Determinants of Change in Medicaid Pharmaceutical Cost Sharing: Does Evidence Affect Policy?

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ATIENT COST SHARING HAS BEEN A DOMINANT cost-containment strategy in Medicaid since its inception. During the 1980s, coincident with large increases in the cost of the state pharmaceutical benefit programs, many Medicaid programs raised pharmaceutical copayments or introduced prescription reimbursement limits (e.g., three prescriptions per recipient per month), sometimes with adverse clinical and economic consequences. However, despite the major economic and health impact of these cost-containment policies, there is little information on how state policy makers select and evaluate them. We surveyed key informants in 48 Medicaid programs to investigate the factors influencing recent changes in drug cost-sharing policies; their expected positive and negative outcomes; internal and external factors constraining policy choices; whether, and how, the effects of the policy were evaluated; and the role of objective research data in influencing policy decisions. In organizing our analysis, we differentiated between state policy infrastructures that predisposed key actors to make certain kinds of decisions and the external political and economic forces that often precipitated policy changes.

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The rapid rise in public and private pharmaceutical expenditures during the 1980s fueled debate about appropriate policies to moderate this growth without threatening the public's health (Soumerai and Ross-Degnan 1990). Through Medicaid and pharmaceutical assistance programs for the near-poor elderly, states have been the largest public insurers of prescription drugs for low-income, elderly, and disabled persons (Soumerai and Ross-Degnan 1990). Although they comprise 7.8 percent of total health expenditures in Medicaid, at a cost of \$7.97 billion, in 1993, prescription drugs have been one of the most rapidly increasing costs (Health Care Financing Administration 1980–93; Schondelmeyer and Thomas 1990). This is due primarily to rapid price inflation, as indicated by an annual rise of 11.6 percent in the Consumer Price Index for Drugs between 1980 and 1993 (Bureau of Labor Statistics 1980–93).

We focused our analyses on two types of patient cost-sharing requirements, prescription reimbursement limits and copayments, policies for which the scientific literature has produced good empirical evidence regarding effects on utilization, costs, quality, and outcomes of care. This strong evidence provides the opportunity to examine the role of research information in the policy development process. Our recent comprehensive and critical review of the literature (Soumerai et al. 1993) on the effects of these policies led us to these conclusions:

- Several adequately controlled studies indicate that copayments as low as one dollar per prescription in Medicaid have resulted in declines of 5 to 10 percent in overall drug utilization. Some evidence exists that even modest cost sharing can reduce the use of both essential agents and less essential drugs. However, no definitive evidence exists that typical copayments in Medicaid adversely affect health status or raise other costs.
- Prescription limits (caps) have had a sizable impact on the use of both "essential" medications (e.g., insulin and furosemide) and ineffective drugs. With a three drug per patient monthly cap, prescriptions filled by chronically ill elderly and disabled recipients decreased by 48 percent overall; these reductions were minimally offset by out-of-pocket purchases.
- Prescription limits (e.g., three-drug caps) have been found to increase total costs and nursing-home admissions significantly among elderly persons with chronic illnesses and to increase adverse pa-

tient outcomes, requiring emergency mental health services and partial hospitalizations among schizophrenic patients (Soumerai et al. 1991, 1994). These studies of just two identified high-risk populations indicate that the increased costs of nursing-home admissions and mental health services resulting from a three-drug cap greatly exceed the statewide drug savings. The data strongly suggest that state and federal drug benefit programs should avoid imposing arbitrary prescription limits as cost-containment strategies because they *raise* total health care costs and harm chronically ill patients.

Copayments and prescription caps are prevalent in state Medicaid programs. At the time of our survey, 21 states required copayments of between 50 cents and three dollars, and 11 did not provide drug benefits beyond a predetermined prescription cap (commonly three to six prescriptions per patient per month). Although caps on services may be applied to all recipient populations, federal law prohibits the imposition of cost sharing on individuals under age 18 (or 21 by state option); pregnancy-related services; certain institutionalized individuals; emergency services; family planning services; and categorically needy HMO enrollees (National Pharmaceutical Council 1981–94).

Little has been published about the determinants of cost-containment policies at the state level. However, previous work on the barriers to adoption of research results by health and social service organizations (Solomon and Shortell 1981; Brown 1987) is relevant to our research questions concerning the use of scientific data in Medicaid decision making. The literature identifies some commonly cited barriers to research transfer:

- 1. lack of *relevance* of information to the primary goals of service providers (Averch 1975; Cox 1978)
- 2. lack of timeliness of data when decision makers could use them (Banta and Bauman 1976; Weiss 1977, 1978)
- 3. lack of *effective communication* to decision makers because messages are not delivered in readily interpretable formats and language, are not targeted to leading decision makers, or lack credibility (Soumerai and Ayorn 1990)
- 4. lack of organization and resources to implement research findings (Brown 1987)

Related organizational and political barriers in complex or bureaucratic organizations include: lack of independent authority or power of policy makers to implement desired changes (Williams 1971); lack of readiness to accept change (Kiresuk, Larsen, and Lund 1981); instability of staff; and little institutional support for the use of research information (Solomon and Shortell 1981).

