HEALTH CARE REFORM

Medicaid Drug Selection Committees and Inadequate Management of Conflicts of Interest

Nicole Yvonne Nguyen, PharmD; Lisa Bero, PhD

Background: Drug selection decisions for state Medicaid reimbursement programs should be based on the best available evidence and free of conflicts of interest (COIs), but little is known about how the committees identify and manage COIs of the members. The objectives of this study were to (1) describe the content of Medicaid drug selection committees’ COI policies for the US states and the District of Columbia, (2) categorize the policies by strength, and (3) identify characteristics of a strong policy.

Methods: For all states with Medicaid Preferred Drug Lists (47 states and the District of Columbia), we conducted a systematic search of official Medicaid websites and contacted Medicaid staff by e-mail and/or telephone to identify drug selection committee COI policies. We conducted a content analysis of the policies, extracting data on COI disclosure parameters, management strategies, and review processes using predefined categories modified through an iterative process.

Results: Policy documents were obtained for 27 of the programs (56%)—14 from websites and 13 by contacting Medicaid officials. We found high variability in COI policies, lack of public availability, and inconsistent enforcement and management of COI among states. The most common management strategy was disclosure of COI in 67% of policies (18 of 27), followed by self-recusal in 52% of policies (14 of 27). Only 15% of policies (4 of 27) ban certain relationships with industry.

Conclusions: Current policies are not transparent and not standardized, and no state policy included all model components. Wide variations suggest that some policies may not adequately protect drug selection decisions against COI and industry influence. With expected growth of Medicaid due to health care reform, the selection of drugs for Medicaid patients should be protected from the influence of COI.


CONFLICT OF INTEREST (COI) occurs when an individual’s professional judgment or an institution’s primary mission is unduly influenced by secondary interests, such as financial or personal gain.1 Widespread financial relationships with industry have been reported among physicians, researchers, and educators.2,3 Pharmaceutical industry-sponsored clinical trials have been associated with outcomes that favor the industry sponsor’s product compared with studies with other sponsors. The favorable outcomes can result from differences in the design, conduct, or publication of the studies.2,4-7 Pharmaceutical companies promote their products by offering gifts, consultation fees, and honoraria to individual practitioners and researchers. These practices can have an impact on therapeutic decision making because they skew the body of scientific evidence in favor of newer, more expensive, on-patent drugs.2

Managing COI is important in the setting of drug selection for formularies or reimbursement lists to ensure that products are selected based on evidence and with minimal bias. In US hospitals, physicians who had interactions with drug companies were more likely to request that drugs be added to their hospital formulary and request specific companies’ drugs over alternative companies’ drugs, compared with physicians without industry relationships.8 Federal decisions to approve new drugs have also been influenced by industry relationships.9,10 These examples suggest that financial ties with pharmaceutical companies can influence the decisions made on drug selection committees.

See Invited Commentary at end of article

To protect against COI, policies to limit financial and other relationships with the pharmaceutical industry may be implemented within governmental and medical institutions.2,11-14 Conflict of interest policies among national drug regulators dif-
In this study, we focus on COIs that can affect reimbursement decisions of public programs, specifically pharmacy and therapeutic (P & T) committees that make drug selection decisions for state Medicaid reimbursement programs. The current code of federal regulations stated in the Center for Medicare and Medicaid Services (CMS) prescription drug benefit manual describes the requirements for COI policies for P & T committees. However, the CMS policy requires only 2 members of the committee to be free of COI and does not provide definitions of COI for disclosure. We compared the content of Medicaid drug selection committee COI policies to a model policy for (1) disclosure parameters, (2) management strategies, and (3) process for reviewing COI. The model policy is adapted from the Public Health Service Conflict of Interest Regulations (http://grants1.nih.gov/grants/policy/coi/index.htm). Our objectives are to (1) describe the content of Medicaid drug selection committees’ COI policies for all 50 US states and the District of Colombia, (2) categorize the policies by strength, and (3) identify the characteristics of a strong policy.

STUDY DESIGN AND DATA SOURCE

This study is a content analysis of Medicaid drug selection committee COI policies. Our study focused on the Medicaid fee-for-service population because reimbursed medicines for this population are based on the state Preferred Drug Lists (PDLs) and are directly affected by state PDL and P & T Committee policy. Tennessee, New Jersey, and New Mexico were excluded because their entire Medicaid population is served by managed care organizations, resulting in a final sample size of 48 Medicaid programs (47 states plus the District of Columbia).

This research was exempt from the committee on human research (institutional review board) because it involved the study of existing publically available data and documents or talking to public officials about their everyday work.

