

DEADLINE FOR PHYSICIANS AND TEACHING HOSPITALS TO REVIEW SUNSHINE ACT DATA APPROACHING

As required by the Physician Payments Sunshine Act (“Sunshine Act”)[i], manufacturers of many drugs, medical devices, biologicals and other medical supplies — as well as applicable group purchasing organizations (“GPOs”) — will soon complete (March 30, 2020) their reporting to the Centers for Medicare and Medicaid Services (“CMS”) of payments made and other investment interests given to physicians and teaching hospitals in 2019. Even though the Sunshine Act requirements apply to applicable manufacturers and GPOs, there are a number of things physicians and teaching hospitals should know and also be prepared to do by May 14, 2020.

BACKGROUND

The Sunshine Act was enacted as part of the Patient Protection and Affordable Care Act in an effort 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[ii] submit to CMS information related to any “payment or other transfer of value to a covered recipient . . . with respect to the preceding calendar year.”[iii] 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.[iv] These reporting requirements are designed to serve the broader goal of preventing inappropriate financial influence on research, education and clinical decision-making.

AFFECTED PARTIES

The term “covered recipients” refers to all physicians (excluding medical residents) who are not bona fide employees of the applicable manufacturer reporting the payment, as well as teaching hospitals that receive payments for various medical education programs.[v] In October 2018, the definition of “covered recipient” was expanded to include five (5) additional provider types: (i) physician assistants; (ii) nurse practitioners; (iii) clinical nurse specialists; (iv) certified registered nurse anesthetists; and (v) certified nurse-midwives. Transfers of value from applicable manufacturers and GPOs to these additional provider categories will be reportable beginning in calendar year 2022.[vi] This means that payment data collected during calendar year 2021 for the additional categories of providers listed above will be reportable in 2022. As a result, teaching hospitals and physician group practices should consider how this change will impact their relationships with applicable manufacturers and GPOs in 2021. In addition, this modified definition will require greater diligence on the part of teaching hospitals and physician group practices to ensure accurate information is reported for all covered recipients.

NATURES OF PAYMENT

Payment or transfers of value can fall into eighteen (18) different categories referred to as “natures of payment.”[vii] The following is a non-exhaustive list of the most commonly reported categories by applicable manufacturers and GPOs, as well as certain examples of each listed category:

1. *Research* – A broad range of payments and transfers of value made in connection with research activity are subject to special reporting rules.[viii] Such payments might include direct compensation to physicians, funding for research study coordination, or payments to a physician to cover expenses associated with a given research study. Payments for **medical research writing and/or publication** are also reportable if such writing/publication is subject to a written agreement, research protocol or both.
2. *Consulting Fees* – Consulting fees (including those supported by a properly executed personal services arrangement supported by a legitimate business need) paid to a physician are reportable under the Sunshine Act. For example, a payment made by an applicable manufacturer to a physician for the design of a novel research study would be considered a consulting fee. Another example includes a manufacturer paying a physician to use a new product and give opinions on that product. Additionally, if an applicable manufacturer makes a **payment to a clinic for consulting services**, but requests that a specific physician at the clinic actually perform the consulting service, then the payment would ultimately be a reportable indirect payment to that physician.
3. *Current or prospective ownership or investment interests* – Any ownership or investment interests a physician or teaching hospital

currently holds, as well as ownership interests or investments that physicians and teaching hospitals have not yet exercised are also reportable annually. For example, if a physician learns that a drug manufacturer is developing a new medication that he or she thinks will likely become a success, he or she may ask the company to invest in the medication. If the company agrees, then the physician will (sometime in the future) own a percentage of the company. The same scenario could apply to a physician's immediate family members.

4. *Food and Beverage* – Payments and transfers of value related to food and beverage are also subject to specific reporting rules.^[ix] For example, if an applicable manufacturer provides a platter of food to several physicians in a group setting, the manufacturer must “calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal.”^[x] On the other hand, in the event an applicable manufacturer offers buffet meals, snacks or coffee to physician attendees at a conference, such food and beverage is **not reportable** as it would be difficult to “definitively establish the identities of the physicians who partook in the food or beverage.”
5. *Travel and Lodging* – If a physician is paid by an applicable manufacturer to speak at an out-of-town conference, travel and lodging would be one of three reportable payments (along with associated food and beverage costs and consulting fees).^[xi] Therefore, payments to a physician related to a single speaking engagement may appear in the Open Payments system as multiple line items.
6. *Compensation for Services Other than Consulting; Honoraria* – These two (2) categories can act as a “catch-all” for payments that do not fit squarely into other categories. For example, **promotional speaking engagements** on behalf of an applicable manufacturer could be reported under either category. Honoraria are typically for one-time engagements, whereas ongoing promotional speaking relationships might fit better under “Compensation for services other than consulting.”

EXCEPTIONS

Notably, the Sunshine Act does not require manufacturers and GPOs to report transfers of value less than \$10.79; however, if an applicable manufacturer or GPO makes several transfers to the same physician or teaching hospital worth less than \$10.79 each but more than \$107.91 in the aggregate within the calendar year, then all transfers are reportable under the Act.^[xii] (Note that these thresholds will increase annually based on the Consumer Price Index.) Other non-reportable transfers under the Sunshine Act include, but are not limited to: (i) product samples which are not intended to be sold; (ii) educational materials that directly benefit patients; (iii) loans of covered devices for short-term trial periods of up to ninety (90) days; (iv) discounts (including rebates); and (v) in-kind items used for the provision of charity care.^[xiii] Additionally, payments provided to a physician related to **legal proceedings**—including prosecution, legal defense, settlement, or judgment of a civil or criminal action—are not reportable under the Sunshine Act.