We hypothesized that many of these factors would also be identified as important barriers to rational drug cost-containment policy making, especially those related to the timeliness of information and the organizational and political constraints on Medicaid agencies. By using openended qualitative methods, we also hoped to highlight important but previously unidentified factors influencing the adoption of cost-containment policies. Increased understanding of how Medicaid agencies reach specific policy decisions could ultimately help to identify strategies to improve the policy development process. The dissemination of evidence-based cost-containment policies will increase the likelihood of cost savings while minimizing patient harm.

Methods

We conducted in-depth, semistructured telephone interviews with key informants in 48 states (response rate = 96 percent) to elicit open-ended responses concerning their perception of critical problems, issues, and constraints preceding a pharmaceutical policy change that had been instituted in the last several years. We identified specific instances of change in cost-containment policies through a review of annual reports of Medicaid pharmaceutical programs produced by the National Pharmaceutical Council (1981-94). For this study, we report the results of interviews conducted with 28 informants from 19 of the 22 states that changed cost-sharing policies between 1986 and 1993, including prescription reimbursement limits (n = 11) and copayments (n = 8). We investigated key policy proponents; their rationales for acting, anticipated positive and negative effects, and reservations about the policy change; their attempts to evaluate the impact of the policy; and the ways in which the pharmaceutical industry, the federal government, and academic researchers influenced the process.

During 1993 and 1994 we interviewed key informants in 11 states that had recently instituted, tightened, relaxed, abolished, or proposed

to abolish prescription reimbursement limits (table 1). We also interviewed Medicaid program staff in a state whose governor had attempted to abolish the pharmaceutical benefits program entirely: an extreme form of benefits limit. In addition, we interviewed respondents in eight states that had instituted, raised, lowered, or abolished prescription copayments.

Most of the 28 respondents (55 percent) were Medicaid drug program administrators responsible for managing the pharmacy program when the policy changes occurred. The remaining respondents included Medicaid directors or policy analysts (18 percent), pharmacy consultants (18 percent) contracted by Medicaid to institute drug policies, and legislators (9 percent). When primary respondents could not answer specific questions, and to obtain other experts' viewpoints, we interviewed a second and, in some cases, a third or fourth policy maker in the Medicaid program, state legislature, or other organization who had specific knowledge about the issues being addressed. We assured all respondents that their individual answers would not be identified by name, or even by state. Based on respondents' frank and open disclosures of frequently sensitive political processes, these assurances of anonymity probably helped to reduce response bias.

TABLE 1 Distribution of Study Policy Changes and States^a

Prescription reimbursement limits	n(%)	Rx copay ^c	n(%)
Instituted or tightened cap to: 3 Rx's/month	5(46) 4	Instituted or raised copay	4(50)
5 Rx's/month	1	Instituted differential copay ^d	3(37)
Relaxed or abolished cap ^b Prevented cap or drug	4(36)	Abolished copay	1(13)
program elimination	2(18)		

^aThe states were Arkansas, Colorado, Florida, Georgia, Idaho, Illinois, Maine, Maryland, Massachusetts, Mississippi, Missouri, New Hampshire, New York, North Carolina, Nevada, Pennsylvania, South Carolina, Texas, and Wyoming.

Includes one state with a legislative bill to eliminate cap.

Fifty cents to two dollars per prescription.

Requires higher copay for brand-name drugs (if generic substitute is available); includes one proposed change at time of interview. Abbreviation: Rx, prescription.

Results

In this section, we present our findings on underlying structural issues facing state Medicaid policy makers, the objectives and perceived effects of policy changes, and the influence on decision making of the pharmaceutical industry, federal agencies, and academic researchers.

Structural and Political Issues

A number of state-specific structural or background factors contributed in important ways to the capacity of state Medicaid programs to develop and evaluate drug cost-containment policies: the key proponents in policy development; recurring budgetary problems; external societal and governmental pressures; constraints on human resources and information systems; and lack of a long-term planning and evaluation framework.

Policy Proponents. Policy proponents, defined as the most important individuals or groups promoting the policy change, generally include the legislature (either individuals or committees), the governor (including the budget office), and Medicaid staff (including administrators or drug program staff). Respondents identified Medicaid administrators and staff as the actors who were largely responsible for change in about half of the policy decisions; the governor's office and the legislature were each considered to be key proponents in approximately one-third of decisions (table 2).

