, who felt that omitting companies' proprietary information potentially compromised the clinical quality of the PDL decisions. One interviewee from the state said that manufacturer dossiers typically include more marketing and economic information. Another interviewee with P&T committee experience expressed the opinion that "if the clinical research [contained in such dossiers] had a strong scientific grounding, then a manufacturer most likely would not be afraid to share such results in public."[41]

Oregon officials explained that the PMPDP process highlights the need for industry to conduct higher quality clinical research studies on drugs' effectiveness.
In some therapeutic categories reviewed to date, the Oregon EPC and HRC subcommittees lacked adequate information to answer many of the specific questions comparing drugs' clinical effectiveness. In some of their reports, subcommittee members indicated that there was "insufficient evidence to draw any conclusions about the comparative effectiveness, nor incidence and nature of adverse events"[42] between drugs. For example, the Oregon EPC reported that the "data regarding comparative efficacy and comparative adverse event rates of long-acting opioids are quite limited."[43] Further it was not possible to draw any reasonable conclusions about "…the comparative efficacy…for specific subpopulations as characterized by race, gender, or age."[44]

Officials expressed concern that manufacturers sponsor most clinical studies currently, and that such studies may be designed to reflect favorably on a company's products and

[40] The Office for Oregon Health Policy and Research Web Site. The Oregon Health Plan Practitioner-Managed Prescription Drug Plan Submission Protocol, Version 2.0. Available at: http://www.ohppr.state.or.us/index.htm. Accessed May 12, 2003.
[41] Interview with a state official.
[42] Language found in the Oregon Health Resources Commission's subcommittee reports for proton pump inhibitors (June 2002) and long-acting opioid pain killers (June 2002).
[43] Chou, R and Clark, E. Drug Class Review on Opioid Analgesics for Non-Cancer Pain. *Oregon Evidenced-base Practice Center*, April 9, 2002.
[44] Ibid.

obtain regulatory approval. Officials hope that Oregon's process—and potentially processes in other states looking to leverage Oregon's experience—will encourage manufacturers and academic researchers to pursue new, high quality research that can more directly address the state's PMPDP questions in future reviews.

According to state officials, budget pressures along with the challenge of promoting voluntary PDL compliance made the attempt to implement a PA enforcement policy inevitable.

In launching the PMPDP, Oregon officials hoped that a number of factors would encourage prescribers to voluntarily comply with the new list. For example, they believed that doctors would choose to use preferred products once they understood the clinically based selection process. The administration also hoped that Governor Kitzhaber's background as a physician would present an advantage as he championed the program among his peers. Soon after the PMPDP's list was created, Governor Kitzhaber and other physicians within the Department of Human Services launched an educational campaign throughout the state. They promoted the program at physician meetings and solicited help from the Oregon Medical Association (OMA) and physician members of the HRC in publicizing the clinical research.

State officials ultimately determined that more physician outreach and education were needed for the program to remain voluntary and still achieve necessary savings targets. Interviewees from the past and current administrations emphasized that physician detailing activities and a closer collaboration with the OMA to promote the list may have been helpful. Because of the state's fiscal crisis, however, resources to run a more effective educational campaign were not available. While the program gained national attention largely because of support from AARP, it remained difficult to connect with rural Medicaid providers throughout the state. Interviewees also noted the challenge of countering manufacturers' campaigns to encourage physicians to include DAW instructions when prescribing non-preferred products.

The state indicated that it designed the PA requirement to present an educational opportunity for providers, versus impose a heavy administrative burden on their practices.

After nine months of operating the PMPDP with voluntary compliance, Oregon officials felt that pressures to meet certain savings goals compelled them to implement a new PA enforcement policy. Oregon's market share shifts and cost savings during these initial months did not compare to results publicized in some other states with more rigorous Medicaid PA programs, and were inadequate to meet savings goals.[45]

Unlike other states, however, Oregon designed its PA requirement not as a burdensome deterrent for physicians, but rather as an opportunity to inform prescribers about the research basis underlying the state's product selections. Prescribers only had to contact

[45] Michigan's PDL, enforced with PA, affecting 300,000 Medicaid beneficiaries and containing over 44 therapeutic classes, reportedly saved the state over $45 million during its first year in operation. Oregon's PDL, affecting 150,000 Medicaid beneficiaries and containing 5 therapeutic classes, was estimated to save the state between $3 and $5 million during its first year.

the state to listen to or read an educational message regarding preferred products before obtaining PA. However, some physician interviewees admitted that, given busy practice schedules, it was unlikely that they and their colleagues would spend the time to listen to the state's messages.

The state had hoped that even its "soft" PA policy would create incentives for manufacturers to offer supplemental rebates and that the enforcement would affect market share shifts necessary to achieve an additional $12 million in savings per year.[46] As HB 3624 prohibits the state from using PA in the PMPDP, Oregon officials recognized that new forms of enforcement were necessary to achieve significant savings.

Beneficiary Advocate Perspectives

Beneficiary representatives acknowledged that Oregon's evidence-based research process produces prescription drug information that can benefit all consumers and prescribers.
Some beneficiary organizations—most notably representatives from AARP—described Oregon's PMPDP research results as an objective tool to help consumers understand the literature on different drugs' effectiveness. Interviewees mentioned several characteristics of the PMPDP process that gave them comfort in supporting this position. First, the process is open and beneficiaries are represented on the committees tasked with making drug selection recommendations. Second, the process of analyzing a therapeutic class generally takes several months to complete, which allows plenty of time for researchers and state officials to consider many important factors when making selections. Third, the process is transparent; beneficiaries, physicians and other Medicaid stakeholders are aware of the questions and evidence that drive drug selections. Fourth, the state is committed to allowing independent researchers at the Oregon EPC review the clinical evidence, and the Oregon EPC has a credible, unbiased reputation. Finally, the review process is ongoing; subcommittees are supposed to review new evidence every six months to ensure selections appropriately meet beneficiary needs.

Beneficiary advocates noted that the mandates for evidence-based research, drug exemption, voluntary compliance, and open process mandates included in SB 819 present a useful model for other states pursuing Medicaid PDLs. SB 819's patient protections minimized beneficiary resistance.
Compared to other PDL states such as Florida and Michigan, Oregon did not confront significant beneficiary opposition when launching the new PMPDP. While most beneficiary representatives across the country consistently have spoken out against very restrictive PDL and other Medicaid policies, Oregon-based groups supported SB 819 because it included many important patient protections. Specifically, the new law mandated that physicians must have the final say in whether a beneficiary can obtain a non-preferred product. This language was thought to protect against the state adopting a strict PA requirement. Advocates were also pleased that all product selections were to be informed by evidence-based research (versus special interests), and that sensitive mental health, HIV/AIDS and cancer products would be exempt from the policy. Finally,

[46] Cain, B. "Physicians not Supporting Cost-Saving Rule," *The Register-Guard*, July, 14, 2003.

advocates supported the state's commitment to following an open, transparent process when selecting preferred products.

Beneficiary advocate interviewees supported SB 819 as a PDL model for other states to pursue when such a policy is inevitable. As mentioned above, AARP became the most vocal supporter of the PMPDP, actively working with other states to promote adoption of Oregon's research process. While AARP's and other groups' support for Oregon's PMPDP did continue even when the state added the PA requirement, some interviewees noted that their original endorsement of the policy was heavily based on the state's promise to maintain voluntary compliance.

Although Oregon's PMPDP development process was transparent, some beneficiary advocates felt that the state did not appropriately seek and value public input when it implemented the PA requirement.
Advocates especially questioned Oregon's commitment to incorporate public feedback when the state pursued the new PA policy in April 2003. Most beneficiary advocate interviewees objected to the state's decision to enforce the PMPDP through PA procedures, and challenged officials' authority to institute this change.

Other complaints from beneficiary stakeholder groups about the PA administrative rule focused on the state's failure to adequately publicize meeting times. Also, some beneficiary advocates were only permitted to present testimonies to staff members who recorded their message at these meetings, versus in front of a live audience of policymakers. They felt that such a format decreased the presentation impact and provided no guarantee that testimonies were actually heard. Further, one beneficiary advocate explained that it became clear that OMAP would not consider testimony representing beneficiary interests when the office mailed letters to providers to notify them of the PA policy change before the date when beneficiary testimony was to be heard. (Some manufacturer representatives also complained generally about being notified of state PMPDP meetings only two to three days in advance, leaving little time to collaborate with physicians to testify on their behalf.)

