

PROFESSION

Critics rap delay in doctor-payment reporting rules

HHS missed its deadline to formulate rules on reporting how much industry pays physicians. Lawmakers, the drug industry and consumer groups call for speedy implementation.

By **KEVIN B. O'REILLY**, *amednews* staff. *Posted Nov. 14, 2011.*

Industry and consumer-advocacy groups are voicing concerns about Health and Human Services Dept. delays in implementing the physician-payment disclosure provisions in the Patient Protection and Affordable Care Act.

The agency missed the law's Oct. 1 deadline for issuing regulatory guidance to pharmaceutical and medical-device companies on how to report payments to physicians. Reporting of any consulting fees, honoraria, travel and entertainment worth more than \$10 given to doctors is supposed to start March 31, 2013, with the information available on a searchable federal government website starting Sept. 30, 2013. Beginning in 2012, companies are required to start collecting the data to be reported publicly.

"We're getting to crunch time on this," said Blair Childs, senior vice president of public affairs for Premier Inc., a Charlotte, N.C., purchasing and quality improvement alliance that asked HHS to speed the process. The Centers for Medicare & Medicaid is doing the regulatory work.

"We've been a strong advocate of this kind of transparency for years," Childs said. "We're all benefited by transparency around conflicts of interest. You don't want patients being suspicious that there's ulterior motives, and it's better to have the information out there."

Sens. Charles Grassley (R, Iowa) and Herb Kohl (D, Wis.), who co-sponsored the Physician Payments Sunshine Act integrated into the health system reform law, sent a letter Oct. 3 to CMS Administrator Donald M. Berwick, MD, asking why the agency had not met the deadline. In an Oct. 28 response, Dr. Berwick wrote, "We have been working to implement the statutory provision," but he offered no date when that would be done.

Grassley and Kohl were not happy. "Given how straightforward and detailed the Sunshine Act provisions were, it's troubling that the response to our letter would come a month late without any indication on progress, a timeline or what caused the delay," Kohl said. "The lack of guidance leaves a great deal of uncertainty, and I'm sure that's why many of the affected companies have joined us in calling for swift implementation."

In an Oct. 25 letter to HHS Secretary Kathleen Sebelius, the advocacy groups Consumers Union and Community Catalyst joined trade associations representing pharmaceutical companies, device makers, medical imaging and biotechnology companies in urging the agency to "work quickly." Industry groups also asked for a three-month extension to abide by the delayed regulations.

"Complying with this provision is important to America's biopharmaceutical research companies," said Matthew Bennett, senior vice president of the Pharmaceutical Research and Manufacturers of America. "The longer the delay for CMS' long-awaited guidance, the more burdensome such compliance may become."

CMS hasn't said when it will issue the sunshine rules. "We agree with the important goals of transparency and are working to determine the best way to implement this provision effectively," a spokesperson told *American Medical News*. "Our goal is to move forward implementing this provision in a way that fully meets the intent of the law but does not impose an unnecessary regulatory burden."

President Obama signed a January executive order directing all federal agencies to slash regulatory red tape.

Industry payments falling

Even with the Sunshine Act delays, disclosure already appears to be having an effect on ties between physicians and industry.

A dozen drug companies are publicly reporting payments to doctors and other health professionals, often in compliance with Justice Dept. settlement agreements. Six companies have disclosed payments for speaking services in 2010 and 2011. The companies' average quarterly payments fell by 12%, or \$6.5 million total, according to data compiled by the nonprofit news outlet ProPublica in September.

Five device makers cut the number of orthopedic surgeons they paid between 2007 and 2008, when disclosure was required under a Justice Dept. settlement. Nearly 1,000 orthopedic surgeons were paid in 2007, compared with 526 in 2008, said an Oct. 24 *Archives of Internal Medicine* study.

Industry support for continuing medical education fell for the third straight year in 2010 to \$830 million, down 31% from \$1.2 billion in 2007.

ADDITIONAL INFORMATION:

WEBLINK

Sens. Charles Grassley and Herb Kohl Oct. 3 letter to CMS Administrator Donald Berwick, MD (www.grassley.senate.gov/about/upload/Grassley-Kohl-CMS.pdf)

Dr. Berwick's Oct. 28 response to Sen. Kohl (www.grassley.senate.gov/about/upload/Sunshine-Act-CMS-Response.pdf)

Industry and consumer groups' Oct. 25 letter to HHS Secretary Kathleen Sebelius (freepdfhosting.com/608e6493b1.pdf)

President Obama's executive order on reducing regulatory burdens (www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf)

ProPublica's "Dollars for Docs" database (projects.propublica.org/docdollars)

"Financial Payments by Orthopedic Device Makers to Orthopedic Surgeons," *Archives of Internal Medicine*, Oct. 24 (archinte.ama-assn.org/cgi/content/short/171/19/1759)

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