




GETTING READY FOR THE PHYSICIAN PAYMENT 'SUNSHINE' RULE



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Getting Ready for the Physician Payment ‘Sunshine’ Rule



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On February 1, 2013, the Centers for Medicare and Medicaid Services (CMS) published the long-awaited final regulations for the Physician Payment Sunshine Act (Act or Sunshine Act). The Sunshine Act implements a provision of the Affordable Care Act that requires (1) certain manufacturers to report payments and transfers of value to physicians and teaching hospitals, and (2) certain manufacturers and group purchasing organizations (GPOs) to report ownership or investment interests of physicians and their immediate family members.

In turn, the government will make this information publicly available with the stated intention that the transparency will shed light on inappropriate relationships and prevent unnecessary health care costs due to conflicts of interest. The Sunshine Act is strictly a disclosure law and, therefore, does not prohibit payments or ban investment interests.

Under the Sunshine Act, applicable manufacturers and GPOs must begin to collect data on August 1, 2013 and electronically submit reports to CMS by March 31, 2014. CMS will publish aggregated data on a public website by September 30, 2014 and will make that data

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available for download. CMS will not grant reporting extensions and has indicated that late reporting will be deemed a failure to report.

Given the fast-approaching deadlines and the significant penalties imposed by the Act for non-compliance, entities should move swiftly to determine their compliance obligations and implement internal systems to capture and synthesize reportable information.

WHO NEEDS TO REPORT?

Two types of entities are required to report under the Sunshine Act: applicable manufacturers and applicable GPOs.

Applicable Manufacturers

Manufacturers subject to the Act include any entity that operates in the United States (or in any United States territory, possession, or commonwealth) *and* (1) is engaged in the production, preparation, propagation, compounding, or conversion of at least one covered product *or* (2) is under common ownership and providing assistance or support to such a manufacturer with respect to a covered product.¹

A covered product is a drug, device, biological, or medical supply that is reimbursable under Medicare, Medicaid, or Children’s Health Insurance Program (whether separately or as part of a bundled payment) and that requires a prescription (if a drug or biological) or premarket approval by or notification to the Food

¹ 42 C.F.R. § 403.902 (2013).

and Drug Administration (for a device or a medical supply that is a device).²

Manufacturers are deemed to operate in the United States if they have a physical location or conduct activities (including selling a product) within the country, either directly or through an authorized agent.³ Entities are deemed to be under common ownership when the same individual(s) or entity(ies) directly or indirectly own 5% or more of the total ownership of both entities.⁴ Those entities are providing assistance or support if they conduct necessary or integral services with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product.⁵

In the final regulations, CMS clarified that the following entities are subject to the Sunshine Act:

- Foreign manufacturers that sell covered products in the United States.
- Distributors and wholesalers that hold title to a covered drug, device, biological, or medical supply.
- Manufacturers that hold FDA approval, licensure, or clearance for a covered product, even if they do not actually manufacture it.
- Entities that manufacture a covered product under a written agreement with the holder of the FDA approval, license, or clearance of the covered product (but such entities may be entitled to report only payments or interests related to the covered product).⁶

In contrast, hospitals, hospital-based pharmacies, and laboratories that manufacture a covered product solely for their use or use of their patients do not have to comply with reporting requirements.⁷ Similarly, pharmacies that meet certain conditions specified in the regulations are exempt from the Sunshine Act.⁸

Applicable Group Purchasing Organizations

An applicable GPO is an entity that operates in the United States and purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.⁹

The Sunshine Act captures entities that purchase covered products for resale or distribution, including not only traditional GPOs but physician-owned distribu-

tors that otherwise fall within the definition of applicable GPO.¹⁰

WHAT NEEDS TO BE REPORTED?

Payments or Other Transfers of Value

Most manufacturers subject to the Sunshine Act must report *all* payments or other transfers of value exceeding \$10 to covered recipients, even if those payments are unrelated to covered products.¹¹ But applicable manufacturers that derive less than 10% of their total gross income from covered products during the preceding year are only required to report payments and other transfers of value related to the covered products.¹²

Covered recipients are physicians (unless bona fide employees of manufacturers) and teaching hospitals. Physicians are doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors, who are legally authorized to practice in a state (whether or not actively engaged in practice).¹³

Teaching hospitals are institutions that receive direct Medicare graduate medical education payments, indirect medical education (IME) payments, or psychiatric hospital IME payments during the last calendar year. CMS will annually publish a list of applicable teaching hospitals that received education payments at least 90 days before the reporting year.¹⁴

