

March 2006

State Experience in Creating Effective P&T Committees

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Medicaid agencies report that pharmacy costs are a major driver of overall spending growth in Medicaid programs.¹ Many states believe clinical evidence can help curtail pharmacy costs while ensuring beneficiary access to needed prescription drugs as medications—even expensive ones—can be cost-effective and improve quality of life.

In 2004 the Commonwealth Fund funded the National Academy for State Health Policy and Georgetown University to conduct a series of site visits to examine state efforts to manage the pharmacy benefit in Medicaid programs. With input from a broad-based advisory group of state officials and other experts, a site visit team selected six states (California, Florida, Kansas, Michigan, Missouri, and Washington) where they met with agency staff, pharmacy vendors, pharmacists, physicians, Drug Utilization Review and Pharmacy and Therapeutics committee members, and consumers/advocates.

This brief summarizes state experience in creating and managing Pharmaceutical and Therapeutics (P&T) committees. Three other briefs in this series will examine state efforts concerning the behavioral health pharmacy benefit, prior authorization processes, and the role of the Drug Effectiveness Review Project in providing comprehensive reviews of clinical evidence to states. States face critical issues in designing and implementing their efforts that range from the make-up of their P&T committees, to the way in which prior approval requests are submitted. The briefs in this series describe in detail the efforts of our six site visit states.

PREFERRED DRUG LISTS AND P&T COMMITTEES

Preferred drug lists (PDLs) are a major tool that many Medicaid agencies use to apply scientific evidence to pharmacy benefit management in order to restrict inappropriate use while ensuring medically necessary access to medications. Within those drug classes subject to a PDL, states define individual prescription drugs as *preferred* or *nonpreferred*. Most Medicaid agencies create incentives for beneficiaries and providers to use the preferred drugs by requiring them to obtain permission from the agency before a prescription for a nonpreferred drug can be filled. Although Federal law, in recognition

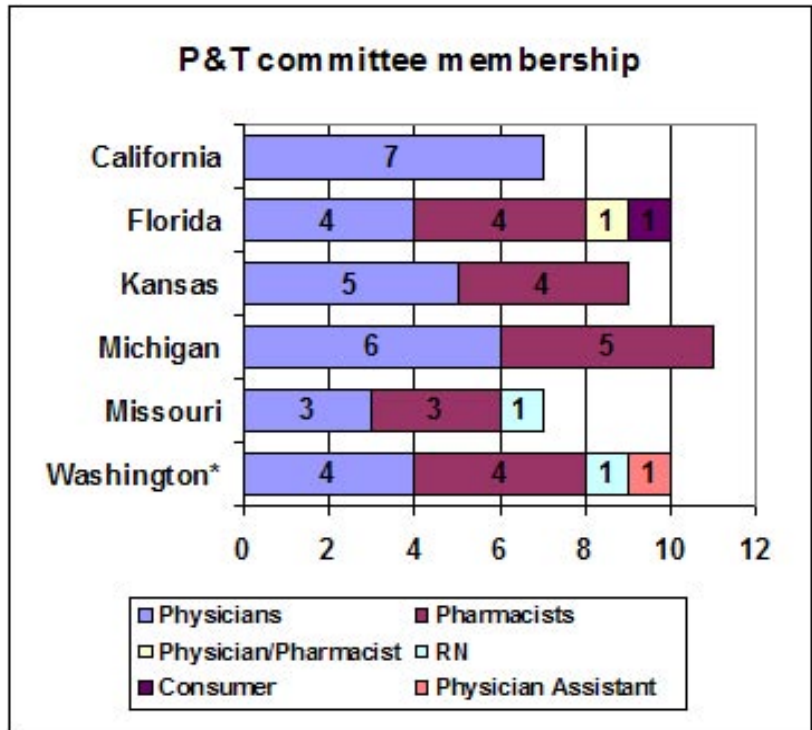


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of the extremely low incomes of most Medicaid beneficiaries, restricts cost sharing for Medicaid services to a “nominal” standard, some agencies have nonetheless used co-pays to encourage the use of preferred drugs instead of nonpreferred drugs.²