According to beneficiary representatives, Oregon's PA process restricted patient access to necessary drugs; physician profiling and education efforts should replace any attempts to enforce PA.
While beneficiary advocates appreciated Oregon Medicaid officials' need to increase compliance with the PMPDP given current budget pressures, many emphasized that physician profiling and education efforts should enforce the PMPDP, instead of a PA policy. Some interviewees referred to the Department's attempt at a PA policy as a "quick, bureaucratic solution to save money," potentially restricting access to necessary drugs for the most vulnerable populations, which typically remain in Medicaid fee-for-service. Representatives emphasized that the state should seek to obtain savings through improved PMPDP educational efforts coordinated through physician specialty organizations, and through profiling activities that identify poly-pharmacy, incorrect dosing and other potential quality concerns.

Pharmaceutical Manufacturer Perspectives

Manufacturers argued that Oregon's PA policy did not comply with the legislative mandate contained in SB 819.
Like beneficiary advocates in the state, pharmaceutical manufacturers supported the PDL mandate included in SB 819. Manufacturer lobbyists in the state pushed heavily for the specific language in the bill requiring Medicaid officials to consider clinical evidence when weighing PDL decisions and to give physicians the final say in whether a patient needed access to a non-preferred product. Manufacturers also worked hard for the passage of HB 3624 in the 2003 legislative session, to reverse the Department's administrative rule requiring PA for non-preferred products, and explicitly clarify that legislation is necessary for the Department to add PA to the PMPDP in the future.[47]

Manufacturers emphasized that the absence of clear clinical evidence indicating one drug's effectiveness versus another does not give Oregon Medicaid officials license to select preferred products based on cost.
Interviewees from the drug industry consistently described a fundamental difference between the way the state and industry interpreted the clinical analysis conducted by the Oregon EPC and HRC subcommittees. While manufacturers generally agreed on the appropriateness of the questions driving the Oregon EPC's clinical assessment, they firmly opposed the state's position that when there was "insufficient evidence to draw any conclusions about the comparative effectiveness,"[48] the state could select preferred products based primarily on cost. Manufacturer representatives maintained that the lack of evidence made it inappropriate to treat drugs in particular classes as clinically equivalent. As one interviewee explained, "Instead of waiting for more studies [to more directly address the state's questions], the state wrongfully moved ahead and made decisions based solely on cost. When significant evidence is lacking, all drugs should be included on the list."[49]

Manufacturer representatives challenged aspects of the state's review process, particularly the Oregon EPC's stringent literature reviews and the lack of specialist perspective in some of the HRC committee processes. Some manufacturer representatives were not content that the EPC only considered randomized controlled trial information when assessing products' clinical effectiveness. They emphasized that the Oregon EPC reviewers do not consider information from observational databases[50] or practice guidelines developed by state or national physician societies that can reflect important physician and patient experience data not captured in randomized controlled trials. Especially in classes in which the randomized controlled trial information is inadequate to address outstanding effectiveness questions, disease registries and other patient claims databases may enhance the understanding of how different patients react to

[47] House Bill 3624 (2003) Enrolled SECTION 22.
[48] Proton Pump Inhibitor Subcommittee Report. *Oregon Health Resources Commission*. June 2002.
[49] Interview with a pharmaceutical manufacturer representative.
[50] Observational databases include patient information that can be collected for a variety of purposes and can be studied retrospectively to address a specific clinical question. Examples include the ARAMIS database, http://aramis.stanford.edu/ and the Oregon Diabetes Collaborative registry database, www.ompro.org/diabcollab/index.html.

different products in real world settings (versus a controlled environment). Similarly, some physician guidelines may reflect clinicians' perspective on treating a certain ethnic or other subgroup of the population not followed in a particular study.

Manufacturers also raised concerns about the disproportionate number of white males as subjects in randomized clinical trials; the Oregon EPC's heavy reliance on such studies may lead to treatment recommendations that are not sensitive to the needs of certain ethnic groups which account for a large proportion of some Medicaid populations. As stated above, state officials emphasized that manufacturers fund the majority of these studies, and they hope that the state's review process will encourage manufacturers and other entities to pursue new research to address unanswered questions in the literature.

In defending its decision to establish a high bar for the data considered in the Oregon EPC process, state officials emphasized their commitment to exclude *any* potential bias from the pharmaceutical industry. While observational studies may be included to examine potential safety issues for a class of products (versus efficacy), physician guidelines are not considered given the risk that a guideline development process may be directly sponsored by a manufacturer.

One manufacturer representative noted the lack of physician specialists on some of the HRC committees, which are responsible for generating questions for the Oregon EPC to consider in its literature review, and also preparing final recommendations for OMAP. Specific concerns focused on the statin and NSAID committees. Subcommittee members listed in the state's statin September 2003 update report did not include any cardiologists or endocrinologists. The NSAID August 2003 update report did not list any members specializing in gastroenterology or cardiology, specialties that deal specifically with the benefits and side-effects of NSAIDs versus COX-2 inhibitors. Oregon does not include any COX-2 inhibitor drugs on its PDL.

While individuals involved in the state's process acknowledged some challenge in identifying specialists without any ties to the pharmaceutical industry in certain fields, they stated that there was always an appropriate mix of experts engaged on the committees and that the public meeting process allowed manufacturers and other stakeholders ample time to participate and ensure that their perspectives were heard.

Manufacturers felt that their proprietary clinical data could not always be submitted in the review process because of inadequate confidentiality protections. Some manufacturer interviewees believed that Oregon's clinical approach was compromised by the fact that inadequate confidentiality protections prohibited some companies from submitting important product information. Manufacturers often prepare clinical dossiers, which contain disease product information, clinical and economic data from published and unpublished studies, and disease-based economic models that project the potential health and financial consequences of new product utilization in a market. The PMPDP submission protocol sent to manufacturers clearly indicated that all

submitted data, including manufacturer dossiers, would become part of the public record.[51]

Manufacturers contrasted Oregon's approach to other state Medicaid PDL and managed care formulary processes, in which such information generally is considered confidential. Oregon Medicaid officials defended their commitment to developing the PMPDP in an open, public process, and did not feel an exception should be made to protect confidential clinical dossiers.

Manufacturers expressed concerns regarding the potential for other state Medicaid programs to rely solely on the Oregon EPC's research to implement PDLs enforced with a strict PA policy. While Oregon may present a useful model for pursuing an open, transparent process to develop its PMPDP, manufacturer interviewees emphasized that other Medicaid programs should not adopt Oregon's approach to selecting preferred products in the absence of clear clinical evidence. Industry representatives argued that the state should not promote drugs as clinically equivalent products when clinical literature does not support such a claim. If Oregon's PDL continues to be marketed as a "clinically-based PDL," other Medicaid programs, large HMOs and other drug purchasers may adopt policies of restricting patient access through PA to drugs not recommended by Oregon, which may result in patient harm.

In considering the multi-state initiative, manufacturer interviewees also were concerned that it will become increasingly difficult to ensure that local specialists' clinical perspectives are reflected in the question development process and the analysis of the Oregon EPC's research results as more states engage in the effort. Demographic differences and varying physician experiences across states may not be accounted for.

Physician Perspectives

Physicians interviewed noted that their participation in the PMPDP development process is important to create physician support for the policy.
Physicians generally find it difficult to accept practice guidance or treatment restrictions if they or respected peers are not involved in the development of such policies. Physicians interviewed for this Report appreciated Oregon's efforts to include physicians on the HRC subcommittees responsible for recommending preferred products to the state Medicaid agency. Moreover, some physician association representatives stated early in the state's review process that they did not have difficulty recruiting physician volunteers for the subcommittee appointments, despite busy practice schedules and the four to five day obligation over a six-week period. Physician participation and the extensive evidence-based reviews help to ensure that the PMPDP is not completely cost-driven and in the opinion of one interviewee, "gave the PMPDP more merit versus private sector HMO formularies."

[51] The Office for Oregon Health Policy and Research Web Site. The Oregon Health Plan Practitioner-Managed Prescription Drug Plan Submission Protocol, Version 2.0. Available at: http://www.ohppr.state.or.us/index.htm. Accessed May 12, 2003.

