



Porzio Compliance Alert

December 19, 2011

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CMS Publishes Draft Regulations to Implement the Sunshine Act

By Christine N. Bradshaw, Esq.

On December 14, 2011, the Centers for Medicare & Medicaid Services ("CMS") issued a Notice of Proposed Rulemaking, announcing the publication of draft rules to implement section 6002 of the Patient Protection and Affordable Care Act, commonly known as the Sunshine Act. The much-anticipated regulations, which the Sunshine Act required the Department of Health and Human Services to provide by October 1, 2011, were published in the Federal Register today, December 19, 2011.

The draft rule itself is relatively concise; CMS includes, however, a lengthy preamble that provides significant commentary on and explanation of the proposed definitions and requirements set forth in the draft rule. For some industry members, this guidance will serve as the impetus to begin preparations for capturing and reporting payments. For others, the proposed rules will serve as a roadmap for updating existing data capture systems and reporting tools. CMS's proposed rule confirms that nationwide disclosure requirements are here to stay, and now is the time to prepare, both from a systems and processes perspective.

This Compliance Alert provides an overview of the main areas of commentary provided by CMS, as well as the preamble's more noteworthy points.

Timing

CMS proposes to delay the data collection commencement date. In its preamble, CMS acknowledges that final regulations will not be issued in time for applicable manufacturers and group purchasing organizations ("GPOs") to receive the requirements before the statutorily defined data collection commencement date of January 1, 2012. CMS proposes that data collection begin 90 days from the publication of the final rule, and requests comments on whether 90 days is sufficient for manufacturers and GPOs to comply with the rule's requirements. With the comment period open until mid-February 2012, publication of the final rule and the 90-day preparation period would delay the data collection commencement date until late Spring 2012 at the earliest.

Reports

The preamble specifies that the payment transparency and ownership reports be handled separately. Applicable manufacturers and GPOs would submit data electronically in a comma-separated value ("CSV") file format. A sample template of the report format accompanies the

proposed rule. Additionally, the chief executive officer, chief financial officer, or chief compliance officer from each entity submitting a report will be required to certify that the data is true, correct, and complete.

Research Payments

The preamble to the proposed rule provides insight into the disclosure requirements related to research payments, including clinical trial payments, but reporting entities will require further clarification. CMS proposes to identify research payments as direct or indirect. Direct research payments would be those made by an applicable manufacturer to a physician or teaching hospital. Indirect research payments would be those provided to a clinic or other non-teaching hospital institution, either by the applicable manufacturer itself or through a clinical research organization ("CRO"). CMS further proposes that indirect payments be reported under the names of the physicians who serve as principal investigators ("PIs") on the research projects. The entity receiving payment would also be listed with the payment. CMS suggests that the amount reported, whether a direct or indirect payment, be the full amount paid and not a portion of the total or a broken-out amount intended for the PI(s). CMS requests feedback from interested parties on whether this approach is reasonable, and whether other types of research payments require clarification.

Beyond reporting requirements, the Sunshine Act requires that CMS delay the publication of research payments until after the earlier of FDA approval, licensure or clearance of the underlying product, or four years after the payment date. CMS proposes that applicable manufacturers and GPOs indicate in disclosure reports whether a particular payment's publication should be delayed. Reporting entities would resubmit these payments each year, again noting the need for a delay in publication. In the report filing following approval, licensure, or clearance, the reporting entity would indicate that the payment is no longer eligible for delayed publication. For payments occurring more than four years ago, CMS would automatically publish the payments regardless of whether a delay is indicated on the filing.

Other Noteworthy Provisions

Among others, the following are noteworthy comments provided by CMS in the preamble to the proposed rule:

- A manufacturer becomes an "applicable manufacturer" when it has one drug, device, biological, or medical supply available for coverage. Upon becoming an "applicable manufacturer," the company must disclose all payments or other transfers of value made to a covered recipient regardless of whether the payment or transfer relates to a covered drug, device, biological, or medical supply.
- Companies that manufacture only over-the-counter drugs or biologicals or only Class I or certain Class II medical devices or supplies are not "applicable manufacturers."
- Under the Sunshine Act, companies under "common ownership" with an applicable manufacturer are also subject to the law's requirements. CMS's draft regulations propose that common ownership exists when any person or entity directly or indirectly owns any portion of two or more entities. This definition would include, but not be limited to, parent companies and subsidiaries and brother/sister corporations. CMS is also considering limiting the definition to any owner who has at least a 5% stake in two or more entities. Under the proposed rule, certain scenarios would require the various companies to report separately, despite having common ownership; in other situations, the companies would be permitted to choose whether to report together or separately.

- CMS will provide a list of institutions it considers to be "teaching hospitals."
- Applicable manufacturers and GPOs should use the information available in the National Plan & Provider Enumeration System ("NPDES") to report names, addresses, specialties and National Provider Identifier numbers of physician covered recipients.
- CMS provides a proposed methodology for calculating food and beverages amounts, but is soliciting comments on other "equitable, but not overly burdensome," methods. Food and beverage provided at conferences and similar events would be exempt from disclosure.
- Payments and other transfers of value of less than \$10 are excluded from reporting requirements, except when the total of all payments to a covered recipient exceeds \$100. CMS proposes that when all payments must be disclosed, payments or transfers of less than \$10 that fall into the same Nature category be aggregated and reported as a single disclosure. The preamble provides two examples to clarify this proposed methodology.
- Applicable manufacturers and GPOs must retain all contracts, records, documents, and other evidence related to disclosure requirements for at least five years from the date the payment or other transfer of value is published on the public website.

Comments

Interested parties may submit comments until 5 p.m. Eastern Standard Time on February 17, 2012. All comments should reference file code CMS-5060-P.

Electronic submissions: www.regulations.gov; follow the "Submit a comment" instructions.

Regular mail submissions: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-5060-P, PO Box 8013, Baltimore, MD 21244-8013. Comments must arrive by the February 17th deadline.

Express/overnight mail submissions: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-5060-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Hand/courier submissions: In Washington, D.C., Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, D.C. 20201; in Baltimore, MD, please call to schedule delivery - (410) 786-1066, Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

All industry members should consider taking a proactive position with respect to these regulations. CMS appears interested in industry comments, and in providing reasonable requirements that are not overly onerous for applicable manufacturers and GPOs. CMS will post all comments received on the www.regulations.gov website.

Porzio Compliance Alerts are a complimentary service to our clients, colleagues and friends, which provide cutting edge analyses and insight into the legal and regulatory challenges confronting today's life sciences industry. The Alerts provide general information only and are not intended to be comprehensive on the subject addressed or to provide legal advice.

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