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"I Can See Clearly Now, the Rain is Gone": Preparing for Implementation of the "Sunshine" Provisions in Federal Health Care Reform

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With 900-plus pages in the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, Health Care Reform), it is hard to keep up with all of the provisions that will affect, but not directly regulate, physicians. This article will summarize upcoming mandatory disclosures by pharmaceutical and device manufacturers regarding their relationships with physicians.

Physician Payment Sunshine Act – 42 U.S.C. § 1320a-7h(a)
Beginning Jan. 1, 2012, manufacturers of drugs, devices, biological products, or medical supplies must track all payments or other transfers of value to physicians in preparation for filing the first annual report of such payments to the U.S. Department of Health and Human Services (DHHS) on March 31, 2013. 42 U.S.C. § 1320a-7h(a)(1)(A). Annual reports will include all payments or other transfers of value during the preceding calendar year, and reports must be filed by the 90th day of each calendar year thereafter. Id. By Sept. 30, 2013, DHHS shall establish a searchable website that allows the public to review the information reported by manufacturers, with certain exceptions, and each June 30 thereafter, DHHS shall update the information based on the preceding calendar year's reports. Id. § 1320a-7h(c)(1)(C). There will be a 45-day period prior to DHHS making the information publicly available for manufacturers and physicians to review and submit corrections to the information. Id. To help physicians understand what will be reported about them, here is a breakdown of the significant "transparency" provisions in Health Care Reform.

Who Must Report – "Applicable Manufacturers"
Entities operating in the United States (or in a territory, possession, or commonwealth of the United States) who are engaged in the production, preparation, propagation, compounding, or conversion of a drug, biological product, device, or medical supply (or entities who are under common ownership with, and provide assistance or support to, a United States-based entity engaged in such activities) for which payment is available under Medicare, Medicaid, or a Children's Health Insurance Program must submit annual reports to DHHS. Id. § 1320a-7h(e)(2), (5), (9).

The federal law contains preemption provisions related to state sunshine laws, and manufacturers will continue to be required to make disclosures of payments according to state laws that are not captured in the federal report. Id. § 1320a-7h(d)(3). North Carolina does not have a state sunshine law, and therefore, this article will not discuss the preemption provisions of the federal law in depth.

What Must Be Reported – "Payments or other transfers of value to a physician"
A "physician" means a medical doctor, doctor of osteopathy, dentist, podiatrist, optometrist, or chiropractor who is legally authorized to provide services within the scope of his or her license. Id. § 1320-7h(e)(6)(A)(i), (11). There is an exclusion from the definition for physicians who are employees of the reporting manufacturer. Id. § 1320-7h(e)(6)(B). Note that the definition does not include nurse practitioners, physician assistants, psychologists, or other Ph.D.s. The definition of a "covered recipient"

also includes teaching hospitals. Id. § 1320-7h(e)(6)(A)(ii).

A "payment or other transfer of value" means a transfer of anything of value. Id. § 1320-7h(e)(10). There is an exception for a transfer of anything of value that is made indirectly to a physician through a third party in connection with an activity or service where the manufacturer is unaware of the physician's identity. The exception would be applicable when a manufacturer pays a market research company to conduct research on its behalf and the market research company (with no input from the manufacturer) selects and pays a physician for his or her services and the manufacturer does not know the physician's identity based on results of the research. Id. § 1320-7h(e)(10)(A). Examples in the statute of payments or other transfers of value, which is not an exhaustive list, include cash or a cash equivalent, in-kind items or services, stock, stock options, dividends, profits, and other ownership interests or returns on investment. Id. § 1320-7h(a)(1)(A)(v). DHHS will have the ability by regulation to expand the examples of a transfer of anything of value.

What Is Not Reported

Payments or other transfers of value that are excluded from reporting are:

• Transfers of anything with a value of less than $10, unless the aggregate value of all transfers of value to the physician during a calendar year exceed $100 (e.g., meals, pens, pads);
• Product samples that are not intended to be sold;
• Educational materials that directly benefit patients or are intended for patient use;
• Loans of a covered device for not longer than 90 days;
• Items or services under a contractual warranty (including replacement) if the warranty is included in the agreement for the covered device;
• Transfers of value to a physician when the physician is a patient and not acting in a professional capacity;
• Discounts (including rebates);
• In-kind items used for the provision of charity care;
• Dividends or other profit distributions from publicly traded security or mutual fund;
• Payments to a physician for the provision of health care to employees covered under a manufacturer's self-funded plan;
• Payments solely for non-medical professional services; and
• Transfers of value to a physician solely for services with respect to a civil or criminal action or an administrative proceeding. Id. § 1320-7h(e)(10)(B).

