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Financial C	onflict of Interest
Regulation	S:
Assessing	and Addressing
the Impact	

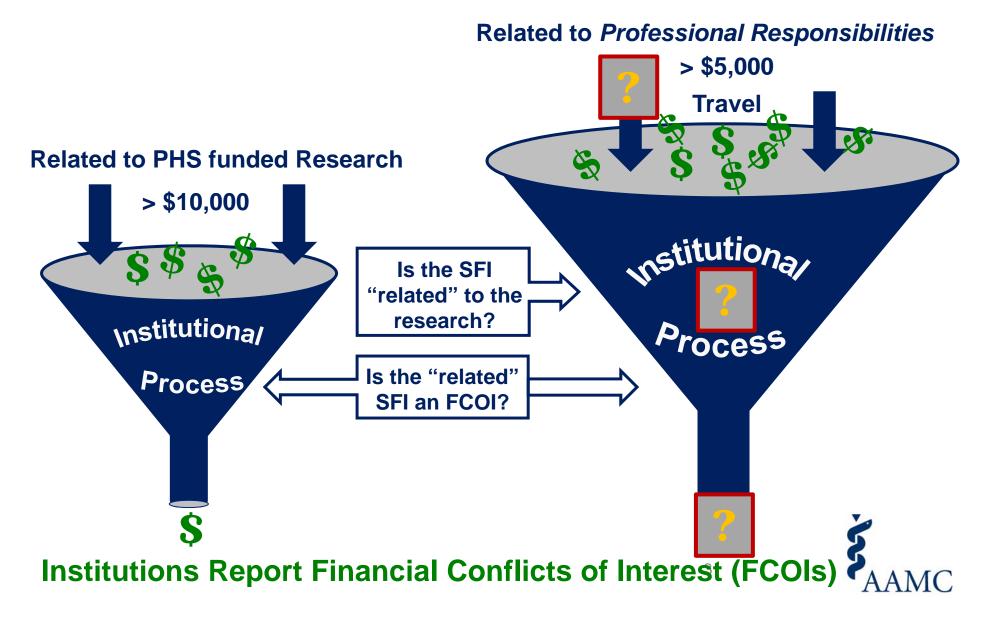
Heather H. Pierce, JD, MPH Senior Director and Regulatory Counsel June 4, 2015

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



<u>2012</u>: Investigators Disclose Significant Financial Interests (SFIs):

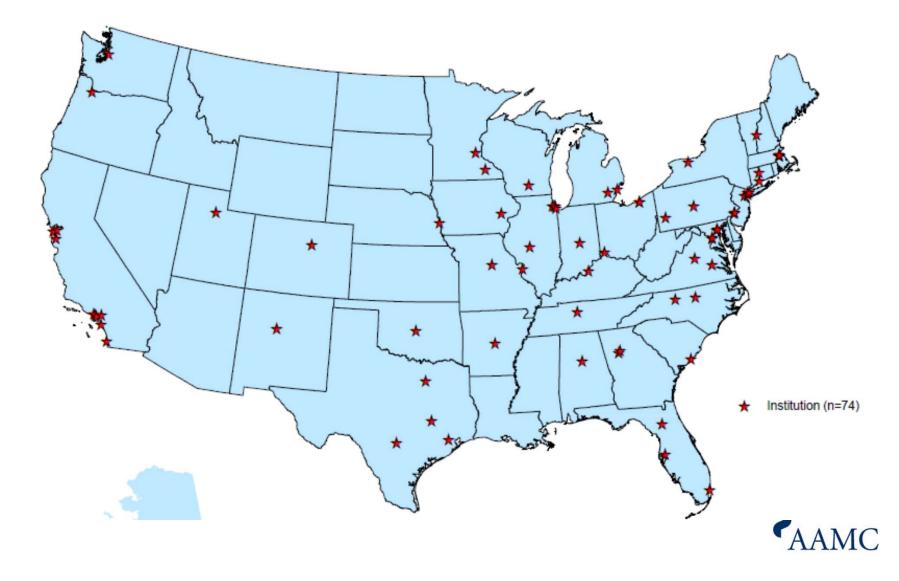


The AAMC COI Metrics Project:

Measuring the Cost, Effect, and Effectiveness of the PHS FCOI Regulations



74 AAMC member institutions are providing annual aggregate data to AAMC

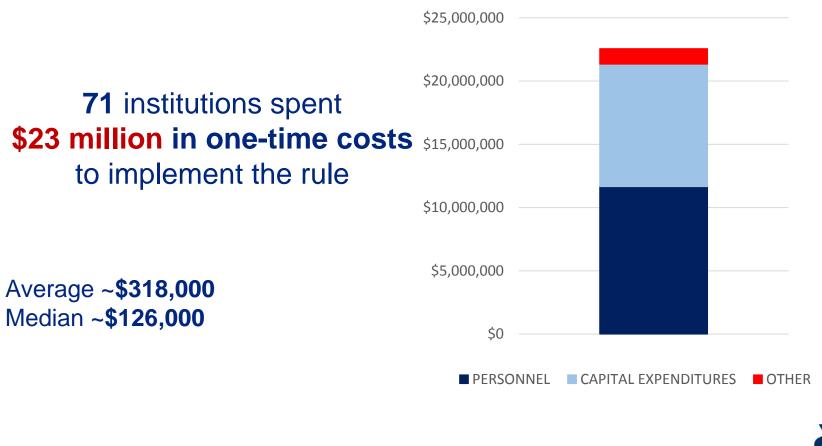


Information Collected and Analyzed

- 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

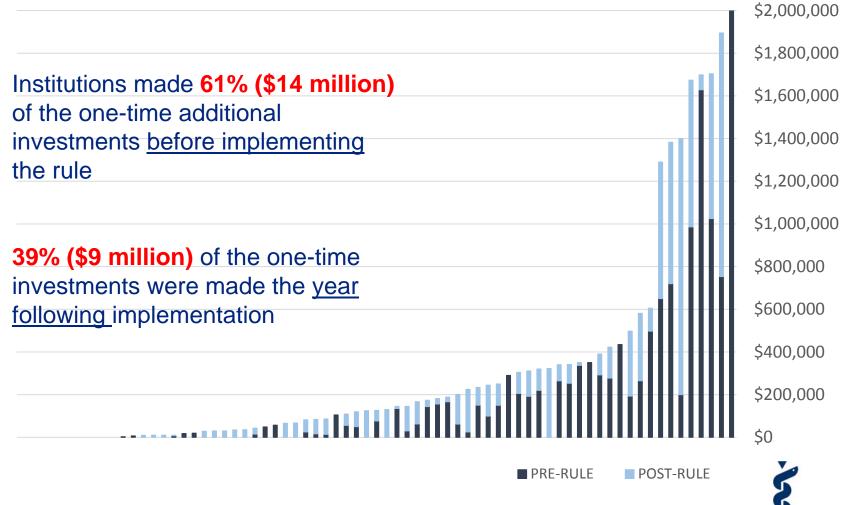


Results: Institutional Investment to Implement and Administer the Rule

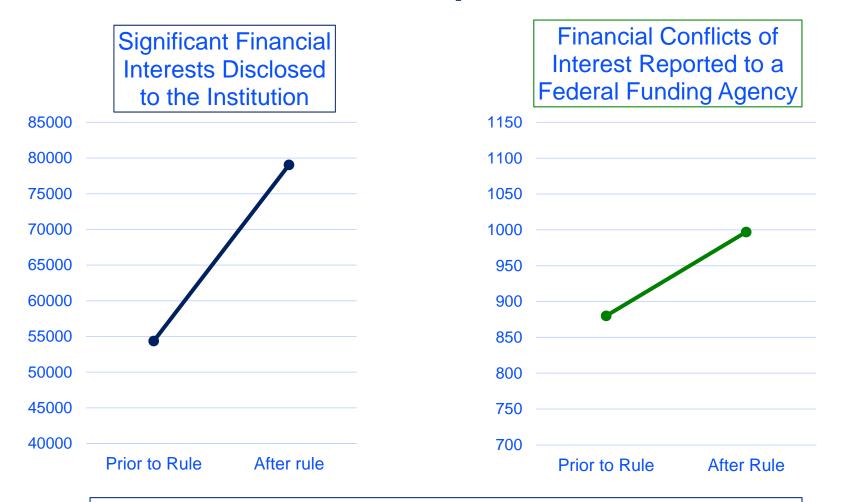




One-Time Investments Made Before and After the Implementation Deadline



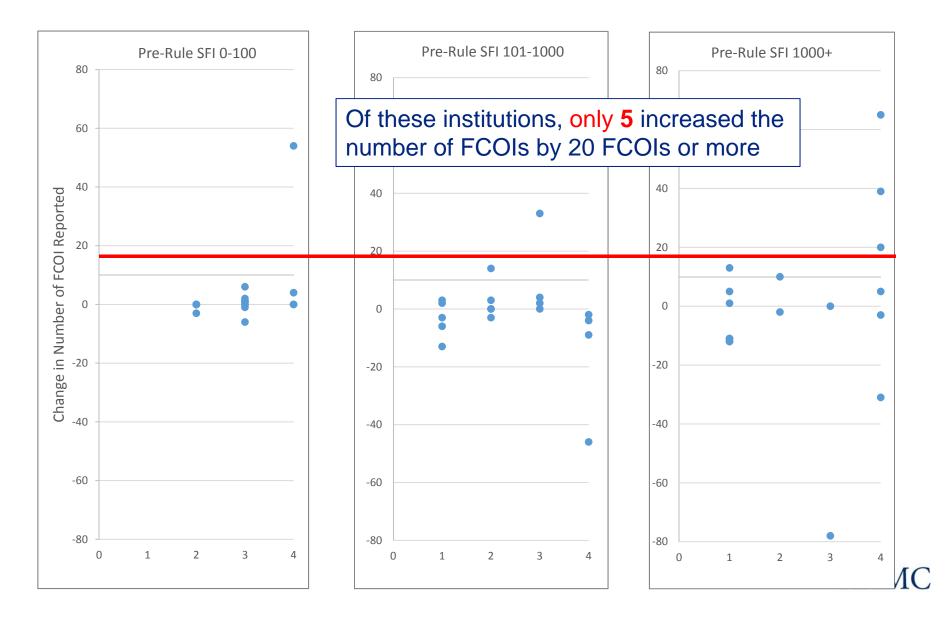
Change in the Number of SFIs Disclosed and FCOIs Reported



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



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 had a substantial impact on the costs and personnel at medical schools and teaching institutions must undertake to review 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.1 The revised rule maintained the previous regulatory framework but made specific changes to

and After Rule Implementation

Pre-Rule SII 0-55

Conflict

Number of Financial Reported Pre-andP

Change h /

the values and types of financial interests and the resources needed to comply that investigators must disclose to their own institutions (significant financial interests, or SFIs)2 as well as the processes SFIs and manage any identified financial conflicts of interest (FCOIs).3 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

Pre-Rule SFI 1000-

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Figure: Change In the Number of Financial Conflicts of Interest Reported as a Function

Pre-Rule SEI 100-998

of the Number of Significant Financial Interests Disclosed to Institutions Before

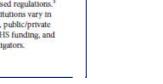
with the regulations in the year prior to the implementation deadline with the resources needed for compliance in the following years.

Through the COI Metrics Protect. 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 ts 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 outmoded, ineffective, insufficient, or excessively burdensome, and to modify. streamline, expand, or repeal them in accordance with what has been learned."4

Methods

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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.3 The 74 participating institutions vary in geographic location, size, public/private status, total amount of PHS funding, and number of funded investigators.





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



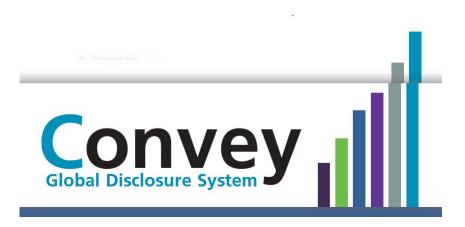
Addressing the Burden of Disclosure





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









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Questions and Discussion

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