Organizations representing health care professionals were largely uninvolved in the cost-sharing policies that we studied. According to respondents, physician input is most intense on issues like professional autonomy in selecting and prescribing (e.g., limitations on use of single-source drugs); the medical establishment does not focus on patient-directed cost-sharing issues. None of the informants reported that physicians' organizations contributed in any meaningful way to formulating these policies. Pharmacists' organizations participated more actively in development of cost-sharing policies because of their financial stake in them. For years, pharmacists' dispensing fees have been reduced by Medicaid programs as a cost-control measure. Pharmacists must, by law, dispense medications even if patients cannot afford the copayment. In some cases, state pharmacy associations opposed copayments because

TABLE 2 Key Proponents of Policy Change

	Number of states ^a		
Key proponents (any mention)	Rx cap	Rx copay	
Governor's office	5	1	
Medicaid director ^{b,c}	6	5	
Legislature	5	3	
Legal services/patient advocacy	0	0	
Pharmaceutical industry	1	0	
Medical association	0	0	
Pharmacy association	0	0	

 $^{^{}a}N = 19$ states.

they viewed them as a threat to their members' income. In several states, the Pharmaceutical Manufacturers' Association, now known as Pharmaceutical Research and Manufacturers of America (PhRMA), actively opposed either higher copayments for single-source drugs or strict prescription limits that threatened to reduce utilization severely. However, PhRMA was less opposed to mild copayments. Only occasionally were patient advocacy organizations influential in the policy process; they tended to focus on mitigating the deleterious effects of the most stringent prescription limits on Medicaid recipients.

Recurring Budgetary Problems. All respondents in states (n = 12) that instituted or tightened prescription reimbursement caps or copayments agreed that they had done so because of budgetary and economic conditions. Economic downturns, legislative constraints on Medicaid budgets, drug price increases, or unrelenting overall increases in total Medicaid expenditures were cited as specific pressures. The dominance of budgetary issues in some states is illustrated by the fact that several programs alternated between stricter and more permissive prescription caps according to changing economic conditions. Prescription drug benefits, as an "optional" Medicaid service, represent an easy target for quick budget cuts.

External Precipitating Factors. A common theme that emerged from the interviews is the deleterious impact of sudden budgetary crises,

^bOr designated staff.

^{&#}x27;Including a specific representative. Abbreviation: Rx, prescription.

sometimes precipitated by outside forces like changes in federal legislation. One major example, preceding the interviews, was the federal Omnibus Budget Reconciliation Act (OBRA) of 1990, which made it extremely difficult for states to continue to operate restrictive formularies (limited drug lists), an essential component of pharmaceutical cost-containment strategy in many states. This prohibition against formularies was a negotiated settlement between Congress and the pharmaceutical industry in return for reduced drug prices in Medicaid. However, its cost-raising effects for state Medicaid programs eventually resulted in the abolishment of this provision in 1993. Interestingly, OBRA '90 was mentioned as the important precipitating event in four of the seven states that proposed, instituted, or tightened prescription caps. In two of the remaining three states, the governor or the legislature promoted the cap policy as a response to other severe budgetary problems.

In the year following OBRA '90, the governor's budget office of one Midwestern state proposed legislation to eliminate all nonrequired drug coverage in Medicaid. The respondent considered this a "side effect," or "agitated response to the OBRA '90 prohibition to reduce drug reimbursement." About one-third of respondents in states that changed drug-reimbursement caps after 1990 cited OBRA '90 as the main stimulus.

Limited Time for Decision Making. The nexus of rapidly changing external forces and local budgetary constraints often imposes extremely brief time frames for decision making. The previously mentioned governor's budget office proposal to eliminate Medicaid drug benefits was immediately opposed by the Medicaid director:

The Budget Office claimed that there was no study which showed that removing drug coverage would harm recipients or have cost effects in other ways. . . . The anticipated 1993 Medicaid drug budget was \$324 million, which was the amount needed to balance the state budget. Eliminate the Medicaid drug program, and the entire state budget would balance. . . . Medicaid only had a week to make a case to keep drug benefits. . . .

This case study is revisited below in the section on influences of the pharmaceutical industry, federal agencies, and academic researchers.

The Medicaid program in a large Southern state recently faced even more unreasonable demands for rapid decisions when the legislature's budget staff suddenly announced a fiscal need to tighten the state's monthly prescription limit from six to three per recipient. The demonstrated hazards of such an approach caused the Medicaid staff to resist this change. Drug program staff were given only three hours to develop alternative cost-cutting policies that would achieve the same savings. According to one respondent, the staff attempted to wield "scalpels instead of a meat-axe," and ultimately succeeded by changing copayment levels, instituting drug price rebates, and establishing drug utilization review and prior authorization procedures, all of which necessitated rapid staffing increases.