Other physicians, however, emphasized the importance of the HRC including all specialists' perspectives in final recommendations to ensure new policies concur with physician practice standards and guidelines. For example, one Oregon rheumatologist expressed concern at an HRC subcommittee meeting that the state's decision to exclude COX-2 inhibitors from the NSAID class contradicted the practice "guidelines [that are] based upon consensus experts as well as evidence-based medicine…[from] the American Academy of Family Medicine, American College of Rheumatology, American Geriatric Society, and the American Pain Society."[52] Dr. Elizabeth Tindall from the Oregon Rheumatology Alliance further challenged the state's conclusions, stating that:

> "Our Physician Statement on COX-2 drugs is on our Web site, and this basically does refute the conclusions of this group (NSAID HRC subcommittee) in that we feel that selective COX-2 inhibitors have been shown to significantly reduce GI complications when compared to nonselective agents. But the cost savings of having reduced GI complications in high-risk patients more than compensate for the increased cost of COX-2 inhibitors under current market conditions."[53]

Physicians considered the voluntary compliance feature and clinical review process as critical for generating physician support for the PMPDP policy when it was first announced.

As its title indicates, the PMPDP was originally designed explicitly as a "practitioner-managed" policy in which physicians were to have the ability to prescribe any non-preferred product with relative ease. The physician community supported this unique approach to Medicaid PDL policy and appreciated Oregon's inclusion of physicians in the program development process. Physicians also applauded the state's effort to conduct evidence-based reviews, even though as one physician explained after reading several HRC subcommittee reports, "…basically it appears that [the state] couldn't find much evidence to rule one drug better than another…which brings the PMPDP process back to price, which is exactly what currently happens in managed care plans."[54]

Physician support for the PMPDP waned when the PA policy was implemented, as providers felt that any PA requirement can detract from patient care and create administrative burdens for a practice.

Some physician interviewees working in practices treating large Medicaid fee-for-service patient populations complained about the PMPDP's temporary PA requirement. Although the state emphasized that PA was not difficult to obtain, physicians warned that any policy requiring the office to make a phone call detracts from patient care, could harm beneficiaries, and ultimately cost the state more money. For example, a nurse in one physician's office explained that although most of the claims are approved, the process is still burdensome since it requires multiple faxes with First Health for each

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[52] Oregon Health Resource Commission Meeting Minutes. August 22, 2003, 1:30 PM to 4:30 PM. Available at: www.ohpr.state.or.us/hrc/pdf/Minutes/8-22-03%20HRC%20Minutes.pdf. Accessed December 10, 2003.

[53] Ibid. The August 2003 NSAID HRC subcommittee report states that, "Even though evidence may demonstrate decreased adverse gastrointestinal events of C0X-2 inhibitors compared to other non-steroidal anti-inflammatory agents, limitations of studies currently available for review preclude a confident conclusion overall that these are clinically significant safety advantages."

[54] Interview with an Oregon physician.

prescription. Physicians also feared that the PA rules could become more of a "nuisance" for their practices over time.

Although Oregon's PMPDP process results could assist physicians in remaining current with the latest clinical effectiveness studies, physicians explained that the state's educational efforts about the initiative have been insufficient to accomplish policymakers' goals.
Provider interviewees knowledgeable about the PMPDP research process emphasized the importance of Oregon's thorough and independent clinical reviews. Some beneficiary advocates also acknowledged that while physicians ultimately should have final control over prescribing decisions, both physicians and patients could benefit from referencing Oregon's therapeutic category reviews to understand current research findings.

Interviewees, however, expressed concern that the state did not adequately promote the research among physicians. Educational campaigns must be developed to make the research appropriately relevant to various types of providers, such as family practice physicians and internists. Providers admitted that this task can be difficult given that physicians in general are overwhelmed with educational materials. Providers and state officials also acknowledged that the "process is better understood at the national level than it is at the local level, especially among rural physicians." In other words, while AARP and other states are attracting policymakers' attention to the PMPDP, rural Oregon physicians that are not engaged in the process may not be aware of the clinical reviews.

Pharmacist Perspectives

Pharmacists felt that PDLs in general can help to lower prescription drug spending and deflect attention from pharmacy reimbursement rates.
Pharmacists in Medicaid PDL states consistently do not speak out against such policies as a tool to contain rising prescription drug spending. In Oregon, pharmacists' organizations neither supported nor opposed the PMPDP as detailed in SB 819; the voluntary compliance policy decreased the program's savings potential. In the months that PA was implemented, however, pharmacists were more vocal in backing the policy, viewing the PMPDP as a cost saving tool that potentially minimized the risk that policymakers would attempt to reduce pharmacy reimbursement rates.

Pharmacists believed that additional communication with pharmacies regarding the "dispense as written" exemption was necessary when the PMPDP was launched.
Pharmacists experienced some administrative challenges due to the complexity of the original DAW policy when the PMPDP was launched. The state did not thoroughly explain the new requirements to pharmacists and did not address inconsistencies between the new policy and the operations of the existing point of sale system used by the state. Specifically, Oregon already had several DAW coding rules related to its existing generic policy (e.g., typing DAW0 into the system means "dispense as generic" and DAW1 means "dispense brand even though generic is available.") Failing to communicate

adequately with pharmacists before the program was initiated resulted in a meaningful amount of non-reimbursed, administrative time for pharmacists.

VI. CONCLUDING OBSERVATIONS

Oregon's is one of many state Medicaid programs that have turned to a PDL strategy to address rising prescription drug costs. States' experiences with these new initiatives must continue to be studied, as a clear model has not yet emerged to guide Medicaid officials in how to implement PDLs in a way that achieves targeted savings amounts with full assurance that beneficiary care will not be compromised. This Report detailing Oregon's policy successes and challenges raises several important observations and questions for Medicaid stakeholders nationwide who are interested in PDL developments.

Oregon's original efforts to design a PDL program with clear beneficiary protections and a commitment to run an open policymaking process were embraced by many key stakeholders.
In contrast to findings from two previous case studies of PDL efforts in Florida and Michigan, Medicaid stakeholder interviewees in Oregon expressed less resistance to and concern about the state's original PMPDP process. The Oregon legislature included several patient protections in SB 819. For example, it was mandated that the program use evidence-based studies to create the list of preferred products, and that the state could only make cost determinations *after* drugs' comparative effectiveness was considered. Drugs used for the primary treatment of mental health, HIV/AIDS, and cancer were explicitly exempted from the plan. SB 819 also directed the state to conduct public meetings around the program and coordinate with the appropriate clinical associations to ensure that providers were informed of the benefit changes. Most importantly, the legislature clearly stated that "a practitioner may prescribe any drug that the practitioner indicates is medically necessary for an enrollee…."[55]

Although many beneficiary and manufacturer stakeholders and some providers disagreed with Oregon's final list of recommended products and expressed concern about the Department's attempt to add a PA requirement, most interviewees appreciated the state's efforts to conduct a clinical review, and the relative transparency of the policymaking process when the PMPDP was originally implemented. It is unclear if the resistance Oregon faced when adding PA could have been managed had the state sought additional public input on the change. When implementing policies such as PA that are bound to generate opposition, states describe the challenge of creating public dialogue around the change while simultaneously moving forward swiftly in the interest of short-term savings goals.

States may have the opportunity to obtain greater stakeholder buy-in for PDL and other Medicaid cost containment policies if they pursue open policymaking processes and incorporate and publicize specific beneficiary protections. Making PDL decision-making processes and criteria more public, without disclosing confidential pricing and clinical

[55] Senate Bill 819 (2001) SECTION 3, subsection (4).

data, can help policymakers defend against common claims that states are developing important program changes "behind closed doors." Such claims recently surfaced in West Virginia, leading to legislative oversight committee hearings in which policymakers and Medicaid stakeholders requested testimony from the state's vendors to become more informed about the state's PDL process. Allowing key stakeholder groups an opportunity to help develop patient protections to which the state will be held accountable can also help to alleviate public backlash and ensure that beneficiary interests are maintained.

Oregon's implementation of a PA requirement highlighted the challenge of changing prescribing patterns without some type of enforcement mechanism. One of the key questions that guided the research for this Report was, "Will Oregon officials establish a model for how to achieve necessary Medicaid savings with a voluntary PDL, and will beneficiaries support this model?" A couple of states in the past several years have shifted from voluntary to mandatory PDL policies, and the question focused on whether Oregon's experience would be different and why.

The state can be credited for achieving some results with only a voluntary policy – for example, preferred NSAID products increased market share from 43 percent to 52 percent in the first two months of implementation. However, the agency concluded that this performance was inadequate to meet a $7 million savings goal in the first year. In May 2003, approximately nine months after launching the PMPDP, Oregon passed an administrative rule detailing new PA requirements for physicians seeking to prescribe non-preferred drugs to Medicaid beneficiaries.

