MD LawALERT

JANUARY 16, 2012

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NEW ORLEANS, LOUISIANA

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CMS REQUIRES PUBLIC DISCLOSURE OF PAYMENTS TO PHYSICIANS BY DRUG, DEVICE, BIOLOGICAL, AND MEDICAL SUPPLY MANUFACTUERERS

BY KATHLEEN L. DEBRUHL, ESQ. AND LINDSEY E. SURRATT, ESQ.

Beginning January 1, 2012, the sun will shine on transactions between physicians and manufacturers of drugs, devices, biologicals, and medical supplies. The Patient Protection and Affordable Care Act ("PPACA"), will require manufacturers to disclose information to the Centers for Medicare and Medicaid Services ("CMS") regarding payments or other valuable items or services provided to physicians and teaching hospitals. This information will be collected beginning in 2012 and will be provided to CMS in 2013. CMS will then publish this information on a public website. Certain manufacturers and group purchasing organizations ("GPOs") will also be required to disclose information about their physician owners or investors, and immediate family members of physicians who are owners or investors. Although these regulations are not yet final, this Proposed Rule provides physicians and manufacturers with an idea about what to expect when the disclosure requirements become final and effective.

WHO ARE COVERED RECIPIENTS?

PPACA requires disclosure of details about payments or other valuable items or services provided to "covered recipients." "Covered recipients" include both physicians and teaching hospitals. Physicians who are not considered an employee of an applicable manufacturer are also considered "covered recipients." The term "Physician" includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors. CMS plans to post a list each year of the teaching hospitals covered by the disclosure requirement.

WHAT TYPE OF INFORMATION MUST BE DISCLOSED?

If the "covered recipient" is a physician, the following information must be disclosed:

- The physician's full name, NPI number, business address, and specialty.
- The date of the payment or transfer of value.
- The drug, device, biological, or medical product associated with the payment or transfer of value, indicated by the item's market name.
- The form of the payment or transfer of value, e.g. cash or cash equivalent, in kind items or services, stock, stock options or other ownership interest, dividend, profit, or return on investment.
- The nature of the payment or transfer of value, e.g. consulting fees, honoraria, gifts, entertainment, food, travel (including specified destination(s)), education, charitable contribution, research, royalty or license, current or prospective ownership interest, grant, or compensation for serving as faculty or speaker for a medical education

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program.
- The market name of the covered drug, device, biological, or medical supply.

WHO MUST DISCLOSE?

A manufacturer, according to the regulations, may include other companies that do not fit the traditional definition of a manufacturer. An "applicable manufacturer" is a manufacturer that is engaged in the production, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or any territory, possession, or commonwealth of the United States. An "applicable manufacturer" also includes an entity that is under common ownership with the manufacturer described above, which provides assistance or support with respect to the production, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply. "Common ownership" may be direct, or indirect. CMS is considering whether to define "common ownership" as any amount of ownership or two or more entities, or to limit the definition to those situations where the same individual(s) or entity owns five percent (5%) or more of two or more entities. This definition could include physician-owned distributorships where a manufacturer owns part of the distributorship.

A Group Purchasing Organization, or GPO, that purchases, arranges for, or negotiates the purchase of a product for a group of individuals, not solely for the use of the GPO itself, is also required to collect and disclose information regarding payments to physicians.

WHAT IS A COVERED DRUG, DEVICE, BIOLOGICAL OR MEDICAL SUPPLY?

A "covered drug, device, biological, or medical supply" is defined as any drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid or CHIP. Payment for a "covered drug, device, biological, or medical supply" is considered available whether the item is reimbursed separately or paid for as part of a composite rate payment.

The definition of covered drugs and biologicals is limited to those drugs and biologicals which require a prescription to be dispensed. This does not include drugs and biologicals which are "over-the-counter." Similarly, the definition of a "covered drug, device, biological, or medical supply" is also limited to those devices or medical supplies which require pre-market approval by, or notification to, the Food and Drug Administration ("FDA"). This does not include medical supplies such as tongue depressors or elastic bandages.

EXCLUSIONS FROM DISCLOSURE REQUIREMENTS

CMS has identified the certain exclusions from the disclosure requirements. These include, but are not limited to:

- Transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of a covered recipient, exceeds $100 in any calendar year.
- Product samples that are not intended to be sold or are intended for patient use.
- 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, to permit evaluation of the device by the covered recipient.
- Discounts, including rebates.
- A dividend or profit distribution from an ownership or investment in a publicly traded security or investment fund.
- If a covered recipient is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding, such as expert witness fees.
- Payments or transfers of value made to a covered recipient through a third party where the manufacturer does not know the identity of the covered recipient.

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MOVING FORWARD INTO 2012

The Final Rule may change some of the requirements listed above. Manufacturers will not be required to begin collecting data until the Final Rule is released by CMS, most likely in mid-2012. However, manufacturers may voluntarily begin collecting this data beginning January 1, 2012. Once the data is provided to CMS by the manufacturers, the information listed above will be made publicly available, and may be utilized by patients, other consumers, the media, employers, competitors, state and federal law enforcement agencies, and consumer advocacy groups. There are monetary penalties of up to $150,000 annually for failure to report. These monetary penalties can increase up to $1 million dollars annually for a knowing failure to report. Although the obligation to collect data and submit it to CMS is on the manufacturers, physicians who may possess an ownership or investment interest in a manufacturer should contact an attorney to insure compliance with the disclosure requirements. Physicians who want to avoid or minimize public scrutiny once this information is disclosed should also examine their relationships with manufacturers.

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ABOUT THE AUTHORS

Kathleen L. DeBruhl & Associates, L.L.C., is a regional healthcare law firm with a national client base which offers its physician and other healthcare provider clients strategic and legal expertise on their healthcare business needs including corporate organization, joint ventures, mergers and acquisitions, and contractual and financial arrangements. The Firm counsels and defends clients on highly complicated healthcare regulatory matters involving physician ownership and financial relationships, reimbursement, fraud and abuse, and compliance with the myriad of laws and regulations imposed upon the healthcare industry by both federal and state governments.

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