



April 2008

# Drug and Medical Device Procurement

*The Prescription Project promotes evidence-based prescribing and works to eliminate conflicts of interest in medicine due to pharmaceutical marketing to physicians.*

*It is promoting policy change by working with*

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

*Created with The Pew Charitable Trusts, the Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession.*

## A Toolkit for Academic Medical Centers

### I. Introduction

Pharmaceutical and therapeutics (P&T) committees are an effective tool for hospitals and health centers to ensure the practice of quality, cost effective and evidence-based medicine in their facilities. Conflict of interest issues arise when individuals who have a direct role in decisions related to drug or medical equipment procurement also have financial relationships with drug manufacturers, including any receipt of gifts, grants, contracts or an otherwise compensated relationship.

It is essential that academic medical centers (AMCs) establish policies to ensure that conflicts of interest do not influence purchasing decisions and jeopardize quality, evidence-based care.

Although most health systems have a P&T committee, many do not have a similar committee governing the purchasing of medical equipment. Consequently, purchases of equipment and implantable devices are made based on what is requested by individual physicians. Recently, the relationships between orthopedists and industry were brought to light.<sup>1</sup> Because there are fewer clinical studies on equipment and devices, it is inevitable that more importance is given to physicians' experiences. Still, those ultimately voting on decisions should be free from conflict.

### II. Policy Considerations

AMCs should adopt strong policies to manage the involvement of individuals with industry relationships in drug and device procurement processes and decisions.

*This toolkit is one in series prepared by the Prescription Project to assist medical schools and teaching hospitals developing new policies to address the conflicts of interest that arise from pharmaceutical and medical device industry marketing. For further assistance or more information, please email [policy@prescriptionproject.org](mailto:policy@prescriptionproject.org).*

- **Recusal**  
 The general preference is that no one with any industry relationships should serve on a committee that makes purchasing decisions. Those with relationships should recuse themselves from decisions where they have a financial relationship, however indirect.
  - This does not preclude clinicians with financial relationships from presenting to a purchasing committee as content experts, but these experts should not vote on, or make, purchasing decisions.
  
- **Disclosure**  
 All members of the P&T and device procurement committees should be required to disclose all personal and professional relationships with industry prior to joining and annually thereafter. Additionally, at any point where a purchasing committee is entertaining discussion regarding possible changes to the formulary or other purchasing decisions, the committee chair should ask whether committee members have any relationships to disclose. Disclosure should include any financial interest they, or their immediate family, have in companies that may benefit from decisions. AMCs we have interviewed have found it helpful to ask for disclosures at the beginning of each meeting. P&T committee members are reminded to announce if they have a conflict with any of the products being reviewed.
  - Financial interests may include equity ownership, compensated positions on advisory boards, a paid consultancy, speaking agreements or other forms of compensated relationships. (This standard is not intended to prohibit indirect financial interests, such as investments in mutual funds that may own pharmaceutical company shares.)
  
- **Ensuring that evidence, not marketing, determines the formulary**  
 Pharmaceutical industry representatives should not be permitted to participate in, or observe, P&T committee deliberations. The committee should be aware that pharmaceutical representatives often enlist physicians to request that their product be placed on the formulary, sometimes going so far as to fill out the request form. Some policy solutions are to require the requesting physician to disclose all financial relationships, and to reject product requests from physicians who have conflicts with the company. Based on our interviews with several P&T members and chairs, P&T committees can often discern a request filled out at the behest of a pharmaceutical representative. These submissions are often not the result of conflicts of interest, but simply the path of least resistance for a harried clinician. Industry-initiated formulary requests should be prohibited.
  
- **Reinforcing the formulary**  
 Sales representatives should not be permitted to market non-formulary or non-approved drugs and devices, or should be permitted to do so only after disclosure of non-approved status. Sanctions should be specified for non-compliant sales representatives.
  
- **Compliance with state law**  
 In some jurisdictions, existing laws expressly forbid individuals with financial conflicts of interest from making purchasing decisions (see UC Davis, below).

## Implementation Strategies

Some AMCs have found it beneficial to proactively review products as they come onto the market, rather than wait for additional requests. Proactive reviews eliminate the opportunity for pharmaceutical representatives to lobby physicians and P&T members to have a drug reviewed and approved.

Prescription Project interviews suggest that a strong and respected clinical pharmacy staff helps ensure that the formulary is understood and followed. At one medical center, clinical pharmacists have replaced vendors as the information source for physicians. Physicians at the medical center feel confident that they have access to current and unbiased drug information.

## III. Example Policies

Several academic medical centers have taken steps to ensure that the drugs and medical devices they offer to patients are determined by a thorough evidenced-based review process free from industry marketing and compensation influence.

### *Stanford University School of Medicine*

- Individuals having a direct role making institutional decisions on equipment or drug procurement must disclose to the purchasing unit, prior to making any such decision, any financial interest they or their immediate family have in companies that might substantially benefit from the decision. Such financial interests could include equity ownership, compensated positions on advisory boards, a paid consultancy, or other forms of compensated relationship. They must also disclose any research or educational interest they or their department have that might substantially benefit from the decision. The purchasing unit will decide whether the individual must recuse him/herself from the purchasing decision.