While Oregon officials described some efforts to educate providers about the PMPDP and encourage compliance with the voluntary PDL, most acknowledged that "much greater education and outreach was needed." The state had hoped that the combination of Governor Kitzhaber's medical background along with physician meetings around the state to emphasize the clinically based selection process would generate provider interest in the PDL results. Such efforts did not prove to be enough to encourage behavior change and many interviewees explained that many providers—especially rural providers—still lacked a complete appreciation for the PMPDP research and its potential utility to their practice decisions.

While some interviewees offered suggestions to improve provider education, such as physician detailing activities and improved collaboration with OMA and other physician societies, they also emphasized that obtaining funds to cover such activities in the current budget environment was unrealistic. The expense of innovative outreach efforts presents a dilemma for Medicaid officials seeking to implement voluntary PDLs: such activities increase implementation costs, raising the PDL savings target even higher.

Oregon's market share information for the two months after PA was implemented demonstrated the role that some type of enforcement mechanism plays in generating savings. For example, NSAID products included on the PDL jumped to 79 percent share in the two months after the PA requirement was established. It will be important to

monitor these levels and the effect that future state profiling and education activities have on market share now that the Legislature has prohibited PA enforcement.

Oregon's evaluation of the PMPDP could address the state's ability to achieve savings goals and promote safe and effective prescribing practices in the absence of a strong enforcement mechanism.

SB 819 included an important mandate that the state evaluate its experience with the PMPDP. Specifically, SB 819 stated that a legislative commission must

> "review the impact of the implementation of the PMPDP, including but not limited to review of whether the program realizes any savings, whether there is an increase in physician and hospital costs for individuals receiving medical assistance, and whether there is an impact on the ability of an individual receiving medical assistance to obtain prescription drugs…"[56]

The legislative commission must report any findings to the Legislative Assembly in order to make necessary changes. It will be important for such results to be shared with stakeholders in the state and other policymakers looking to learn from Oregon's experience in developing new physician profiling and educational campaigns to promote PDL compliance in the absence of PA. This inquiry is particularly important for medically complex patients, dual eligibles, and institutionalized patients who consume a disproportionate share of the prescription drug resources.

The HRC has also begun to consider the importance of evaluating how the state's extensive prescription drug research has impacted patient health. The state emphasized the importance of understanding how the information has been useful to and changed the behavior of physicians, consumers and other decision makers. While funding is not currently available to conduct such work, one state official expressed an openness to work with outside groups to address these broader impact questions.

Although Oregon's temporary PA requirement was not as restrictive as policies in other states, provider interviewees stressed the need to monitor any barrier to physician prescribing for their potential effects on patient access and health outcomes.

Compared to other Medicaid PDL policies, Oregon's PA process was considered less burdensome, i.e., it was not difficult to obtain PA as the physician clearly had the final say in the decision. The state designed the PA procedures more as an educational step to increase physician compliance, rather than a step to deny claims. Given this PA approach, interviewees acknowledged that Oregon was less likely to have a significant impact on product market share than other Medicaid programs.

Provider interviewees warned, however, that *any* added administrative burden can detract from patient care. Even if the PA steps were designed to educate physicians about the state's research findings, dealing with multiple faxes or phone calls utilizes valuable physician time. The potential still existed that a beneficiary's health could be compromised because of delays in the PA process.

[56] Senate Bill 819 (2001) SECTION 4, subsection (2).

Conflicting perspectives from the manufacturer and beneficiary communities, and the state exposed a fundamental dilemma regarding the interpretation of existing prescription drug research studies.
Several of the HRC subcommittees' reports concluded that there was a lack of significant evidence to make the determination that one drug was more effective than another in a therapeutic category. In such situations, the state considered drug pricing to determine various products' preferred status. SB 819 mandated that Oregon must first evaluate a drug's clinical effectiveness before considering cost, and the state has attempted to establish a high standard of requiring superior evidence of either effectiveness or safety.

Manufacturers consistently disapproved of Oregon's decision to treat all drugs in a class as clinically equivalent (and therefore make decisions based on price analyses) when there was insufficient evidence to demonstrate differences in effectiveness. In such cases, according to industry, all drugs should be included on the PDL.

This debate reflects a fundamental dilemma that emerges when trying to compare and select products in a given therapeutic class according to available clinical research. There is little outside funding for and industry lacks incentives to conduct head-to-head trials necessary to directly address many of the comparative efficacy questions that Oregon raises during the PMPDP review process.

A couple of interviewees with private sector P&T committee experience acknowledged that private sector payors confront the same clinical data problem when developing formularies for their enrollees. For those categories where insufficient information is available to confirm the exact difference between products, payors and/or their pharmacy benefit managers may consider patient experience information from observational databases and other claims files. These benefit managers, however, also move to a consideration of price and other factors to make final product recommendations.

This situation raises another dilemma regarding whether or not the Medicaid program should be held to a different standard than payors in the private sector. Some stakeholders argue that Medicaid programs, funded by taxpayers, should be allowed to use the same cost containment tools found in the private sector. Others emphasize that Medicaid programs, providing care for the poor and vulnerable, must set a different standard given the unique needs of the population they serve.

Relying on strict reference pricing systems to make some Medicaid PDL decisions can raise concerns about beneficiary access, given to the general lack of clear evidence regarding drugs' relative effectiveness.
Oregon's binary reference pricing policy – where all clinically equivalent (as determined by the HRC) drugs within five percent of the preferred product's AWP are included on the PDL, while those above five percent are excluded – has the potential to result in some restrictive decisions for beneficiaries. For example, there is the possible challenge of considering dosage form pricing differences within a reference-based system. In the estrogen class, topical estradiol is not included on Oregon's PDL—only oral estradiol is

included. Because there is no explicit explanation for this omission in the state's reports for the class, it is likely due to the higher price point of the topical form. Both Michigan and Florida have listed either the cream or patch form of estradiol on their respective Medicaid PDLs.

Some interviewees argued that Oregon should have considered more of a "middle ground" in making some of its PDL decisions. When meaningful uncertainty exists regarding a drug's comparative effectiveness or safety for some beneficiaries—even if this uncertainty has not yet been explained in medical literature—the state should err of the side of inclusion. The state also could have listed some questionable products on the PDL on a conditional basis, until the state or CMS further studies the utilization of these products by Medicaid beneficiaries.

Oregon's clinical review process led to the development of a more restrictive list of preferred products when compared to two other Medicaid PDLs. However, Oregon's limited preferred drug selections may not restrict access to drugs for beneficiaries as much as other Medicaid PDLs that are enforced with PA processes. An analysis of the PMPDP versus PDLs in Michigan and Florida, indicates that Oregon's list is more exclusive than the other state Medicaid lists in most classes. (The analysis is included in Appendix G.) Oregon's PDL lists fewer preferred products than Michigan and Florida in seven of nine drug classes evaluated.

Most notably, when compared to Michigan and Florida, Oregon's drug selections in the NSAIDs, estrogens, skeletal muscle relaxants, and oral hypoglycemic categories stand out as being more restrictive. Oregon does not include any COX-2 drugs and largely limits the number of non-selective NSAIDs in the NSAIDs category. Florida includes COX-2 inhibitors on its list. Oregon's list of estrogens includes only oral products, while Michigan and Florida list at least some alternative estrogen forms for providers. Oregon only prefers two of twenty-two skeletal muscle relaxant agents as compared to twelve in Florida and sixteen in Michigan. Oregon did not select any of the single source oral hypoglycemics reviewed (Amaryl, Starlix, and Prandin) where Michigan covers two of three and Florida lists them all.

However, unlike Michigan and Florida, Oregon's drug selections do not necessarily correlate to restricted beneficiary access, because Oregon's PDL is not enforced with PA. Physicians in Oregon only have to write "medically necessary" or another comparable notation on a prescription when prescribing a non-preferred product, versus peers in other states who have to endure more burdensome PA processes.

When compared to the private sector, the analysis in Appendix G demonstrates that Oregon's PDL is similar to those developed by the managed care plans, CareOregon and Regence Blue Cross Blue Shield of Oregon. Oregon's Medicaid PDL is less restrictive (PPIs, opioids, estrogens) or equally restrictive (statins, urinary incontinence treatments, triptans) than the private managed care plans included in the analysis for most categories. Oregon is more restrictive than the managed care plans in the NSAIDs, skeletal muscle relaxants, and oral hypoglycemic agents categories.

Oregon's PMPDP development process and results may have a significant impact on future state Medicaid PDL efforts.
Over the past year, several state Medicaid programs have expressed interest in leveraging Oregon's PMPDP evidence-based research. To date, eight states have begun to collaborate with Oregon to use the results of the state's literature reviews in their own PDL selection processes, and together sponsor future research on new drug classes. Negotiations with nine other organizations, including some outside of Medicaid, are ongoing.