Lack of Political Power. One major structural constraint reported by Medicaid administrators was their lack of authority to implement the most rational policies. Medicaid directors or staff were identified as key proponents in only two of seven proposed or successful attempts to tighten prescription caps, and in half of decisions to institute or raise copayments. Although Medicaid program staff were often the most aware of specific risks and benefits of alternative policies (based on their experience with Medicaid patients and advocates and their familiarity with published studies), they were often constrained by political forces. In the words of one Medicaid staff member:

In public hearings, the Medicaid drug program administrator cannot disapprove publicly of anything that will save money even if it doesn't make sense, because we have a Governor bent on cutting government. It's a caustic thing with the legislature. The previous Bureau of Medical Services director was fired for not dancing with the Governor. . . .

In a Southern state a no-new-tax pledge by the governor defeated a legislative proposal to eliminate a three-drug cap despite evidence that such a change would be budget neutral. Medicaid staff often recognize that medications represent essential medical services, but they lack hard, persuasive, and relevant data to convince either legislative committees or the governor's office that drug benefits are cost effective, especially for chronically ill and disabled individuals whose functional independence in the community often depends on access to pharmaceuticals.

Another barrier to cost-effective policy making is the compartmentalized budget and accounting process in state government. Important economic benefits of access to essential medications are sometimes not apparent because they occur as savings in other nondrug health services. For example, although Medicaid drug program staff might be aware

that reimbursement limits can raise hospital and nursing-home utilization, they still accept the constraints because they consider their drug program budget in isolation.

Lack of Infrastructure for Policy Formulation and Evaluation. Many Medicaid programs lack staff with the training, experience, and analytic skills necessary to select optimal policies. Respondents were often unabashedly frank when describing the subjective nature of the analytic processes leading to policy. For example, one program manager in a Southern state that tightened its prescription cap to five prescriptions per month expressed frustration with OBRA '90 restrictions and the arbitrariness of the decision process: "We were very limited in what we could do. We did a review of the number of prescriptions received by the average recipient. It was 4.8, so we just said 5."

In deciding to institute a differential copayment, Medicaid staff in one Western state relied mainly on their own ideas and on ideas generated by staff from neighboring states: "The policy is a result of Medicaid staff's 'gut reaction.' The staff was looking for ways to decrease expenditures. The policy grew out of staff discussions. . . ."

In addition to policy analysis shortcomings, many programs lack staff and skills in policy implementation. Protection of vulnerable populations requires a more complex policy (e.g., specific exemptions for multiply chronically ill persons, AIDS patients, and others for whom medications are highly cost-effective). Many respondents indicated that their programs lacked the capacity to make fine policy adjustments. For example, respondents in several states cited the administrative convenience of a prescription cap policy without these safeguards. According to one respondent, "It is easiest to cap prescriptions . . . and less disruptive to physicians." Similarly, although prior authorization policies may target inappropriate utilization more selectively, several respondents indicated that staff resources were insufficient to administer them.

Objectives and Perceived Effects

The reported rationale and expected effects of cost-containment policies often reflect dominant societal and governmental perceptions about Medicaid recipients and have as their major themes reducing unnecessary uti-

lization; increasing patient responsibility; and minimizing negative policy effects by selecting the "lesser evil" among competing alternatives.

Policy Objectives. Cost cutting was cited as the predominant objective in all 12 states that instituted or tightened caps or copayment policies. In many cases respondents could cite expected drug cost savings, based on historical drug utilization data (but not including increased costs in other sectors). Other positive effects reported for increased copayment levels were keeping pace with rising drug prices and maintaining consistency with private insurers.

Respondents in five states that reduced benefits reported choosing policies in order to moderate the negative impact of cutbacks. According to one drug program manager in a Southern state: "We had to do something, and this [raising copayments] was the lesser evil." In a Northern state, Medicaid program staff were happy to succeed in instituting a mild copayment policy instead of the governor's proposal, a much more restrictive two-prescription per month cap: "There was an uproar by patient advocates and the advisory committee when they found out that the state was trying to get a two-prescription limit."

The belief that increased patient cost sharing would inject greater patient responsibility and rationality into the drug utilization process was another important theme. Three of seven respondents felt that copayments would increase physician and patient awareness of costs and involvement in their care and reduce inappropriate use of medication. According to a respondent from a Northern state that was instituting a higher copayment for single-source drugs, the policy "would cause recipients—who, in fact, pay the copayment—to ask their physician to give them a generic, and get involved in their own health care." Despite data suggesting that copayments tend to reduce both appropriate and inappropriate therapy (Lohr et al. 1986), another respondent reiterated: "The copay should help reduce unnecessary prescriptions . . . and make patients think about drugs." Several respondents from Southern states also expressed the opinion that copayments deter recipients from fraudulently obtaining drugs for other individuals.

