Analysis IN BRIEF

AAMC
Tomorrow's Doctors, Tomorrow's Cures®

Volume 15, Number 4
April 2015

Association of
American Medical Colleges

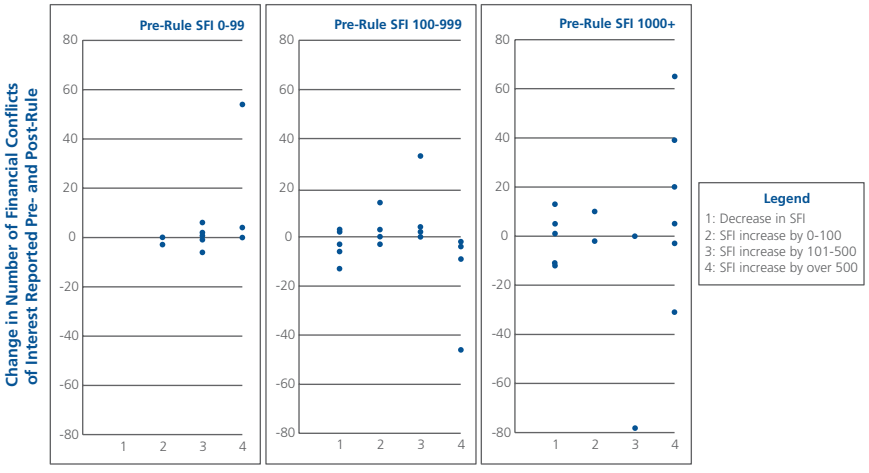
Implementing the Regulations on Financial Conflicts of Interest: Results from the AAMC Conflict of Interest Metrics Project

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 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 the values and types of financial interests that investigators must disclose to their own institutions (significant financial interests, or SFIs)[2] as well as the processes institutions must undertake to review 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 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 outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned."[4]

Figure: Change in the Number of Financial Conflicts of Interest Reported as a Function of the Number of Significant Financial Interests Disclosed to Institutions Before and After Rule Implementation



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

1. 42 CFR § 50.601.
2. Generally, investigators must now disclose SFIs with a value equal to or greater than $5,000 (instead of $10,000), SFIs related to their "institutional responsibilities," not just related to PHS-funded research, and sponsored or reimbursed travel.
3. Institutions now have responsibility for determining if a disclosed SFI is related to PHS-funded research and if it is a FCOI. Once an institution makes a FCOI determination, the institution must report each FCOI to the NIH or other PHS funding entities.
4. Executive Order No. 13563, "Improving Regulation and Regulatory Review," 76 Fed. Reg. 3821 (Jan. 18, 2011).
5. Institutions participating in the project chose an annual timeframe based on their internal disclosure policies (e.g., calendar year, fiscal year, academic year). No information about individual investigators or identified FCOIs was collected.

The baseline survey captured data from the year before the August 24, 2012 compliance deadline, including information about institutional COI policies, the number of full-time equivalent (FTE) employees who administered related activities, the number of SFIs disclosed to the institution, and the number of FCOIs reported to NIH or other PHS entities during a 12-month period. This survey also captured the costs incurred by the institution in implementing or preparing to implement the requirements. A second survey collected similar information from the year after the regulation's requirements were fully implemented.

Results

Following the implementation of new obligations and policy changes, more than three-quarters (79 percent) of the institutions reported an increase in the number of disclosed SFIs, while less than half (45 percent) reported an increase in the number of FCOIs reported to a PHS funding entity.[6]

The 56 institutions that provided the number of SFIs disclosed to them by investigators before and after the rule reported an overall increase of 45 percent of SFIs, from 54,354 to 79,035.[7] A total of 880 FCOIs were reported to a PHS funding entity by 66 institutions the year before the rule was implemented, and 997 FCOIs were reported the year after implementation of the rule, reflecting a 13 percent overall increase in the number of FCOIs. For the institutions that provided complete data on both disclosed SFIs and reported FCOIs, the percentage of SFIs found to be FCOIs decreased after implementation of the regulations, from 4.8 to 1.4 percent. Notably, only 5 of these institutions increased the number of reported FCOIs by 20 or more. Institutions with more than 1000 SFIs disclosed before implementation demonstrated the greatest variation in the changes in reported FCOIs after implementation (see Figure).

Participating institutions incurred significant costs beyond their ongoing program administration costs to fully implement the regulations. The total investment by 71 institutions was almost $23 million ($22,557,744) for an average of approximately $318,000 per institution and a median investment of approximately $126,000. The $23 million included $11.6 million in one-time personnel costs, $9.7 million in capital expenditures, primarily financial interest-tracking software, and $1.2 million in other costs, such as training. Institutions made 61 percent ($14 million) of these investments before implementing the rule and 39 percent ($9 million) in the year following implementation of the regulations.

After the regulations were implemented, personnel administering COI-related activities at 71 institutions increased on average from 1.9 FTE employees to 2.7 FTE employees. Participating institutions also were asked in 2012 to predict the annual administration costs of their COI programs following implementation of the rule and then report what the actual annual costs were the following year. In 2012, 61 institutions estimated that it would cost an average of $289,016 annually and reported in 2013 an actual cost of $329,078.

Discussion

As demonstrated by the initial results from the AAMC COI Metrics Project, the number of SFIs reviewed by institutions dramatically increased after implementation of the rule, without a proportional increase in the number of reported FCOIs. Institutions indicated that the increases in disclosed SFIs likely were the result of both the decreased disclosure threshold and the requirement to disclose financial interests related to all institutional responsibilities, not just those related to federally funded research; however, institutions were largely unable to determine the contribution of each factor in the increase.

When the cost of implementation is considered, there is a question as to whether the rule accomplished its intended goals in a manner that appropriately balanced the benefits and burdens of the requirements. It is worth considering whether the objectivity of research is better ensured because of these changes, and whether the incremental increase in the number of reported and managed FCOIs has a tangible effect on the research enterprise as a whole.

Ongoing surveys seek to understand the continued effect of these regulations and the qualitative impact of the regulations on institutions, faculty, and staff, as well as the impact on research or other relationships with industry. The results suggest a model for future assessment of specific regulations. Prospective modeling or pilot programs to understand a regulation's probable impact could allow an agency to better assess whether a new rule will accomplish the intended aims of a proposed regulation before it is finalized.

Authors
Heather H. Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel, Scientific Affairs, AAMC, hpierce@aamc.org

Anurupa Dev, PhD, Science Policy Analyst, Scientific Affairs, AAMC, adev@aamc.org

Daria Grayer, JD, MA, Lead Specialist, Science Policy and Regulations, Scientific Affairs, AAMC, dgrayer@aamc.org

Association of American Medical Colleges
655 K St., NW, Suite 100
Washington, D.C. 20001-2399
analysis@aamc.org
www.aamc.org/data/aib

6. Not every participating institution could report on all requested metrics, primarily as a result of the variation and limitations of the software or processes used in the review and processing of financial interest information.
7. The number of SFIs disclosed does not include responses from institutions that significantly revised their policies to prohibit many types of interactions with industry during the survey timeframe, as this resulted in a significant decrease in disclosable SFIs for reasons unrelated to the requirements of the revised regulations.