Unlike past multi-state efforts that focused on drug *purchasing* activities[57], the Oregon collaborative has focused on the research process behind PDL decisions. As one state official explained, "Evidence doesn't have borders." Other state Medicaid programs see an opportunity to share the costs of organizing and sponsoring independent clinical research reviews. States will collaborate to prioritize therapeutic categories for review and work together to develop appropriate research questions. In such a model, no single program will have to cover the full expense of maintaining research analyses current, which can be a major challenge for Medicaid PDL policies.

While most interviewees acknowledged the opportunity to spread the burden of conducting literature reviews across states, some raised concerns about exactly how Oregon's research results will be applied in new markets. In Oregon, state officials provide all Medicaid stakeholders the opportunity to engage in the PMPDP development process. Several Oregon physicians participate on the HRC committees, which formulate the questions that guide the literature reviews. Open meetings allow the public to engage in the discussion around HRC recommendations. This stakeholder involvement is an important part of the overall Oregon PMPDP process that other states should consider when contracting to leverage Oregon's research results, as clinical protocols and physician experiences my vary in some regions. Support for the program may not transfer to new markets if such opportunities for participation do not exist for local stakeholders.

Some interviewees were also concerned that state Medicaid programs will leverage the evidence-based label applied to Oregon's research to defend against stricter PA controls. The Oregon EPC's consideration only of randomized controlled trials to assess drugs' comparative effectiveness resulted in inconclusive information in many cases, which had the effect of elevating the importance of pharmaceutical pricing in the state's process. In other words, the more times the state was faced with inconclusive results in the literature, the more times it had to move to a consideration of price differences to select products.

In Oregon, the absence of a PA process, however, reduces the concern that Medicaid beneficiaries will have problems accessing excluded medications in necessary situations.

[57] States have made several attempts to combine their buying power to extract greater supplemental rebates from manufacturers in PDL programs. While recent efforts led by First Health and Michigan, Vermont and South Carolina have attracted some attention, no multi-state purchasing pool has yet succeeded in impacting the Medicaid market.

The state's recommendations represent another piece of information for physicians to consider in their prescribing decisions. Other states will have to consider the relative restrictiveness of Oregon's results when applying them in their own programs, especially if they will require patients to obtain PA before receiving a non-preferred drug.

While many questions will need to be addressed before the exact impact of an Oregon collaborative can be fully assessed—for example, how multiple states will work through potential differences and include all local perspectives when developing the clinical questions for the research—it is clear that states are seeking any effort to reduce program costs. Interest in the collaborative is likely to continue. When collaborating, it will be important for states to consider aspects of the Oregon process beyond just the research results to ensure that local stakeholder interests are served.

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Appendix B: Interview List

2 state representatives from Oregon during the 2001 administration

4 state representatives from Oregon during the 2003 administration

4 beneficiary representatives

3 Medicaid providers

2 pharmacy representatives

5 drug manufacturer representatives

Appendix C: Sections of SB 819

Oregon Legislation Authorizing the Adoption of a Practitioner-Managed Prescription Drug Plan for the Oregon Health Plan

The text of Sections 1 through 5 read as follows:

SECTION 1. The Legislative Assembly finds that:
(1) The cost of prescription drugs in the Oregon Health Plan is growing and will soon be unsustainable;
(2) The benefit of prescription drugs when appropriately used decreases the need for other expensive treatments and improves the health of Oregonians; and
(3) Providing the most effective drugs in the most cost-effective manner will benefit both patients and taxpayers.

SECTION 2. It is the policy of the State of Oregon that a Practitioner-managed Prescription Drug Plan will ensure that:
(1) Oregonians have access to the most effective prescription drugs appropriate for their clinical conditions;
(2) Decisions concerning the clinical effectiveness of prescription drugs are made by licensed health practitioners, are informed by the latest peer-reviewed research and consider the health condition of a patient or characteristics of a patient,
including the patient's gender, race or ethnicity; and
(3) The cost of prescription drugs in the Oregon Health Plan is managed through market competition among pharmaceutical manufacturers by publicly considering, first, the effectiveness of a given drug and, second, its relative cost.

SECTION 3. (1) The Department of Human Services shall adopt a Practitioner-managed Prescription Drug Plan for the Oregon Health Plan. The purpose of the plan is to ensure that enrollees of the Oregon Health Plan receive the most effective prescription drug available at the best possible price.
(2) Before adopting the plan, the department shall conduct public meetings and consult with the Health Resources Commission.
(3) The department shall consult with representatives of the regulatory boards and associations representing practitioners who are prescribers under the Oregon Health Plan and ensure that practitioners receive educational materials and have access to training on the Practitioner-managed Prescription Drug Plan.
(4) Notwithstanding the Practitioner-managed Prescription Drug Plan adopted by the department, a practitioner may prescribe any drug that the practitioner indicates is medically necessary for an enrollee as being the most effective available.
(5) An enrollee may appeal to the department a decision of a practitioner or the department to not provide a prescription drug requested by the enrollee.
(6) This section does not limit the decision of a practitioner as to the scope and duration of treatment of chronic conditions, including but not limited to arthritis, diabetes and asthma.

SECTION 4. The President of the Senate and the Speaker of the House of Representatives shall designate an appropriate interim legislative committee or legislative commission to:
(1) Receive regular reports on the development and implementation of the Practitioner-managed Prescription Drug Plan;
(2) Review the impact of the implementation of the Practitioner-managed Prescription Drug

Plan, including but not limited to a review of whether the program realizes any savings, whether there is an increase in physician and hospital costs for individuals receiving medical assistance, and whether there is an impact on the ability of an individual receiving medical assistance to obtain prescribed drugs; and

(3) Report its findings and recommendations periodically to the Emergency Board and to the Seventy-second Legislative Assembly.

SECTION 5. ORS 414.325 is amended to read:

414.325. (1) As used in this section, 'legend drug' means any drug requiring a prescription by a practitioner, as defined in ORS 689.005.

(2) A licensed practitioner may prescribe such drugs under this chapter as the practitioner in the exercise of professional judgment considers appropriate for the diagnosis or treatment of the patient in the practitioner's care and within the scope of practice. Prescriptions shall be dispensed in the generic form pursuant to ORS 689.515, 689.854 and 689.857 and pursuant to rules of the [*division*] Department of Human Services unless the practitioner prescribes otherwise and an exception is granted by the [*division*] department.

(3) [*Except as provided in subsections (4) and (5) of this section, the division shall place no limit on the type of legend drug that may be prescribed by a practitioner, but*] The department shall pay only for drugs in the generic form if the federal Food and Drug Administration has approved a generic version of a particular brand name drug that is chemically identical to the brand name drug according to federal Food and Drug Administration rating standards, unless an exception has been granted by the [*division*] department.

(4) [*Notwithstanding subsection (3) of this section*,] An exception must be applied for and granted before the [*division*] department is required to pay for minor tranquilizers and amphetamines and amphetamine derivatives, as defined by rule of the [*division*] department .

(5) [*(a)*] Notwithstanding subsections (1) to (4) of this section [*and except as provided in paragraph (b) of this subsection, the division*] the department is authorized to:

[*(A)*] (a) Withhold payment for a legend drug when federal financial participation is not available; and

[*(B)*] (b) Require prior authorization of payment for drugs [*which*] that the [*division*] department has determined should be limited to those conditions generally recognized as appropriate by the medical profession.

