

## DEADLINE FOR PHYSICIANS, ADVANCE PRACTICE PROVIDERS AND TEACHING HOSPITALS TO REVIEW SUNSHINE ACT DATA APPROACHING

As required by the **Physician Payments Sunshine Act** (“Sunshine Act”), by March 31, 2022, manufacturers of many drugs, medical devices, biologicals and other medical supplies, as well as applicable group purchasing organizations (“GPOs”), will report to CMS payments made and other investment interests given in 2021 to physicians, teaching hospitals and — for the first time — a variety of advanced practice providers. Following this reporting, impacted providers and teaching hospitals will have the opportunity to review reported payments and investments and to dispute any incorrect reports until May 15, 2022. Read on to learn how to prepare for this deadline, including the impacts of important changes to the law and a changing enforcement climate.

### BACKGROUND

The Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, is intended to promote transparency with regard to payments made by pharmaceutical and medical device manufacturers to physicians and teaching hospitals. The Sunshine Act requires that all Applicable Manufacturers and GPOs submit to CMS information related to any “payment or other transfer of value to a Covered Recipient . . . with respect to the preceding calendar year.” Manufacturers and GPOs must also report any ownership or investment interests held by a physician or their immediate family members as that term is defined in the Stark Law (e.g., a physician’s spouse, natural or adoptive parent, a child or sibling of the physician, etc.) in those corporations during the preceding year. These reporting requirements are designed to serve the broader goal of preventing inappropriate financial influence on research, education and clinical decision-making.

### CHANGES IN REPORTING YEAR 2022

#### *New Affected Parties*

Until this reporting year, the term “Covered Recipients” has referred only to physicians (excluding medical residents) and teaching hospitals. This year, however, **changes made in 2018** expanding the definition of “Covered Recipient” have gone into effect. For the first time, transfers of value to five additional provider types are reportable. The categories of providers are: (i) physician assistants, (ii) nurse practitioners, (iii) clinical nurse specialists, (iv) certified registered nurse anesthetists and anesthesiologist assistants, and (v) certified nurse midwives (all “advanced practice providers”).

This change will require greater diligence on the part of teaching hospitals and physician group practices to ensure accurate information is reported for all Covered Recipients.

#### *New Natures of Payment Categories*

CMS has identified 18 different categories, referred to as “natures of payment,” into which reportable transfers of value may fall. In a **article**, we reviewed and provided examples illustrating the most commonly reported categories by Applicable Manufacturers and GPOs: research, consulting fees, current or prospective ownership or investment interests, food and beverage, travel and lodging, compensation for services other than consulting, and honoraria.

In January 2021, four new nature of payment categories were added, which will be included in reporting for the first time in 2022. These categories are:

1. **Debt Forgiveness.** Forgiveness of debt owed by a Covered Recipient to a reporting entity must be reported.
2. **Long-Term Medical Supply or Device Loan.** Any loan of medical supplies or medical devices for a period of greater than 90 days must be reported. This includes devices or objects loaned for a period of 91 or more days or the loan of a 91 or more day supply of medical supplies in a one-year period.
3. **Acquisitions.** Buyout payments made to Covered Recipients who have ownership interest in a company that has been acquired are reportable. For example, if a medical device manufacturer purchases ownership interest in a company owned in whole or in part by a physician or a physician’s immediate family member, such acquisition would be a reportable event.

4. *Compensation for Serving as Faculty or as a Speaker for a Medical Education Program.* Payment for serving as faculty or as a speaker for a medical education program must be reported. For example, if a drug company gives money to a teaching hospital for physician education, such compensation must be reported.

## REPORTING AND DISPUTE PERIOD

Applicable Manufacturers and GPOs must complete their reporting by the 90<sup>th</sup> day of the following calendar year—this year, March 31. Annually, on April 1, the review and dispute process commences, and lasts only 45 days, until May 15. During this 45-day window, Covered Recipients may use CMS’s online National Physician Payment Transparency Program (known as the Open Payments system) to formally dispute any information they believe is incorrect. If a Covered Recipient fails to lodge a formal complaint in this manner, the information will be published on June 30 as originally reported. If the physician or teaching hospital lodges a formal complaint within the dispute period and the dispute is not resolved within 15 days after the end of the 45-day dispute period, any information disputed by the Covered Recipient will be published with a notation indicating that such information is disputed. The only way the information will be correctly published is if the dispute is resolved within the 15 days after the end of the 45-day dispute period and the Applicable Manufacturer or GPO corrects the submission. Note, however, that physicians and teaching hospitals can only file a dispute with CMS but cannot report any corrections to reported information. Beyond the close of the 45-day window, disputes filed with CMS by December 31 of the calendar year will be noted in the next data refresh.

