HHS Issues Final Regulations on Financial Conflict of Interest; Steps Back on Online Disclosure

The Department of Health and Human Services took a partial step back on requiring institutions to post researchers' significant financial information online, in the final rule released Aug. 23.

The revised regulations state that institutions must make the information publicly accessible and "may do so by posting the information on a public website or by making the information available in writing within five business days of any request."

HHS noted the department received comments on the proposed rule concerned about privacy issues and that "posting information about investigator [financial conflict of interest (FCOI)] without appropriate context would foster a negative perception of FCOI. Other comments indicated the rule might conflict with some state laws.

"We are strongly committed to the value of transparency to the public and we also appreciate the concerns," the HHS notice said. "In keeping with the increasing number and range of public disclosure initiatives...we believe it is important to make available to the public critical information affecting Public Health Service-funded research. We believe the language that we have finalized in this rule strikes a reasonable balance of the public and private interests at issue."

The final rule does not require the information to be provided in a specific format. "Therefore, an institution could choose to provide the information as a simple document or spreadsheet," HHS said.

De Minimis Threshold Levels for Disclosure Remain the Same as in Proposed Regulations

As was the case in the notice of proposed rulemaking, the final rule amends the definition of "significant financial interest" to a de minimis threshold of $5,000 for disclosure that generally applies to payments and/or equity interests. The old rules had a $10,000 threshold.

HHS noted some comments said the regulations also should address non-financial conflicts of interest. "While we acknowledge that non-financial conflicts of interest can influence the scientific process, we chose to retain the focus of these regulations on FCOIs because we believe this is a discrete area in which there is a heightened need to strengthen management and oversight."

Several comments said all investigator significant financial information (SFI) or all payments from pharmaceutical companies should be provided. "We disagree," HHS said, adding only SFIs determined to be financial conflicts of interest for federally funded research "provide the appropriate level of transparency." The department added, "Institutions are free to expand upon this requirement by providing information on all SFIs of their investigators."
HHS retained the provision that if an institution’s policy on FCOI includes standards that are more stringent than the regulations, the institution must adhere to its policy and provide FCOI reports in accordance with its own standards. “Many respondents indicated that this provision would provide a substantial disincentive to institutions to adopt more stringent standards...and could lead to a lack of consistency in reporting and increased confusion.”

HHS noted that “the principle that an institution must follow its own policies, even if they go beyond — but as long as they are consistent with — federal policies and regulations, is an established standard of NIH grants policies... We concluded that full reporting of all institution-identified FCOIs related to PHS-funded research is necessary for appropriate accountability by the institution and for robust oversight.”

HHS said that it considered hosting the information on a central website but decided “institutions are in a better position to provide and maintain this information. [Institutions] will be able to put the information into context by relating the information to the institutions’ FCOI policies or other information about the investigator.”

In announcing the final rule, HHS Secretary Kathleen Sebelius said, “Our financial conflict of interest rules must keep up with the times if we are to maintain our leadership role in the global scientific community.” National Institutes of Health Director Francis Collins added that “strengthening key provisions of the regulations with added transparency will send a clear message that NIH is committed to promoting objectivity in the research it funds.”

“The growing complexity of biomedical and behavioral research, the increased interaction among government, research institutions, and the private sector...as well as increased public scrutiny, all have raised questions as to whether a more rigorous approach to investigator disclosure, institutional management of financial conflicts, and federal oversight is required,” HHS said.

**Feds Don’t Want To Hinder Relationships**

“We want to emphasize that the revisions are not designed to prevent or hinder relationships among government, academia and industry. Rather, the revisions are aimed at facilitating such relationships by increasing transparency and accountability so that the resulting research is considered objective and in the interest of the public.”

The final rule, which amends the PHS regulations “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding Is Sought” (42 C.F.R. Part 50, Subpart F) and “Responsible Prospective Contractors” (45 C.F.R. Part 94), must be implemented no later Aug. 23, 2012, by institutions applying for or receiving PHS grants, cooperative agreements or contracts. However, institutions must comply “immediately upon making its institutional FCOI policy publicly accessible,” HHS said.

“Due to the extent of potential differences in the nature, scope and applicability of federal disclosure requirements, we do not agree that it is feasible to harmonize all requirements at this time, although we believe these regulations could serve as a basis for ongoing collaboration and coordination regarding the topic of conflicts of interest,” the HHS notice said.

HHS revised the final rule so that institutional sanctions against an investigator travel with the investigator to another institution. “This revision is intended to reference the range of options for the [research funder] to consider, depending on the specific circumstances at issue,” HHS said.

The final regulation revises the definition of “investigator” “to emphasize that institutions should consider the roles of those involved in research and the degree of independence with which those individuals work,” HHS said. The department added that the new definition is
“not significantly different from the 1995 regulations,” so the number of investigators affected “should not change substantially. We recognize that the scope of investigator SFI disclosures, if not the actual numbers, will increase…and that the number of FCOI reports may increase as well.”

The final rule also modified the definition of institutional responsibilities to clarify that the institution defines the investigator’s responsibilities in its FCOI policy.

