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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.

Persistent technical issues heighten concern over Sunshine's data accuracy

--By Lauren Miller, Arnold & Porter LLP

The Physician Payment Sunshine Act requires certain manufacturers of drugs and medical devices to report payments or transfers of value they make to U.S. physicians and teaching hospitals. On Sept. 30, the Centers for Medicare & Medicaid Services (CMS) published on the Open Payments Database reported payments that applicable manufacturers made to physicians and teaching hospitals from Aug. 1 to Dec. 31, 2013. Prior to publication, physicians were allowed to register, review and correct inaccurate information housed in the Open Payments Database. Originally scheduled to last 45 days, this review and correction process was marred by a number of complaints and technical issues that have raised significant doubts about the accuracy of the data CMS released.

Physician complaints and technical issues prompted CMS to shut down the database on three separate occasions during the review period. The initial shutdown – from Aug. 3 to Aug. 14 – was prompted by a physician's complaint that payments from another physician with a similar name were being incorrectly attributed to him. While investigating this complaint, CMS discovered "intermingled data" in the Open Payments Database including errors in physicians' names, medical license numbers and national provider numbers. As a result, CMS announced that it would exclude approximately one-third of reported payments from this reporting cycle. CMS spokesman Aaron Albright noted that the Agency planned to return these records to applicable manufacturers for inclusion in the next reporting cycle – slated for June 2015. The remaining two database shutdowns were reportedly due to routine maintenance, each taking the system offline for a number of hours on Aug. 27 and Sept. 5. As a result of the three shutdowns, CMS extended the review, dispute and correction process to Sept. 11.

Despite these issues, CMS maintains that the Open Payments Database was ready to be released to the public Sept. 30 as planned. In a written statement, the Agency's Deputy Administration and Director for the Center of Program Integrity affirmed the CMS's commitment to data integrity, noting the Agency took "swift action" after receiving physician complaints. In a separate press release, CMS assured that inaccurate information will not be published.

Despite the extension and assurances by CMS, many physicians, industry groups, and professional organizations (including both the American Medical Association and the Pharmaceutical Research and Manufacturers of America) did not believe that the information contained in the Open Payments Database was ready for publication. In response to problems plaguing the Open Payments Database, AMA asked CMS to delay the publication of payments for 6 months – until Mar. 31, 2015 – reasoning that such an extension would ensure that physicians had a sufficient amount of time to register, review the data, and obtain

corrections to the data as needed before it was publically disclosed. To act otherwise, many believed, could potentially lead to the release of inaccurate information, misinterpretations and reputational harm.

Even though CMS has announced that it will continue to update the Open Payments Database in the coming weeks, it is unclear what policy, if any, the Agency will establish for physicians to report and correct potential inaccuracies.

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