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PROFESSION

HHS bolsters scrutiny of researchers' drug industry ties

Physicians and other investigators receiving federal grants will have to disclose any medical industry payments exceeding $5,000 starting next year.

By KEVIN B. O'REILLY, amednews staff. ***Posted Sept. 5, 2011.***

Physician researchers receiving federal grants will have stricter conflict-of-interest rules to follow starting in August 2012.

The first change to Dept. of Health and Human Services regulations in this area since 1995 comes in response to widely reported cases of federally funded researchers failing to disclose millions in pay from medical industry firms. Researchers soon must publicly disclose any industry payments, stock holdings and equity interests of more than $5,000 during the previous year. Their academic institutions will have to file plans with the funding agency explaining how they are managing conflicts of interest posed by such financial relationships.

"It's been 16 years since the conflict-of-interest rules were reviewed and updated by the federal government," said National Institutes of Health Director Francis S. Collins, MD, PhD, who announced the new rules in August. "In those 16 years, biomedical and behavioral research and the resulting financial relationships have become quite complex. Now is the time for the federal rules governing those relationships to be modernized as well.

"We are committed to transparency, objectivity and preserving the integrity of research so that it is free of any concerns about conflicts of interest that might affect the judgments of our scientists," Dr. Collins said. "Just the same, we are also very interested in seeing flourishing partnerships between NIH-funded researchers and industry."

Previously, only prior-year industry payments of $10,000 or more had to be reported to the federal funding agency and only if the researcher considered them to be related to the funded work. Starting in 2012, all industry payments of more than $5,000 must be reported regardless of whether investigators consider them germane.

Under the 1995 rules, organizations receiving federal funding had to declare only that they had managed, reduced or eliminated any financial conflicts. Under the new rules, they must share with the funding agency key elements of their plans for doing so. Examples of conflict-management strategies include appointing an independent monitor to oversee the design, conduct and reporting of the research, and disqualifying people with conflicts from participating in the research.

Medical schools, which receive more than half of the NIH grants awarded to external scientists, applauded the new regulations.

"Today's final rule from the NIH is an important step forward on the path to strengthening the integrity of biomedical research through enhanced requirements for disclosure and transparency," said Darrell G. Kirch, MD, president and CEO of the Assn. of American Medical Colleges.

Dr. Kirch said the association will work with the NIH and its member schools to implement the new rules. HHS estimates that the new rules will affect 3,000 organizations and 38,000 physicians and other investigators. The estimated cost for all organizations to comply with the rules is more than $5.3 million annually, HHS said.

A prior version of the regulations would have required organizations to post online any of their federally funded researchers' financial ties to industry. But the adopted rules say they can opt to provide such information in writing within five days of receiving a request from any member of the public, said Sally Rockey, PhD, deputy director of the NIH's Office of Extramural Research.

Asked in a news briefing why the rules do not require Web disclosure, Rockey responded, "Some organizations may not have a website."

Critics of industry influence on medical research said the new rules do not go far enough.

"The amount of money and the management plan should be publicly available on the Web," said Paul Thacker, who investigated researchers' ties to industry as a staffer for Sen. Chuck Grassley (R, Iowa) and now works for the Washington-based Project on Government Oversight. "It would be so simple for them to just put on the NIH's website who the principal investigator is, what's the amount of the grant and have a separate section that says, 'Here's the

person's financial conflicts and here's how they are being managed by the university.' How hard would that be? ... That's an internship project for a college student."

Under the Patient Protection and Affordable Care Act's so-called sunshine provisions, physicians who get $10 or more from any industry firm will have the information listed on a publicly searchable website starting Sept. 30, 2013.

The American Medical Association says the sunshine provisions are in line with its general principles on transparency, but the Association said it is working to ensure that physicians have the opportunity to review and correct information before it is posted. The AMA said it will monitor the law's effect on commercial support for continuing medical education and research.

Scrutinizing FDA rules

While conflict-of-interest rules for federally funded researchers are being tightened, talk is growing that they may be loosened for physicians asked to serve on Food and Drug Administration advisory committees. In May, the FDA reported that 23% of its advisory committee seats were vacant due to rules that limit the number of physicians and other experts who have financial relationships with industry from serving.

Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research, has been quoted in several news reports as saying that it is difficult to find experienced experts without industry ties to serve. The current rules, which can be changed only by congressional action, say no more than 13% of any advisory committee's membership can have financial relationships with industry. FDA Commissioner Margaret A. Hamburg, MD, echoed the point in a recent talk with the advocacy group Public Citizen.

Experts say the Prescription Drug User Fee Act, which expires in 2012 and must be renewed for the FDA to continue functioning as an agency, could become the vehicle to attach a looser set of rules. In Senate and House hearings on the FDA, members from both parties have criticized the rules for slowing the process of determining whether new drugs and devices should be approved.

But supporters of tighter oversight say the FDA is not doing enough to seek out experts without financial ties to industry and that the problem is lessening, with the vacancy rate on committees falling since 2009.

ADDITIONAL INFORMATION:

Overseeing research conflicts

Under new rules the Dept. of Health and Human Services adopted in August, academic and other nonprofit institutions receiving federal funding for medical research must:

- Ask physicians and other investigators to report any medical industry payments, stock holdings or equity interests exceeding $5,000 in the previous year.
- Disclose researchers' significant financial ties to industry on a public website or respond to any request from the public for the information in writing within five days.
- Formulate a plan to manage, reduce or eliminate any financial conflicts and share the key elements of the plan with the federal agency funding the research.

Source: "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors," *Federal Register,* Aug. 25 (**federalregister.gov/a/2011-21633**)

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