



Statement for the Record

United States Senate Special Committee on Aging
Roundtable: “Let the Sunshine In: Implementing the Physician
Payments Sunshine Act”

*Physician Payment Reporting Provisions
in Corporate Integrity Agreements*

Statement of:

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**PHYSICIAN PAYMENT REPORTING PROVISIONS
IN CORPORATE INTEGRITY AGREEMENTS**

This statement summarizes the history and evolution of corporate integrity agreement (CIA) provisions that require drug and device manufacturers to report information about payments that they make to physicians.

The Department of Health and Human Services Office of Inspector General (OIG) has long recognized the importance of transparency about financial relationships between physicians and health care companies, including manufacturers of drugs and medical devices. OIG has emphasized the benefits of transparency in testimony before Congress. *See, e.g.*, Testimony of Lewis Morris to House Committee on Ways and Means, Subcommittees on Health and Oversight, June 15, 2010, and Testimony of Gregory E. Demske to Senate Special Committee on Aging, February 27, 2008.

OIG has required transparency about the payments of drug and device manufacturers to physicians through CIAs entered as part of fraud settlements with specific manufacturers. As OIG has stated in prior testimony, the requirement of public disclosure of these payments will help the Government, as well as the health care industry and the public, to monitor relationships and should have a sentinel effect to deter kickbacks and other inappropriate payment relationships.

In recent years, the U.S. Government (working through the Department of Justice and OIG) has entered numerous settlements with drug and device manufacturers to resolve allegations that the companies defrauded Medicare, Medicaid, and other Federal health care programs. OIG routinely requires drug and device manufacturers to enter CIAs with OIG as a condition for permitting the manufacturers to continue to do business with the Federal Government. Although CIAs contain many standard terms, they are negotiated documents that vary according to the particular entity, the alleged fraud, and relevant risk areas. Among other things, CIAs require the manufacturers to establish or maintain comprehensive compliance programs that include designating a compliance officer, establishing policies and procedures, training, and auditing. The CIAs also require the manufacturers to report certain information to OIG, and OIG monitors the manufacturers' compliance with the terms of the CIAs.

OIG understands that drug and device manufacturers routinely have financial relationships with physicians. There are legitimate reasons that such relationships may exist, but many such relationships may be suspect under existing fraud and abuse laws or may otherwise create conflicts of interest. OIG has concerns about any relationship that raises the inference that the manufacturer is paying the physician, in part, to influence the physician to use, recommend, or prescribe the manufacturer's products. In 2008, OIG began to require more transparency about the relationships between manufacturers and physicians through its CIAs with such entities. These CIAs require the manufacturers to post on their company Web sites information about payments they make to physicians. Manufacturers must post the information on both a quarterly and an annual basis. The specifics of the requirement have

changed over time in different CIAs, but OIG has continued to include a public disclosure requirement, where appropriate, in CIAs with drug and device manufacturers. To date, the payment-posting provisions have been included in 15 CIAs with drug and device manufacturers.¹

The early CIAs containing the payment-posting provisions predated the passage of section 6002 of the Patient Protection and Affordable Care Act (ACA) (also known as the Sunshine requirements). Accordingly, the definition of the term “payments” used in the early CIAs was not based on a statutory standard. Following the passage of ACA, OIG aligned the definition of “payments” in CIAs with the definition of “payments” in section 6002 of ACA to minimize confusion and inconsistency that could be caused by different definitions. Current CIAs explicitly define “payments” for CIA purposes to include all “payments or other transfers of value” as those terms are defined in section 6002 of ACA and any regulations promulgated thereunder.

OIG has occasionally received questions from the manufacturers under CIAs about the payment-posting requirements. To the extent that OIG received specific questions about how manufacturers should interpret the definition of “payment” for purposes of the CIAs, OIG has generally answered such questions with the caveat that manufacturers must follow the definition of payments as set forth in section 6002 of ACA and any implementing regulations.

Section 6002 of ACA requires that the Centers for Medicare & Medicaid Services (CMS) consult with OIG on implementing its provisions. CMS has consulted with OIG in developing its regulations, as required by the statute.

OIG remains committed to preventing and detecting fraud and abuse, to using CIAs effectively to promote compliance, and to working with internal and external stakeholders to ensure the integrity of the Federal health care programs.

¹ The testimony and CIAs referenced in this statement may be found on the OIG Web site at: <http://www.oig.hhs.gov>.