

UNDER SCRUTINY:

SHB's Government Enforcement & Compliance Update

GOVERNMENT ENFORCEMENT & COMPLIANCE

Our clients face unprecedented enforcement scrutiny and novel legal theories. Today, government enforcement actions can include civil as well as criminal investigations and litigation. They can involve a host of independent actors including federal and state prosecutors, regulators, whistleblowers and their counsel, and class-action attorneys. These cases must be defended under the watchful eye of investors and the public.

Our Government Enforcement & Compliance Practice consists of former prosecutors – including a former U.S. Attorney, former Justice Department officials and even former corporate executives – who counsel and defend companies, their executives and employees in the full range of criminal, civil and regulatory government enforcement actions at the state and federal level. We counsel clients on how to avoid enforcement scrutiny. When investigations do arise, however, we work with our clients to resolve them as efficiently, cost-effectively and quietly as possible.



HHS PROPOSES NEW FINANCIAL CONFLICTS OF INTEREST RULES

Citing the growing complexities of collaborations between investigators and the private sector, the Department of Health and Human Services (HHS) has proposed new rules for Financial Conflicts of Interest (FCOI).

Published in the May 21, 2010, *Federal Register*, the rules seek to reduce conflicts by increasing disclosures, expanding the definition of a conflict and increasing institutional oversight and reporting.

The proposed changes to 42 CFR Part 50 Subpart F and 45 CFR Part 94 will affect each institution that applies for Public Health Service (PHS) grants or cooperative agreements for research. The rules are likely to greatly increase the FCOI reporting burden on institutions. HHS will accept comments for 60 days.

Proposal to Reduce Levels Triggering Disclosure and Expand Financial Interest Definition

HHS proposes new and expanded definitions to increase what is considered a Significant Financial Interest (SFI). First, the current financial disclosure level would be reduced from \$10,000 to \$5,000. The proposed rule change is apparently due to a body of scientific research which has found that even negligible funds can influence behavior. Thus, lowering the disclosure level will reveal a greater number of potential conflicts and biases.

The agency is aware, however, that this change is not without substantial costs. It recognizes that the expanded definition is likely to lead to increased administrative costs for both investigators and institutions. Both are expected to see an increase in the number of SFIs disclosed.

Second, in addition to lowering the threshold, the definition of what is considered a financial interest would expand. All PHS-funded investigators would be required to disclose to their institutions any SFIs related to their institutional responsibilities, not just SFIs related to the PHS-supported, as currently required. Institutional responsibilities would include an investigator's professional responsibilities, including

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activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and services on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

HHS to Expand Management and Reporting of Financial Conflicts of Interest

HHS also proposes to expand the oversight requirements for institutions as well as their duty to publically report all conflicts of interest. Under the new rules, before spending any funds under a PHS-funded research project, officials must (i) review all SFIs; (ii) determine whether any SFI is related to PHS-funded research; and (iii) determine whether a financial conflict of interest exists, and, if so, develop and implement a "management plan" to address and manage the conflict. Although the current rules require institutions to "manage" conflicts, the "management plan" requirement is an addition to the rules. Although HHS does not specify the elements of a plan, it does note that the "plan" is related to the greater disclosure requirements for institutions.

The new disclosure requirements provide that, before an institution spends any funds under a PHS-funded research project, the institution must post on a publicly accessible Website information on certain SFIs that the institution has determined are related to PHS-supported research and constitute a financial conflict of interest. Generally, this information would include the investigator's information and his position in the research, the SFI's nature and the approximate dollar value.

This requirement is in similar form to the recently enacted Patient Protection and Affordable Care Act, P.L. 111-148, which includes several public disclosure provisions. Title VI, section 6002, requires designated manufacturers of covered drugs, devices and biological or medical supplies to submit particular information to HHS about certain payments made to designated physicians and teaching hospitals annually beginning March 31, 2013, and requires HHS to make such information publicly available no later than September 30, 2013.

A new subsection (b)(1) would establish greater reporting requirements. Specifically, before spending any funds under a PHS-funded research project, institutions would be required to provide to the PHS Awarding Component a financial conflict of interest report regarding any investigator SFI found to be conflicting and ensure that a "management plan" has been implemented.

Other Provisions Would Revise Remedies, Change References and Definitions and Require More Training

HHS proposes minor revisions to the remedies in the event of a conflict. Small changes to existing references and definitions are also proposed. HHS hopes to increase compliance and accuracy by requiring investigators to receive more training about an institution's FOCl policies before receiving funds and at least every two years thereafter.

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Finally, HHS requests comments on the general topic of Institutional Conflict of Interest. Although no proposed rules have been put forth, HHS finds the area one of "increasing interest" and then presents an opportunity to file initial thoughts on how "institutional conflict of interest" would be defined and what a policy should address to maintain PHS objectivity in research.

Burdens Likely to Increase

These rules are likely to substantially increase the review and reporting burden for institutions and investigators alike. Yet, it appears that despite the burdens of these new rules, HHS is attempting to reduce FOICs with the least burdensome methods that it feels adequately address the problems. A full copy of the proposed rules and HHS discussion is available at <http://edocket.access.gpo.gov/2010/2010-11885.htm>.

This analysis was prepared by SHB Partner [Carol Poindexter](#) and SHB Associate [Alison Spinden](#).