er incentives. For example, how can risk-sharing arrangements be used effectively when providers are not part of integrated systems? And more research is needed to establish the appropriate scope and magnitude of pay for performance to complement enhanced risk-sharing regimes.

The focus on providers should not mean an absence of involvement by patients in improving the effectiveness and efficiency of care. Along these lines, there may be promise in efforts to reward consumers for the same care-quality processes included in provider pay for performance. Consumers, too, must have some perceived financial stake — and choices — in cost control. Offering them a financial incentive to entrust their care to a provider team with the capabilities and incentives to deliver coordinated, effective, and efficient care might be a near-term way of accomplishing this goal.

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1. Newhouse JP and the Insurance Experiment Group. Free for all? Lessons from the RAND Health Insurance Experiment. Cambridge, MA: Harvard University Press, 1993.
2. Buntin MB, Damberg C, Haviland A, et al. Consumer-directed health care: early evidence about effects on cost and quality. Health Aff (Millwood) 2006;25:w516-w530.
3. Peikes D, Chen A, Schore J, Brown R. Effects of care coordination on hospitalization, quality of care, and health care expenditures among Medicare beneficiaries: 15 randomized trials. JAMA 2009;301:603-18.
4. Hibbard JH, Stockard J, Tusler M. Does publicizing hospital performance stimulate quality improvement efforts? Health Aff (Millwood) 2003;22:84-94.
5. Curtin K, Beckman H, Pankow G, Milillo Y, Green RA. Return on investment in pay for performance: a diabetes case study. J Healthc Manag 2006;51:365-76.

Controlling Conflict of Interest — Proposals from the Institute of Medicine

Robert Steinbrook, M.D.

As Congress considers mandating the disclosure of industry gifts and payments to physicians on a searchable federal government Web site,[1] others have been developing proposals for reforming physician–industry relations, and key changes are being made to policies at various academic medical centers, professional societies, and companies. In late April 2009, the Institute of Medicine (IOM) issued a report on conflicts of interest that is notable for its breadth — it covers many aspects of medical research, education, and practice as well as both individual and institutional financial relationships — and the variety of its proposals (see box).[2]

The IOM defined a conflict of interest as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest." The primary interests of concern include "promoting and protecting the integrity of research, the welfare of patients, and the quality of medical education." Secondary interests "may include not only financial gain but also the desire for professional advancement, recognition for personal achievement, and favors to friends and family or to students and colleagues." Of course, public attention has focused primarily on financial conflicts of interest, and the IOM did so as well, viewing them as "not . . . necessarily more corrupting" than other secondary interests but "relatively more objective, fungible and quantifiable" and "more effectively and fairly regulated."

In general, the IOM committee, chaired by Dr. Bernard Lo of the University of California, San Francisco, supports further restrictions on and oversight of financial associations — but not "a goal of $0 contributions from industry,"[3] as was recently proposed for professional medical associations. Some of the IOM recommendations involve prohibitions, such as bans on faculty participation in companies' speakers bureaus and other promotional activities in which they "present content directly controlled by industry" and bans on gifts of any amount from medical companies. In some areas, such as research, the committee recommends permitting structured involvement in exceptional cases of physicians who have substantial financial interests in industry but also have expertise that is deemed essential. Noteworthy ideas include standardizing the content and format of disclosures of financial relationships, a new system of funding for accredited continuing medical education (CME) that is "free of industry influence" (although the committee did not agree on

Overview of IOM Recommendations about Conflict of Interest in Medicine.