Respondents in seven states that relaxed their caps and copayment policies (or prevented their enactment) expected several positive effects: reduced inequities in access; increased access to essential medications; reduced administrative difficulties in exempting essential drugs from a cap policy (e.g., the highly effective, but expensive, antipsychotic agent,

clozapine, requires weekly prescriptions); cutting down on drug wastage or abuse associated with larger prescriptions induced by the policies; and reduced hospital and nursing-home admissions.

Unintended Effects

When asked whether tightened prescription caps produced negative effects, four of five respondents mentioned possible decreases in access to needed medications, in patient care-seeking, and in quality of care. Advocacy groups, and some physicians, were the principal voices of opposition to increasingly restrictive policies. (However, physicians as a rule did not try to influence policy decisions.)

Half the respondents in states instituting or increasing copayments cited possible negative effects: reduced access to needed medications when there were differential copayment levels for single-source versus multisource products; cost transfers to patients who can least afford it; failed drug treatment; visits to emergency rooms to obtain medications; and concentrated adverse effects for individuals with multiple and/or chronic illnesses.

Barriers to Evaluation. Although many respondents were aware (from their own experience, professional networks, or published data) that prescription caps and copayments might reduce quality of care, none of the Medicaid programs evaluated the potentially negative impact of these policy changes. In two of seven states that increased copayments, Medicaid staff informally analyzed attributed savings. Three of 11 states conducted uncontrolled analyses of yearly shifts in drug expenditures following changes in prescription caps, but they did not evaluate possible offsetting increases in other health expenditures or declines in quality of care.

Lack of expertise and negative perceptions about evaluation discouraged its use. The statements of several respondents suggest considerable naiveté regarding the appropriate use of evidence and the causal relations among policy changes, health care utilization, costs, and patient outcomes. For example, based on aggregate counts of visits, one Medicaid staff member in a state that implemented a cap concluded, "There was some concern that people . . . might avoid seeking care. This seems not to have occurred."

Based on similar inappropriate analyses, drug program managers in two Southern states that were instituting a higher copayment level stated:

Respondent 1: In the 1970s, the co-pay caused prescription volume to drop by 20 percent, but it came back after a few months.

Respondent 2: You can look at current utilization and tell that cost-sharing has not put people in the hospital or caused any precipitous reduction in drug use.

Of course, seat-of-the-pants analyses do not adjust for prepolicy trends or coincident policy changes. In addition, significant harmful effects on vulnerable subgroups are unlikely to be seen in gross utilization data.

Whereas some respondents were aware of the need for evaluation, they simply lacked the necessary resources. One drug program manager in a state that increased its copayment level reports: "We didn't have the time or the staff to evaluate the effects of the policy. . . . Sorry, we're flying blind. I can't tell you of any reports at all."

Indifference toward evaluation is readily apparent in the comments of a Medicaid staff member in a state that recently lowered its monthly cap from four to three prescriptions: "Either way you go, it [evaluation] doesn't matter at an administrative level."

Influence of the Pharmaceutical Industry, Federal Agencies, and Academic Researchers

Given the limited capacity of state Medicaid programs to analyze the potential and actual consequences of various policy alternatives, it is important to assess whether industry, the federal government, or academic experts have provided sufficient technical assistance and critical scientific input. We asked all respondents to rate the degree to which these three sources of information and influence contributed to decisions to institute or modify their cost-sharing policies (table 3) and to describe how this input was provided.

Industry. The pharmaceutical industry was seen as actively involved about one-third of the time, particularly in policy decisions that affected prescribing of single-source agents (e.g., differential copayment levels

TABLE 3	
Input Provided by Industry, Government, and Aca	demia on Policy Change

Source	P	nput ^a	
	None	Some	Extensive
Pharmaceutical industry	12	5	1
Federal government	12	4	2
Academic researchers	14	3	1

 $^{^{}a}N = 18$ states.

for brand-name drugs or across-the-board restrictions like prescription caps). The industry exerted its influence through lobbying directed at the legislature and through meetings with Medicaid program staff. A number of respondents questioned the credibility of industry-sponsored studies, which always support an antiregulatory position. However, several others felt that industry representatives were helpful in providing important information (including some from noncommercial sources) in the form of relevant published data, position papers promoting physicians' professional autonomy in prescribing, and details about specific drugs that should be exempted.

