

Re-Thinking Risk Assessment: Are you Counting the Ants While the Elephants Run By?

Conflict of Interest

Code on Interactions with Healthcare Professionals, Pharmaceuticals Research and Manufacturers of America (PhRMA), Effective January, 2009

Code of Ethics on Interactions with Health Care Professionals, Advanced Medical Technology Association (AdvaMed), Effective July 1, 2009

Guidelines for Interactions between Clinical Faculty and the Pharmaceutical Industry: One Medical School's Approach, David L. Coleman, MD, Alan E. Kazdin, PhD, Lee Ann Miller, MS, RPh, Jon S. Morrow, MD, PhD, and Robert Udelsman, MD, MBA, Yale University Medical School, February, 2006

Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers, Troyen A. Brennan, MD, MPH, David J. Rothman, PhD, Linda Blank, David Blumenthal, MD, MPP, Susan C. Chimonas, PHD, Jordan J. Cohen, MD, Janlori Goldman, JD, Jerome P. Kassirer, MD, Harry Kimball, MD, James Naughton, MD, Neil Smelser, PhD, American Medical Association, JAMA, January 25, 2006

Institutional Academic-Industry Relationships, Eric G. Campbell, PhD, Joel S. Weissman, PhD, Susan Ehringhaus, JD, Sowmya R. Rao, PhD, Beverly Moy, MD, Sandra Feibelman, MPH, Susan Dorr Goold, MD, MHSA, MA, JAMA 2007

Frequently Asked Questions About the School of Medicine's Conflict-of-Interest Policy, Stanford University School of Medicine, <http://med.stanford.edu>, 2004

A Layman's Guide to Conflict of Interest, University of Pennsylvania, www.upenn.edu, 2007

Senator Grassley, Psychiatric Ethics, and Conflict of Interest, Health Care Organizational Ethics Blog, October 4, 2008

Guidance Regarding Certain Physician Investments in the Medical Device Industries, Office of the Inspector General, October 6, 2006

Conflict of Interest: Part 1 – Elements of Successful Mitigation, Journal of the Association of Healthcare Internal Auditors, Inc., Mark Ruppert, Spring, 2003

Conflict of Interest: Part 2 – Automating Elements of Successful Mitigation, Journal of the Association of Healthcare Internal Auditors, Inc., Mark Ruppert, Fall, 2003

PHYSICIAN PAYMENT SUNSHINE ACT 2009 (*JAMA Web Site*)

U.S. Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI) introduced [The Physician Payment Sunshine Act](#) to require manufacturers and group purchasing organizations to report on a wide range of payments to physicians and physician-owned entities.

If passed, beginning in 2010, the government will require yearly reporting of all physician payments over a cumulative value of \$100 dollars - with the first report being due by March 31, 2011 - and made available to the public by September 30, 2011.

The bill is similar to the original Bill introduced in 2007, but not taken up by Congress. It incorporates many of the recommendations made by the Medicare Payment Advisory Commission (MedPAC).

The bill includes many additional physician financial relationships, including their health related business interests. The bill uses the "direct payment" system, thus excluding most company grants to certified education providers.

Companies will report:

- Name;
- Business Name;
- Address;
- Value of the payment or transfer of value;
- Dates of the payments or transfers; and
- Description of the form of payment or transfer of value.

Items required to be reported:

- Consulting Fees;
- Compensation for services other than consulting;
- *Honoraria*;
- Gifts;
- Entertainment;
- Food;
- Travel;
- Education;
- Research;
- Charitable Contributions;
- Royalties or licenses;
- Current or prospective ownership or investment interests;
- Compensation for serving as a faculty member or as a speaker for a continuing medical education program;
- Grants; and
- Any other nature of the payment or other transfer of value as defined by the secretary.

If the payment or other transfer of value is related to marketing, education, or research concerns, a specific covered drug, device, biological, or medical supply, companies will be required to report and include the link to the drug. Also, reporting will be required on whatever the Secretary of Health and Human Services (HHS) deems appropriate.

Research

Reporting of research payments will be required, and some reporting will be delayed by whichever date is earlier:

- Two years after the date of transfer of value was made; or
- After the date of Food and Drug Administration (FDA) Approval.

Companies will also be required to aggregate amounts of payments or transfers of value to recipients.

Physician Ownership

The bill requires reporting of physician ownership interests in private companies, including:

- The dollar amount invested;
- The current value; and
- Any payment or transfer of value to the owner, including dividends or other payments.

Excluded from Reporting:

- Payments in the aggregate of less than \$100;
- Product samples;
- Patient education materials;
- The loan of a device for less than 90 days;
- Warranty replacements (devices);
- Items for use as a patient;
- Discounts and rebates;
- In-kind items used in charity care; and
- Dividends or distributions from a publicly-traded company.

Penalties

For unintentional failure to report, penalties will include fines from \$1,000 - \$10,000 for each payment not reported with a cap of \$150,000/year.

For intentional failure to report, the penalties will be steeper - the fines are \$10,000 - \$100,000 for each payment not reported with a cap of \$1 million/year.

Implementation

The Bill has a short timeframe to implement; the Secretary of HHS has until November of 2009 to establish procedures for implementation of the Bill.

The website for which this implementation will be hosted, has a search mechanism by company or physician and is in a format that is clear, understandable, and easily downloaded.

The website will contain a description of any enforcement actions and penalties as a result of the legislation.

The Secretary has tremendous leeway in adding required information to the law and can add any other information that he or his team deems helpful to “consumers.” The Secretary will be required to consult with consumers, consumer advocates, and “other interested parties” to ensure that information is made available.

The federal government will also make available to each state, a report of physician payments that is specific to the respective state.

Pre-emption

The Bill will pre-empt state laws for disclosure of payments or transfers of value for items described.

They do not pre-empt state laws that have additional reporting requirements on information not required in the Bill. Further, if a state wanted to require disclosure for samples or rebates, this Bill would not limit that activity.

For Continuing Medical Education (CME)

The language is for direct payments or transfers of value, at the request of, on behalf of, or designated on behalf of, a covered recipient (a physician, physician medical practice or physician group practice). For direct payments to those entities, reporting will be required for education, compensation for serving as faculty, or as a speaker for a CME program, and grants.

Summary

This is similar to the original Bill introduced in 2007, but not taken up by Congress. This bill incorporates many of the recommendations made by the Medicare Payment Advisory Commission.

Transparency is going to happen. The short time frame for implementation and the strict requirements may be ambitious.

The watered down language of the State Pre-Emption Section makes this Bill seriously flawed, in that states can add anything they want to the reporting requirements, and the companies will still be in the same position (reporting to multiple states) before the legislation passed.

If adopted, this legislation will have significant impact on the income and perceptions of physicians.