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What Hospitals and Physicians Need to Know about CMS's Proposed Rule Interpreting the Physician Payment Sunshine Act

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Wilson Hayman

Kenneth L. Burgess

Centers for Medicare & Medicaid Services (CMS) issued on December 14, 2011 its much-anticipated proposed rule interpreting the requirements of the Physician Payment Sunshine Act (Act), enacted by Congress as Section 6002 of the Patient Protection and Affordable Care Act on March 23, 2010. In its press release accompanying the proposed rule, CMS touted the Act and rule as fostering transparency which will discourage inappropriate financial relationships and give patients the information they need to evaluate their health care providers. The Act requires manufacturers of drugs, devices, biological, and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) to report to CMS any payments or other transfers of value they made to physicians and teaching hospitals during the preceding year. The Act also requires manufacturers and group purchasing organizations (GPOs) to report certain information regarding ownership or investment interests held by a

physician or immediate family member in the manufacturer or GPO during the same time frame.

The initial reports by manufacturers and GPOs to CMS are due on March 31, 2013, for the preceding year, and on the 90th day of each calendar year thereafter. The Act requires the Secretary of the Department of Health and Human Services (Secretary) to make such information available to the public on a website no later than September 30, 2013, and on June 30 of each successive calendar year. Several states which have previously enacted similar laws drawing public attention to manufacturers' compensation to physicians have seen a reduction in such payments. CMS is currently soliciting comments concerning the proposed rule, which must be received no later than 5:00 p.m. Eastern Time on February 17, 2012.

Definitions. Under the proposed rule, the following key definitions clarify the Act's provisions and determine who and what are covered by the reporting requirements:

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 the CHIP. In the proposed rule, CMS has clarified that this includes such items which are reimbursable either separately or as a part of a fee schedule or composite payment rate. However, covered drugs and biological are limited to those that require a prescription to be dispensed, not over-the-counter drugs and biological. Covered devices and medical supplies are limited to those that require premarket approval by or notification to the FDA. However a manufacturer that produces just one prescription drug or biological, or one device or medical supply not requiring FDA approval or

notification, must report all its transfers of value to covered recipients, whether or not they are related to the covered drug, device, biological, or medical supply.

An “applicable manufacturer” is defined as an entity that is 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 an entity under common ownership with such an entity which provides assistance or support to such entity with respect to those activities in the U.S.
An “applicable GPO” is defined as an entity operating in the U.S. which purchases, arranges for, or negotiates the purchase of a covered drug device, biological, or medical supply for a group of individuals or entity, not solely for use by the GPO itself.

A “physician” is defined to include doctors of medicine, osteopathy, dental surgery, dentistry, podiatry, optometry, or chiropractic licensed to practice their respective specialties in the particular state, other than employees of the applicable manufacturer. See 42 USC §§ 1320a-7h(e)(11), 1395x(r).

A “teaching hospital” is defined as any institution that received Medicare payments for Direct Graduate Medical Education, IPPS Indirect Medical Education, or Indirect Graduate Medical Education for psychiatric hospitals during the previous calendar year. Because a list of these institutions is not now publicly available, CMS proposes to publish a list of hospitals covered by the Act annually. This would include transfers of value to employees of the teaching hospital, including physicians, non-physician researchers, nurses, etc. Please note that while the Act and the implementing rule do not govern transfers of value to other, non-teaching hospitals, such hospitals could still

be implicated by the Act based on payments to their physician employees or medical staff members.

Reporting Payments by Manufacturers. Physicians and teaching hospitals need to be aware of what payments or other transfers of value from manufacturers will be reported to CMS. By statute, the phrase "payments or other transfer of value" includes cash or cash equivalent, in-kind items or services and stock, stock option or any other ownership interest, dividend, profit, or other return on investment. The manufacturer must identify them as falling into one of the following categories: consulting fees, compensation for services other than consulting, honoraria, gift, entertainment, food and beverage, travel, education, research, charitable contribution, royalty or license, current or prospective ownership or investment interest, direct compensation for serving as faculty or speaker for a medical education program, grant, or any other payment or transfer of value.

Special Rules Apply to Reporting Research. A research payment may need to be reported as both a direct research payment to the hospital and an indirect research payment to the particular physician who serves as the principal investigator in a clinical trial and ultimately receives the payment. While research payments must be reported to CMS according to the same schedule as other payments, CMS (if notified by the manufacturer) will not publicly post the payment until CMS's first annual publication after the earlier of either (1) the date of approval, licensure, or clearance by the FDA, or (2) four calendar years after the date of payment. The applicable manufacturer must report to CMS each year whether a particular payment is subject to pending FDA approval and eligible for delay in publication by CMS.