DATA COLLECTION

We used a systematic search strategy to locate documents containing committee policies. First, we collected publicly available documents from official Medicaid websites from July through December 2011 using the Google search engine. The search terms were “[state name] Medicaid Pharmacy and Therapeutics,” and “[state name] Preferred Drug List Committee.” Once official Medicaid websites were located, they were searched in a stepwise manner for their drug selection committee policies, minutes, agendas, and contact information. Next, we e-mailed and/or telephoned the listed contacts for each committee for which we did not obtain written policies (n=34) from November 2011 through February 2012, requesting written copies of state policies. In most cases, e-mail addresses specific to Medicaid PDL and P & T committee personnel were available on websites. If not, we obtained contact information for Medicaid Pharmacy Services, then Medicaid or Department of Health Services more generally. Our unit of analysis is the official written policy, so verbal and written statements made by administrators during correspondence were not coded in the content analysis.

METHODS

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RESULTS

IDENTIFICATION OF POLICIES

We obtained policy documents from 27 of the 48 Medicaid programs—14 from websites and 13 from contacting committees (Figure 1). (All documents are available from the authors.) Programs that did not have policies available on their website (n=34) were contacted; 19 responded. Six programs responded but did not provide written documentation of their policies: California, Massachusetts, Mississippi, Florida, Utah, and Virginia. One participating program official stated that the committee’s policies are not publically available: “[Our] Medicaid [program] has policy and procedures, conflict of interest and confidentiality policy and attestations for committee members. Those documents are not in the pub-
lic domain." Two programs confirmed that they did not have a COI policy. Another participant, a bureau chief for Medicaid Pharmacy Services from one state wrote,

I get to know the P & T members pretty well, and to date, have not had any problems with conflict of interest. Our Committee positions are voluntary, and the Agency does not pay an honorarium for members to attend... The lack of honorarium creates a disincentive for participation by physicians/pharmacists who act as paid speakers or consultants for the pharmaceutical industry. They want to get paid, and I don't believe that the pharmaceutical industry would pay a committee member an honorarium to be on the committee and attend meetings. That would really be "over the top."

The types of documents analyzed from different states included P & T operating procedures, P & T bylaws, acknowledgment of review of ethical practices form, COI statements, and disclosure forms. Of the 27 policy documents analyzed, 20 (74%) specifically address COI. States whose policies did not address COI are Alabama, Alaska, New York, North Carolina, North Dakota, Ohio, and Vermont.

CONTENT ANALYSIS

The frequencies of the 12 policy components identified for the 27 policies addressing COI are as follows.

<table>
<thead>
<tr>
<th>Component</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclosure requirement</td>
<td>18 (67)</td>
</tr>
<tr>
<td>Self-recusal requirement</td>
<td>14 (52)</td>
</tr>
<tr>
<td>Disclosure frequency</td>
<td>13 (48)</td>
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<tr>
<td>Public availability</td>
<td>11 (41)</td>
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<tr>
<td>Defined monetary cut offs</td>
<td>11 (41)</td>
</tr>
<tr>
<td>Disclosure form available</td>
<td>9 (33)</td>
</tr>
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<td>Enforcement</td>
<td>8 (30)</td>
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<tr>
<td>Assigned reviewer</td>
<td>8 (30)</td>
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<td>Immediate family relationships</td>
<td>7 (26)</td>
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<tr>
<td>Reporting window specified</td>
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<tr>
<td>Additional management strategies</td>
<td>5 (19)</td>
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<tr>
<td>Banned relationships</td>
<td>4 (15)</td>
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</table>

The requirements for disclosure at a stated frequency occurred most often, along with a requirement for self-recusal. Banned relationship and other management strategies were described least often.

The Table shows the strength of the policies by state. The strength of the policies ranged from having 9 of 12 components (Washington and Idaho) to having 2 components (Texas and Nevada).

Disclosure Parameters

Disclosure forms varied across policies; no policy specifically stated that disclosures would be available to the public. Minnesota policy (obtained from Minnesota Medical Program; e-mail communication, February 12, 2012) stated that committee members are required to disclose the following relationships with pharmaceutical companies: "employment... any paid honoraria or expert testimony, any free travel... stock owned... any free goods or services valued at more than $50." Committee members were also required to disclose other affiliations such as "any academic or inter-organizational relationships, financial relationships, professional associations and personal relationships that may affect your independence of judgment." Other state policies merely noted that disclosure is required without giving specific examples of what must be disclosed.

