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

Risks to physicians associated with Sunshine Act disclosures

Part 2 in this series focuses on the increased risks to physicians from Sunshine Act reporting and transparency.

--By Alan E. Reider, Daniel A. Kracov, and Abraham Gitterman, Arnold & Porter LLP

As noted in part 1 of this series in the April 25 issue of *Ocular Surgery News*, the Physician Payments Sunshine Act requires "applicable manufacturers" of drugs, devices, biologicals or medical supplies covered under Medicare, Medicaid or CHIP to report annually to the Centers for Medicare and Medicaid Services, in an electronic format, certain payments or other transfers of value to "covered recipients" — physicians and teaching hospitals. These include, but are not limited to, payments for meals, travel, research, consulting, honoraria, training or education, grants, textbooks, journal reprints and other related items.

Transparency in the health care industry has been a centerpiece of the Obama administration. Numerous initiatives have focused on enhancing government transparency and providing consumers and patients with more information about how federal health care agencies make decisions that affect the cost and quality of the health care patients receive. Consistent with this policy, CMS recently released data detailing Medicare payments to more than 880,000 health care professionals. The U.S. Department of Health and Human Services explained that this "[h]istoric [data] release gives consumers unprecedented transparency on the medical services physicians provide and how much they are paid." Jonathan Blum, former CMS principal deputy administrator, explained in a news conference that CMS wants "the public, press and researchers to mine the data to help [CMS] find outliers and identify spending that doesn't make sense or appears to be wasteful or fraudulent," and noted that the "data release can help reduce fraud and waste in the system."

As anticipated, the release of this data triggered extensive coverage by the press, and much of the coverage was sensationalized. Physicians who received the highest payments were prominently displayed on the front page of their local newspaper, and questions were raised about whether such payments suggested improper conduct. At the same time, in somewhat of a retreat from its initial position, in a posting on its website, CMS "cautioned against drawing immediate conclusions about potential fraudulent or wasteful activities by providers who received particularly high levels of Medicare reimbursement." Nonetheless, much of the damage had been done.

Potential concerns for physicians as a result of Sunshine Act disclosure

The response to the release of Part B payment data may foreshadow the increased scrutiny that will occur when CMS posts physician payment data on the Open Payments website, scheduled for late September. Further, because there has been so much focus on questionable relationships between physicians and industry over the past several years, there are a number of issues and potential concerns

that physicians should anticipate in advance of data publication, including but not limited to scrutiny under the federal Anti-Kickback Statute; scrutiny under state laws, particularly disclosure requirements; and potential violations of physicians' corporate or institutional policies (eg, conflicts of interest).

The federal Anti-Kickback Statute (AKS) prohibits any person from knowingly and willfully offering, paying, soliciting or receiving any remuneration "directly or indirectly, overtly or covertly, in cash or in kind" to induce or reward referrals of items or services reimbursable by a federal health care program. The Office of Inspector General of HHS, which enforces the AKS and other federal health care laws, has interpreted "remuneration" to include anything of value, in cash or in kind. Therefore, discounts, free services, equipment, meals, educational materials, grants or honoraria, or other commercial incentives may violate the AKS if they are provided by a manufacturer or its subsidiaries with an improper intent and they are not structured to meet the requirements of an available safe harbor.

While the Sunshine Act and posting of manufacturer payments to physicians or teaching hospitals does not itself signify an inappropriate or unlawful relationship, CMS, OIG, and other government agencies and interested parties may use payment data (coupled with reimbursement or prescriber data) to otherwise suggest improper relationships or influence. For example, within hours of the CMS release of the Part B payment data, members of Taxpayers Against Fraud, a nonprofit advocacy group with approximately 400 whistleblower lawyers, began analyzing the data "to see if doctors are prescribing an unusually high amount of the pharmaceutical company's product."

In addition, federal and state prosecutors or whistleblowers could use the payment data to call into question the medical necessity of treatment provided and to analyze claims tied to physicians, "including the number of surgeries conducted, and prescriptions for off-label use of medications or high cost drugs," which could lead to additional investigations. Such information may be easier to gather in some cases because the Sunshine Act requires manufacturers to report, and CMS to post, the specific product (eg, drug or device) associated with a payment related to education, marketing or research.