### *University of California Davis*

- Under the California Political Reform Act [see below], State of California employees who have a financial conflict may not participate in any decision making affecting public investments. This has been interpreted to include purchasing decisions made by the faculty and staff of the University of California system. UC faculty and staff may not participate in any purchasing decisions in which they have a conflict. Members of the P&T committee not only may not vote, but also may not participate in the discussion about a product with which they have a conflict.
- Hospital and medical group formulary committees and other committees overseeing purchases of medical devices, nutritional products or other products or services that are provided upon prescription or suggestion of a health care professional, will follow the Political Reform Act regulations, which include restrictions on the participation of individuals who have financial relationships with vendors affected by the purchase decisions.
- The decision to add or delete drugs from the hospital formulary is made by UCDHS's Pharmacy and Therapeutics (P&T) Committee. The request to add a drug shall be made to the committee by an attending staff physician.

**Tufts Medical Center (formerly Tufts New England Medical Center)**

- Prearranged meetings between vendor representatives and TMC faculty or staff personnel should focus primarily on technical considerations. Competitive information from other suppliers (i.e., pricing, terms, etc.) must not be divulged nor should commitments of any type be made at these meetings, including product preference. If an unsolicited written quote is offered, they are non-binding and must be presented to the Purchasing Office for a review of the pricing, terms and conditions of the proposal and/or a determination on the requirement for additional quotations as may be necessary.
- Promotion of drugs against TMC restrictions, drug utilization guidelines, or clinical guidelines/initiatives is prohibited. Non-formulary drugs or drugs not on the Preferred Drug List may only be discussed if the pharmaceutical vendor fully discloses this status to the TMC physician or staff member. Pharmaceutical vendors who do discuss such agents without an appropriate disclosure will be immediately suspended from visiting TMC sites pending review of the event.

**California Political Reform Act****§ 87103. Financial Interest.**

A public official has a financial interest in a decision within the meaning of Section 87100 if it is reasonably foreseeable that the decision will have a material financial effect, distinguishable from its effect on the public generally, on the official, a member of his or her immediate family, or on any of the following:

(a) Any business entity in which the public official has a direct or indirect investment worth two thousand dollars (\$2,000) or more.

(b) Any real property in which the public official has a direct or indirect interest worth two thousand dollars (\$2,000) or more.

(c) Any source of income, except gifts or loans by a commercial lending institution made in the regular course of business on terms available to the public without regard to official status, aggregating five hundred dollars (\$500) or more in value provided or promised to, received by, the public official within 12 months prior to the time when the decision is made.

(d) Any business entity in which the public official is a director, officer, partner, trustee, employee, or holds any position of management.

(e) Any donor of, or any intermediary or agent for a donor of, a gift or gifts aggregating two hundred fifty dollars (\$250) or more in value provided to, received by, or promised to the public official within

12 months prior to the time when the decision is made. The amount of the value of gifts specified by this subdivision shall be adjusted biennially by the Commission to equal the same amount determined by the Commission pursuant to subdivision

(f) of Section 89503.

For purposes of this section, indirect investment or interest means any investment or interest owned by the spouse or dependent child of a public official, by an agent on behalf of a public official, or by a business entity or trust in which the official, the official's agents, spouse, and dependent children own directly, indirectly, or beneficially a 10-percent interest or greater.

**§ 87105. Manner of Disqualification.**

(a) A public official who holds an office specified in Section 87200 who has a financial interest in a decision within the meaning of Section 87100 shall, upon identifying a conflict

of interest or a potential conflict of interest and immediately prior to the consideration of the matter, do all of the following:

- (1) Publicly identify the financial interest that gives rise to the conflict of interest or potential conflict of interest in detail sufficient to be understood by the public, except that disclosure of the exact street address of a residence is not required.
- (2) Recuse himself or herself from discussing and voting on the matter, or otherwise acting in violation of Section 87100.
- (3) Leave the room until after the discussion, vote, and any other disposition of the matter is concluded, unless the matter has been placed on the portion of the agenda reserved for uncontested matters.
- (4) Notwithstanding paragraph (3), a public official described in subdivision (a) may speak on the issue during the time that the general public speaks on the issue.
  - (b) This section does not apply to Members of the Legislature.

**§ 87200. Applicability.**

This article is applicable to elected state officers, judges and commissioners of courts of the judicial branch of government, members of the Public Utilities Commission, members of the State Energy Resources

Conservation and Development Commission, members of the Fair Political Practices Commission, members of the California Coastal Commission, members of planning commissions, members of the board of supervisors, district attorneys, county counsels, county treasurers, and chief administrative officers of counties, mayors, city managers, city attorneys, city treasurers, chief administrative officers and members of city councils of cities, and other public officials who manage public investments, and to candidates for any of these offices at any election.

## REFERENCES

<sup>1</sup> Editorial "Patient Care, Professionalism and Relations with Industry." Journal of Orthopaedic Research. March 2008. 279-280.