

# Advisory

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## *New Transparency Requirements for Drug, Device, Biological and Medical Supply Manufacturers: Begin Preparing Now*

Pharmaceutical, medical device, biological and medical supply companies should begin preparing now to address new U.S. reporting requirements concerning payments and transfers of value to physicians and teaching hospitals and ownership and investment interests held by physicians or their immediate family members. The new reporting requirements are courtesy of the Patient Protection and Affordable Care Act of 2009 ("PPACA"), the federal health care reform legislation. They are among many requirements in the legislation designed to enhance transparency and accountability in the health care industry. While sponsors of certain FDA-regulated clinical trials have long been required to report to the FDA certain financial arrangements with clinical investigators, PPACA's new reporting requirements are much broader in scope and application than existing FDA reporting requirements. PPACA's reporting requirements apply to companies operating in the U.S. (or in a territory, possession, or commonwealth of the U.S.) that manufacture drugs, devices, biologicals, or medical supplies for which payment is available under Medicare or Medicaid ("Manufacturers").<sup>[1]</sup> However, it is not clear what it means to be "operating in the U.S." for purposes of the reporting requirements.

Although Manufacturers do not need to submit reports until early 2013, the 2013 reports must disclose to the federal Department of Health and Human Services ("HHS") all payments, transfers of value, and ownership and investment interests held in 2012. HHS will post on a website the information it receives.<sup>[2]</sup> Accordingly, over the next year, Manufacturers should

review their conflict of interest and payment policies and practices concerning physicians and teaching hospitals to ensure that they will withstand scrutiny by regulators and the general public. If any areas of concern are noted, Manufacturers should implement remedial steps to address them as soon as possible and, in all cases, before 2012. Moreover, Manufacturers should ensure that they have in place by the end of 2011 a tracking mechanism that can capture all of the information that must be reported.

The first reports are due to HHS by March 31, 2013. Thereafter, reports are due by the 90th day of each calendar year for payments and transfers made, and ownership and investment interests held, in the preceding year. (For example, payments made in 2013 must be reported no later than the 90th calendar day of 2014.) Manufacturers must submit the reports electronically in accordance with procedures that HHS is required to establish by October 1, 2011.

### **DIRECT PAYMENTS AND OTHER TRANSFERS OF VALUE.**

Manufacturers must report direct payments or other transfers of value made to physicians or teaching hospitals in the preceding calendar year. The annual report must include:

- the name and business address of the recipient, and if the recipient is a physician, his or her specialty and National Provider Identifier;

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- the amount of the payment or other transfer of value, and the date on which it was made;
  - a description of the form and nature of the payment or other transfer of value (for example, whether the payment (i) was in the form of cash, in-kind items or services, or stock options, and (ii) was in the nature of a consulting fee, grant, gift, food, travel, entertainment, charitable contribution, or royalty or license);
  - if the payment or other transfer of value is related to marketing, education or research specific to a drug, device, biological, or medical supply, the name of such drug, device, biological or medical supply; and
  - any other information HHS determines appropriate.
- educational materials that directly benefit patients or are intended for patient use;
  - discounts and rebates;
  - in-kind items used for the provision of charity care; and
  - a payment made indirectly through a third party where the identity of the physician or hospital recipient is unknown to the Manufacturer.

**OWNERSHIP OR INVESTMENT INTERESTS.**

Manufacturers additionally are required to report annually to HHS any non-public ownership or investment interest in the Manufacturer held by a physician (or an immediate family member of a physician) during the preceding calendar year. The report must include:

- the dollar amount invested by the physician (or immediate family member);
- the value and terms of the ownership or investment interest;
- information regarding any payment or other transfer of value provided to the physician (or to a third party at the physician's request); and
- any other information HHS determines appropriate.

Where the Manufacturer provides the payment or other transfer of value to a third party at the request of the physician or hospital, it must report the payment or transfer in the name of the requesting physician or hospital.

**EXCEPTIONS.**

Some payments are excluded from the reporting requirements. Among other exceptions, Manufacturers are not required to report:

- payments or other transfers, the value of which is less than \$10 in a calendar year, unless the aggregate amount of such payments or transfers in a calendar year exceeds \$100. (These dollar amounts will be increased for inflation beginning in 2012);
- product samples that are not intended to be sold and are intended for patient use;<sup>[3]</sup>

PPACA does not require manufacturers to report ownership and investment interests in publicly traded securities and mutual funds.