[*(b) The division may not require prior authorization for therapeutic classes of nonsedating antihistamines and nasal inhalers, as defined by rule by the division, when prescribed by an allergist for treatment of any of the following conditions, as described by the Health Services Commission on the funded portion of its prioritized list of services:*]

[*(A) Asthma;*]

[*(B) Sinusitis;*]

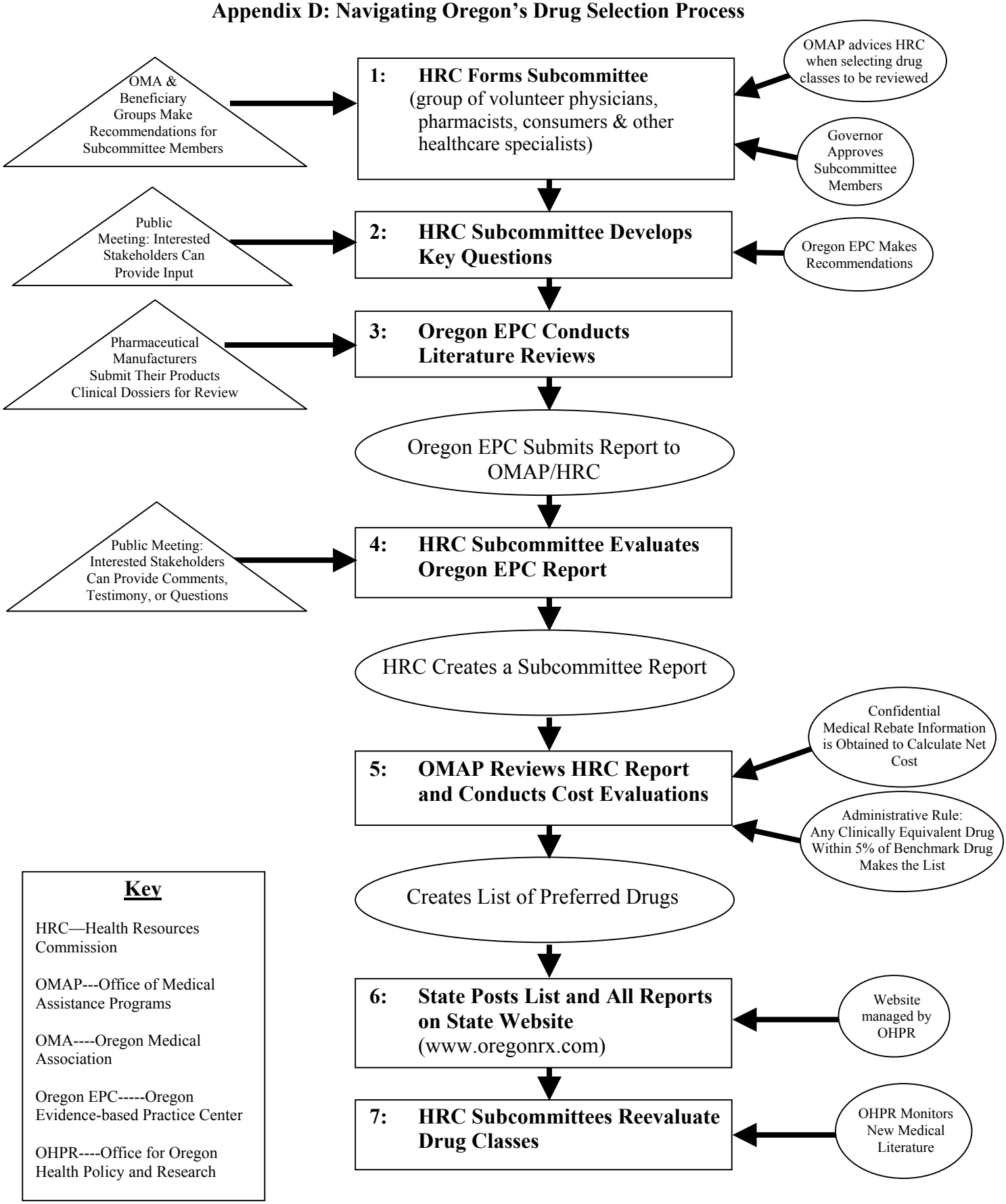
[*(C) Rhinitis; or*]

[*(D) Allergies.*]

(6) Notwithstanding subsection (3) of this section, the department may not limit legend drugs when used as approved by the federal Food and Drug Administration to treat mental illness, HIV and AIDS, and cancer.

Source: Oregon Senate Bill 819 (2001) SECTIONS 1-5.

Appendix D: Navigating Oregon's Drug Selection Process



Appendix E: List of Preferred Drugs for the PMPDP

Preferred Drugs for Nine Therapeutic Classes (12/03)
Long-Acting Opioid Analgesics for Non-cancer Pain: (*) long acting-morphine sulfate (generic) Kadian levorphanol (generic) methadone (generic) Oramorph SR
Proton Pump Inhibitors (PPIs): (*) Protonix Aciphex Prevacid Prilosec OTC
Statins (Cholesterol Lowering Drugs): (*) lovastatin (generic) Pravachol
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs): (*) naproxen (generic) ibuprofen (generic) piroxicam (generic)
Estrogens: (*) estradiol (oral generic) Activella Cenestin Estrace (oral) estropipate (generic) FemHRT Menest Ogen Ortho-Est Premarin (oral) Premphase PremPro
Urinary Incontinence Drugs: (*) Oxybutynin (tablets and liquid)
Triptan Drugs: (*) Maxalt Imitrex (all forms)

Maxalt MLT
Zomig
Zomig ZMT

Skeletal Muscle Relaxants:
Antispasmodics for chronic neurological conditions:
(*) baclofen (generic)
Acute/chronic musculoskeletal spasms:
(*) cyclobenzaprine (generic)

Oral Hypoglycemics:
(*) glyburide (generic)
glipizide (generic)

(*) Benchmark drug chosen in the class

Source: Oregon's Practitioner-Managed Prescription Drug Plan Web site. Oregon Health Plan Drug List. Available at: http://www.oregonrx.org/oregon_health_plan_drug_list.htm. Accessed December 12, 2003.

Appendix F: Administrative Rules Governing PMPDP Implementation

Selections from May 2003 Oregon Administrative Rules

410-121-0030: Practitioner-Managed Prescription Drug Plan (PMPDP)

(1) Practitioner-Managed Prescription Drug Plan (PMPDP)

(a) The Practitioner-Managed Prescription Drug Plan is a plan that ensures that fee for service clients of the Oregon Health Plan will have access to the most effective prescription drugs appropriate for their clinical conditions at the best possible price;
(b) Decisions concerning the clinical effectiveness of the prescription drugs are made by licensed health practitioners, informed by the latest peer-reviewed research and consider the health condition of a client or characteristics of a client, including the client's gender, race or ethnicity.

(2) PMPDP Plan Drug List (PDL):

(a) The PDL is the primary tool that the Department of Human Services (DHS) has developed to inform licensed health care practitioners about the results of the latest peer-reviewed research and cost effectiveness of prescription drugs;
(b) The PDL is a listing of prescription drugs for selected classes that DHS, in consultation with the Health Resources Commission (HRC), has determined represents effective drug(s) available at the best possible price;
(c) For each selected drug class, the PDL will identify a drug(s) as the benchmark drug that has been determined to be the most effective drug(s) available for the best possible price. The PDL will include other drugs in the class that are Medicaid reimbursable and which the FDA has determined to be safe and effective if the relative cost is less than the benchmark drug(s). If pharmaceutical manufacturers enter into supplemental discount agreements with DHS that reduces the cost of their drug below that of the benchmark drug for the class, their drug will also be included in the PDL. A copy of the PDL is available on the web at www.omap.hr.state.or.us.

(3) PMPDP Plan Drug List (PDL) Selection Process:

(a) DHS will utilize the recommendations made by the HRC, which result from an evidence-based evaluation process, as the basis for identifying the most effective drug(s) within a selected drug class;
(b) DHS will determine the drug(s) identified in (3)(a) that is available for the best possible price; and considering any input from the HRC, other FDA approved drug(s) in the same class that are available for a lesser relative price. Relative price will be determined using the methodology described in subsection (4);
(c) Drug classes and selected drug(s) for the drug classes will be

reviewed annually or more frequently if in the discretion of DHS, new safety information or the release of new drugs in a class or other information makes this advisable. New drugs will not be added to the PDL until they have been reviewed by the HRC. All changes or revisions to the PDL will be made publicly, using the rulemaking process, and will be published in OMAP's Pharmaceutical Services provider guide.

(4) Relative Cost and Best Possible Price Determination:

(a) DHS will determine the relative cost of all drugs in each selected class that are Medicaid reimbursable and that the FDA has determined to be safe and effective;
(b) DHS will first determine the benchmark drug based on the Average Wholesale Price (AWP) on the first of the month in which DHS reviews that specific drug class;
(c) Once the cost of the benchmark drug is determined, the costs of other FDA approved drugs in the class will be recalculated using AWP, Oregon Maximum Allowable Cost (OMAC) and/or Federal Upper Limits in effect on the first of the month in which DHS reviews that specific drug class (OAR 410-121-0180), less average rebate. Drugs with prices under 105% of the benchmark drug price will be included on the PDL;
(d) DHS will consider price, rebate, and the stability of both, over a period of time in determining the cost effectiveness. DHS may also consider dosing issues, patterns of use and compliance issues. These factors will be weighed with any advice provided by the Health Resources Commission in reaching a final decision.

(5) PMPDP Reimbursement: OMAP will only reimburse for the prescription drugs specifically listed in the PMPDP categories on the Plan Drug List(s). OMAP will only reimburse for drugs not listed in the PMPDP categories by using the exception process.

