Financial Conflict of Interest Regulations: Assessing and Addressing the Impact

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June 4, 2015
Changing the Rules on Conflicts of Interest (42 CFR Part 50)

• Prior regulations promulgated: 1995
• Advance Notice: May 8, 2009
• Proposed Rule: May 21, 2010
• Final Rule: August 25, 2011
• Compliance Date: August 24, 2012 or when the new COI policy was on the institution’s website
2012: Investigators Disclose Significant Financial Interests (SFIs):

Related to *Professional Responsibilities*

- $5,000 or more
- Travel

Related to PHS funded Research

- $10,000 or more

Is the SFI "related" to the research?

Is the "related" SFI an FCOI?

Institutions Report Financial Conflicts of Interest (FCOIs)
The AAMC COI Metrics Project:
Measuring the Cost, Effect, and Effectiveness of the PHS FCOI Regulations
74 AAMC member institutions are providing annual aggregate data to AAMC
Information Collected and Analyzed

- Baseline data – one year before implementation of the regulations
- Up to 3 years after implementation
- Data include:
  - One-time investments and ongoing administration costs
  - Significant Financial Interests reviewed and FCOIs reported (including assessment of $10K - $5K threshold change and travel reporting)
  - Policy changes
  - Personnel changes
- Benchmarking data to each participating institution
- De-identified data to NIH for retrospective review
Results: Institutional Investment to Implement and Administer the Rule

71 institutions spent $23 million in one-time costs to implement the rule.

Average ~$318,000
Median ~$126,000
Institutions made 61% ($14 million) of the one-time additional investments before implementing the rule.

39% ($9 million) of the one-time investments were made the year following implementation.
Disclosed SFIs found to be FCOIs decreased from 4.8 to 1.4% after implementation of the regulations.
Change in the Number of FCOIs Reported as a Function of the Change in Disclosed SFIs

Of these institutions, only 5 increased the number of FCOIs by 20 FCOIs or more
Administering the COI Program

In 2012, 61 institutions estimated that it would cost on average $289,016 annually.

In 2013 those institutions reported spending $329,078.

Personnel administering the program increased from 1.9 to 2.7 FTE employees.
Implementing the Regulations on Financial Conflicts of Interest: Results from the AAMC Conflict of Interest Metrics Project

Revised regulations related to the identification and management of potential conflicts of interest have a substantial impact on the costs and personnel at medical schools and teaching hospitals conducting federally funded research. In 2011, the U.S. Department of Health and Human Services issued changes to the regulations designed to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias. The revised rule maintained the previous regulatory framework but made specific changes to the values and types of financial interests that investigators must disclose to their own institutions (significant financial interests, or SFIs) as well as the processes institutions must undertake to review SFIs and manage any identified financial conflicts of interest (FCOs). This situation posed a unique opportunity to assess the institutional impact of a single regulatory scheme and to create a model for a retrospective evaluation of regulatory burdens and benefits.

This Analysis in Brief presents key results from the first two years of the AAMC Conflict of Interest (COI) Metrics Project, which was initiated to understand the impact of these changes by comparing the information reviewed by institutions and the resources needed to comply with the regulations in the year prior to the implementation deadline with the resources needed for compliance in the following years.

Through the COI Metrics Project, the AAMC will provide the National Institutes of Health (NIH) with detailed, de-identified aggregate data to assist in the agency’s assessment of this rule, should it undertake such a review. Agency-level review of regulatory burden is mandated by a January 2011 Executive Order recognizing that “our regulatory system must ... identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends” and requiring that federal agencies “consider how best to promote retrospective analysis of rules that may be outdated, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.”

Methods:
The AAMC invited all member medical schools and teaching hospitals to participate in the COI Metrics Project by providing the association with annual aggregate data related to their compliance with the revised regulations. The 74 participating institutions vary in geographic location, size, public/private status, total amount of PHS funding, and number of funded investigations.

www.aamc.org/data.aib
Additional Data and Next Steps

Survey includes policy and COI office structure questions

Benchmarking reports to participating institutions

Aggregate, unidentified data to NIH

Second annual survey is ongoing

Future analysis will include retrospective reviews, public accessibility, FCOIs
Addressing the Burden of Disclosure

- **2009** Institute of Medicine Report: Conflict of Interest in Medical Research, Education, and Practice
- **2010** IOM Multi-Stakeholder Event [Sunshine Act]
- **2011** IOM-Convened Working Group [PHS FCOI Regulations]
- **2012** Discussion Paper and JAMA Editorial
- **2013** IOM Implementation Committee
From IOM Recommendation to Prototype

- Secure, user-controlled
- Draws from single source of financial interests
- Interoperable with COI management systems – based on data standards
- Intuitive and easy to use for both individuals and subscribing organizations
- Provides relevant disclosure information based on organization criteria and user assessment
Welcome to Convey

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Questions and Discussion

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