

to limit the diffusion of new health care technology or to regulate the prices and salaries paid by the private health care sector. One lesson of the recent Medicaid expansions, however, is that intergovernmental financing programs are the most plausible fiscal route to health insurance expansions. States will complain about having to pay their share, though Congress could tie increased federal funding to innovative case management for chronic diseases (or other performance measures). Federal budget officials will also be skeptical, but any national health insurance system is going to cost money, and at least in this scenario the cost would be divided among the federal treasury, the

states, and the businesses or individual consumers who buy in.

Proposals for national health insurance have a long history of failure in this country. But expanding Medicaid in combination with an individual mandate offers a good policy solution that might have enough political appeal to succeed. And if the recession and other priorities discourage President Obama from seeking universal coverage in one fell swoop, the model could be phased in, starting with a more modest Medicaid expansion, a buy-in program, and an individual mandate covering only children. Ultimately, I see the Medicaid model as providing the most likely path to solving the crisis of the uninsured.

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Dr. Sparer is a professor of health policy at the Mailman School of Public Health, Columbia University, New York, and the editor of the *Journal of Health Politics, Policy and Law*.

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Online Disclosure of Physician–Industry Relationships

Robert Steinbrook, M.D.

The Cleveland Clinic and some of its leading physicians have been criticized for their financial associations with industry and the limited disclosure of these relationships to patients and the public. In response, the medical center has strengthened its policies and oversight with regard to conflicts of interest and required that all industry relationships be submitted for approval. Since December 2008, it has also disclosed on its Web site (www.clevelandclinic.org) some of the industry ties of its 2000 physicians and researchers and their immediate families.¹

The posting of physicians' financial information by a leading academic medical center, along with continuing revelations about prominent doctors and their apparent failures to accurately report or disclose their links to industry, has intensified interest in the on-

line disclosure of these relationships.² Concerns about privacy notwithstanding, accurate, interpretable, and timely online disclosures can provide immediate access to potentially relevant information and demonstrate that relationships are not being hidden. Other similar efforts include the voluntary posting by some faculty members at the Duke Clinical Research Institute of their conflict-of-interest statements (www.dcri.org/research/coi.jsp; see box for the categories of commercial relationships tracked by the institute) and the provision of financial disclosure statements for the members of the editorial board of *Psychiatric Times* (www.psychiatrictimes.com/editorial-board) and the trustees of the North American Menopause Society (www.menopause.org/aboutnams/trustees.aspx).

More online disclosures are

forthcoming. For example, Eli Lilly and Merck have said that they will soon begin disclosing on their Web sites some payments to physicians, and the University of Pennsylvania School of Medicine and its health system have made a similar promise. Massachusetts is in the process of requiring the reporting and subsequent online disclosure of fees, payments, or subsidies "with a value of at least \$50" as part of new regulations on the conduct of pharmaceutical and medical-device manufacturers³; it is uncertain whether the requirements will be limited to payments for sales and marketing activities or include consulting fees and research grants as well. Six other states and the District of Columbia have laws or regulations with regard to the conduct of pharmaceutical or medical-device manufacturers, but only in Minnesota are

Conflict-of-Interest Reporting at the Duke Clinical Research Institute.***Categories on the "Commercial Relationships Tracking Form" for 2007-2008**

1. A research grant or contract from this company partially supports my university salary.
2. A research grant or contract from this company supports my research projects.
3. Educational activities or lectures for this company generate revenue for Duke (<\$10,000 or ≥\$10,000).
4. Consulting or other services (including CME) for this company generate personal income, outside of my university salary (<\$10,000, \$10,000-\$25,000, or >\$25,000).
5. Consulting or other non-CME services for this company generate personal income, outside of my university salary, (<\$10,000, \$10,000-\$25,000, or >\$25,000).
6. I receive significant personal royalties (>\$10,000 per year) from this company.
7. I or a member of my immediate family has equity in this company (>\$10,000 or >1%).

* Faculty members voluntarily report monetary amounts of industry payments on an annual basis. The form for 2007-2008 can be viewed at www.dcri.org/research/coi.jsp. CME denotes continuing medical education.

disclosures explicitly required to be public records (www.phcybrd.state.mn.us/main_pay.htm), and this requirement applies only to drug companies. On a national level, Congress may mandate the disclosure of many industry gifts and payments to physicians on a searchable federal government Web site, under a pending bill known as the Physician Payments Sunshine Act.² If the act becomes law, it would preempt state reporting and disclosure requirements.

Online disclosure is the latest response to concern about financial conflicts of interest and the propriety of various associations between medicine and industry. Advantages of industry funding, such as the support of drug and device development and pivotal clinical trials, must be balanced against the disadvantages, such as the potential for influencing prescribing and use of medical devices and supplies, increasing the costs of care, fostering a mindset of entitlement among doctors, and undermining the independence and integrity of the profession.²

At present, physicians and researchers often report industry payments confidentially to their medical school or medical center.

