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PROFESSION

Health reform mandates disclosure of industry gifts

Payments or gifts to physicians of \$10 or more will be disclosed under new legislation. Experts disagree on the impact of the law's "sunshine" provisions.

By KEVIN B. O'REILLY, *amednews* staff. Posted April 5, 2010.

Physicians who receive nearly any kind of payment of \$10 or more from a drugmaker, device maker or other medical industry firm will see the information listed on a publicly searchable Web site starting Sept. 30, 2013.

The "sunshine" provisions of the health system overhaul President Obama signed into law in March also apply to teaching hospitals and are aimed at curbing industry's influence on medical decision-making.

"We will now have an unprecedented level of transparency on physician-industry financial relationships," said Allan Coukell, a former pharmacist who directs the Pew Prescription Project, a group that advocates greater regulation of drug marketing and manufacturing. "It's important because there's so much concern that these financial relationships are used to promote products and really change the care that patients receive."

Any manufacturer of drugs, devices, biologics or supplies covered under Medicare, Medicaid or the State Children's Health Insurance Program must report food, entertainment, gifts, consulting fees, honoraria and more that they give to physicians and teaching hospitals. Doctors will get a chance to review the information before it goes public.

Pay or gifts of less than \$10 need not be disclosed publicly unless the aggregate annual value exceeds \$100. Research funding also must be reported but does not have to be disclosed publicly for four years or until the product under development is approved, whichever comes first.

Industry firms must report the information annually to the Dept. of Health and Human Services, which then will post it on a publicly available Web site searchable by physician name. The federal law will preempt state provisions asking for the same information, but states still can require other types of data.

Will the new disclosure requirements make doctors and teaching hospitals think twice about accepting payments or gifts from drugmakers? More important, will the provisions change patient care for the better?

Some firms have sought to get ahead of the law. Merck & Co., GlaxoSmithKline, Eli Lilly and Co., and Cephalon already disclose payments to physicians on their company Web sites. A few medical centers such as the Cleveland Clinic in Ohio and Stanford University Medical Center in California also divulge their physicians' financial relationships with industry.

Altered landscape?

Daniel J. Carlat, MD, assistant clinical professor of psychiatry at the Tufts University School of Medicine in Massachusetts, said the disclosure trend will pick up steam as the law's provisions come closer to taking effect in 2013, and physicians will be discouraged from accepting payment from drugmakers to give lectures not certified by the Accreditation Council for Continuing Medical Education.

"The entire landscape of industry-physician relationships will change dramatically," said Dr. Carlat, a critic of drugmaker payments to physicians. "Many more universities will forbid faculty from giving promotional talks, and more drug companies will start voluntarily reporting payments before the law takes effect."

Thomas P. Stossel, MD, who helped found the Assn. of Clinical Researchers and Educators, a group that defends physician-industry relationships, said the disclosure could scare away some physicians from collaboration with drugmakers.

"The media will use the information to embarrass the people who are most successful at getting speaking gigs," said Dr. Stossel, who directs the division of translational medicine at Boston's Brigham and Women's Hospital. But, he said, patients are unlikely to benefit from greater disclosure.

"Despite 20 years unopposed of all this [anti-drugmaker] propaganda, surveys show patients don't care," Dr. Stossel said. "It's a bad solution looking for a problem. We will have spent a lot of money and effort and distracted time from more worthwhile pursuits for something that's not making any difference for patients."

In a statement, Pharmaceutical Research and Manufacturers of America Senior Vice President Ken Johnson lauded Congress for setting a national standard that preempts varying state disclosure laws.

The law is consistent with the American Medical Association's general principles on transparency, but the Association is working to ensure that physicians have the opportunity to review and correct information before it is reported, so that it does not mislead patients. The AMA also will monitor the law's effect on industry support of continuing medical education and medical research, and push for complete federal preemption of state laws.

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ADDITIONAL INFORMATION:

What needs to be disclosed

The Patient Protection and Affordable Care Act requires drugmakers, device manufacturers and other medical suppliers to report annually any "payment or transfer of value" to individual physicians and teaching hospitals. Payments or gifts worth less than \$10 need not be reported, unless they total \$100 or more during a calendar year.

Subject to disclosure

- Charitable contributions made on a physician's behalf
- Compensation for nonconsulting services
- Consulting fees
- Continuing medical education speaker or faculty fees
- Current or prospective ownership or investment interests
- Education
- Entertainment
- Food
- Gifts
- Grants
- Honoraria
- Research
- Royalties or licenses
- Travel

Exempt from disclosure

- Anything physicians receive in their roles as patients
- Devices loaned for fewer than 90 days for physicians to evaluate
- Discounts
- Dividends or profits from stock ownership in publicly traded industry firms
- Educational materials that directly benefit patients or are intended for patient use
- In-kind items used for providing charity care
- Items or services provided under contractual warranty
- Product samples intended for patient use

Source: "Legislative text of Physician Payment and other transparency provisions included in HR 3590: Patient Protection and Affordable Care Act of 2009," Pew Prescription Project, March 21 (www.prescriptionproject.org/tools/sunshine_docs/files/Sunshine_Leg_Language.pdf)

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