In order to lodge a formal complaint, Covered Recipients must be registered on the Open Payments system. Registration is two-fold, with Covered Recipients first registering in the Identify Management System that confirms the Covered Recipient’s identity and then registering in the CMS Portal to view the data that has been reported. Because the registration process can take weeks, it is important for providers and teaching hospitals to register as soon as possible.

## ENFORCEMENT

Until recently, there were no public enforcement actions of the Sunshine Act. Between October 2020 and May 2021, however, three enforcement actions layering Sunshine Act and Anti-Kickback Statute violation allegations reached settlement.

In **October 2020**, medical device manufacturer Medtronic USA, Inc. paid \$1.1 million to settle a Sunshine Act claim and an additional \$8.1 million to settle related Anti-Kickback Statute claims. In that case, the U.S. Department of Justice (“DOJ”) alleged that, in order to persuade a South Dakota neurosurgeon, Dr. Asfora, to use Medtronic devices, Medtronic hosted 74 events at Dr. Asfora’s struggling restaurant, ultimately paying over \$87,000 to the restaurant. While Medtronic did report the cost of food and drinks spent on these events, it did not report the indirect payments made to Dr. Asfora via his restaurant, or that such payments were made at Dr. Asfora’s request.

In **May 2021**, the DOJ settled two Sunshine Act claims. The first of these settlements, like the Medtronic settlement, relates to activities conducted by Dr. Asfora. According to the DOJ, Dr. Asfora received profit distributions from two medical device manufacturers—Medical Designs LLC and Sicage LLC—in exchange for using devices produced by the two companies. Medical Designs and Sicage neglected to disclose Dr. Asfora’s ownership interests in the companies. Dr. Asfora, Medical Designs and Sicage together paid \$100,000 to resolve the Sunshine Act Claim and \$4.4 million to resolve related Anti-Kickback Statute and False Claims Act allegations.

Also in **May 2021**, the DOJ settled with Medicea USA, Inc. In that case, the DOJ alleged that French medical device manufacturer Medicea paid for meals, entertainment and travel expenses for U.S.-based physicians attending the Scoliosis Research Society’s congress in France in 2013. Medicea failed to report the full value of these payments and ultimately agreed to pay for \$1 million to settle the Sunshine Act allegations and an additional \$1 million to settle the related Anti-Kickback Statute allegations.

## PRACTICAL TAKEAWAYS AND SUGGESTIONS FOR APPLICABLE MANUFACTURERS

- *Track* – Applicable Manufacturers should ensure they are tracking payment and transfers of value for the five new covered recipient types: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants and certified nurse-midwives. Additionally, since there are four new nature of payment categories, Applicable Manufacturers should ensure that any payment or transfer of value is accurately classified and recorded in the appropriate category.

## PRACTICAL TAKEAWAYS AND SUGGESTIONS FOR COVERED RECIPIENTS AND HOSPITALS

- *Registration and Verification Process* – Physicians, advanced practice providers and teaching hospitals should **register** with CMS’s Identity Management System (“IDM”) to request access to the Open Payments system as soon as possible. At the link above, navigate to the

drop-down box labeled “Choose Your Application” and select “Open Payments: Physician Payments Sunshine Act.” Then, simply follow the instructions to complete the Open Payments registration process. Any physicians who registered in IDM and requested access to Open Payments last year do not need to register again. However, any account inactive for the past 180 days may be locked. Therefore, all physicians and advanced practice providers are encouraged to verify access to IDM and check Open Payments data as soon as possible and perhaps every 180 days.

- *Track* – Physicians, advanced practice providers and teaching hospitals should track all interactions with industry involving payments or transfers of value to ensure the accuracy of data reported in the Open Payments system on an annual basis.
- *Dispute* – If data is inaccurate, particularly as it relates to the category classifications for payments or other transfers of value, Covered Recipients should submit a dispute with CMS within the initial 45-day review and dispute period or no later than December 31 of the year reported. Covered Recipients may also negotiate the dispute with the Applicable Manufacturers or GPOs and ensure they correct any inaccuracies by resubmitting a report to CMS.

It is possible that some Applicable Manufacturers and GPOs, in opting for a more conservative approach, will elect to submit payments and transfers of value which actually should have been excluded from reporting. To preempt unnecessary patient concerns associated with such information, physicians, advanced practice providers and teaching hospitals may want to ensure these non-reportable payments are removed from the Open Payments system by filing a timely dispute.

- *Policy and Procedures* – Hospitals may consider developing and implementing internal policies and procedures for Sunshine Act compliance educating medical staff on the law and requiring physicians and advanced practice providers to internally report and/or independently track payments received.

If you have any questions or would like help with a Sunshine Act compliance matter, please contact:

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