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CMS proposes to share physician payment Sunshine Act data with federal agencies

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From international law firm Arnold & Porter LLP comes timely views on current regulatory and legislative topics that weigh on the minds of today's physicians and health care executives.

Many have speculated as to how aggressively the government will use the financial information collected under the Physician Payments Sunshine Act to investigate the relationships between manufacturers and physicians. Now we know more about the government's intentions.

The information being collected includes itemized reporting by manufacturers of certain drugs, devices, biologicals or medical supplies of payments or other transfers of value to physicians and teaching hospitals that exceed $10 per transfer or $100 in the aggregate per year. These include payments for meals, travel, research, consulting, honoraria, training or education, grants, textbooks, journal reprints and payments related to physician recruitment.

Despite the fact that the Centers for Medicare and Medicaid Services has acknowledged that financial ties between physicians and industry "alone do not signify an inappropriate relationship," and that a physician's or teaching hospital's "inclusion on the public website does not indicate that relationships are necessarily improper or illegal," it appears that CMS is going to share the data with other federal agencies in a way that will facilitate and make it easier to investigate physician-industry relationships.

On May 30, 2014, CMS announced a sweeping proposal that would permit the agency to share payment information submitted by manufacturers to other federal government agencies, such as the U.S. Department of Justice, the Office of Inspector General of the U.S. Department of Health and Human Services, and other components, subdivisions or contractors within CMS.

In the notice, CMS proposed to use and share manufacturer's detailed payment information to support litigation involving the agency; assist with fraud, waste, and abuse detection and prevention activities; and support research and program evaluation activities.

Unfortunately, the standard CMS will use to determine whether it will share the information is that the "records are both relevant and necessary" to any litigation or other activity, and "that the use of such records is compatible with the purpose for which the agency collected the records." CMS also proposed to share payment information with CMS entities such as Medicare Administrative Contractors when CMS deems the disclosure "reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy or otherwise combat fraud, waste or abuse in such program."

Given the Sunshine Act's broad recordkeeping and audit requirements, coupled with the proposed "reasonably necessary" standard for data sharing, there is great concern that when CMS conducts an audit of a manufacturer for all payments related to, for example, speaking arrangements, the agency may end up reviewing a trove of information such as specific contracts which, while confirming compliance with the Sunshine Act, may also open the door to a broader investigation into potential kickbacks — particularly if there are frequent or large payments.

Although it is true that the payment information is publicly available anyway, and therefore searchable by agencies such as the Department of Justice and Office of the Inspector General, information reviewed during an audit is not publicly available, including assumptions documents. The CMS proposal to proactively share payment information, potentially including payment information obtained during an audit, will give investigators access to potential evidence much more quickly than they would otherwise have (eg, through subpoenas) and could assist the government in initiating or following through on certain investigations.

This amplifies the possibility that federal and state prosecutors or whistleblowers could more quickly obtain evidence to support allegations questioning the clinical judgment of those physicians who receive payments or other transfers of value from manufacturers of products they use or prescribe. This is because manufacturers are required to submit not only payment information but also report the drug or device in connection with which the payment was made for education-, research- or marketing-related payments. This could allow enforcement agencies to review medical records and claims submitted by the physicians receiving these payments to determine whether they prescribed drugs or used devices inappropriately or unnecessarily because of the reported payments.

At the end of the day, the fear is that it will be much easier for the government to bring actions against manufacturers and physicians, alleging that the payments were kickbacks to induce the physician to use a product and that the claims for procedures or prescriptions involving those products were falsely submitted.

Applicable manufacturers began collecting required payment data on Aug. 1, 2013, and have already begun reporting to CMS payment data from this date through Dec. 31, 2013. CMS expects to publish the data for this period on the Open Payments website by Sept. 30, 2014, in a searchable format. Stakeholders have 30 days to submit comments on this proposal.

Given that contracts between manufacturers and physicians will be subject to audit, physicians should ensure that all current or proposed arrangements or contracts with manufacturers meet all conditions of the personal services safe harbor of the federal AKS (ie, a signed, written agreement for at least 1 year that covers all of the services to be performed on an itemized performance schedule, etc.). For example, physicians should ensure that contracts properly reflect and describe the type of work and services for which the physician was engaged or will perform, that the physician actually performed the work or intends to perform the work in the given period, that the work was reasonable and necessary, and that the physician was paid fair market value for their work and services. Physicians should also confirm that such contracts or arrangements are in compliance with institutional policies or procedures.

Manufacturers may also want to revisit internal policies and procedures to ensure adequate recordkeeping, retention and documentation practices are enforced and complied with, particularly concerning contracts with physicians and teaching hospitals.

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