What Will Be in the Report

The annual report must contain the following information:

• Name of physician;
• Physician's business address, specialty and National Provider Identifier (NPI) (however, the NPI will not be published on the website);
• Amount of each payment or other transfer of value to the physician;
• Each date on which a payment or other transfer of value was made to the physician;
• The form of such payment or other transfer of value (e.g., cash, stock, or in-kind service);
• A description of (or reason(s) for) the payment or other transfer of value to the physician (e.g., consulting, honoraria, gift, entertainment, food, travel, education, research, charitable contribution, royalty or license payment, current or prospective ownership or investment interest, speaker fees, grant, or any other category of payment as may be designated by DHHS through regulation); and
• If a payment to a physician is related to marketing, education, or research specific to a drug or device, the name of the drug or device. Id. § 1320-7h(a)(1)(A).

Furthermore, if the manufacturer provides a payment or other transfer of value to an entity or individual at the request of, or designated on behalf of, a physician, the manufacturer must report the payment under the name of the physician. Id.

Manufacturers will be permitted to mark certain payments or transfers of value to physicians that appear in their reports as a "trade secret" if the payments relate to a drug or device that is under development. Id. § 1320-7h(c)(1)(E). Publication of such payments will not occur for at least four years (although it could be earlier if the drug or device receives approval or clearance from the Food and Drug Administration (FDA)). DHHS will be responsible for honoring confidentiality and not publishing the "trade secret" payments, which has caused many manufacturers to anxiously await the implementing regulations to determine how DHHS will preserve their trade secret information.

Other Provisions of the Law

The federal law includes civil monetary penalties for each payment or other transfer of value that a manufacturer fails to report, and stiffer penalties for a knowing failure to report, subject to total annual caps. Id. § 1320a-7h(b)(1), (2).

The federal law also requires manufacturers (and medical device supply chain companies, including group purchasing organizations) to report certain details related to ownership or investment interests by physicians and their immediate family members in such manufacturers (other than publicly traded securities or mutual funds) and all transfers of value to such physician owners or investors. Id. § 1320-7h(a)(2).

Possible Results of the Law

As a result of the federal law, manufacturers may begin probing more thoroughly into a physician's background and qualifications before entering into a financial relationship with the physician because the manufacturer will be publicly "linked" to the physician (and any "bad press" regarding the physician). Manufacturers may also require more data supporting payments to physicians as "fair market value" so that when the information is made publicly available, payments that may result in scrutiny by state and federal prosecutors and governmental agencies can be justified. Finally, certain departments within a manufacturer, such as research and development or medical affairs, will now need to track all payments to physicians, which may result in more "red tape" related to the manufacturer's processes and data supporting the payments.

There is also much debate as to whether it will become more difficult for clinical research organizations (and manufacturers) to find physicians who are willing to be principal investigators for clinical trials due to their compensation being made publicly available.

Manufacturers will hopefully have better guidance as to what is reportable once regulations are issued, which is supposed to be no later than Oct. 1, 2011. But until then, manufacturers are likely establishing policies to begin tracking all payments or transfers of value on or after Jan. 1, 2012.

Prescription Drug Sample Transparency – 42 U.S.C. § 1320a-7i(a)

Beginning on April 1, 2012, all prescription drug samples provided to practitioners (not just physicians) during the preceding calendar year will be reported annually each April 1 to DHHS. The reporting requirements will apply to manufacturers and authorized distributors of record of applicable drugs, which means FDA approved-drugs that are paid for by Medicare, Medicaid, or a Children's Health Insurance Program. The name, address, and professional designation of the practitioner to whom the drug samples were distributed, as well as the identity and quantity of drug samples requested and the samples actually distributed to the requesting practitioner, must be reported.

It is not clear whether DHHS will publish regulations with additional information that may need to be reported by the manufacturers and distributors, the format for reporting, and whether DHHS will make such information available to the public (similar to the payments or other transfers of value by

manufacturers to physicians). Previously, manufacturers were only required to make drug sample information available upon request of the FDA.

Conclusion

The transparency provisions of Health Care Reform are intended to allow the public to see a manufacturer's financial relationships with a physician, which presumably will allow a patient to question whether a physician's clinical decision-making may be unduly influenced by the financial relationship. Some manufacturers have already "voluntarily" begun reporting payments to physicians, but the transparency requirements of Health Care Reform may capture more types of payments and more detailed information about such payments, which will require manufacturers to spend some time preparing for the reports. Once the information becomes available toward the end of 2013, it will be interesting to see how the public perceives the information and if there are significant changes in the financial relationships between physicians and manufacturers.

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