

CMS Requests Comments on the Dispute Resolution Process Associated with the Physician Payment Sunshine Act

by Robert E. Wanerman, Natasha F. Thoren, Daniel G. Gottlieb, and Benjamin M. Zegarelli

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On May 5, 2014, the Centers for Medicare & Medicaid Services (“CMS”) announced an opportunity to submit comments on the dispute resolution and correction procedures proposed in the final rule on the Open Payments reporting system,¹ which CMS created under Section 6002 of the Affordable Care Act, typically referred to as the “Sunshine Act.”² Although CMS had previously solicited comments on dispute resolution and correction when it published the final Sunshine Act regulations on February 8, 2013,³ CMS recognized that additional questions and “sensitivities” still surround the dispute resolution and correction process and thought it appropriate to provide an additional chance to submit comments focused on that process. **All interested parties must submit comments to CMS by 5 p.m. (EDT) on June 2, 2014.** CMS will accept comments electronically at <http://www.regulations.gov>, or by mail, email, or facsimile.⁴ Comments will be made publicly available. We urge all interested parties to submit comments to this important regulation.

For an overview of the Sunshine Act generally, see the Epstein Becker Green health reform alert titled [“Federal Transparency Is Now a Reality: Challenges and Opportunities for Pharma, Devices, and PBMs.”](#) Additionally, see the Epstein Becker Green health reform alert titled [“CMS Issues Final Regulations on Federal ‘Sunshine’ Law for Manufacturers and GPOs”](#) for an overview of the Sunshine Act regulations.

¹ 79 Fed. Reg. 25,596 (May 5, 2014).

² The Open Payments reporting system is an online portal on CMS’s website allowing pharmaceutical, biologic, and medical device manufacturers to disclose industry-physician financial relationships. See *Open Payments*, CMS.gov, <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html> (last updated May 6, 2014).

³ 78 Fed. Reg. 9458 (Feb. 8, 2013).

⁴ *The Federal Register* notice provides information regarding the submission of comments by regular mail, express mail, email, and facsimile.

Open Payments Dispute Resolution and Correction

CMS's Sunshine Act regulations stated that applicable manufacturers, applicable group purchasing organizations ("GPOs"), covered recipients,⁵ and physician owners or investors would have an opportunity to review Open Payments reports, which CMS requires applicable manufacturers and GPOs to submit annually.⁶ The Open Payments reports disclose transfers of value to covered recipients, or ownership of or investment in the reporting entity by a physician or a physician's immediate family member. CMS will notify the individuals or entities named in these reports so that they may either certify or dispute the reported information. From the time of notice, covered recipients and physician owners or investors must have at least 45 days to review and submit corrections to the information before CMS publishes the report on its website.

Any covered recipient or physician owner or investor that disagrees with the report may initiate a dispute that will be sent automatically to the applicable manufacturer or GPO. A dispute may be initiated any time after the review period begins but before the end of the calendar year. If the parties reach a resolution and submit a correction to CMS any time within 60 days after the review period begins, CMS will publish the corrected information online with the other certified reports. Disputes that remain unresolved beyond the 60-day period may still be resolved by the parties, but CMS will publish the information as originally submitted with a notation that the report is disputed. If the dispute is resolved later, CMS will publish the corrected information after the subsequent Open Payments reporting cycle.

During the review period, if an applicable manufacturer or GPO discovers an error or omission in its report, it must submit corrected information to CMS immediately after confirming the error or omission. CMS will then notify the affected covered recipient or physician owner or investor, who must then certify (or re-certify, if the individual or entity has already done so) the information or initiate a dispute.

Key Considerations Regarding Solicitation of Comments

The Open Payments dispute resolution and correction process is a critical tool for physicians and teaching hospitals because Open Payment reports will be publicly available online, and any false or inaccurate information may harm the physician's or teaching hospital's reputation. This dispute resolution process is also important for applicable manufacturers and GPOs, because they will have an opportunity to correct any inadvertent errors or omissions. Therefore, affected entities should consider submitting comments to ensure that the process will be reasonably accessible and that all parties are given ample opportunity to correct any inaccuracies prior to the information becoming public.

⁵ "Covered recipient means—(1) Any physician, except for a physician who is a bona fide employee of the applicable manufacturer that is reporting the payment; or (2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the [Social Security] Act during the last calendar year for which such information is available." *Id.* § 403.902.

⁶ 42 C.F.R. § 403.908 (2013).

In particular, teaching hospitals and physicians have indicated to us that they are concerned about how research payments may be presented.⁷ To reduce the likelihood of disputes going forward, applicable manufacturers may wish to provide more content in Open Payments reports regarding these particular payments, and CMS should evaluate how to characterize and display such payments. These considerations will promote implementation of a dispute resolution process utilized for true disputes, rather than disputes about transfer of value characterization.

CMS recently announced that physicians and teaching hospitals will be able to register in the Open Payments reporting system beginning on June 1, 2014. However, these entities will not be able to review information or initiate disputes until sometime in the third quarter of 2014. Since CMS expects data submission will be complete on August 1, and initial aggregate data may be available to the public as early as September 30, physicians and teaching hospitals may be left with little time (possibly less than 45 days) to review and, if necessary, dispute reported information pertaining to them.

In an effort to ease the dispute resolution process, some manufacturers have implemented their own review and dispute process, enabling physicians and teaching hospitals to view the data that the manufacturer plans to report prior to the reporting deadline. However, not all affected physicians or teaching hospitals will be afforded such an opportunity to preview manufacturer or GPO Open Payments reports.

Given this uncertainty, all affected manufacturers, GPOs, physicians, and teaching hospitals should consider submitting comments on these procedures to ensure that CMS recognizes the importance of providing access to the Open Payments system as soon as possible.

Epstein Becker Green is available to assist with drafting and submitting comments to CMS.

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*This Client Alert was authored by **Robert E. Wanerman**, **Natasha F. Thoren**, **Daniel G. Gottlieb**, and **Benjamin M. Zegarelli**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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⁷ Teaching hospitals and physicians engaged in industry-supported research activities are concerned that the reported lump payment associated with various names (e.g., Research – \$20,000 for Teaching Hospital A and Principal Investigators B, C, and D) may not clearly communicate to the public who actually received the transfer of value or the value received. The potential lack of clarity regarding these payments may lead to negative and inaccurate inferences regarding these payments and their recipients.

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