Payments to residents, non-physician prescribers (such as nurse practitioners), and non-healthcare departments of universities affiliated with teaching hospitals (unless an indirect payment is made with the teaching hospital as the known recipient) do not have to be reported.¹⁵

The Sunshine Act excludes 14 types of payments or other transfers of value from reporting requirements, including the \$10 threshold for payments or other transfers of value (unless the total annual value of such payments exceeds \$100 annually).¹⁶

In addition, manufacturers are not required to report indirect payments or other transfers of value if they are unaware of the identities of the recipients *and* do not act in deliberate ignorance or reckless disregard of those identities. But manufacturers must report indirect payments if they become aware that the payments were made to covered recipients (whose identities are known) anytime during the reporting year up through the second quarter of the following year.¹⁷

Other statutory exclusions from reporting requirements include, but are not limited to, product samples, educational materials for patients, short-term device loans, discounts (including rebates), in-kind items for

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ 42 C.F.R. § 403.904(b)(2).

⁶ 42 C.F.R. § 403.904(b)(4).

⁷ 42 C.F.R. § 403.902.

⁸ Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9,458, 9,461 (Feb. 8, 2013) (to be codified at 42 C.F.R. pts. 402 & 403).

⁹ 42 C.F.R. § 403.902.

¹⁰ 78 Fed. Reg. at 9,493.

¹¹ 42 C.F.R. § 403.904(a).

¹² 42 C.F.R. § 403.904(b)(1).

¹³ *Id.*

¹⁴ 78 Fed. Reg. at 9,470.

¹⁵ 78 Fed. Reg. at 9,467-68.

¹⁶ 42 C.F.R. § 403.904(i).

¹⁷ 78 Fed. Reg. at 9,490-91.

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charity care, dividends in publicly traded securities or mutual funds, and payments or transfers of value that are solely in the context of personal, non-business relationships.¹⁸

For each reportable payment or transfer of value, manufacturers must report (1) the covered recipient's identifying information (name, business address, and, if a physician, specialty, National Provider Identifier, and state professional license number), (2) amount of payment, (3) date, (4) form of payment (cash, in-kind items, stock or dividends), (5) nature of payment, and (6) related covered product (if applicable).¹⁹

Manufacturers must report the nature of payment using one of the categories specified in the Act, which include consulting fee, compensation for other services, honoraria, gift, entertainment, food and beverage, travel and lodging, education, research, charitable contribution, royalty, speaking fee, grant, or space rental fee.²⁰

Ownership and Investment Interests

Both applicable manufacturers and applicable GPOs must report any ownership or investment interests of physicians and their immediate family members. Those interests include stock, stock options, partnership shares, limited liability company memberships, loans, bonds, and other financial interests.²¹ Interests in publicly traded securities or mutual funds, interests arising from retirement plans, stock options received as compensation (until exercised), or unsecured loans subordinated to credit facilities do not have to be reported.²²

In addition, manufacturers and GPOs do not have to report investment interests held by physicians and their immediate family members of which they are unaware *provided* they do not act in deliberate ignorance or reckless disregard of that information.²³

If physician owners and investors are known or can be easily ascertained, manufacturers and GPOs must report for each interest: (1) the physician's identifying information (name, business address, specialty, National Provider Identifier and state professional license number), (2) the dollar amount, and (3) value and terms of the interest.²⁴ Manufacturers and GPOs are not required to report the name or relationship of immediate family members holding ownership or investment interests, but may instead aggregate interests of multiple family members.²⁵ GPOs also must annually report payments or other transfers of value to physician owners and investors.²⁶

HOW AND WHEN TO REPORT?

Manufacturers and GPOs must electronically submit reports containing the required data by March 31, 2014 and by the 90th day of each subsequent calendar year.²⁷

The chief executive officer, chief financial officer, chief compliance officer, or another comparable officer

must attest that the reported information is timely, accurate, and complete to the best of his or her ability.²⁸ Manufacturers and GPOs also may but are not required to submit an assumptions document to describe any methodologies or assumptions used when reporting their data.²⁹ The assumptions document will not be public, but could be accessed by other divisions of the Department of Health and Human Services (HHS), the Office of the Inspector General (OIG), and the Department of Justice during an audit or investigation.³⁰

WHAT OCCURS DURING THE REVIEW PROCESS?

