



Physician Payments Sunshine provisions in Health Care Reform

The Physician Payments Sunshine provisions in health care reform legislation require drug and medical device manufacturers to publicly report gifts and payments made to physicians and teaching hospitals.

The Physician Payment Sunshine provisions were included in the Patient Protection and Affordable Care Act of 2009 (H.R. 3590, section 6002) which was signed into law on March 23, 2010. The Centers for Medicaid and Medicare (CMS) administers the sunshine provisions through the CMS Open Payments program.

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 in-kind 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.

How specific are disclosures?

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.

What are the penalties for non-compliance?

For each failure to report, fines of up to \$10,000 will be applied, not to exceed \$150,000 annually. For each knowing failure to report, fines of up to \$100,000 will be applied, not to exceed \$1,000,000 annually.

Implementation *(dates below reflect delays in implementation)*

Starting on August 1, 2013, manufacturers must record all transfers of value. This information is to be reported to CMS by March 31, 2014, and annually thereafter. CMS will then post this information on a publicly available, searchable on-line database as of September 30, 2014 and on June 30 each year thereafter.

Originally developed in collaboration with Pew Prescription Project.