Preferred drugs are judged most commonly by state P&T committees, based on clinical evidence, to be either therapeutically equivalent or superior to *nonpreferred* drugs. These determinations are important for more than just encouraging the use of clinically appropriate drugs. States use the PDL to negotiate supplemental rebates³ from pharmaceutical manufacturers. Indeed, it is the ability of states to generate supplemental rebates that appears to produce much of the observed cost savings that are generated by the use of PDLs.

Although all six site visit states reported that their PDLs had contained pharmacy costs, access to appropriate medications was somewhat more difficult to assess. There are indications that beneficiaries were able to obtain needed prescription drugs under their state’s PDL. Providers in several states reported frustration, especially during implementation, with the new requirements; others expressed concerns about content and the development of the PDL itself. However, physician representatives in all six states reported that they were able to prescribe the drugs their patients needed. Also, site visit states did not report any deleterious effects on the health of beneficiaries, although most did not provide data to back their claim. In 2003, Michigan reviewed the case histories of 82 beneficiaries who had been denied a medication and found no cases in which a hospitalization resulted from the denial.⁴



Officials in the site visit states generally believe that an effective PDL needs to be grounded in both clinical evidence and experience. To do that, states establish P&T committees that consist largely of clinical professionals, and provide them with the available clinical evidence to evaluate the merits of drugs on a class-by-class basis. If a drug is judged superior to others in its therapeutic class, it is placed on the preferred list. If the drugs are therapeutically equivalent, then the preferred drugs are selected based on cost. Generally, P&T committees consist of about ten members (mostly physicians and pharmacists) who hold formal meetings. However, there is some variation even here—California’s committee is an informal advisory group that does not hold in-person meetings.

This brief summarizes the experiences of the six site visit states in developing effective P&T committees. Specifically, we examine two elements that states should consider when implementing or managing a P&T Committee: 1) member selection, and 2) committee functions.

P&T COMMITTEE MEMBER SELECTION

Selection criteria for P&T committees serve both practical and political functions. The purpose of a P&T committee is to develop the parameters for a PDL by applying committee members' clinical experience to the evidence—thus committee members need extensive clinical experience and the ability to analyze large amounts of information.

When stakeholders respect the committee members and their clinical experience, they will more easily accept the decisions of a P&T committee. Stakeholders may also find it problematic when they do not respect the composition of the committee. Consumers and advocates in Michigan took issue with the number of state employees on the P&T committee—an issue that was resolved in early 2005 when the state legislature capped at two the number of seats for state employees. Site visit states generally agree that the P&T committee membership should include practitioners from a range of professional disciplines who are in active practice (ideally serving Medicaid beneficiaries), and are respected by their peers.

Include a Range of Professional Disciplines

The P&T committees in four of the six site visit states were composed exclusively of pharmacists and physicians. Washington's membership also included a nurse and a physician assistant. Florida's P&T committee reserved a seat for one consumer representative and one to represent the interest of pharmaceutical manufacturers. Several other site visit states considered including non-clinicians on the P&T committee, but decided not to do so. They believed that including them would bring political considerations into a process meant to produce recommendations based on both clinical evidence and practical experience.

Informants in all site visit states agreed that a P&T committee needs to consider relevant clinical experience when developing its recommendations. This is particularly important for certain classes such as psychotropics and some heart drugs. As a result, all states included a variety of specialists on the committee to increase the likelihood that at least one member has expertise on each class of drug the committee might evaluate. Also, because it is not possible to include a representative of every specialty on a committee, most committee members reported that they had a process for obtaining input from specialties that were not represented.