No Need to Specify Approaches in Regs

The notice of proposed rulemaking asked if the regulations should be amended to require specific approaches for certain types of research or specific types of financial interests or conflicts of interest. “The majority of respondents thought that this approach would not account for the full range of research projects as well as the large variation in circumstances in which FCOI may arise,” HHS said. “We agree and note that the monetary threshold is the same regardless of the type of research, financial interest, or identified FCOI at issue.” HHS added, “Institutions are free to differentially manage FCOI, depending on the nature of the research, as long as they remain in full compliance with the regulations…We believe that institutions are in the best position to evaluate the circumstances and determine the most appropriate management strategies for specific cases.”

“Given the wide range of contexts in which a conflict with PHS-funded research may arise, we believe that specifying particular standards or specific criteria may not cover all types of FCOI,” HHS said, noting “institutions may choose a variety of measures...in their evaluation of SFIs and in any specific management plan.”

HHS noted that reduction or elimination is not the only acceptable way to manage a financial conflict of interest. “We want to clarify that we do not intend to imply that every FCOI must be eliminated; the goal of the regulations is to ensure appropriate management so as to maintain objectivity of the research,” HHS said.

Disclose Payments for Subject Accrual

The final rule said payments related to the accrual of subjects to clinical trials should be disclosed by investigators.

“Paid authorship” was specifically referenced in the revised regulations because HHS is particularly concerned about situations in which investigators may have accepted payment from private entities in return for allowing their names to be used as authors on publications for which they had very limited input... We wish to make clear to institutions and investigators that such activity may be subject to the disclosure and reporting requirements, depending on the circumstances of a given case, such as the amount of payment.”

To minimize burden on investigators while providing institutions with an “appropriate level of information,” HHS required institutions’ FCOI policies to specify for travel reimbursement “at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.” Although the regulations do not require disclosure of the monetary value of the sponsored or reimbursed travel, in accordance with the institution’s FCOI policy, the institutional official(s) can determine if further information is needed, including a determination or disclosure of monetary value, to establish whether the travel constitutes an FCOI with the PHS-funded research. In addition, travel that is reimbursed or sponsored by a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. §1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education is not subject to this disclosure requirement.”
SFI Definitions Revised

HHS revised the SFI definition to include intellectual property rights and interests, such as patents and copyrights, "upon receipt of income related to such rights and interests. Therefore unlicensed intellectual property that does not generate income is excluded.”

HHS also revised the SFI definition to exclude salary, royalties or other remuneration paid by the institution to the investigator if the investigator is employed or appointed by the institution; any ownership interest in the institution held by the investigator, if the institution is a commercial or for-profit organization; income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for the same types of entities. In addition, if a private organization is acting as a contractor to a federal, state or local government agency, “such income is excluded from the definition.”

HHS noted that if an investigator is employed by an institution and also has equity in a for-profit company, the equity would only be excluded from disclosure requirements if the company is the institution that applies for or receives PHS research funding in which the investigator is participating. HHS also clarified that intellectual property rights assigned to the institution, and agreements to share in royalties related to such rights, are excluded from the SFI definition.

If an investigator transfers to another institution and that institution is not the source of royalties, the royalties would be included in the SFI definition. HHS also revised the regulations to exclude income from investment vehicles, such as mutual funds and retirement accounts, “as long as the investigator does not directly control the investment decisions made.”

Training Requirement Extended

The draft rules proposed investigators complete training regarding the institution’s FCOI policy, the investigator’s responsibilities, and the regulations, prior to engaging in PHS-funded research and at least once every two years. Many comments thought that every two years was too frequent. HHS agreed “every two years may be too frequent; however, we believe it is important to ensure that investigators receive training beyond the initial period in order to maintain objectivity in PHS-funded research over the long term.”

The rule was changed to training investigators prior to engaging in research and then at least every four years, but “immediately” when: “the institution revises its financial conflicts of interest policies or a procedure in any manner that affects the requirements of investigators; an investigator moves to a new institution; or an institution finds that an investigator is not in compliance with the regulations or with the institution’s financial conflicts of interest policy or management plan.”

A few comments suggested the regulations stipulate the requirements for designated officials and how the institution should ensure that the designated officials do not themselves have conflicts of interest. “We have not implemented those changes because we believe that the institution is in the best position to determine the qualifications and characteristics of the designated official(s) in the institution’s policy.”

HHS also clarified that investigators who have not previously disclosed their SFIs to the institution’s designated official(s) must do so no later than at the time of application or the date of contract proposal submitted for PHS-funded research.
It was suggested that institutions establish internal databases for disclosures of investigator SFI, which could be easily updated. HHS said it was “concerned that could impose an unnecessary administrative burden and expense to institutions. As long as institutions have a process in place to comply fully with all regulatory requirements, they may collect disclosures from investigators in the manner that is most appropriate for their policies and procedures.”

HHS noted that many respondents were concerned the proposed revisions did not allow institutions to involve investigators in determining whether a SFI was related to PHS-funded research. HHS revised the rules “to explicitly state that the institution may involve the investigator in the designated official(s)’s determination of whether an SFI is related to the PHS-funded research.”

The final rule revises the length of time the information will remain available to at least three years from the date that the information was most recently updated, which aligns the rule with the HHS records retention policy.

HHS considered requiring the reporting of exact dollar amounts, rather than ranges, but decided “the exact amount of some types of financial interests, such as equity, may change frequently, which could create ambiguity and intensify the administrative burden.”

HHS also removed a requirement that the FCOI report contain a rationale for including the conflicted investigator in the research “to minimize confusion.”

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