Such reporting, however, may be voluntary and may not be subject to verification. There are wide variations in the level of detail, reporting procedures, and stringency of institutional policies and oversight. The information may be actively reviewed or merely collected. A physician or researcher may be required to limit or refrain from certain activities, such as participating in industry-sponsored speakers' bureaus, consulting for industry, or serving as a clinical investigator for a study in whose outcome he or she has a financial interest. Institutions may require disclosure of industry associations — for example, to patients, research subjects, professional societies, or medical journals. However, because reporting and oversight are private, there is usually no way of knowing the extent of compliance.

Disclosure itself does not eliminate bias or conflicts of interest, but it can make financial relationships widely known and be used as a starting point for asking questions. At present, however, financial ties are not consistently disclosed, and this variation can result in confusion. A study of 746 articles (with 2985 authors) on coronary-

artery stents (all published in 2006) found that 83.1% of the articles contain no disclosure statements (including statements that there were no conflicts to disclose) and only 5.6% of the authors had a disclosure statement in at least one article. Different articles' disclosure statements for the same authors were compared, and in 26 instances (involving 16 authors), one article disclosed an author's financial interests while another declared that the author had nothing to disclose.⁴ Differences in journals' reporting requirements or authors' behavior could account for some of these inconsistencies.

At the Cleveland Clinic, physicians and researchers are required to report their relationships with industry whenever those relationships change materially, and at least once a year. The reporting is done online through an internal database. As part of a separate online "find a doctor" directory, the clinic lists physicians' relationships with industry along with other background information. Although physicians review their directory listings in advance for accuracy, disclosure is mandatory.

The clinic currently discloses speaking and consulting fees (including those related to continuing medical education [CME]) of \$5,000 or more per year paid to its physicians and scientists by the pharmaceutical or medical-device industry, as well as current or potential royalty payments for inventions or discoveries; ownership of stock or stock options for activities as a founder of a company, inventor, or consultant; and service in a fiduciary capacity, such as that of an officer or director. In addition, in some instances physicians are expected to disclose their associations directly to research subjects or to patients — for example, before implanting an orthopedic de-

vice. The online disclosures are complete for about 90% of the faculty, and more will be added soon. About 20% of faculty members have ties to at least one company that meet the disclosure requirements; 15% receive more than \$5,000 a year from at least one company.

The Cleveland Clinic does not currently disclose the amounts of payments, nor does it list payments for research; ownership of stock or stock options unrelated to activities as a company founder, inventor, or consultant; payments for speaking or consulting that are not directly from industry, such as those from medical-education and communication companies; or the clinic's institutional relationships with industry. Discussions are ongoing, however, about expanding the disclosures to cover research grants and institutional relationships, as well as the amounts of payments. The clinic is also preparing a brochure for patients to explain its policies and is surveying patients about what information they would find most useful.

Disclosures would be most valuable if interested parties agreed on definitions for categories of relationships and payments, uniform approaches to calculating amounts, and standards for information to be made public. Inconsistent practices may create confusion and the

impression that some payments are being hidden. For example, if a physician is paid nothing for participating in an international clinical trial but is reimbursed \$10,000 for travel and lodging expenses to attend an organizing-committee meeting, the reimbursement may or may not be disclosed. Total payments for consulting or speaking will be larger if they include fees related to CME and fees from medical-education and communication companies in addition to payments for non-CME services that are received directly from industry. When payments are related to research or royalties, it may not be clear what amount is paid to institutions and what to individual researchers. There are other categories that should be accounted for, such as payment for service as an expert witness. And monetary thresholds for disclosure vary widely, from \$50 in Massachusetts, to \$500 for the proposed federal Web site, to \$5,000 at the Cleveland Clinic.

The Cleveland Clinic's initiatives are a work in progress, but they represent a step toward more complete disclosure of physician-industry relationships. Notwithstanding the substantial commitment of time and resources required to provide accurate, clear, and comprehensive information, other academic medical centers,

medical societies, and organizations that fund research could consider establishing online databases as well. Databases that are based on reporting by physicians could complement the disclosure of payments by companies. A simpler and more efficient alternative that has been advocated by Robert Califf of Duke University would be to establish a searchable national database. The database might be administered by the National Library of Medicine or another federal agency, and it might be analogous to ClinicalTrials.gov, the online registry of clinical trials, or opensecrets.org, the database of the Center for Responsive Politics, which tracks money in U.S. politics.

Dr. Steinbrook (rsteinbrook@attglobal.net) is a national correspondent for the *Journal*.

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Health Care and the Recession

Thomas H. Lee, M.D., James J. Mongan, M.D., Jonathan Oberlander, Ph.D., and Meredith B. Rosenthal, Ph.D.


A video is
available at
NEJM.org



On January 9, 2009, the *Journal* hosted a videotaped discussion of the likely effects of the recession on health care and the prospects for health care reform in the United States. The participants discussed the potential changes in Washington health care politics and payment policy, possible changes at U.S. hospitals and academic medical centers, and the ultimate effects of such shifts on patients.