

SUNSHINE ACT COMPLIANCE BEGINS: CMS PROVIDES RELATED PAYMENT TRACKING APPS, Q&AS AND OTHER RESOURCES

This article is Part III in a five-part series of articles discussing the recently published federal Physician Payment Sunshine Act ("Sunshine Act"). This article focuses on recent updates and resources provided by the Centers for Medicare and Medicaid Services ("CMS") to assist in Sunshine Act compliance. The [first article](#) in the series provided an overview of the major sections of the Sunshine Act and CMS's implementing rule, with a focus on issues of importance to health product manufacturers and entities sharing an ownership structure with manufacturers. The [second article](#) discussed issues specific to group purchasing organizations and physician investment in health product manufacturers. Subsequent articles will address reporting of payments associated with clinical and pre-clinical research, the market research exemption, the valuation of payments and transfers of value and the continuing impact of similar state transparency requirements.

EXECUTIVE SUMMARY

Beginning August 1, 2013, applicable manufacturers and group purchasing organizations must comply with the Sunshine Act. The Sunshine Act, also known as the OPEN PAYMENTS program by CMS, requires applicable manufacturers and group purchasing organizations to report to CMS certain payments and transfers of value to physicians and teaching hospitals. In preparation for this reporting, CMS has taken several actions to clarify ambiguous requirements and provide compliance resources to physicians and health product manufacturers. Some of these actions are described in this article.

MOBILE APPS FOR REPORTING AND TRACKING DATA

CMS has developed two free mobile device applications for physicians and industry to help track their reportable financial ties and financial transfers/payments. In a [press release](#), CMS said physicians can use the apps to help validate reports that manufacturers submit. The apps can only be used for tracking, as data loaded into the apps will not interact with CMS's systems and therefore cannot be used for direct data reporting to CMS or its contractors. CMS also said it cannot validate the accuracy of data stored in the apps, nor will it be responsible for protecting data stored in the apps.

SEEKING COMMENTS ON DISPUTE RESOLUTION PROCESS, ETC.

CMS is seeking comments by September 20, 2013 on Sunshine Act registration, attestation, dispute resolution, assumptions document and data retention requirements. In a [Federal Register notice](#) published July 22, 2013, CMS said it is specifically seeking input on:

1. The necessity and utility of the proposed information collection;
2. Ways to enhance the quality, utility and clarity of the information to be collected; and
3. The use of automated collection techniques or other forms of information technology to minimize the information collection burden.

TRAINING CALL

CMS held a MLN Connects National Provider Call on August 8, 2013 to provide an update on program policy, with a focus on third-party payments and indirect payments. There was a question and answer session following the presentation and information about the Physician Resource Toolkit. CMS has posted the presentation slides for this call on the [event's website](#) and may soon post transcripts, video and audio files of the call.

QUESTIONS AND ANSWERS BY TOPIC CATEGORY

CMS has also posted several rounds of *answers to frequently asked questions* for the Sunshine Act. The following are just a few of the frequently asked questions and CMS's subsequent answers by subject matter category.

CME Programs. Are payments (including travel, lodging and meal costs) provided as compensation to speakers at CME events run by CME providers accredited or certified by bodies other than those enumerated in 42 CFR § 403.904(g)(1)(i) eligible for the exclusion from reporting? (Answer: No, the only authorized accrediting/certifying bodies are: the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association's Continuing Education Recognition Program, the American

Medical Association and the American Osteopathic Association.)

Corrections and Disputes. When can covered recipients and physician owners or investors initiate a dispute? (Answer: Any time after the 45-day review and correction period begins, but before the end of the calendar year.)

Drugs and Devices. Is a medical device considered eligible for payment by Medicare, Medicaid or CHIP for purposes of OPEN PAYMENTS reporting if a test performed using the device is eligible for payment, but not the device itself (e.g., MRI machines, CT, x-rays, ultrasounds machines)? (Answer: Yes, if a medical device is used to perform a service that is reimbursable under Medicare, Medicaid or CHIP, the device is considered a covered device for purposes of OPEN PAYMENTS.)

Employment Recruitment. Are applicable manufacturers required to report meals, travel, lodging and other similar expenses made in connection with interviewing prospective physician employees? (Answer: Yes.)

Exemptions. Are payments from an applicable manufacturer to covered recipients in order to purchase products or materials considered reportable under OPEN PAYMENTS (e.g., an applicable manufacturer purchasing reagents from a teaching hospital)? (Answer: Yes, there is no reporting exclusion for these payments.)

Group Practices. If an applicable manufacturer makes a payment or transfer of value to a group practice rather than a specified physician, should the payment be reported in the name of one physician or to all the physicians included in the group practice? (Answer: A payment or other transfer of value provided to a group practice of covered recipients should be attributed to individual physician covered recipients in a manner that most fairly represents who requested the payment, on whose behalf the payment was made or who are intended to benefit from the payment or other transfer of value.)

Payments. Should all physician covered recipient investigators who perform research (i.e., sub-researchers not directing or in charge of the research overall) be listed on the research reporting templates when reporting research payments, even if such sub-researchers are not considered "principal investigators"? (Answer: No, applicable manufacturers are only required to report the names of principal investigators as that term is normally used in industry.)

Non-physicians. If a non-physician employee of a teaching hospital receives a transfer of value such as a meal, would that need to be reported as a transfer of value to the teaching hospital? Similarly, if employees of a physician's office receive a transfer of value, will that need to be reported as a transfer of value to the physician? (Answer: No, unless the covered recipient benefits from the transfer of value to its employee or the payment was made at the request of a covered recipient.)

Should an applicable manufacturer report a payment made to a clinic as part of a contract for consulting services if the applicable manufacturer requests that a specific physician practicing at the clinic perform the services? (Answer: Yes, this is an indirect payment to a physician through a third-party, as the payment made to the clinic is ultimately transmitted in part to the physician through the clinic.)

PRACTICAL TAKEAWAYS

The Sunshine Act creates a mandatory annual reporting obligation for applicable manufacturers and certain group purchasing organizations. Covered recipients should understand these reporting requirements by utilizing resources published by CMS and entities like the American Medical Association. Covered recipients should also ensure that applicable manufacturers' data is accurate by reviewing the data prior to submission; utilizing CMS's tracking resources, such as email listserves and smartphone apps; and understanding available dispute resolution options.

If you have questions about the Sunshine Act, would like help designing a Sunshine Act compliance strategy or would like assistance submitting comments on CMS's collection of information, please contact:

- Mark R. Dahlby at 414-721-0902 or mdahlby@hallrender.com;
- Scott J. Geboy at 414-721-0451 or sgeboy@hallrender.com; or
- Your regular Hall Render attorney.