For 33% of states with written policies (9 of 27), committee disclosure forms were readily available. While the forms varied in detail, most asked open-ended questions. No forms provided a checklist. Oregon's disclosure form provided sections to fill in names, addresses, and explanations of relationships with businesses, lobbyists, and other sources of income. Colorado and Georgia forms requested the affiliated organization or company name and relationship. Kentucky's also required reporting of the drug name or type of COI being disclosed.

The required frequency for disclosure was found in 48% of policies (13 of 27) and ranged from annually to monthly. Delaware disclosure statements are renewed at every P & T committee meeting. Forty-one percent of policies (11 of 27) defined monetary cutoffs for disclosure. For example, the Oregon policy included sources of income producing 10% or more of total gross income, shared business with lobbyist, business investments or service fees more than $1000, and honorarium more than $50. Kentucky required disclosure of any relationships in excess of $50 000 per pharmaceutical, biotechnologic, or medical service company, and compensation in excess of $5000 per year for honoraria or consultancies from any single institution.

Some policies (26% [7 of 27]) extended disclosure requirements to the immediate family of the committee members. Wisconsin policy stated, "includes your spouse and any relative by marriage, lineal descent or adoption who receives more than one-half of his or her support from you or from whom you receive more than one-half of your support." Some policies (26% [7 of 27]) specified a disclosure reporting window for past COI, ranging from the past year to the past 5 years.

Management Strategies

The most common management strategy was disclosure of COI to committee administrators in 67% of policies
As shown in Figure 2, the strictness of the management strategies varied by state. On one end of the spectrum, 15% of policies (4 of 27) included the most restrictive management strategy of banning certain relationships with drug manufacturers. For example, Nevada committee members “may not have a current affiliation with a business or corporation that manufactures prescription drugs” (Nevada Medicaid Program; e-mail communication; February 6, 2012). On the other end of the spectrum, Colorado* and Kansas policies explicitly stated that the existence of such relationships will not “automatically preclude an individual from participating on the committee” (Kansas Medicaid Program; e-mail communication; February 7, 2012). Washington** and Idaho§ defined a gradient of industry relationships, some that are disallowed and others that must be disclosed. For example, Idaho committee members are prohibited from employment, contractual relationships, and participating as a director or committee member for pharmaceutical companies or pharmacy benefits management companies, and from holding greater than 1% stock in pharmaceutical companies. Beyond these relationships, Idaho required disclosure.

Figure 2. Summary of management strategies by state. “Banned relationships” means that all or some industry relationships were prohibited for committee members. Intermediate strategies included self-recusal and other management strategies. Disclosure alone refers to policies that only require disclosure statements from committee members. *Management strategies included all 3: banned relationships, intermediate strategies, and disclosure.

### Table. Strength of Policies by State

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Abbreviations: Add, additional; AR, assigned reviewer; BR, banned relationships; CO, Colorado; CT, Connecticut; discl, disclosure; DE, Delaware; DMC, defined monetary cutoffs; enforce, enforcement; freq, frequency; GA, Georgia; ID, Idaho; IF, immediate family; IN, Indiana; KS, Kansas; KY, Kentucky; MD, Maryland; ME, Maine; MN, Minnesota; MS, management strategies; NE, Nebraska; NV, Nevada; OR, Oregon; PA, Pennsylvania; PW, posted on website; req, requirement; Ri, Rhode Island; RW, reporting window; SR, self-recusal; TX, Texas; WA, Washington; WI, Wisconsin; WY, Wyoming; X, policy component present.

*Total number of components.

Intermediate strategy
- Kentucky
- Washington*
- Nevada
- Texas

Disclosure alone
- Colorado
- Delaware
- Rhode Island
- Kansas
will not make recommendations, give advice or in any way assume responsibility for or participate in any aspect of decision-making relating to the matter where there are potential COI . . . [members are] not required to leave the room, although the member may voluntarily choose to do so . . ." Indiana disallowed voting for these members but still allowed them to participate in discussion. 24 Maryland allowed recused members to submit written comments to the voting committee members. Maine required members to recuse themselves, but also disallowed members to resume voting on the conflicted matters no sooner than 1 year after the declaration date of COI (Maine Medicaid Program; e-mail communication; February 7, 2012). Additional management strategies beyond recusal were noted in 19% (5 of 27) of policies. For example, in Washington, "resignation may be requested if a member must recuse himself or herself from participation in more than one drug class review in a year." 29

Review Process

As shown in the Table, processes for reviewing disclosed COIs were unclear for many states, although 30% of policies (8 of 27) assigned an entity to review disclosed COIs, typically the committee chair. Most policies did not mention any enforcement procedures, although 30% of policies (8 of 27) stated that the consequence for not disclosing COIs was immediate dismissal from the committee. In Idaho, if a committee member failed to take the action required for their COI, the committee could dismiss the member by majority vote.

