

CMS Releases Final Rule to Implement Physician Payment Sunshine Act

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On February 1, 2013, the Centers for Medicare & Medicaid Services ("CMS") released the long-awaited final version of the Physician Payment Sunshine Act (the "Sunshine Act"). The Sunshine Act will make information publicly available concerning payments or other transfers of value from applicable manufacturers to physicians. The Sunshine Act will also make information publicly available concerning physician ownership or investment interests in applicable manufacturers and group purchasing organizations ("GPOs"), including physician-owned distributors ("PODs").

The final rule implements Section 6002 of the Affordable Care Act, and is designed to increase transparency in the health care industry. The reporting requirements contained within the Sunshine Act will directly impact many physicians. As a result, it is important for physicians to analyze the final rule and understand the implications on their business and business relationships. The final rule was officially released in the Federal Register on February 8, 2013, and is available [here](#).

The Sunshine Act contains two separate reporting requirements: (1) payment disclosures; and (2) ownership and investment interest disclosures.

Payment Disclosures

"Applicable manufacturers" of drugs, devices, or medical supplies must annually report all payments or other transfers of value provided to physicians during the preceding calendar year.

Applicable manufacturers are defined as entities that operate in the United States and fall within one of the following categories:

- (i) an entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological or medical supply, but not if such covered product is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers that do not hold title to any covered product;
- (ii) an entity under common ownership with an entity in paragraph (i) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, or conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Covered drug, device, biological, or medical supply means any drug, device, biological or medical supply for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program ("CHIP").

Reporting Requirements The report of an applicable manufacturer must contain all of the following information for each payment or other transfer of value:

1. Name of covered recipient;
2. Address of covered recipient;
3. Identifiers for physician covered recipients (specialty, NPI, state license number);
4. Amount of payment or other transfer of value;
5. Date of payment or transfer of value;
6. Form of payment or transfer of value;
7. Nature of payment or transfer of value;
8. Related covered drug, device, biological or covered supply;
9. Whether the payment is eligible for delayed publication;
10. Whether the payment was made to someone else at the request of the physician;
11. Whether the payment was made to a physician who holds an ownership or investment interest in the applicable manufacturer; and
12. Any additional information to provide context for payment or transfer of value.

Ownership and Investment Interest Disclosures

The second reporting requirement requires “applicable manufacturers” and “applicable GPOs” to disclose any ownership or investment interests in such entities held by physicians or their immediate family members.

Applicable GPOs are defined as entities that: (a) operate in the United States; and (b) purchase, arrange for, or negotiate the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.

Notably, the comments to the final rule make clear that it is CMS’ intent that this definition include more than just traditional GPOs, but also entities such as PODs that purchase covered drugs, devices, biologicals and medical supplies for resale or distribution to others, including groups of individuals or entities.

Reporting Requirements. Reports on physician ownership and investment interests must include the following identifying information:

1. Name of physician (and whether ownership or investment interest is held by family member);
2. Primary business address of the physician;
3. Identifiers for physician (specialty, NPI, state license number);
4. Dollar amount invested by each physician or immediate family member;

5. Value and terms of each ownership or investment interest; and
6. Direct and indirect payments or other transfers of value provided to such physician (or their immediate family member)

Implementation Timeline

Applicable manufacturers and GPOs are required to begin tracking both types of required disclosures on August 1, 2013. The collected information must be reported to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.

The Sunshine Act requires CMS to publish on a publicly available website the data reported by applicable manufacturers and GPOs by September 30, 2014, and by June 30 of each subsequent year.

Prior to publication, CMS is required to provide a period of at least 45 days for applicable manufacturers, applicable GPOs, and physicians to review, dispute, and correct their reported information before posting on the publicly available website.

Penalties for Non-Compliance

Failure to comply with the requirements of the Sunshine Act can result in significant civil monetary penalties (“CMPs”). Specifically, the failure to timely, accurately, and completely report the required information can result in CMPs of up to \$150,000 annually. The penalties can be increased to \$1,000,000 if it is determined that such failure was done knowingly.

Additional Information

For additional information on the Sunshine Act, please contact [Frank Carsonie](#), [Dan O’Brien](#), or any member of Benesch’s Health Care Department.

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