Include Active Practitioners

Stakeholders state staff in most states emphasized the importance of including practicing physicians on their P & T committee. The experience of Medicaid providers is considered particularly valuable. Although academic experts and other physicians may possess the technical expertise to evaluate comparative research, many stakeholders value the practical experience of those in active practice who are familiar with individual responses to medications. Moreover, for conditions such as HIV, clinical advances are occurring so rapidly that clinicians who do not see patients may not be equipped to make judgments based on current practice standards.

Site visit states involve active practitioners on the P&T committee because of their greater insights regarding adherence to the medication regimen, intensity of side effects, and observable differences among low-income individuals. In Kansas, all committee members are in active practice and are considered respected opinion leaders in the provider community. In Michigan, consumers and advocates criticized an early iteration of its P&T committee because its members were not practitioners and did not serve Medicaid consumers.⁵ In Washington, a committee member recalled that the clinical experience of its members led them to postpone a decision to place Vioxx on its PDL even before that drug was withdrawn from the market.

While the site visit states reported a preference for active practitioners, a P&T committee can function effectively without them. As a case in point, California’s informal evaluative body, which state staff and other stakeholders reported to be effective, uses researchers almost exclusively.

Include Opinion Leaders

The site visit states reported that committee decisions are more readily accepted by all stakeholders when members are opinion leaders in their professions whose clinical expertise is respected by their peers and other stakeholders.

All site visit states identify opinion leaders by asking professional associations (such as State Pharmacists Associations or State Medical Associations) to recommend committee members. Washington explicitly states a preference for candidates who are active in their professional associations⁶. Although all the states asked for recommendations, they retained the final authority to appoint committee members. These states did so in order to ensure that members act, and be viewed, as impartial judges of clinical effectiveness. Allowing another organization to select a member would create the perception that the member represented their interests, rather than the public’s. Some stakeholders also reported concerns about impartiality when state staff served on P&T committees.

These six states also work independently to identify opinion leaders. They may identify potential committee members among local practitioners or researchers who have written respected or widely-circulated articles, testified before legislative committees, or otherwise distinguished themselves in areas relevant to pharmaceutical research or practice.

COMMITTEE FUNCTIONS

The purpose of a P&T committee is to produce actionable, evidence-based recommendations that states can use to develop a PDL. P&T committees perform two major functions: receiving input and making recommendations. This section examines state strategies for effectively managing both of those activities.

Table 1: Overview of functions by state

	California	Florida	Kansas	Michigan	Missouri	Washington
What does the committee review?	Other	Other	DERP and Other	DERP and Other	DERP and Other	DERP
Does the committee consider cost?	No	Yes	No	No	No	No
What does the committee produce?	PDL Framework	Provisional PDL	PDL Framework	PDL Framework	Provisional PDL	PDL Framework

Receiving Input

P&T committees in the site visit states usually develop recommendations by applying the knowledge they have acquired through their own clinical experience to clinical evidence, and considering information supplied by stakeholders. Some committees consider cost information as well.

Committees base their decisions on clinical evidence

All site visit states provide summaries of scientific evidence to their committees. Committee members receive this information anywhere from 30 days (Washington) to one week (Michigan) before the committee convenes. The states generally agreed that research summaries are most useful when they include all relevant data, exclude any that is questionable, and organize it to facilitate decisions.

At the time of the site visits, four of the states (Kansas, Michigan, Missouri, and Washington) participated in the Drug Effectiveness Review Project (DERP). The DERP is a subscription service, based at the Oregon Health and Sciences University, which provides comparative reviews of drug effectiveness to states.⁷ These states report that DERP offers the most comprehensive review of available data, has the best standards for the inclusion of scientific evidence, and organizes and presents data in a manner that facilitates the decision-making process.

However, Kansas, Michigan and Missouri also report using clinical evidence that is compiled from sources other than DERP. Missouri uses clinical evidence from at least three other sources (First Health, Heritage, and the Drug Information Center at the University of Missouri at Kansas City), and Michigan uses evidence from at least one other (First Health). All three states feel that using multiple sources helps to validate the clinical findings.