Current policies to manage COIs on Medicaid drug selection committees are not transparent and vary widely in content, suggesting that some policies may not adequately protect against COIs. Our findings show the need for a model COI policy for drug selection committees that can be adapted for individual states. A model policy should (1) be publicly accessible, (2) be comprehensive and provide explicit parameters for disclosure, (3) be equally applicable to all committee members, (4) include management strategies beyond disclosure, and (5) indicate a responsible party for review of COI and enforcement of policies.

In this study, the COI policies were difficult or impossible to find for many states. Only about half of the policies were readily available on state websites, and at least 1 program stated that its policies were not in the public domain. The absence of publicly available policies illustrates a lack of transparency about how COIs are managed. Identification of policies was further complicated by the fact that not all states have designated committees that make their drug selection decisions. Improving public access to policies can increase transparency and public trust in the drug selection process.

In the academic literature, the term COI is used inconsistently. 7 It is crucial that public policies define what constitutes a COI in the context of drug selection. For example, a COI exists when a committee member is asked to make a decision about a drug manufactured by a company that provides financial support, either as direct income or another financial relationship, such as equity, to the committee member. In this study, we found some policies that were explicit and gave examples of COIs that left little room for ambiguity.

The common practice of disclosing COI was found in most of the policies, but it is inadequate as a sole management strategy. While disclosure is necessary to identify COI, it does not mitigate the effect of the COI on decision making. Comprehensive policies offer management beyond disclosure. Lowenstein et al 37 acknowledged the appeal and pitfalls of disclosure in medical practice and advocated for a more effective and complete disclosure system, such as a universal, web-based disclosure form to be stored and made available to the public.

In some states, the only document obtained was the COI disclosure form itself, and these varied. Examples of disclosure forms and criteria for disclosure of COI in various settings have been published. 13,38 These criteria could be modified and used as a standardized disclosure form for drug selection committee members.

None of the policies analyzed included all of the components we examined. Current regulation by the CMS 36,39 requires drug selection committees to "sign and continually update conflict of interest statements" and requires that committees include "at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to . . . pharmaceutical manufacturers." The policy does not specify additional required components of a COI policy. This lack of clarity could be why COI policies vary significantly across states. Two programs, those of Washington and Idaho, had the strongest policies, with 9 of the 12 model components. However, even these states did not provide disclosure forms or define monetary cut offs for disclosure, nor did they outright ban all financial relationships with companies whose products were being reviewed.

Our study has a number of limitations. One was its focus on fee-for-service populations. However, most Medicaid patients are in fee-for-service settings, and prescribing for Medicaid patients enrolled in managed care organizations is directed by the managed care organization's formulary. Our results were also limited by the 56% response rate of committee administrators (19 of 34). However, the policies obtained were representative of a variety of states across the country, and we were able to obtain information from either the Internet or program officials for 33 of 48 programs (69%). Finally, we did not examine compliance with any existing COI policies, nor did we examine the actual COIs of Medicaid drug selection committee members. However, given the lack of transparency about the policies, assessment of committee member COIs would be difficult.

Our findings help inform decision makers about COI issues that are relevant within the setting of drug selection. We have identified model components for disclosure, management, and review. Current Medicaid PDLs are highly variable by state and do not seem to be based on evidence. 40 As health care reform is implemented and
the number of Medicaid patients is expected to grow, drug
selection for this population should be guided by the best
available evidence and free from influences of COI. Fur-
ther research should test whether the proposed model
COI policy could influence the composition of Medi-
care drug selection committees, change the composition
of the drug lists, and reduce public costs and improve
patient care.

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Author Contributions: Both authors had full access to
all the data in the study and take responsibility for the
integrity of the data and the accuracy of the data analy-
sis. Study concept and design: Nguyen and Bero. Acquisi-
tion of data: Nguyen. Analysis and interpretation of data:
Nguyen and Bero. Drafting of the manuscript: Nguyen and
Bero. Critical revision of the manuscript for important in-
tellectual content: Nguyen. Administrative, technical, and
material support: Nguyen. Study supervision: Bero.
Conflict of Interest Disclosures: None reported.
Online-Only Material: Listen to an article about this
article, and others, at http://bit.ly/OSSqSnT.
Additional Information: Dr Nguyen was a UCSF phar-
acy student at the time this work was conducted.
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LLM, DCL, of the University of Toronto, reviewed an ear-
lier version of the manuscript.

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