Reporting Physician Investment Interests in Manufacturers or GPOs. In addition to the reporting requirement for manufacturers summarized above, both manufacturers and GPOs shall report to CMS certain information regarding any ownership or investment interest, other than in a publicly traded security or mutual fund, held by a physician or immediate family member in the manufacturer or GPO during the preceding year. The information to be reported includes the dollar amount invested, the value and terms of such investment, and any payment or transfer of value to the physician holding the interest, or transfer to another entity or individual at the request of the physician.

Exclusions to Reporting Requirement. By statute, no reporting is required for payments and other transfers of value to one physician or teaching hospital of less than $10 in 2012, unless these exceed $100 in a calendar year. These dollar amounts will be increased annually in future years by the annual percentage increase in the consumer price index. Other transfers excluded by statute are transfers of value made indirectly to a physician through a third party when the applicable manufacturer neither has actual knowledge nor acts in deliberate ignorance or reckless disregard of the identity of the physician; product samples intended for patient use but are not for sale; educational materials that directly benefit patients or are intended for patient use; the loan of a device for no more than 90 days for evaluation by the recipient; items provided under contractual warranty; transfers of anything to a physician when he or she is a patient not acting in a professional capacity; discounts and rebates; in-kind items used for the provision of charity care; an ownership or investment interest or dividend or profit distribution from a publicly traded security or mutual fund; payments to employees under a self-insured plan; transfers to non-medical professionals solely for professional

services; and transfers to a physician in payment for services in a judicial or administrative proceeding. These exclusions apply to both payments or other transfers of value and ownership or investment interests.

Timetable for Submission of Information by Manufacturers and GPOs. One surprise in the proposed rule is that CMS will not require manufacturers and GPOs to start collecting data until the final regulations are issued sometime next year, though manufacturers and GPOs may begin collecting data voluntarily. Depending on when the final rule is issued, CMS is considering requiring manufacturers and GPOs to begin collecting data 90 days after publication of the final rule for the remainder of 2012, to be reported to CMS by March 31, 2013.

Notification of Physicians and Hospitals and Opportunity to Review Submitted Information. CMS proposes that once the data has been submitted by manufacturers and GPOs, it will notify them and the physicians and teaching hospitals when the reported information is ready for review. The manufacturers, GPOs, physicians, and teaching hospitals will all have an opportunity to review and submit corrections to the information submitted specific to that entity on a secure website for a period of at least 45 days from the date of CMS's notification before CMS makes the information available to the public. While manufacturers and GPOs will be notified through their established point of contact, physicians and teaching hospitals will be notified through CMS's LISTSERV and a posting, unless they also register with CMS to receive notification about the review processes. Registering to receive notice is recommended if a provider wishes to review the reported information. The physician must contact the reporting manufacturer or GPO to resolve any dispute regarding the reported transfer of

value or investment interest, and the teaching hospital must contact the manufacturer regarding the transfer of value. If there is no agreement to resolve the matter, then CMS will make publicly available both parties' versions of the data. After the review period has expired, no person will be permitted to amend the data for that calendar year.

Availability of Reported Information to Public. CMS is required by the Act to publish by September 30, 2013, on a publicly available website, the data reported for calendar year 2012. For each year thereafter, CMS must publish the data for the preceding calendar year by June 30. CMS proposes to state on the website that publication of the payment or other transfer of value neither indicates that the payment was legitimate, nor indicates a conflict of interest or any wrongdoing. The Act also requires CMS to send annual reports to Congress and to each state summarizing the data reported.
Penalties on Manufacturers and GPOs for Failure to Report. The Act authorizes the imposition of civil monetary penalties (CMPs) in amounts between $1,000 and $10,000 on manufacturers or GPOs for each transfer of value or ownership interest which they fail to report. The total penalty for each annual submission cannot exceed $150,000. However, a manufacturer or GPO which knowingly fails to report is subject to a CMP of not less than $10,000 nor more than $100,000 for each payment or interest it fails to report, not to exceed $1,000,000 for each annual submission of information.

Effect on Hospitals and Physicians. While the Act imposes no penalties on teaching hospitals and physicians, the purpose of the Act is to shed light on the nature and extent of financial relationships and discourage inappropriate relationships and conflicts of interest. The public availability of the reported information will invite inquiring eyes to

review this information. In addition to the inevitable media publicity, it is possible that investigations and prosecution of health care providers may result if inappropriate payments or relationships are revealed which arguably violate the Medicare and Medicaid Anti-Kickback Statute, the Stark Physician Self-Referral law, or similar laws. Thus, physicians and hospitals, including but not limited to teaching hospitals, should be aware of the provisions of the Act and its rules and consider tracking reportable data and retooling their compliance programs to protect themselves from the dissemination of false, damaging information.

301 Fayetteville St., Suite 1900, Raleigh, NC 27601/P.O. Box 1801, Raleigh, NC 27602-1801 P: 919.783.6400 F: 919.783.1075