Once reports are electronically submitted, manufacturers, GPOs, covered recipients, and physician owners and investors will have at least 45 days to review, dispute, and correct reported information before it is posted online.³¹ CMS will notify physicians and teaching hospitals using email listserves, online posting (on both the CMS website and Federal Register), and directly if they have previously registered with CMS.³² The 45-day review period will begin on the date specified in the online notification.³³

Covered recipients and physician owners and investors can sign into a secure website to review data that has been submitted about them for the current and the previous reporting years. If a reviewer disagrees with any reported information, he or she can initiate a dispute, which is sent to the applicable manufacturer or GPO for resolution. The manufacturer or GPO is responsible for resolving the dispute.³⁴ CMS will not be actively involved in mediating dispute resolutions, but plans to monitor whether manufacturers and GPOs have an abnormally high number of disputes or a high rate of unresolved disputes.³⁵

CMS will publish aggregated data on a publicly available website by September 30, 2014, and within 90 days of the last day for data submission after the first year.³⁶ To correct data before publication, manufacturers and GPOs must notify CMS of resolved disputes and changes to the reported information no later than 15 days after the end of the 45-day review period.³⁷ Disputes not resolved by that date may still be resolved, but any changes to the data will not be made until the next time that the data is refreshed (which occurs at least annually). Until corrected, the data will be marked "disputed" and will show only the information provided by the manufacturer or GPO.³⁸

WHAT ARE THE CONSEQUENCES OF FAILING TO REPORT?

HHS, OIG, and CMS may audit, evaluate, and inspect manufacturers and GPOs to determine if they have complied with the Sunshine Act's reporting requirements.

¹⁸ 42 C.F.R. § 403.904(i).

¹⁹ 42 C.F.R. § 403.904(c).

²⁰ 42 C.F.R. § 403.904(e)(2).

²¹ 42 C.F.R. § 403.906.

²² 78 Fed. Reg. at 9,494.

²³ 78 Fed. Reg. at 9,495.

²⁴ 42 C.F.R. § 403.906(b).

²⁵ 78 Fed. Reg. at 9,494.

²⁶ 42 C.F.R. § 403.906(b)(6).

²⁷ 42 C.F.R. § 403.908(a).

²⁸ 42 C.F.R. § 403.908(e).

²⁹ 42 C.F.R. § 403.908(f).

³⁰ 78 Fed. Reg. at 9,482.

³¹ 42 C.F.R. § 403.908(g).

³² 78 Fed. Reg. at 9,499.

³³ 42 C.F.R. § 403.908(g)(2).

³⁴ 42 C.F.R. § 403.908(g)(3).

³⁵ 78 Fed. Reg. at 9,501.

³⁶ 78 Fed. Reg. at 9,503.

³⁷ 42 C.F.R. § 403.908(g)(4).

³⁸ 78 Fed. Reg. at 9,502.

To facilitate such audits and inspections, manufacturers and GPOs must maintain all records and documents for at least 5 years from the date that the payment or other transfer of value or the ownership or investment interest is posted online.³⁹ Manufacturers and GPOs that violate reporting requirements will be subject to civil monetary penalties (CMPs), capped for each entity at \$150,000 for failure to report and \$1,000,000 for knowing failure to report.

Factors that may be considered in determining the amount of CMPs include: (1) the length of time that the entity failed to report, including the time that the applicable manufacturer or GPO knew of the payment or interest, (2) the amount of the unreported payment(s), (3) the level of culpability, (4) the nature and amount of information reported in error, and (5) the degree of diligence exercised in correcting erroneous information.⁴⁰

While the Sunshine Act does not prohibit any payments, companies need to be aware that reported or unreported payments could serve as circumstantial evidence of illegal conduct. For example, payments by a pharmaceutical company to physicians to induce them to prescribe certain drugs could subject a company to criminal liability under the federal Anti-Kickback Statute. Similarly, a company's failure to report payments made to physicians could be viewed by the government as concealment of an illegal relationship. Applicable manufacturers should assume that the government will be reviewing Sunshine Act disclosures, and failures to report, for potential violations of other laws.

NOTEWORTHY CLARIFICATIONS OF THE FINAL RULE

The final regulations clarified several provisions of the Act, including those pertaining to continuing medical education, research, consolidated reporting, and preemption of state law.

Physician Payments for Continuing Medical Education

In the proposed rule, CMS interpreted the nature of payment category for "direct compensation for serving as a faculty or as a speaker for a medical education program" broadly to include all instances in which manufacturers pay physicians to serve as speakers (whether or not they are speaking at continuing medical education programs).⁴¹ In the final regulations, however, CMS created two categories for speaker fees: one for accredited or certified continuing education programs and another for unaccredited or uncertified programs.⁴² CMS also clarified that a manufacturer does not need to report an indirect payment to a speaker at an accredited or certified continuing education program when (a) the program meets requirements and standards of accrediting and certifying bodies, (b) the manufacturer does not select the covered recipient as the speaker or provide the third party vendor with a list of individuals who should be considered as speakers, and (c) the manufacturer does not directly pay the covered recipient speaker.⁴³

³⁹ 42 C.F.R. § 403.912.