- Institutions engaged in medical research and education, clinical care, and the development of clinical practice guidelines should "adopt and implement conflict of interest policies" and "strengthen disclosure policies." They and other interested organizations (such as accrediting bodies, health insurers, consumer groups, and government agencies) should standardize the content, formats, and "procedures for the disclosure of financial relationships with industry."
- Congress "should create a national program that requires pharmaceutical, medical device, and biotechnology companies and their foundations to publicly report payments to physicians and other prescribers, biomedical researchers, health care institutions, professional societies, patient advocacy and disease-specific groups, providers of continuing medical education, and foundations created by any of these entities." Until Congress acts, "companies should voluntarily adopt such reporting."
- Academic medical centers, research institutions, and medical researchers should "restrict participation of researchers with conflicts of interest in research with human participants." Exceptions "should be made public" and occur only if a conflict-of-interest committee "determines that an individual's participation is essential for the conduct of the research" and if there is "an effective mechanism for managing the conflict and protecting the integrity of the research."
- Academic medical centers, teaching hospitals, faculty members, students, residents, and fellows should "reform relationships with industry in medical education"; these institutions and professional societies should "provide education on conflict of interest."
- The organizations that created the accrediting program for continuing medical education and other interested groups should reform the financing system so that it is "free of industry influence, enhances public trust in the integrity of the system, and provides high-quality education."
- Physicians, professional societies, hospitals, and other health care providers should reform physicians' financial relationships with industry; the same standards should apply to community physicians, medical school faculty, and trainees. Physicians should forgo all gifts and other "items of material value" from pharmaceutical, medical-device, and biotechnology companies, accepting only "payment at fair market value for a legitimate service" in specified situations. Physicians should "not make educational presentations or publish scientific articles that are controlled by industry or contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged." Physicians should "not meet with pharmaceutical and medical device sales representatives except by documented appointment and at the physician's express invitation" and should "not accept drug samples except in certain situations for patients who lack financial access to medications." Until institutions change their policies, physicians and trainees "should voluntarily adopt" these recommendations "as standards for their own conduct."
- Medical companies and their foundations should reform interactions with physicians — for example, by instituting "policies and practices against providing physicians with gifts, meals, drug samples (except for use by patients who lack financial access to medications), or other similar items of material value and against asking physicians to be authors of ghostwritten materials." Consulting arrangements "should be for necessary services, documented in written contracts, and paid for at fair market value." Companies "should not involve physicians and patients in marketing projects that are presented as clinical research."
- Groups that develop clinical practice guidelines should restrict industry funding and conflicts of panel members. Various entities, including accrediting and certification bodies, formulary committees, health insurers, and public agencies should "create incentives for reducing conflicts in clinical practice guideline development."
- The governing bodies of institutions engaged in medical research, medical education, patient care, or guideline development "should establish their own standing committees on institutional conflicts of interest" that "have no members who themselves have conflicts of interest relevant to the activities of the institution."
- The National Institutes of Health should revise federal regulations to require research institutions to have policies on institutional conflicts of interest, including "the reporting of identified institutional conflicts of interest and the steps that have been taken to eliminate or manage such conflicts."
- Oversight bodies and other groups should "provide additional incentives for institutions to adopt and implement" conflict-of-interest policies, such as by publicizing the names of institutions that have instituted the recommended policies and those that have not.
- The Department of Health and Human Services and its agencies should develop and fund research agendas on conflict of interest.

what that system should be) and, for the development of clinical practice guidelines, restrictions on industry funding and limits on the participation of individuals with conflicts of interest.

As others have done, the IOM seeks to balance the "important benefits" of physician–industry relations, such as research funding and the development of new tests and treatments, with the "significant risks that the financial goals of industry may conflict with the professional goals of medicine." The committee argued that conflict-of-interest policies should "protect the integrity of professional judgment" and "preserve public trust" rather than leaving physicians and institutions scrambling "to remediate problems with bias or mistrust after they occur"; that disclosure of individual and institutional relationships is "a critical but limited first step" in identifying and responding to conflicts of interest, because of course "disclosure does not resolve or eliminate conflicts of interest"; and that if medical institutions do not voluntarily strengthen their policies and procedures, the pressure for government regulation is likely to increase.

The IOM recommended that Congress enact legislation similar to the Physician Payments Sunshine Act[1] but broader in scope and that it require companies and their foundations to publicly and comprehensively report their payments to physicians and various entities and groups, as the Medicare Payment Advisory Commission has also recently proposed.[4] According to the institute, the information should be "readily available on a searchable public website that allows the aggregation of all payments made to an individual or organization" and that covers not only payments to physicians but also those to nonphysicians who prescribe medications, biomedical researchers, and a variety of organizations including health care institutions, professional societies, CME providers, and patient advocacy and disease-specific groups.