**PENALTIES.**

A Manufacturer that fails to report any of the required information within the required timeframe will be subject to a civil money penalty ("CMP") of between \$1,000 and \$10,000 for each payment or other transfer

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of value or ownership or investment interest not reported. However, the total amount of CMPs that may be imposed with respect to each annual report may not exceed \$150,000.

Increased penalties apply to “knowing” violations. A Manufacturer that knowingly fails to report any of the required information within the required timeframe will be subject to a CMP of between \$10,000 and \$100,000 for each payment or other transfer of value or ownership or investment interest knowingly not reported. However, the total amount of CMPs that may be imposed for knowing violations with respect to each annual report may not exceed \$1 million.

**PUBLIC DISCLOSURE.**

Not later than September 30, 2013, and on June 30 of each calendar year thereafter, HHS must post information reported by Manufacturers for the preceding year in a “clear and understandable” format on a searchable website. The website must disclose (among other things) any enforcement actions taken during the preceding year. Manufacturers and affected physicians, hospitals and group purchasing organizations will have at least 45 days prior to online posting to review and submit corrections to the information they reported.

PPACA provides for delayed public disclosure (but not delayed reporting to HHS) of information concerning payments or other transfers of value made:

- pursuant to a research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical

technology, or the development of a new drug, device, biological or medical supply, or

- in connection with a clinical investigation regarding a new drug, device, biological, or medical supply.

In such cases, the information will not be made available to the public until four calendar years after the date the payment/transfer was made, or the FDA approves the drug, device, biological, or medical supply, whichever is earlier.

**REPORTING REQUIREMENTS UNDER STATE LAW.**

Several states have enacted laws that require manufacturers to report the same or similar information about relationships with physicians and hospitals as that required under PPACA. Effective January 1, 2012, PPACA preempts state reporting laws to the extent they are duplicative of the new federal requirements. However, PPACA does not preempt state laws that require reporting of information not covered by PPACA. For example, state laws requiring public disclosure of payments made to individuals or entities other than physicians and hospitals, and payments to physicians that fall within a PPACA exception, will not be preempted. State laws that prohibit or restrict certain payments to health care professionals or entities will also continue to apply. Moreover, Manufacturers, physicians and hospitals involved in clinical trials must be cognizant of applicable institutional and IRB policies and requirements governing conflicts of interest, and Manufacturers should also consider industry codes of conduct such as the PhRMA and AdvaMed codes on interactions with health care professionals.

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**BEGIN PREPARING NOW.**

In preparation for the March, 2013 reporting deadline, Manufacturers should review their existing physician and teaching hospital payment relationships and policies pertaining to remuneration in general to physicians, hospitals and other individuals or entities that may purchase or prescribe the Manufacturer's products. Manufacturers should also review their policies and practices for addressing ownership and investment interests and managing conflicts of interest with physicians, hospitals and

others. Although Manufacturers should ensure the propriety of these relationships in any event, it is even more imperative to do so now since federally mandated public disclosure is right around the corner. Manufacturers should also ensure that by the end of 2011 they have in place procedures for tracking relevant information about physician and teaching hospital relationships. Finally, Manufacturers must be aware of and responsive to existing reporting requirements under applicable state law.

[1] The requirement to report physician ownership and investment interests also applies to group purchasing organizations operating in the U.S. (or in a territory, possession, or commonwealth of the U.S.) that purchase, arrange for, or negotiate the purchase of a drug, device, biological or medical supply for which payment is available under Medicare or Medicaid.

[2] In recent years, the HHS Office of Inspector General has entered into Corporate Integrity Agreements with a number of pharmaceutical manufacturers requiring them (among other things) to post on a public website information concerning payments to physicians and related entities. Now under PPACA, all Manufacturers are subject to such a requirement.

[3] Although product samples intended for patient use are excluded from Manufacturers' reporting requirements, a separate section of PPACA requires prescription drug manufacturers and distributors, by April 1 of each year beginning in 2012, to report to HHS information about the identity and quantity of drug samples requested by and distributed to practitioners during the preceding calendar year.

*This publication is a summary of legal principles. Nothing in this article constitutes legal advice, which can only be obtained as a result of a personal consultation with an attorney.*

*The information published here is believed accurate at the time of publication, but is subject to change and does not purport to be a complete statement of all relevant issues.*