The federal government figured prominently as Federal Government. a policy influence in six of 18 states reporting. Its input, however, was usually precipitated by communications from states to the Health Care Financing Administration (HCFA) to determine whether proposed policy changes complied with federal laws and regulations. For example, when legislators in one Southern state wished to tighten their reimbursement cap to two prescriptions per month, federal staff questioned whether HCFA could certify the program at that level. In response, the cap was relaxed to three prescriptions per month. In the Midwestern state whose governor wished to eliminate the entire drug program, Medicaid staff held extensive discussions with HCFA to determine the extent of state flexibility in restricting reimbursement for specific populations (e.g., children, pregnant women, and nursing-home residents). In general, however, federal agencies were not described as initiating technical assistance, volunteering specific data, or offering advice on policy alternatives unless they were asked.

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Academic Researchers. Four states reported that academic researchers were actively involved in the process of policy change. However, this reported level of academic involvement in policy decisions is probably an underestimate because we did not systematically collect data on states that avoided considering or instituting cap policies because of evidence about their adverse effects. Nevertheless, three case studies that we did learn about illustrate successful instances of research transfer as well as typical barriers to evidence-based policy making.

The first case illustrates the role of partnerships between state agencies and academic researchers and the importance of Medicaid staff who take the initiative in conducting research and contacting researchers during periods of critical policy development. In the Midwestern state that threatened to discontinue its drug program, Medicaid staff were given one week to provide convincing evidence that removing drug coverage would harm recipients or increase costs. Immediately, several staff members launched computerized literature searches at a nearby medical school and identified several studies on the harmful economic and clinical effects of prescription caps and formularies. They contacted the authors of these studies to obtain additional advice about their specific policy problem. According to the respondent, these publications and the researchers' comments were crucial in preventing the budget office plan from going forward.

To rebut [the Governor's Budget Office], Medicaid used ... research that suggested that even reducing drug benefits had detrimental effects. ... The entire logic of Medicaid's successful case to keep the drug program was based on input from ... [researchers] via telephone, fax, and medical literature search. Medicaid [staff] learned of these researchers' work through a literature search they carried out at ... Med School.

In a second case, the pharmaceutical industry and the state medical association used published university research on the New Hampshire cap to advocate elimination of a prescription cap in a Southern state on the grounds that doing so would reduce hospitalization and nursing-home admissions. As in the first case, economic arguments dominated the list of reasons for expanding drug coverage. In this instance, however, relevant research findings were promoted by the drug industry.

According to the Medicaid respondent, by 1993 this lobbying effort had begun to pay dividends:

The legislature is now receptive not only to continuing current funding, but to dropping the caps as well. . . . We have had many efforts by the PMA [PhRMA], the medical association, and so on to show that if the legislature cut the [cap] program, it would [reduce costs] because of reduced hospitalization and nursing home admissions. . . . So the legislature . . . is now discussing removing caps and hoping that it will cut nursing home and hospital admissions. . . . The New Hampshire study mentioned this idea. . . . It was used by the PMA, however, to suggest it.

A third successful instance of utilizing research to inform policy is the case of the Southern state legislature that gave Medicaid staff three hours to come up with a cost-saving plan that would reduce drug expenditures as much as a three-drug cap. First, staff members' opposition to the cap was based on published evidence of its adverse economic and clinical effects. Second, several academic researchers were members of the state's Drug Utilization Review (DUR) Board, which provided ongoing guidance on both DUR and other drug cost-containment policies.

Several explanations were offered by other states for failure to involve academics: lack of timeliness; perceived irrelevance of academic research to the problem; and state reliance on nonacademic information sources, including other Medicaid programs and conferences. Timeliness emerged as a prominent theme. A respondent from a Midwestern state that discontinued its prescription reimbursement cap explained this clearly: "There was simply no time to get input from these people. We did it on an ad hoc basis as thoroughly as we possibly could, but we needed to keep the program running."

Another constraint on academic policy input is the fact that Medicaid staff often are insufficiently trained in policy analysis, research, and evaluation. A respondent in a state that instituted a differential copayment described the situation thus:

Medicaid staff will gather information from some publications of ... the Public Welfare Association. However, they usually are not familiar with academic journals; they don't search for them, and don't usually take them into account. Occasionally, someone will send in a copy of, for example, JAMA, but the studies usually don't coincide with times when input is needed in the policy process.

Discussion

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Our results underline several critical problems in state Medicaid decision-making structures and processes that can tip these systems toward policies that are both clinically and economically unsatisfactory. However, the divide between researchers and policy makers has been successfully bridged on several occasions, indicating that the impact of objective evidence on policy decisions can be intensified under certain circumstances: for example, when well-trained, proactive analysts in Medicaid seek out research information during the policy-making process and communicate its *relevance* to the important actors; when independent and credible research studies by PhRMA, professional associations, and patient advocacy groups are used to lobby state legislatures; and when Medicaid staff and researchers consult each other personally to clarify how research findings apply to specific decisions.