⁴⁰ 42 C.F.R. § 403.908(d).

⁴¹ 78 Fed. Reg. at 9,479.

⁴² 42 C.F.R. § 403.904(e)(2).

⁴³ 42 C.F.R. § 403.904(g).

Physician Payments for Research

The Sunshine Act treats payments by manufacturers for research purposes differently than other types of payments. The Act defines research as "a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health," which "encompasses basic and applied research and product development."⁴⁴ In the proposed regulations, CMS limited the research category to research activities conducted pursuant to both a written agreement and a research protocol. Backing off from this requirement in the final regulations, CMS determined that research only needs to be subject to a written agreement or a research protocol.⁴⁵

Each research payment must be reported as a single interaction in a separate template. For each payment, manufacturers must provide (1) the name of the entity or individual receiving the payment, (2) the total amount of the payment, (3) the name of the study, (4) the name of the related covered product (if applicable), and (5) the principal investigator. In addition, manufacturers may report the context of the research and the ClinicalTrials.gov identifier.⁴⁶

Payments or other transfers of value conducted under a research agreement and/or research protocol also may be eligible for delayed publication for up to four years.⁴⁷ In particular, a delay will be granted for payments made in connection with (1) research on or clinical investigations of new covered products or (2) research on new applications of existing covered products provided the research does not meet the definition of clinical investigation, which includes phases I through IV of clinical research for drugs and biological and approved trials for devices.⁴⁸ Although the research payments will be kept confidential, manufacturers must report the payments each year and indicate that they are eligible for delayed publication to prevent publication in that reporting year.⁴⁹

Consolidated Reporting

Manufacturers under common ownership may but are not required to file a consolidated report for all of the entities. If multiple entities submit a consolidated report, the report must identify each manufacturer covered by the report. Moreover, the consolidated report must specify on an individual payment level the entity that made each payment or other transfer of value. The Act instructs no single payment or other transfer of value should be reported by more than one entity in the report.⁵⁰

The manufacturer submitting the consolidated report must attest on behalf of itself and all other entities in the report.⁵¹ That manufacturer will be subject to the maximum amount of penalties (\$150,000 for failure to report and \$1,000,000 for knowing failure to report) for each entity included in the consolidated report.⁵²

⁴⁴ 42 C.F.R. § 403.902.

⁴⁵ 42 C.F.R. § 403.910(b).

⁴⁶ 42 C.F.R. § 403.904(f).

⁴⁷ 42 C.F.R. § 403.910(a).

⁴⁸ 78 Fed. Reg. at 9,505.

⁴⁹ 42 C.F.R. § 403.910(c).

⁵⁰ 42 C.F.R. § 403.908(d).

⁵¹ 42 C.F.R. § 403.908(e).

⁵² 78 Fed. Reg. at 9,507.

Preemption of State and Local Laws

The Sunshine Act preempts any state or local laws that require applicable manufacturers to report the same type of information concerning payments or other transfers of value to physicians and teaching hospitals.⁵³ But because of the delay in implementation, CMS encourages manufacturers to continue to comply with those laws until the Sunshine Act takes effect.⁵⁴ Moreover, even after implementation, the Act does not prohibit reporting that is required for public health or health oversight purposes.⁵⁵

CMS notes that most preemption determinations will be done on a case-by-case basis. In the final regulations, however, CMS clarified that state and local authorities may mandate reporting of (1) payments or other transfers of value that do not have to be reported to CMS (such as the statutory exclusions other than the \$10 minimum threshold) and (2) payments or other transfers of value to non-covered recipients or by non-applicable manufacturers.⁵⁶

CONCLUSION

In advance of the date for starting data collection (August 1, 2013), manufacturers and GPOs need to determine whether they are covered under the Act and, if so, develop a system of tracking reportable data. Some immediate action items for manufacturers and GPOs to review with their counsel include:

- Determine whether the company is subject to the Act based on its physical location or activities in the United States.
- Determine if its manufactured products include any covered drugs, devices, biologicals, or medical supplies.
- If subject to the Act, analyze financial data to determine whether gross revenue from covered products

in the preceding year is less than 10% of the company's total gross revenue. If so, only payments related to the covered products will be reportable. If not, all payments to covered recipients will need to be tracked and reported.