Michigan reported that in early 2005, they began using workgroups of P&T committee members to make recommendations concerning specific drug classes and conditions. In addition to research summaries such as those from DERP and First Health, the workgroups also review primary research sources and, where necessary, input from clinical experts.

In Missouri, state staff analyze and use clinical evidence to produce a provisional PDL. Both are then reviewed by the Prior Authorization (PA) committee, the committee with P&T functions. The PA committee may accept the provisional PDL, request more information, or revise it.

Kansas, Michigan, and Washington each provide P&T committee members with the clinical evidence alone (without "processing" the information by, for example, including information on drug cost). This approach allows their committees to review the clinical evidence without potentially prejudicial information from other sources. They believe that limiting the review to clinical evidence focuses the committee's efforts on the clinical merits of the reviewed drugs and leaves them free to draw their own conclusions.

However, in Michigan, the P&T committee reviewed the final PDL in early 2005 after cost data was added. In essence, this allowed the P&T committee to affirm and, where necessary, modify the PDL before it was reviewed by the state.

California presents its committees with all possible information, including some unpublished data that is supplied by manufacturers, and may not be included in the DERP summaries. This allows both the committee and state staff to review evidence for different effects on sub-groups that are important in California with its large and diverse Medicaid population. This approach may also use the expertise of California's advisory group which, unlike those in the other states, is composed almost exclusively of university staff who are experienced judges of research quality.

Florida reported that they are very satisfied with the summaries they received from Provider Synergies, the contractor that reviews clinical evidence.

One committee considers cost along with clinical evidence

Among the six site visit states, only Florida provides information about the cost of drugs to its P&T committee. Florida believes that the committee should develop recommendations that reflect relative cost and clinical evidence of effectiveness. They believe that practitioners are best equipped to assess the tradeoffs between cost and clinical outcomes. For example, clinicians may determine that a more expensive drug might produce substantially better results with fewer side effects. Stakeholders are comfortable with P&T committee recommendations that explicitly include cost considerations.

Most other states take the opposite approach. Kansas and Washington, for example, felt strongly that the P&T committee should evaluate each drug solely on the basis of clinical outcomes. They believe that the consideration of cost by the P&T committee would undermine the legitimacy of the PDL. In these states, cost is considered by state officials only after the P&T review is complete.

Committees use stakeholder input

The site visit states all report that it is important for stakeholders (consumers, providers, and manufacturers) to be able to provide information to P& T committees. Five of the states offer stakeholders the opportunity to present additional evidence at committee meetings. California's advisory group does not hold in-person meetings. However, it does offer manufacturers an opportunity to provide additional (sometimes unpublished) information for consideration by the clinical advisory group and state staff.

Although stakeholder input is important, committees are typically charged with developing recommendations based on scientific evidence. As a result, the five states that hold public meetings have implemented strategies to ensure that the information presented by stakeholders is relevant to the evidence and that committee members are aware of any potential conflicts of interest that stakeholders may have. This is particularly relevant, as states reported that manufacturers often comment at meetings, while beneficiaries rarely do so. Also, since the committee has a limited time in which to accomplish its task, all five states limit the time for public remarks. Specific strategies for managing public comment include:

- In Florida, only one person per company or organization may speak to the committee and members may not question the presenters. Speakers may provide hand-outs to support their remarks but these must be no more than two pages long and of a clinical nature.
- In Kansas, public comment is limited to five minutes per drug. Speakers must provide all hand-outs to the state seven days before the meeting and complete a conflict of interest form that is provided to committee members. Rules governing public input at P&T committee meetings specify that the purpose of comment is to provide key points outlining the evidence-based value of the drug.
- In Michigan, speakers are limited to five minutes and any member of the public may speak. Speakers who include financial information in their presentations are stopped when they mention cost.
- In Missouri, presentations to the PA committee are screened by state staff and must be of a clinical nature.
- In Washington, quarterly meetings are open to the public and anyone may speak, but speakers are limited to three minutes each.