(6) PMPDP Plan Drug List (PDL) Exception Process:

(a) If the prescribing practitioner, in his/her professional judgment, wishes to prescribe a drug not on the PDL, he/she may request an exception, subject to the requirements of OAR 410-121-0040. The prescribing practitioner must call the Managed Access Program (MAP) Help Desk to request an exception for medically appropriate drugs not listed in the PDL categories.
(b) Regardless of the PDL, prescriptions shall be dispensed in the generic form unless practitioner requests otherwise subject to the regulations outlined in OAR 410-121-0155.

410-121-0040: Prior Authorization Required for Drugs and Products

(1) Prescribing practitioners are responsible for obtaining prior authorization for the following drugs and products:

(a) Isotretinoin (Accutane) and Retinoic Acid (Retin A);
(b) Growth hormone;

(c) Oral Nutritional supplements;
(d) Antihistamines (selected);
(e) Nasal inhalers (selected);
(f) Antifungals (selected);
(g) Weight reduction drugs;
(h) Excessive daily doses;
(i) Excessive drug therapy duration;
(j) Coal tar preparations;
(k) Topical antibiotics;
(l) Topical antivirals (selected);
(m) Topical testosterone;
(n) Dronabinol (marinol);
(o) Drugs with cosmetic indications;
    (A) Emollients;
    (B) Dermatologicals
    (C) Hair growth products;
(p) Proton Pump Inhibitors (PPI):
    (A) Non-Practitioner's Managed Prescription Drug Plan (PMPDP) PPI category listed drug on the initial prescription;
    (B) PMPDP PPI category listed drugs after eight weeks of acute anti-ulcer therapy.
(q) Gabapentin

(2) Over-the-counter medications not mentioned above are limited to two prescriptions per therapeutic class per month.

(3) Psychotropic prescriptions for children under 6, cannot be processed when a default 999999 provider number has been entered.

410-121-0060: How to Get Prior Authorization for Drugs

(1) The prescribing practitioner will request prior authorization through the following procedure:

(a) A prescriber electing to order a drug requiring prior authorization may have any licensed medical personnel in their office call the Managed Access Program (MAP) Help Desk to request prior authorization. The prior authorization request may also be transmitted to the MAP Help Desk by FAX using the request form shown in the Appendices of the Pharmaceutical Services guide;
(b) The MAP Help Desk is available 24 hours a day, seven days per week. The MAP pharmacist will ask for some or all of the following information, depending upon the class of the drug requested:
    (A) Client name and recipient ID number;
    (B) Diagnosis IDC-9-CM;
    (C) Drug name, strength, size and quantity of medication;
    (D) Medical justification for use of selected drug;
    (E) Pharmacy name and phone number (if available).

(2) Pharmacists shall:

(a) When the request is approved, the MAP Help Desk will notify the pharmacy when the dispensing pharmacy information is available. It is the pharmacist's responsibility to check whether the drugs are covered, whether the client is eligible, and to note restrictions such as date ranges and quantities before dispensing any medications that require prior authorization. The pharmacy should also check whether the client is enrolled in a managed care plan. An enrollment may have taken place after prior authorization was received;
(b) Prior authorization is given for a specific date of service and an NDC number or product;
(c) After a prior authorization request is approved, the patient will be able to fill the prescription at any Medicaid pharmacy provider. There is no need for a prior authorization number;
(d) Emergency dispensing will be prior authorized for a seven-day supply for clients not enrolled in a managed care plan;
(e) If the prior authorization request has been denied, the MAP Help Desk will notify the pharmacy when the dispensing pharmacy information is available.

(3) Prior authorization does not guarantee eligibility or reimbursement.

(4) Emergency Need: The Pharmacist may request an emergent or urgent dispensing from the First Health Help Desk. Emergency dispensing may be authorized by First Health for a 96-hour supply.

Source: Oregon Department of Human Services

Appendix G: Oregon's PMPDP List Compared to the Florida Medicaid PDL, the Michigan Medicaid Pharmaceutical Product List, and Select Private Sector Formularies

Generic Name	Brand Name	Top 200 Rank	Oregon PDL	Michigan PDL	Florida PDL	CareOregon Formulary[1,2,3]	Choices BCBS Oregon Formulary[4,5]
1. Proton Pump Inhibitors							
esomeprazole	Nexium	52	No	No	No	NC	No (PA)
lansoprazole	Prevacid	18	Yes	No	Yes	NC	Yes
omeprazole	generic		No	No	No	NC	Yes
omeprazole	Prilosec	29	Yes (OTC)	No	Yes (OTC)	Yes (OTC)	No
pantoprazole	Protonix	71	Yes	Yes	No	No (PA)	No
rabeprazole	AcipHex	104	Yes	No	No	No	No
			4 of 6	1 of 6	2 of 6	1 of 6	2 of 6
2. LA Opioid Analgesics							
morphine sulfate LA	generic		Yes	Yes	Yes	Yes	Yes
morphine sulfate LA	Kadian		Yes	No	Yes	NC	No
morphine sulfate LA	Oramorph SR		Yes	No	No	No (PA)	No
morphine sulfate LA	MS Contin		No	No	No	No (PA)	Yes
morphine sulfate LA	Avinza		No	Yes	Yes	NC	No
methadone	generic		Yes	Yes	Yes	Yes	Yes
methadone	Dolophine		No	Yes	No	NC	No
methadone	Methadose		No	Yes	No	NC	No
methadone	Methadone Intensol		No	Yes	Yes	NC	No
levorphanol	generic		Yes	Yes	Yes	NC	No
levorphanol	Levo-Dromoran		No	Yes	Yes	NC	No
fentanyl	Duragesic		No	Yes	Yes	No (PA)	Yes
oxycodone HCL	Oxycontin	111	No	No	No	No (PA)	Yes
			5 of 13	9 of 13	8 of 13	2 of 13	5 of 13
3. Statins							
atorvastatin	Lipitor	2	No	Yes	Yes	Yes (QL)	Yes
fluvastatin	Lescol		No	Yes	Yes	NC	Yes
fluvastatin	Lescol XL		No	Yes	Yes	NC	Yes
pravastatin	Pravachol	50	Yes	No	Yes	NC	No
simvastatin	Zocor	17	No	No	Yes	NC	No
lovastatin	generic		Yes	Yes	Yes	Yes	Yes
lovastatin	Mevacor		No	No	Yes	NC	No
lovastatin	Altocor		No	Yes	Yes	NC	No
lovastatin/niacin	Advicor		No	No	Yes	NC	No
rouvastatin	Crestor		No	No	Yes	NC	No
			2 of 10	5 of 10	10 of 10	2 of 10	4 of 10
4. NSAIDS							
celecoxib	Celebrex	20	No	No	Yes	No (PA)	No (PA)
choline mag trisalicylate	Trilisate		No	Yes	Yes	Yes	Yes
diclofenac potassium	generic		No	Yes	Yes	NC	Yes
diclofenac potassium	Cataflam		No	No	No	NC	No
diclofenac sodium	generic		No	Yes	Yes	NC	Yes
diclofenac sodium	Voltaren		No	No	Yes	NC	No
diclofenac sod/misoprostol	Arthrotec		No	No	No	NC	No
diflunisal	generic		No	No	Yes	NC	Yes
diflunisal	Dolobid		No	No	No	NC	No
etodolac	generic		No	Yes	Yes	Yes	Yes

