Fact Sheet

Physician Payments Sunshine Act

The Physician Payments Sunshine Act (Sunshine Act)—a provision of the Patient Protection and Affordable Care Act—aims to govern certain physician-industry interactions. According to the Centers for Medicare & Medicaid Services (CMS), the goal is to increase transparency in the health care system by increasing public awareness of financial relationships between drug and device manufacturers and healthcare providers.

Once the proposed rule goes into effect, industry will be required to publicly report any gift or payment greater than $10 made to physicians and teaching hospitals. While originally scheduled to go into effect on January 1, 2012, CMS delayed implementation of the Sunshine Act and is accepting comments on the proposed rule until February 17, 2012.

Although a specific date for implementation is uncertain, the new rules will eventually impact all physicians, regardless of specialty.

Are gifts and payments limited?

The law requires public disclosure, but does not limit financial relationships.

Who must report? How often?

All U.S. manufacturers (and other entities under common ownership) of drug, device, biologics, and medical supplies covered under Medicare, Medicaid, or SCHIP must report payments on an annual basis to the department of Health and Human Services, which will post the information on a public website.

The Secretary of Health and Human Services is further required to submit annual summary reports to Congress, as well as annual reports to each state.

What sort of payments count?

The health care reform law requires disclosure of payments whether cash or inkind transfers to all covered recipients including: compensation; food, entertainment or gifts; travel; consulting fees; honoraria; research funding or grants; education or conference funding; stocks or stock options; ownership or investment interest; royalties or licenses; charitable contributions; and any other transfer of value as described by the secretary.

Who is considered a 'Covered Recipient"?

Covered recipients include physicians and teaching hospitals.

What information will be reported?

Reporting companies are required to report the receiving physician's name, address, and national provider identifier; and the value, date, form and nature of the payment using standardized descriptions for the payment types listed above. Where a payment is related to marketing, education, or research specific to a covered drug, device, biological or medical supply, the name of that product must be reported. All of this information, except for national provider identifiers, will be available to the public.

Are there types of gifts or payments that are exempt?

The law exempts educational material provided for the benefit of patients, rebates and discounts, loans of covered devices, items provided under warranty, dividend or investment interests in a publicly-traded security or mutual fund, and payments made to a physician who is a patient, or an employee of the reporting company. In addition, the law exempts payments less than $10 until the aggregate annual total per company, per covered recipient, reaches $100, at which point all payments (retroactively) must be disclosed. Prescription drug and device samples are also exempted from the Sunshine provision, but a separate section of the health reform law requires reporting of information on samples to HHS.

Delayed reporting of payments for research or product development

Payments related to clinical trials or product development agreements for new products are allowed a publication delay of four years or until product approval, whichever comes first. Product development agreements for "new applications" of existing technologies are also allowed this publication delay. Product development agreements are not defined.

What else will be disclosed?

The law requires manufacturers and group purchasing organizations to disclose physician ownership or investment interest.

Would the bills affect existing state laws?

States are prohibited from collecting the same information required to be reported under this section. States may continue to collect other types of data not captured or excluded from reporting (with the exception of de minimis and threshold limits), as well as data for public health purposes or legal proceedings.

Implementation

CMS is accepting comments on the proposed rule until February 17, 2012. Final regulations will be issued within 90-180 days thereafter, at which time manufacturers must record all transfers of value. This information is to be reported to HHS by March 31, 2013, and annually thereafter. Once the data has been submitted, CMS will provide a 45-day review period for physicians to contest any data with which they do not agree. HHS will then post this information on a publicly available, searchable on-line database as of September 30, 2013, and on June 30 of each year beginning thereafter.

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