

## **The Physician Payment Sunshine Act: What Do the New Reporting Requirements Mean for Physicians?**

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Section 6002 of the Patient Protection and Affordable Care Act (“PPACA”) requires applicable manufacturers to report certain payments or transfers of value made to covered recipients. In addition, applicable manufacturers or group purchasing organizations must disclose any investment or ownership interests held by a physician (or his or her immediate family member) in the manufacturer or group purchasing organization. This information will then be made available to the public through a searchable Internet website.

This provision, known commonly as the “physician payment sunshine” provision of PPACA, reflects a growing trend towards increased scrutiny of relationships between physicians and manufacturers and towards encouraging transparency in such relationships. Providers should remain cognizant of these requirements, and should take sufficient steps to ensure that their relationships with manufacturers are appropriate.

### **Reporting Requirements**

Section 6002 generally requires drug, device, biological or medical supply manufacturers to record and report payments made to physicians or teaching hospitals (“covered recipients”) or to any entity or individual on the request of or designated on behalf of a covered recipient. Each report must contain the name, address, and, if applicable, NPI of the covered recipient; the amount of the payment; the date(s) on which any payment was made; a description of the form of payment (e.g. cash, in-kind items or services, etc.); a description of the nature of the payment (e.g. consulting fees, honoraria, gift, etc.); and, if the payment or transfer is related to marketing, education or research specific to a covered drug, device, biological or medical supply, the name of such product.

In addition, section 6002 requires drug, device, biological or medical supply manufacturers and any group purchasing organization that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological or medical supply to record and report any ownership or investment interests held in the entity by a physician or his or her immediate family member. Each report must contain the dollar amount invested by each physician holding such an interest; the value and terms of each such interest; and any payment or other transfer of value provided to a physician holding such an interest.

Although the scope of these reporting requirements is very broad, there are several enumerated exceptions. Such exceptions include, but are not limited to, payments or transfers of less than \$10 in value, unless the aggregate amount transferred to the particular covered recipient during the calendar year exceeds \$100 in value; product samples intended for patient use and not intended to be sold; educational materials that directly benefit patients or are intended for patient use; the loan of a covered device for a short-term trial period (not to exceed 90 days); discounts (including rebates); and dividends or other profit distributions from publicly traded securities or mutual funds.

These requirements are scheduled to become effective on January 1, 2012, and manufacturers must submit the first required reports to the Secretary of the Department of Health and Human Services by March 31, 2013. Annual reports must be submitted by the ninetieth day of each calendar year thereafter. Failure to submit required reports will subject the manufacturer to civil monetary penalties, with enhanced penalties for knowing failures to report.

### **Relevance to Physicians**

Although the physician payment sunshine provision of PPACA only imposes reporting requirements on applicable manufacturers or group purchasing organizations, these requirements are nonetheless relevant for individual physicians as well. As noted, these requirements reflect a growing trend towards increased transparency into and scrutiny towards relationships between physicians and manufacturers.

For example, the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and Advanced Medical Technology Association (“AdvaMed”) have both published guidelines cautioning pharmaceutical and medical device manufacturers against entering into certain relationships or engaging in certain behaviors that may result in inappropriate influence over a physician’s independent decision making.

Likewise, the Office of Inspector General (“OIG”) recently published the Roadmap for New Physicians, which is designed to educate physicians as to how to safeguard against fraud and abuse. This Roadmap specifically discusses physician relationships with vendors, and cautions physicians against relationships that may interfere with their professional judgment or may raise fraud and abuse concerns.

Although section 6002 of PPACA does not explicitly prohibit payments or transfers of value to physicians or teaching hospitals or physician ownership or investment in manufacturing companies, it does require a manufacturer to report such payments or investment/ownership interests. Because this information will ultimately be made available to the public, any such payments and relationships will inherently be under far more scrutiny than they have ever been before. With the increased attention to combating fraud and abuse nationwide, it is likely that such payments and relationships will only garner more attention in coming years.

It is therefore important for physicians to act with these guidelines in mind and to ensure that all relationships with manufacturers and vendors be structured appropriately. Physicians should enact comprehensive compliance programs, and should ensure that such programs contain specific policies regarding interactions with vendors, including acceptance of gifts. In addition, physicians who engage in consulting arrangements should have any contracts with vendors reviewed by an attorney. Failure to ensure that relationships with manufacturers are appropriate may not only inappropriately impact a physician’s clinical judgment, but it may also ultimately lead to significant fraud and abuse risks for the physician as well.

## **Conclusion**

The physician payment sunshine provision of PPACA mandates that applicable manufacturers and group purchasing organizations record and report certain payments made to physicians or teaching hospitals or ownership or investment interests held by physicians. Although these requirements only apply to manufacturers, it is nevertheless important for physicians to keep this trend towards increased transparency in mind as well and to ensure that relationships with vendors are structured appropriately.

For further information, or for assistance in developing or evaluating a compliance program or in reviewing consulting agreements, please contact Laura C. Range, Esq. at 248-544-0888.

Laura C. Range is an associate at Wachler & Associates, P.C., where she practices in all areas of health care law, with specific concentration in regulatory compliance, transactional and corporate matters, and Medicare and other third-party payor audit defense and appeals. Prior to joining the firm, Ms. Range worked in the compliance office of a large hospital in Texas, where she assisted in evaluating and developing compliance policies for the institution. Ms. Range is a member of AHLA and the State Bar of Michigan Health Law Section. Contact her at (248) 544-0888 or [lrangle@wachler.com](mailto:lrangle@wachler.com).