Generic Name	Brand Name	Top 200 Rank	Oregon PDL	Michigan PDL	Florida PDL	CareOregon Formulary[1,2,3]	Choices BCBS Oregon Formulary[4,5]
etodolac	Lodine		No	No	No	NC	No
fenoprofen	generic		No	Yes	Yes	NC	Yes
fenoprofen	Nalfon		No	No	Yes	NC	No
flurbiprofen	generic		No	Yes	Yes	Yes	Yes
flurbiprofen	Ansaid		No	No	No	NC	No
ibuprofen	generic	19	Yes	Yes	Yes	Yes	Yes
ibuprofen	Motrin		No	No	No	NC	No
indomethacin	generic		No	Yes	Yes	Yes	Yes
indomethacin	Indocin		No	No	No	NC	No
ketoprofen	generic		No	Yes	Yes	Yes	Yes
ketoprofen	Orudis		No	No	No	NC	No
ketoprofen ER	Oruvail		No	No	No	NC	Yes
ketorolac (injectable)	generic		No	Yes	Yes	NC	No
meclofenamate	generic		No	Yes	Yes	NC	Yes
mefenamic acid	Ponstel		No	No	Yes	NC	No
meloxicam	Mobic		No	No	Yes	NC	No
nabumetone	generic		No	Yes	Yes	NC	Yes
nabumetone	Relafen		No	No	Yes	NC	No
naproxen	generic	58	Yes	Yes	Yes	Yes	Yes
naproxen	Naprosyn		No	No	No	NC	No
naproxen sodium	generic	58	Yes	Yes	Yes	Yes	Yes
naproxen sodium	Anaprox		No	No	No	NC	No
naproxen sodium	Naprelan		No	No	No	NC	No
oxaprozin	generic		No	Yes	Yes	NC	Yes
oxaprozin	Daypro		No	No	No	NC	No
piroxicam	generic		Yes	Yes	Yes	Yes	Yes
piroxicam	Feldene		No	No	No	NC	No
rofecoxib	Vioxx	31	No	No	Yes	No (PA)	No (PA)
salsalate	generic		No	Yes	Yes	Yes	Yes
salsalate	Disalcid		No	Yes	Yes	NC	No
sulindac	generic		No	Yes	Yes	Yes	Yes
sulindac	Clinoril		No	No	No	NC	No
tolmetin	generic		No	Yes	Yes	NC	Yes
tolmetin	Tolectin		No	No	Yes	NC	No
valdecoxib	Bextra	143	No	No	Yes	NC	No (PA)
			4 of 45	20 of 45	31 of 45	11 of 45	20 of 45
5. Estrogens							
conj. estogens	Premarin	6	Yes	Yes	Yes	Yes	Yes
conj. estogens (cream)	Premarin		No	Yes	Yes	Yes	Yes
conj. estogens	Cenestin		Yes	Yes	Yes	NC	Yes
conj. estogens/medroxypr.	PremPro	46	Yes	Yes	Yes	Yes	Yes
conj. estogens/medroxypr.	Premphase		Yes	Yes	Yes	Yes	Yes
estradiol	generic	94	Yes	Yes	Yes	Yes	Yes
estradiol	Estrace		Yes	Yes	No	NC	No
estradiol (cream)	Estrace		No	Yes	No	NC	No
estradiol (patch)	Various		No	Yes	Yes	Yes	Yes
estradiol (patch)	Climera		No	Yes	Yes	NC	No
estradiol (patch)	Esclim		No	Yes	Yes	NC	No
estradiol (patch)	Estraderm		No	Yes	Yes	NC	No
estradiol (patch)	Vivelle		No	Yes	Yes	NC	No
estradiol/norethindrone	Activella		Yes	Yes	Yes	NC	No
estradiol/norethindrone (patch)	Combipatch		No	Yes	Yes	Yes	No

Generic Name	Brand Name	Top 200 Rank	Oregon PDL	Michigan PDL	Florida PDL	CareOregon Formulary[1,2,3]	Choices BCBS Oregon Formulary[4,5]
ethinyl estradiol	Estinyl		No	Yes	Yes	NC	No
ethinyl estradiol/norethindrone	FemHRT		Yes	Yes	Yes	NC	Yes
ethinyl estradiol/norethindrone	OrthoPrefest		No	Yes	Yes	NC	No
estropipate	generic		Yes	Yes	Yes	Yes	Yes
estropipate	Ogen		Yes	Yes	No	NC	No
estropipate	Ortho-Est		Yes	Yes	No	NC	No
esterified estrogen	Menest		Yes	Yes	Yes	NC	No
esterified estrogen	Estratab		No	Yes	No	NC	No
esterified estrogen/ methyltestost.	Ethyltest		No	Yes	No	NC	No
			12 of 24	24 of 24	18 of 24	8 of 24	9 of 24
6. Urinary Incontinence Drugs							
flavoxate	Urispas		No	Yes	Yes	NC	No
oxybutynin	generic		Yes	Yes	Yes	Yes	Yes
oxybutynin	Ditropan/XL		No	Yes	Yes	NC	No
tolterodine	Detrol/XL		No	Yes	Yes	NC	No
			1 of 4	4 of 4	4 of 4	1 of 4	1 of 4
7. Triptan Drugs							
almotriptan	Axert		No	No	Yes	Yes (QL)	No
eletriptan	Relpax		No	No	No	NC	No
frovatripan	Frova		No	No	No	NC	No
naratriptan	Amerge		No	No	No	NC	No
rizatriptan	Maxalt/MLT		Yes	No	Yes	NC	Yes
sumatriptan	Imitrex		Yes	Yes	Yes	Yes (QL)	Yes
zolmitriptan	Zolmig/MLT		Yes	Yes	No	Yes (QL)	Yes
			3 of 7	2 of 7	3 of 7	3 of 7	3 of 7
8. Skeletal Muscle Relaxants							
baclofen	generic		Yes	Yes	Yes	Yes	Yes
baclofen	Lioresal		No	Yes	No	NC	No
dantrolene	Dantrium		No	Yes	No	Yes	No
cyclobenzaprine	generic		Yes	Yes	Yes	Yes	Yes
cyclobenzaprine	Flexeril		No	Yes	No	NC	No
carisprodol	generic		No	NC	Yes	NC	Yes
carisprodol	Soma		No	NC	Yes	NC	No
carisprodol and aspirin	Soma Compound		No	NC	Yes	NC	No
carisprodol and aspirin	generic		No	NC	Yes	NC	Yes
carisprodol, aspirin, and codeine	generic		No	NC	Yes	NC	Yes
carisprodol, aspirin, and codeine	Soma Cmpd w Codeine		No	NC	Yes	NC	No
chlorzoxazone	generic		No	Yes	Yes	Yes	Yes
chlorzoxazone	Parafon Forte		No	Yes	No	NC	No
metaxalone	Skelaxin		No	Yes	Yes	NC	No
methocarbamol	generic		No	Yes	Yes	Yes	Yes
methocarbamol	Robaxin		No	Yes	No	NC	No
orphenadrine	generic		No	Yes	No	NC	Yes
orphenadrine	Norflex		No	Yes	No	NC	No
orphenadrine, aspirin, and caffeine	generic		No	Yes	No	NC	Yes
orphenadrine, aspirin, and caffeine	Norgesic		No	Yes	No	NC	No
quinine	generic		No	Yes	Yes	NC	Yes
tizanidine	Zanaflex		No	Yes	No	NC	No
			2 of 22	16 of 22	12 of 22	5 of 22	10 of 22

Generic Name	Brand Name	Top 200 Rank	Oregon PDL	Michigan PDL	Florida PDL	CareOregon Formulary[1,2,3]	Choices BCBS Oregon Formulary[4,5]
9. Oral Hypoglycemics							
acetohexamide	generic		No	Yes	Yes	NC	Yes
acteohexamide	Dymelor		No	Yes	No	NC	No
chlorpropamide	generic		No	Yes	Yes	NC	Yes
chlorpropamide	Diabinese		No	No	No	NC	No
glimepiride	Amaryl		No	No	Yes	NC	No
glipizide	generic		Yes	Yes	Yes	Yes	Yes
glipizide	Glucotrol/XL		No	No	Yes (XL)	Yes (XL)	Yes (XL)
glyburide	generic		Yes	Yes	Yes	Yes	Yes
glyburide	Diabeta, Glynase, Micronase		No	No	No	NC	No
tolazamide	generic		No	Yes	Yes	Yes	Yes
tolazamide	Tolinase		No	Yes	No	NC	No
tolbutamide	generic		No	Yes	Yes	Yes	Yes
tolbutamide	Orinase		No	Yes	No	NC	No
nateglinide	Starlix		No	Yes	Yes	NC	No
repaglinide	Prandin		No	Yes	Yes	NC	No
			2 of 15	11 of 15	10 of 15	5 of 15	7 of 15

Note: Drugs not listed on a PDL are available in the Oregon Medicaid program with a provider exemption and in the Michigan and Florida Medicaid program with PA. All PDLs were accessed December 2003.

[1] CareOregon is a non-profit managed care plan for the Oregon Health Plan. This formulary was accessed December 2003.
[2] Drugs listed as No (PA) are included in the formulary but can only be obtained via prior authorization.
[3] NC means not covered and not in the formulary. They may be obtained by the physician via special request. QL means there is a quantity limit for the drug.
[4] The Choices formulary is used for Regence Blue Cross Blue Shield (BCBS) of Oregon, Regence HMO Oregon, and Regence Health Maintenance of Oregon, Inc. Accessed December 2003.
[5] Drugs not listed on the Choices formulary are available in any BCBS plan with a higher co-payment.

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