

# Transparency: Working with Patient Groups

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# Focus on Interactions with Health Care Professionals

- Persuade health care professionals and industry to “rethink” their relationships
  - Interference with clinical decision-making
    - Risk to patients
    - Increasing health care costs
  - Conflicts of interest in research and publication of evidence influencing decision-making regarding “safety and efficacy” as well as “medical necessity “
- Give the public information to judge the potential influence of the financial relationship on his/her HCP
- Gives the government a road map to relationships of interest

# Demand for Greater Transparency

- Enforcement Agencies
  - Department of Justice
  - Office of the Inspector General
  - State Attorneys General
- Legislative Bodies
  - Congress
    - MedPAC (Medicare Payment Advisory Committee)
  - State legislatures
- Scientific Bodies
  - Institute of Medicine
  - Journal Editors
- Consumer Advocacy Groups



## The American Psychiatric Association Phases Out Industry-Supported Symposia

**ARLINGTON, Va. (March 25, 2009) — The American Psychiatric Association Board of Trustees voted this month to phase out industry-supported symposia along with industry-supplied meals at its annual meetings.**

With this move, the APA remains at the leading edge of a trend throughout medicine to increase transparency and reduce potential financial conflicts of interest. Symposia at major medical meetings that supply doctors with continuing medical education credits are sometimes funded by pharmaceutical companies, a practice that has invited a concern that the sessions may be biased in favor of the sponsoring company's medications.

"Although we took great care to avoid biased reporting at all our symposia, we came to the conclusion that the only way to totally eliminate the risk is to have the symposia supported by the APA alone," said Nada L. Stotland, M.D., M.P.H., president of the APA.

The decision includes the elimination of industry-supplied meals that were provided during the industry-supported symposia. "There is a perception that accepting meals provided by pharmaceutical companies may have a subtle influence on doctors' prescribing habits," said James H. Scully Jr., M.D., the APA's Medical Director and CEO.

"While industry-funded meals used to be normal operating procedure at medical meetings, a sea change is currently underway in how we manage industry relationships," he said. "What was acceptable five years ago isn't necessarily acceptable today. Change is necessary, and the APA wants to stay at the forefront of a new and better way of doing things."

## Stanford medical school to provide online disclosure of faculty's consulting activities

On April 1st, Stanford University School of Medicine announced that it is planning to post the industry-related activities of its physicians and researchers on a publicly accessible Web site in order to increase the transparency of the relationships that drug and device companies have with professionals' medicine and biomedical research.

The announcement follows the Cleveland Clinic, which in December said it would make industry relationships with their physicians and investigators available to the public.

“Industry collaborations are critical to furthering research efforts and innovative patient care, but at the same time, concerns over these activities are eroding the public trust.”

Philip Pizzo, Dean of the medical school.

About 1,200 physicians and faculty will be impacted.

The policy applies when faculty members or other Stanford physicians receive consulting payments for speaking or other honoraria of \$5,000 or more per year from a commercial entity for activities related to their professional activities.

Stanford also plans to post in the online profiles information about:

- companies from which the researcher or clinician has the right to receive royalties for inventions or discoveries;
  - the companies in which the person holds equity as a result of activities as a founder, inventor, or consultant; and
  - the companies for which the person serves as a director or holds other fiduciary offices.
- industry-directed funding of continuing medical education.

## Federal Legislation -- Physician Sunshine Act

- S. 301: “A bill to. . . provide transparency in the relationship between physicians and manufacturers of drugs, devices or medical supplies for which payment is made under Medicare, Medicaid or SCHIP.”
- Requires Annual “Transparency Reports”
  - Reporting of manufacturer payments or other transfers of value to a covered recipient or to an entity or individual at the request of or designated on behalf of a covered recipient
- Preemption: the legislation will serve as a minimum standard leaving states free to enact more restrictive requirements

## State Efforts

- Handful of states have enacted transparency laws with a focus on industry relationships with HCPs
- Example
  - Massachusetts
    - The Pharmaceutical and Medical Device Manufacturer Code of Conduct or the Marketing Code of Conduct
    - Adopt a marketing code of conduct in compliance, implement training, and investigative procedures
    - Starting July 1, 2010 companies are required to report annually the value, nature, purpose, and particular recipient of any fee, payment, subsidy, or economic benefit with any value of at least US \$50 provided to an HCP
  - Vermont
    - Legislation passed May 11, 2009

## Support of Patient Groups Not a Primary Target

- Not viewed as a primary driver of product utilization
- Backlog of cases involving industry and HCPs, no resources to detangle patient group relationships
- Legal theories involving HCPs less complicated
  - False Claims Act reaches parties that submit or cause to be submitted false requests for payment to the government
  - Federal Anti-Kickback Statute requires a showing of criminal intent to influence referrals
  - Beneficiary Inducement Prohibition
- Political challenge



## Patient Assistance Programs

- The one area of scrutiny between industry and patient groups focuses on industry funded patient assistance programs
- Two different models
  - The independent charitable organization
  - The company foundation

## Charitable Organization PAPs

- Independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug or provider choices
- Concerned that pharmaceutical manufacturers may seek improperly to maximize profits by creating sham “independent” charities to operate PAPs that ensure the manufacturer's contributions only or primarily benefit patients using its products
  - Pharmaceutical manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products

## OIG PAP Criteria

- (i) Neither the pharmaceutical manufacturer nor any affiliate of the manufacturer (including, associated contractors such as wholesaler, distributor, or pharmacy benefits manager)) exerts any direct or indirect influence or control over the charity or the subsidy program;
- (ii) The charity awards assistance in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary (i.e., the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer);
- (iii) The charity awards assistance without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or pharmaceutical insurance plan;
- (iv) The charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and
- (v) The pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products

Thank you  
**QUESTIONS?**