A surgeon asks for an expensive new piece of equipment. The request is forwarded to the value analysis committee. Before considering the purchase, the committee would like to know whether the surgeon has financial ties to the company that sells the product. Is the surgeon consulting with the company? Is he or she conducting a company-sponsored clinical trial? Does the physician own company stock?

Financial disclosure is the trend. More organizations are requiring physicians who make product requests to sign a conflict-of-interest statement. In some cases, physicians must sign a disclosure to be allowed to vote on a purchasing decision. Disclosure also is the norm for employees, including administrators, managers, and sometimes staff.

“In this day and age, with Enron, WorldCom, Tyco, and other corporate scandals, as well as what we’ve seen in health care, conflict-of-interest policies and disclosures are not only a best practice but a necessity,” says Lisa Murtha, JD, of the Health Care Compliance Association.

In organizations Murtha has consulted with, physicians are expected to sign a conflict-of-interest disclosure as part of the credentialing process.

“Typically, the doctors are the ones who are most familiar with the technology,” says Murtha, who has served as compliance officer for the University of Pennsylvania, Children’s Hospital of Philadelphia, and other institutions.

“Often, sales people with the technology companies contact the clinical people first to get them charged up about a piece of equipment they ought to buy,” she notes. “Because of the relationships that develop, it’s critical for doctors to complete a disclosure form. That way, it’s clear whether they have a relationship with the company that would somehow compromise their business judgment in purchasing that piece of equipment.”

No disclosure, no vote

At Swedish Medical Center, a 3-hospital system in Seattle, physicians who want their vote included in a purchasing decision must sign a conflict-of-interest statement, a requirement of the value analysis process.

“They must sign, or their vote doesn’t count. It’s not an option anymore, and it’s been accepted quite well,” says Allen Caudle, vice president of supply chain management. He notes that Swedish has a “robust” value-analysis system, which has been in place for about 5 years.

Under the hospital’s conflict-of-interest policy, those who must sign statements, in addition to corporate officers and administrators, are members of the pharmacy and therapeutics committee, value-analysis teams, and institutional review board. The policy gives Caudle responsibility for coordinating disclosures for the value-analysis teams. In addition, the director of corporate compliance coordinates disclosure for all those covered by the policy.

Decisions on high-stakes physician-preference items such as orthopedic implants are made by an ad hoc committee of physicians from that specialty. Swedish performs about 2,000 hip and knee implants a year, and some of its surgeons design implants for orthopedic companies.

When a vote is taken, physicians submit their votes in writing to the department chair, who opens them along with the vice president in charge of that value-analysis team. If a vote does not have a matching conflict-of-interest form, it is not counted.

Caudle explained how the process will work for a new contract Swedish is negotiating for knee implants. The goal will be to select 2 primary knee implant...
vendors, which Swedish has already achieved for spinal surgery. The vendors will be selected by an ad hoc committee of 15 of the 60 orthopedic surgeons chosen by the department chair. The ad hoc committee sets the criteria for who can vote, which include performing at least 20 knee implants in the past year and signing a disclosure statement.

As part of the deliberations, Caudle will present data to show the hundreds of thousands of dollars that can be saved by consolidating to 2 vendors rather than using 3 or 4 companies.

“The physicians have been pretty upfront” about disclosing any financial ties, Caudle says. “Their colleagues know about their relationships, and it isn’t a big secret. It’s not that they can’t have those relationships. It’s just that they have to document them and let us know about them if they want to vote.”

The medical staff is increasingly aware of the legal reasons for disclosure, says Kate Rogers, RN, MSN, CNOR, Swedish’s director of surgical services. “They understand and are accepting the way business is done here.”

Rolling out a new policy

Two organizations that recently added physician financial disclosure to their product-evaluation process are Spectrum Health, a 7-hospital system based in Grand Rapids, Mich, and OSF Saint Francis Medical Center, Peoria, Ill, one of the nation’s largest Catholic hospitals, with 710 beds.

