

## **Physicians Beware: Manufacturers of Drug, Device Biological or Medical Supplies Must Report Payments to Physicians**

By Adrienne Dresevic, Esq. and Neda Mirafzali, Esq.

Section 6002 of the Patient Protection and Affordable Care Act (“PPACA”) established new Federal reporting obligations for applicable manufacturers of covered drug, device, biological or medical supplies (“Applicable Manufacturers”). One such provision requires Applicable Manufacturers to electronically report to the Secretary payments or other transfers of value (“Payment”) to physicians (and teaching hospitals) beginning March 31, 2013 to be made public on a website. On December 19, 2011, the Centers for Medicare and Medicaid Services (“CMS”) issued its proposed rule (“Proposed Rule”).

### ***Who Must Report***

Applicable Manufacturers must report Payments to physicians made in the preceding calendar year. CMS proposes *Applicable Manufacturer* be defined as an entity that is (1) engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the U.S.; or (2) under common ownership with an entity in (1), which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution in the U.S.

### ***What Must Be Reported***

CMS proposes expanding the statutory reporting requirement to include reporting Payments made by an Applicable Manufacturer *or third party (on behalf of an Applicable Manufacturer)* to another individual *at the request of (or designated on behalf of)* a physician. The Proposed Rule delineates the following information to be reported:

- The physician’s name (even if the Payment was provided to another individual or entity at the request of, or designated on behalf of, the physician);
- The physician’s address and NPI;
- The amount of each Payment;
- The date on which each Payment was provided to the physician;
- The *form* of each Payment (*e.g.*, cash or cash equivalent, in-kind items or services, stock, stock options, etc.);
- The *nature* of each Payment (*e.g.*, consulting fees, compensation for services other than consulting, honoraria, gift, entertainment, food and beverage, travel and lodging, etc.);
- For Payments related to marketing, education, or research specific to a covered drug, device, biological or medical supply, the name under which that covered drug, device, biological or medical supply is marketed;
- Whether the Payment is subject to delayed publication (*e.g.*, there is a product research and development agreement, clinical investigations, etc.);

- For Payments made to an entity or individual at the request of (or designated on behalf of) a physician, the name of the other individual or entity that receives the Payment; and
- Whether the Payment was provided to a physician who holds an ownership or investment interest in the Applicable Manufacturer.

All payments or transfers of value need not be reported. CMS proposes thirteen (13) exclusions from reporting:

1. Payments made indirectly to a physician through a third party in cases where the Applicable Manufacturer is unaware of the identity of the physician;
2. For CY 2012, Payments of less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds \$100 in a calendar year (adjusted for inflation) (e.g., If a Manufacturer purchases a physician coffee for \$3, three times in a year, the Manufacturer is not required to report it because the cost of each coffee is less than \$10 and the aggregate cost is less than \$100. However, in the same example, if the physician also had a \$200 speaker fee, the speaker's fee *and* the coffee must be reported.);
3. Product samples not intended to be sold and are intended for patient use;
4. Educational materials directly benefiting patients or intended for patient use;
5. The loan of a covered device for not more than 90-days, to permit evaluation of the covered device;
6. Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement;
7. Payments to a physician when the physician is a patient and not acting in the professional capacity of a physician;
8. Discounts, including rebates;
9. In-kind items used for the provision of charity care;
10. A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund;
11. For an Applicable Manufacturer who offers a self-insured plan, payments for the provision of healthcare to employees under the plan;
12. For a physician licensed as a non-medical professional, a Payment to the physician if the Payment is solely for the non-medical professional services of the licensed non-medical professional; and
13. A transfer of anything of value to the physician, if it is payment solely for the services of the physician with respect to a civil or criminal action or an administrative proceeding.

### ***How to Report***

Applicable Manufacturers must electronically report to CMS Payments to physicians by March 31, 2013 and the 90<sup>th</sup> day of each subsequent year. Applicable Manufacturers making no reportable

Payments in the previous year would not be required to submit a report. For those Applicable Manufacturers submitting a report, CMS proposes requiring a certification by the CEO, CFO or chief compliance officer of the Applicable Manufacturer that the information submitted is true, correct and complete to the best of his/her knowledge and belief. If an Applicable Manufacturer discovers an error or omission in its report, it must submit corrected information to CMS immediately upon discovery of the error or attestation. CMS will allow for a 45-day grace period in which Applicable Manufacturers will have the opportunity to review and submit corrections prior to CMS making the information public. Failure to report could result in civil monetary penalties of up to \$150,000, and up to \$1,000,000 for *knowingly* failing to report.

Even though physicians are not obligated to directly disclose and report under the new rule, they should begin to familiarize themselves with this new reporting requirement (and the impending final rule). As part of overall compliance, it will be important for physicians to maintain their own records of any Payments that they receive (directly or indirectly) from manufacturers. Because the information will be made public, physicians receiving such Payments should also request that the manufacturer provide them with the information that will be reported to ensure that any information disclosed under the rule is consistent with their own records.