Unfortunately, the data demonstrate that the skills, authority, and infrastructures necessary to identify more rational policies are absent in some states. Prescription caps and copayments are known to reduce both appropriate and inappropriate drug utilization (Soumerai et al. 1993). Of the two policies, prescription caps pose the greater clinical and economic risks for chronically ill, poor patients. Although it is possible that carefully designed exemptions for essential drugs or high-risk patients could mitigate the worst effects, many programs are incapable of effectively administering such exemptions. In seeking administrative simplicity, for example, a state might set prescription caps near the mean level of use, despite the likelihood of such a step harming the sickest elderly and disabled recipients while failing to decrease inappropriate drug use among healthier Medicaid enrollees.

A second barrier to rational policy is scarcity of quantitative data for evaluating policy changes. This information gap is very troubling, especially in the light of evidence that some policies harm vulnerable patients and shift high costs to other state and federal insurance programs (Soumerai et al. 1991, 1994). By analogy, an experimental study that substantially changed the access to effective treatments of large groups of patients without their advice or consent would be unlikely to receive approval from human subjects review committees.

Compartmentalized budgeting presents a third barrier to evidencebased policy, in that it creates incentives for controlling costs in one program while ignoring possible cost shifting to other programs or agencies. As Schroeder and Cantor (1991) have argued, "Although piecemeal efforts at cost containment may accomplish their narrow goals, this achievement may come at the considerable price of diminished access, decreased quality, or excessively intrusive (and even expensive) bureaucracy." Obviously, the solution to this problem requires systemwide changes in organizational structures and incentives.

Rational policy is also impeded by the lack of any strong lobbies concerned with the impact of cost sharing. Physicians and other health professionals have been largely mute on the subject of policy changes that affect access to care unless these changes limit their own therapeutic prerogatives or impact their income. Moreover, advocacy groups often become involved in only the most extreme situations, and then in a reactive, rather than a participatory, role.

Finally, several factors conspire to limit the links between policy makers and evidence: lack of timeliness of research; inadequate training of Medicaid staff in interpreting data; and negative attitudes toward the relevance of research for "real-world" problems. Examples of empirical data being used to sway policy makers clearly illustrate the importance of presenting evidence to them during the "teachable moments" of the decision-making process. Moreover, these examples suggest the possible benefit of training programs to inform Medicaid policy makers and increase their receptiveness to relevant health services research findings.

Previous studies (Weiss 1977, 1978; Solomon and Shortell 1981; Brown 1987) identified similar barriers to the use of research utilization: timeliness; relevance to decision makers' goals; interpretability of communications; and organizational and political roadblocks. Our report echoes these findings, but it also highlights the important role both of external agencies, like the governor's office and the legislature, that often applied pressure for policy implementation with no awareness of its potential impact, and of federal mandates and prohibitions (e.g., OBRA '90) that resulted in compensating, crisis-oriented budget cuts. This study, more than previous ones, highlights the fact that state drug program managers were often not unaware of the adverse effects of policies; in fact, they sometimes cited research studies relevant to a policy change in response to our open-ended questions. However, as studies of clinicians' treatment practices have also shown, knowledge of the benefits or risks is necessary, but often insufficient in itself, to cause behavioral change (Soumerai and Lipton 1994). Political pressures for quick "budget fixes" often prevailed. In a few cases, Medicaid staff with more sophisticated skills in policy analysis or communications were able to bargain for less hazardous policy alternatives. The several successful applications of evidence in policy making suggest testable hypotheses for future research concerning the positive effects on the policy process of:

- 1. training Medicaid staff to analyze policy and uncover critical findings from previous research
- 2. promoting more regular communication between policy makers and researchers
- 3. creating alliances between important interest groups (e.g., patient advocates and pharmaceutical companies)

Our methods had several limitations. First, the study included only Medicaid programs that had made changes in specific cost-containment policies during the last several years. Thus, we cannot generalize our results to states that maintained consistent cost-sharing policies throughout the last decade where policy determinants may differ. In addition, our observation period coincided with the implementation of OBRA '90 requirements. These requirements exerted severe fiscal pressures on states that could no longer maintain restrictive formularies, thus increasing the likelihood of their adopting alternative cost-containment policies. Nevertheless, external budgetary pressures are common occurrences in Medicaid policy making and are themselves an interesting research subject.

Another, perhaps unavoidable, limitation of our study is its focus on specific cost-sharing policies within the drug program and the absence of data on how policy makers allocate increased revenues or cuts across different Medicaid budgets or between Medicaid and other government-provided services. While important, such decisions are inherently complex and very difficult to study. In this analysis, our focus was not on whether drug benefits should be raised or lowered, but which cost-containment policies were adopted and why. The published evidence on the economic and quality-of-care effects of alternative drug cost-containment policies is stronger than that for many other Medicaid policies (Soumerai et al. 1993). We know, for example, that a one-dollar copayment is

less likely to produce unintended cost shifting than a three-prescription cap (Soumerai et al. 1994). Similarly, we know that a carefully targeted prior authorization procedure promoting inexpensive, generic nonsteroidal antiinflammatory agents (NSAIDs) in preference to brand-name alternatives can save millions of Medicaid dollars each year without increasing expenditures for other medical services (Smalley et al. 1995). Future research and technical assistance might help state policy makers understand the likely risks and benefits of other feasible policy choices in their states.