Spectrum Health’s new policy asks physicians to complete a disclosure statement prior to bringing a product request to the value-analysis committee. The 1-page statement asks the physician to fill in the name of the product being evaluated, sign his or her name, and list any financial arrangements with companies or other parties related to the product. The statement is backed by an administrative policy mandating use of the statement.

“We aren’t saying they can’t have these arrangements. We just want to know if they are doing it and if that could influence their decision,” Christopher Baskel, director of supply chain management, says.

Gail Greco-Bieri, Spectrum’s equipment, materials, and instrument coordinator, adds, “Our bottom-line goal is to provide the best product to our patients and to be fiscally responsible. To do that, we need to understand why a doctor believes so strongly that a product is the best one out there.”

Baskel proposed the disclosure statement to Spectrum’s risk and compliance department when the conflict-of-interest policy was up for renewal. The disclosure applies to “agents” of the hospital, such as physicians who are not employees and participate in product evaluations.

The policy was piloted by a group of obstetricians led by Donald Heggen, MD, and they have signed off on it. The new policy is being communicated to the rest of the medical staff by the director of medical affairs. It will apply not only to products being considered for surgery but to the institution as a whole, including radiology and the cath lab.

“We found that once you explain the policy, and the physicians understand it, they don’t seem to have a problem with it,” Baskel says.

His advice for others who want to introduce financial disclosure for physicians: “Work with your risk and compliance and your legal departments. Get some political clout behind you.”

Disclosure part of new technology process

At OSF Saint Francis, disclosure is an expectation of the new technology assessment process, rolled out last fall. All members of the technology value-analysis committee, employees and physicians alike, must sign a disclosure form annually. Committee members who have a financial relationship with a company whose product is being evaluated are expected to refrain from voting.

In addition, physicians who submit a product request are expected to sign a disclosure statement on the back of the new product/technology request form.

The statement says, in part: “This information is shared with committee members and is considered when discussing your request. A potential conflict-of-interest issue does not disqualify someone from requesting the product/technology. The com-
mittee recognizes that many departments and members of the medical staff have relationships with manufacturing companies. Physicians with expertise in this area have often received research grants or other support from companies. However, the committee feels it is important to disclose these relationships.”

The form asks physicians to indicate whether they:

- have a proprietary interest in the company that makes the product being evaluated
- own stock in the company (excluding mutual funds)
- serve on the company’s board of directors
- expect to (or currently receive) royalties from the company.

The form also asks if the physician or department has received financial support from the company, including research funding, support for continuing education, travel support, or other funding.

So far, physicians have accepted the policy, says Rita Menold, RN, technology value analyst for surgery and allied services. “As long as their requests are still considered, they are OK with the disclosure,” she says.

Disclosure by managers, staff

It’s the norm for hospitals to require administrators, managers, and sometimes staff to sign conflict-of-interest disclosures, Murtha says. Generally, the policy applies to those with contracting authority but may also apply to employees at lower levels, such as those in the purchasing and billing departments.

Swedish, Spectrum, and OSF Saint Francis all require administrators and managers to sign an annual disclosure policy.

The Swedish policy spells out the rules on gifts and favors from vendors. Basically, an employee may not accept anything more than a token gift, such as a calendar or pen, Caudle says. He personally does not go out to dinner with vendors or accept other favors. When invited, he responds, “Why don’t we have a meeting in my office during business hours?”

OSF Saint Francis has a strict policy on what vendors may bring in, notes Anne Kanaby-Krup, RN, director of surgical services. Any food brought in by vendors must be purchased from the hospital’s catering service. Other than that, “the only thing we accept is education,” she says. “I would much rather have the vendors focus on education than anything else.”

A copy of OSF Saint Francis’s new technology assessment form is in the OR Manager Toolbox at www.ormanager.com

AMA statement on conflict-of-interest

AMA policy states:

“Candidates for election or appointment to medical staff offices, department or committee chairs, or to the medical executive committee should disclose in writing to the medical staff, prior to the date of election or appointment, any personal, professional, or financial affiliations or responsibilities on behalf of the medical staff and encourage hospital medical staffs to incorporate a “disclosure of interest” provision in their medical staff bylaws based on this policy statement.”