Finding wide variations in current conflict-of-interest policies, the disclosure of financial relationships, and the adherence of physicians and researchers to requirements, the IOM called for medical institutions to "adopt, implement and make public" policies for individuals that are consistent with its recommendations and for national organizations to "convene a broad-based consensus development process to establish a standard content, a standard format, and standard procedures for the disclosure of financial relationships with industry." An important part of this process would be to agree on the categories of relationships that should be disclosed and the specific information about each relationship that should be provided. For example, the IOM noted that the term "consulting" needs "further specification" because it may refer to "relationships that range from the provision of promotional or marketing support to a company to the offering of objective technical advice on scientific advances, products in development, or research study design."

In 2007, nearly half of the $2.54 billion in income for CME providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) was from commercial support (companies with a product in the marketplace); over the past decade, commercial support has quadrupled.[5] The committee found that CME "has become far too reliant on industry funding" and that this funding "tends to promote a narrow focus on products," not "a broader education on alternative strategies for managing health conditions and other important issues, such as communication and prevention." It concluded "that the current system of funding is unacceptable and should not continue." However, because the committee could not agree "on a specific path to reform," it suggested that representatives of the member organizations that created the ACCME and other interested groups establish a consensus-development process that would, within 24 months, result in a proposal for a new funding system. A majority of committee members believed that a rapid end to industry funding without "having in place an alternative model" could be "unacceptably disruptive" and thought it would be acceptable to "leave open the possibility of certain forms of indirect industry funding." Others believed that "no form of direct or indirect industry funding was acceptable." It is uncertain how the relevant groups will respond to the recommendation for further study: in March 2009, the ACCME announced that it would "not be taking any action to end the commercial support" of accredited CME and affirmed its systems and standards for keeping CME "free of commercial bias."

With regard to clinical practice guidelines, the IOM found that "the risk of undue industry influence . . . is significant" and made specific recommendations for strengthening conflict-of-interest policies. These include a gen-

eral exclusion of panel members with conflicts of interest, a prohibition on direct funding for guideline development from industry or industry-controlled foundations, and complete disclosure of any remaining financial associations or industry funding. In exceptional circumstances "in which avoidance of panel members with conflicts of interest is impossible because of the critical need for their expertise," groups should take measures such as publicly documenting that they had made good-faith efforts to find experts without conflicts, for example, by advertising for members, appointing a chair without a conflict of interest, limiting members with conflicts to "a distinct minority," excluding participants with conflicts from "deliberating, drafting, or voting on specific recommendations," and publicly disclosing the "relevant conflicts of interest of panel members."

Although specific recommendations may be criticized as either too strong or too weak, the IOM's overall proposals are comprehensive and — if adopted — would most likely have substantial effects on individual physicians and medical institutions. However, there has been no shortage of previous reports and calls for change; the new report lists 16 of the "more prominent reports" that were released between 2001 and 2008 alone. So the institute's proposals could merely provide more fodder for discussion — or perhaps mark a turning point in controlling conflicts of interest in medicine.

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1. Physician Payments Sunshine Act of 2009 (S. 301). (Accessed April 28, 2009, at http://www.thomas.gov/.)
2. Institute of Medicine. Conflict of interest in medical research, education, and practice. Washington, DC: National Academies Press, 2009. (Accessed April 29, 2009, at http://www.iom.edu/CMS/3740/47464/65721.aspx.)
3. Rothman DJ, McDonald WJ, Berkowitz CD, et al. Professional medical associations and their relationships with industry: a proposal for controlling conflict of interest. JAMA 2009;301:1367-72.
4. Medicare Payment Advisory Commission. Report to the Congress: Medicare payment policy. Washington, DC: March 17, 2009. (Accessed April 28, 2009, at http://www.medpac.gov/documents.cfm.)
5. Steinbrook R. Financial support of continuing medical education. JAMA 2008;299:1060-2.