Developing Recommendations

In all site visit states, the P&T committee does not produce the final PDL. In four states, the committee produces a set of recommendations the state can use to create a PDL while adhering to clinical merits.

Florida and Missouri committees' both produce a provisional PDL which must be ratified by another committee. Missouri's provisional PDL is developed by the state in advance of the committee meeting.

In five states, the committee makes decisions about clinical equivalency by member vote. As one P&T committee member in Washington assessed this approach, "Voting makes the committee more credible and forces members to be publicly accountable for their decisions." In California, state staff compile recommendations submitted by each committee member to produce a PDL.

In five states, state staff or contractors integrate P&T committee recommendations with cost data to produce a PDL or a series of clinical edits (clinical edits establish specific clinical conditions under which a prescription should be filled. As previously discussed, in Florida the committee integrates cost and clinical data to produce a recommended PDL. In the five states where the committees do not consider cost:

- In Kansas, Michigan, and Washington, the P&T committees produce a set of recommendations for each drug: clinically essential; clinically inferior; and clinically equivalent to the best alternative in the same class. Those judged essential are included on the PDL and those judged inferior are excluded. The state then selects from among those judged therapeutically equivalent based on price.
- In California, state staff with clinical expertise review feedback from their advisory group, scientific evidence, and cost information in the form of bids by drug manufacturers to decide which drug or drugs within a therapeutic class should be preferred. The staff also produce a series of clinical edits that must be met for a drug to be covered.
- In Missouri, the PA committee produces both a series of clinical edits, and a provisional PDL. The PDL establishes which drugs may be prescribed for a beneficiary among those judged therapeutically equivalent. The PA committee's provisional PDL is then presented to the Drug Utilization Board for final approval. The Board retains the authority to make necessary changes.

CONCLUSION

As the experiences of these states show, creating a PDL is a complicated effort. P&T committees review and evaluate clinical evidence and sometimes other information to produce the framework from which the state develops a PDL. In general, the six site visit states informing this brief report that their P&T committees function more efficiently when:

- Membership includes practitioners from a range of professional disciplines who are in active practice (ideally serving Medicaid beneficiaries), and respected by their peers;
- Members are seen as impartial reviewers who are not tied to either professional associations or to the state administration;
- Meetings balance the need to obtain input from stakeholders with the need to reach decisions within a limited time period;
- Research summaries include all relevant data, exclude questionable data, and organize data to facilitate decisions; and
- It is clear (both in actuality and perception) whether the committee is charged with considering cost in addition to clinical factors.

Notes

¹ Vernon Smith, et al. *The Continuing Medicaid Budget Challenge: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2004 and 2005: Results from a 50-State Survey*. (Washington, D.C.: Henry J. Kaiser Family Foundation. October 2004.) <http://www.kff.org/medicaid/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=48004> (downloaded May 8, 2005)

² Neva Kaye. *Affording Prescription Drugs: State Initiatives to Contain Cost and Improve Access*. (Portland, ME: National Academy for State Health Policy, July 2002.) http://www.nashp.org/_docdisp_page.cfm?LID=666CB5DC-7948-11D6-BD1700A0CC76FF4C. Downloaded May 9, 2005.

³ Supplemental rebates are cash payments—in excess of those obtained through Federal legislation—states receive from pharmaceutical manufacturers in exchange for not restricting access to their products through the use of prior approval.

⁴ *Pharmaceutical Best Practices Initiative Report*, Michigan Department of Community Health, August 2004.

⁵ This accusation was found baseless as part of a lawsuit against Michigan's efforts to establish a PDL.

⁶ <http://rx.wa.gov/committee.shtml> (7/25/2005)

⁷ Additional information on OHSU's DERP project is available in another brief in this series.

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