A final limitation of our method is the possible effect of "social desirability bias," that is, the tendency for respondents to report beliefs, opinions, and behaviors consistent with acknowledged social norms even if their actual behavior deviates from this standard. For example, it is possible that the self-reported reasons for promulgating specific costcontainment policies overemphasized concerns for patient welfare when, in fact, economic or political factors dominated decision making. While such factors undoubtedly influenced our findings in selected cases, this form of bias is likely to be limited for the following reasons: First, six of the 11 changes in cap policies prevented, relaxed, or abolished these potentially ill-advised policies. The decisions were already congruent with research on protecting patient welfare (obviating the need for rationalizations). Second, when social desirability bias is a concern, indepth interviews using detailed and probing questions are more likely than brief, structured surveys to uncover underlying motivations. It is noteworthy that all 12 respondents in states that raised caps or copayments acknowledged the preeminent role of economic and budgetary concerns (over patient welfare) in that decision. Moreover, after assurances of anonymity, several respondents did not hesitate to provide frank and rich details regarding political obstacles to rational policy in their current administrations. Thus, we uncovered ample evidence of policy influences that are neither scientific nor altruistic. Finally, our interpretation of barriers to evidence-based policies was often based on events and actions, rather than opinions. For example, our conclusion regarding the limited role of policy evaluation was derived from detailed information on methods used and reports produced. Our interpretation that crisis-oriented budget decision making was often a barrier to rational policy making was based on descriptions of the events leading up to the crisis.

Recommendations

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Our findings suggest several strategies to strengthen the link between research and policy. First, longer-term relations need to be established between Medicaid programs and independent research-based institutions, such as university health policy research centers. Research centers must respond with timely information when policy makers are actively making decisions and thus are most receptive, in much the same way that opinion leader clinicians influence their colleagues' clinical decisions during consultations at a patient's bedside (Stross and Bole 1980). Clearly, any consultative process at the state level must be both rapid and flexible. In addition, targeted workshops can inform states about specific types of cost-containment policies.

Responsiveness is higher if critical results are actively disseminated in a form that managers and policy makers can effectively absorb. Long and jargon-filled publications are less effective than simple, brief, and graphic communications that clearly demonstrate how research results are relevant to actual policy choices. The perceived credibility of policy researchers may be as important as their results (Soumerai and Avorn 1990). An ideal mechanism would be for research groups to collaborate prospectively with Medicaid programs in planning and evaluating policy innovations. This process might be similar to the prospective change management programs used by private sector consultants assisting in corporate reengineering efforts (Ostraff and Smith 1992; Ghoshal and Bartlett 1995). In several states (e.g., Washington and Virginia), faculty positions and programs in pharmaceutical services research are jointly funded by Medicaid and universities. This practice facilitates ongoing collaboration and policy evaluation.

A second major recommendation to improve policy making is to create an ongoing structured advisory process linking Medicaid programs, governors' offices, and state legislatures. Even when Medicaid staff were aware of the adverse effects of certain policies, they often lacked the appropriate authority or communication channels to prevent ill-advised policies or to suggest alternatives. Crisis-oriented confrontation among the main policy actors is less effective than structured and continuous dialogue. DUR boards, mandated by OBRA '90, may represent a model for such dialogue. DUR boards provide a forum for communication about DUR policy and programs among professional

societies, industry, and Medicaid staff. A similar board to advise on cost-containment policy might include representatives from these groups as well as members of the legislative and executive branch, patient advocacy groups, and research institutions. Such an advisory board could consider the evidence for or against specific policy alternatives and advise on the complex issues involved in measuring economic effects and other consequences of cost sharing.

Finally, the imposition of severe cost-sharing policies reflects a lack of sensitivity to the needs and values of poor, chronically ill patients. These individuals are most vulnerable to economic barriers that restrict access to essential medications. Current congressional proposals to give states more autonomy to decide the scope of Medicaid benefits through block grants represent a clear danger to vulnerable populations, especially in states with weak economies, poor policy structures, and limited advocacy for the poor. We suggest that state policy makers consider the impact of drug cost-sharing policies on the quality of life and independence of chronically ill patients *before* implementing them. Greater attention to the human impact of policy decisions not only makes ethical sense but may also be rewarded by reduced costs of physician or institutional services (Soumerai et al. 1991, 1994).

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