REPORTING AND DISPUTE PERIOD

Applicable manufacturers and GPOs must complete their reporting by the 90th day of the following calendar year—that is usually March 31 but is March 30 of any leap year as is the case in 2020. (Please note that the Open Payments website and other CMS guidance suggests that they may still accept submissions until March 31.) Annually, on April 1, the review and dispute process commences, and lasts only forty-five (45) days, until May 15. During a leap year, as in 2020, the dispute process likely lasts March 31 - May 14, 2020. (Please refer to the Open Payments website to confirm as it appears they may be operating under the timeframe of April 1-May 15.) During this forty-five (45) day window, physicians and teaching hospitals may use CMS' online National Physician Payment Transparency Program (known as the Open Payments system) to formally dispute any information they believe is incorrect. If a physician or teaching hospital fails to lodge a formal complaint in this manner, the information will be published on June 30th as originally reported and made available to the general public without indication that the physician or teaching hospital believes the information to be incorrect. If the physician or teaching hospital lodges a formal complaint within the dispute period and the dispute is not resolved within fifteen (15) days after the end of the forty-five (45) day dispute period, any information disputed by physicians and/or teaching hospitals 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 fifteen (15) days after the end of the forty-five (45) day dispute period and the applicable manufacturer or GPO corrects the submission. Physicians and teaching hospitals can only file a dispute with CMS but cannot report any corrections to reported information.

In order to lodge a formal complaint, physicians and teaching hospitals must be registered on the Open Payments system. Unfortunately, the registration process can last weeks, so it is important for physicians and teaching hospitals to register as soon as possible. In previous reporting years, many physicians have not participated in the review and dispute process. On the other hand, reporters, regulators, patients, hospital systems, and other employers have increasingly utilized Open Payments data to research physicians' relationships with

manufacturers and GPOs especially in light of the new, user-friendly appearance of the data on the Open Payments system. As a result, physicians who fail to verify the accuracy of information submitted by applicable manufacturers and GPOs and formally dispute any incorrect information may be subject to unanticipated consequences.

All is not lost if physicians and teaching hospitals do not dispute incorrect information by the end of the forty-five (45) day dispute period. They have one more opportunity to file a formal complaint with CMS by December 31 of the calendar year. Any such disputes will be noted in the next [data refresh](#).

PRACTICAL TAKEAWAYS AND SUGGESTIONS FOR PHYSICIANS AND HOSPITALS

- *Registration and Verification Process* – Physicians and teaching hospitals should [register](#) with CMS’ Enterprise Identity Management System (“EIDM”) 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 EIDM and requested access to Open Payments last year do not need to register again. However, any account inactive for the past one hundred eighty (180) days may be locked. Therefore, all physicians are encouraged to verify access to EIDM and check Open Payments data as soon as possible and perhaps every one hundred eighty (180) days.
- *Track* – Physicians 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 there is inaccurate data, physicians and teaching hospitals should submit a dispute with CMS within the initial forty-five (45) day review and dispute period or no later than December 31 of the year reported, negotiate the dispute with the applicable manufacturers of GPOs and ensure they correct any inaccuracies by resubmitting a report to CMS.

It is possible that some applicable manufacturers and GPOs, that opt for a more conservative approach, will elect to submit non-reportable payments and transfers of value which actually should have been excluded. To preempt unnecessary patient concerns associated with such information, physicians 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 by educating medical staff on the law and requiring physicians to internally report and/or independently track payments received due to physician’s public connection to the hospital.
- *Preparation for 2021* – Be prepared for the expansion of the definition of “covered recipients” that becomes effective in 2021 and educate physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives on the Sunshine Act and the impact on these non-physician practitioners.

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

- [Ritu Kaur Cooper](#) at (202) 370-9584 or rcooper@hallrender.com; or
- Your regular Hall Render attorney.

[references]

[i] 42 U.S.C. § 1320a-7h.

[ii] As defined by 42 C.F.R. § 403.902.

[iii] 42 U.S.C. § 1320a-7h(a)(1).

[iv] *Id.* § 1320a-7h(a)(2).

[v] In this context, “teaching hospitals” means those hospitals that receive payment for Medicare direct graduate medical education (“GME”), inpatient prospective payment system (“IPPS”), indirect medical education (“IME”), or psychiatric hospital IME programs. 42 C.F.R. § 403.902.

[vi] <https://www.congress.gov/bill/115th-congress/house-bill/6/text?overview=closed>

[vii] 42 C.F.R. § 403.904(e)(2).

[viii] Reported research payments must include: a list of drugs, biologicals, or medical devices evaluated in the research study; the name of the research institution or individual receiving the payment or other transfer of value; the name of the research study; and the total amount of the research payment as outlined in a written research agreement, research protocol, or both. 42 C.F.R. § 403.904(f).

[ix] See 42 C.F.R. § 403.904(g).

[x] 42 C.F.R. § 403.904(g)(1).

[xi] 42 C.F.R. § 403.904(e)(1).

[xii] 42 U.S.C. § 1320a-7h(e)(10)(B)(i).

[xiii] See *id.* § 1320a-7h(e)(10)(B)(ii)-(xii).

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