Additionally, physicians employed by or affiliated with hospitals, academic medical centers or other institutions may be subject to institutional policies and procedures relating to their relationships with manufacturers. For example, some institutions require prior institutional review or approval of consulting relationships; require reporting of such relationships and payments; prohibit all gifts and on-site meals to physicians funded by industry, regardless of the nature or value; and prohibit payments above certain thresholds. The release of payment data on Open Payments, therefore, may risk disclosure of a relationship that does not comply with applicable institutional guidelines.

Finally, those physicians who engage in research-related activities involving preclinical or clinical research for U.S. Food and Drug Administration approval or clearance or National Institutes of Health funded research are subject to government conflict of interest disclosure forms and regulations. Discrepancies between Sunshine Act and NIH or FDA disclosures could lead to NIH freezing grant money for a particular researcher or entire institution, or FDA delaying or rejecting a product application. Such discrepancies also may bring unwarranted attention to individual researchers or their institutions — the same type of issues that Sen. Charles Grassley, R-Iowa, and former Sen. Herb Kohl, D-Wisc., investigated and discussed when they proposed the Sunshine Act.

Recommendations for physicians

It is important to recognize that it may not be possible to avoid unwanted scrutiny from media outlets, institutional staff and other interested stakeholders. However, there are a number of steps that physicians can take to prepare for the Open Payments data release.

First, physicians should register on the CMS Enterprise Portal. Although registration is a voluntary process, it is required if a physician wants to review and dispute any of the data reported about them. Registration for physicians will be conducted in two phases for this first Open Payments reporting year:

- Phase 1 (began June 1) includes user registration on the CMS Enterprise Portal.
- Phase 2 (begins in July) includes physician registration in the Open Payments system and allows a physician to review and dispute data submitted by applicable manufacturers and applicable group purchasing organizations before public posting of the data.

As noted in our first article, physicians have only 45 days to initiate the dispute after receiving notification — if they register with CMS — and any dispute must be resolved no later than 60 days after receiving notification from CMS. Any data that is disputed, if not corrected by manufacturers, will still be made public but will be marked as disputed. Recently, CMS issued a notice soliciting comments on the type of information it will collect from physicians and manufacturers during the dispute resolution process. Therefore, it remains unclear what kind of data physicians will be required to provide in order to initiate a dispute (ie, whether it will be free flowing text or an itemized checklist that allows physicians to dispute specific data elements such as date or amount of payment).

Second, physicians should ensure that all current or proposed arrangements or contracts with manufacturers are compliant and, ideally, meet all conditions of the personal services safe harbor of the federal AKS (eg, a signed, written agreement for at least 1 year that covers all of the services to be performed on an itemized performance schedule). 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 the work and services. Physicians should also confirm that such contracts or arrangements are in compliance with institutional policies or procedures.

Third, physicians should update applicable conflict of interest disclosure forms for medical journals (eg, the ICMJE form) and any disclosure slides that may be used in scientific or promotional presentations. The posting of physician financial information may also bring scrutiny regarding such income from manufacturers from the Internal Revenue Service; peers, colleagues and even students; as well as other interested parties (eg, family, spouses, etc.).

Physicians also may wish to consider downloading mobile apps, purchasing new accounting or tracking software, or updating current systems to help track data that can later be used to confirm or dispute what manufacturers report. Mobile apps and other accounting or aggregate spending software may assist physicians or teaching hospitals in setting internal controls or limits (eg, institutional policies) on the amount of payments or activities that individuals or entities may engage in with certain manufacturers or industry in general.

Further, physicians should consider how their patients may respond to this information; physicians may wish to take pre-emptive action to address it directly by providing patients with information about Open Payments and the nature of interactions the physician has with manufacturers (eg, research, education), and telling patients where they can obtain additional information to ensure that they are fully informed. Useful resources to help draft such materials are available on the Partners for Healthy Dialogues website, which is a collaboration of health care provider groups and manufacturers.

Finally, physicians who are unfamiliar or unaware of the Sunshine Act should consider learning more about the law. CMS has provided two ACCME-accredited continuing medical education programs for physicians that explain what Open Payments is and other steps involved in this process.

Conclusion

Industry-physician collaborations can be quite beneficial for patients and contribute to important scientific developments. The Sunshine Act was never intended to prohibit legitimate physician interactions with manufacturers; rather, it was meant to provide transparency to assist the public in understanding the nature of physician-industry collaborations. Unfortunately, the other edge of this double-edged sword is the misunderstanding about what the data really mean and the largely unwarranted scrutiny that may be generated as a result of these disclosures. Fortunately, physicians now have ample warning about the release of this information and its potential impact. Physicians should use this opportunity to be certain that they are prepared.

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