- Ascertain whether companies are commonly owned for purposes of the Act. If so, management needs to determine whether to file a separate or a consolidated report.
- Review existing payments to covered recipients to determine whether, for legal or policy reasons, some payments should be discontinued prior to August 1, 2013, to avoid governmental or public scrutiny.
- Review research agreements and protocols to determine what research payments may be eligible for delayed publication under the Act.
- Set up a system in advance of August 1, 2013, that will identify which employees will be responsible for tracking and reporting payments and other transfers of value and what steps will be taken to insure the accuracy of the information.
- Confirm that the company has the necessary information to permit reporting of payments to physicians (including specialties, National Provider Numbers, and state professional licenses).
- Obtain the list of teaching hospitals subject to the Act, which will be published annually, so that payments and other transfers of value to those hospitals can be tracked.
- Determine whether the company will submit an assumptions document to describe any methodologies or assumptions used for reporting data, including the classification of payments or other transfers of value.
- Review available records to determine if there are any reportable ownership or investment interests by physicians or their family members.

Due to heightened scrutiny that will be given physician compensation arrangements under the Sunshine Act, applicable manufacturers and GPOs should also implement comprehensive audits and reviews to ensure compliance with the Stark Law, the False Claims Act, the Anti-Kickback Statute, and other applicable federal and state laws.

⁵³ 42 C.F.R. § 403.914(a).

⁵⁴ 78 Fed. Reg. at 9,508.

⁵⁵ 42 C.F.R. § 403.914(b).

⁵⁶ 78 Fed. Reg. 9,509.

Attorneys, Industry Groups React to Sunshine Final Rule

Reacting to the final rule, some health care attorneys warned that it would be burdensome to implement, and questioned whether the public would find the information useful.

Kirk Nahra, an attorney with Wiley Rein in Washington, told BNA that the final rule will create significant burdens for various components of the health care industry.

“At the end of the day, there is a real question as to whether the positive value of this transparency (particularly given all of the other fraud-related restrictions on the kinds of payments involved here) is worth the additional burdens and potential risks for certain kinds of activities (e.g., research) that may benefit the health care system and patients overall,” Nahra said.

Nahra also said it was uncertain whether patients would find the transparency information useful “or whether most patients will know or care about the information.” He also said there was a concern that the information would be used primarily by lawyers seeking to challenge relationships between physicians and drug and device manufacturers.

“Unfortunately, the final rule’s burdens on industry creates a structure where the cost appears to far outweigh the potential benefit.”

—KIRK OGROSKY, ARNOLD & PORTER

Kirk Ogrosky, an attorney with Arnold & Porter in Washington, and former deputy chief of the Fraud Section in the Department of Justice’s Criminal Division, also told BNA that the burdens imposed by the final rule may exceed the benefits. “Unfortunately, the final rule’s burdens on industry creates a structure where the cost appears to far outweigh the potential benefit,” Ogrosky said.

Ogrosky said he was concerned that patients would not be fully capable of utilizing the transparency information in a productive manner and that the information might discourage patients from getting necessary treatments.

Kathleen McDermott, an attorney with Morgan, Lewis & Bockius LLP in Washington, acknowledged that there would be implementation challenges for both the health care industry and CMS, but said that overall the final rule would benefit the public. “These regulations will not cause patient harm,” McDermott said. “Transparency generally is a benefit to the public and patients.”

“There is always a question on whether the granularity of these disclosures really advances meaningful disclosure,” McDermott said. “Patients do not care about pizza and bagels and buffets any more than prosecutors do.”

Laurence Freedman, an attorney with Patton Boggs LLP in Washington, told BNA that the final rule was helpful in clarifying some of the transparency requirements facing the health care industry.

For example, he said that moving the implementation date to August 2013 “helps give industry time to review the rule, train compliance officers and their sales team, and prepare for data collection and reporting requirements.”

However, he said he was concerned about the lack of clarity surrounding reporting payments to teaching hospitals, noting that the final rule includes no list of teaching hospitals and no way for a manufacturer to determine if a client is part of a complex teaching hospital. “If this is not clarified,” he said, “this could have a detriment to research and patient care.”

Christopher White, general counsel and Advanced Medical Technology Association (AdvaMed) senior executive vice president, said the group was pleased CMS provided adequate time for companies to put in place the business systems necessary to ensure compliant reporting.

“Medical device companies are unique in that they must rely on physician experience and feedback to develop better treatments for patients,” White said.

“Disclosure should be limited to information that is helpful to patients in their decision-making process, should be available in a meaningful and easily-understood format that provides the appropriate context for patient education, must not be unnecessarily burdensome, should not compromise proprietary information, and should preserve arrangements with physicians beneficial to patients and continued medical innovation,” he added.

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