



GLOBAL LIFE SCIENCES: US-HEALTHCARE UPDATE

CMS Seeks Comments on its Long-Awaited Sunshine Act Proposed Rule

The Centers for Medicare & Medicaid Services (“CMS” or the “Agency”) recently published a proposed rule (the “Proposed Rule”) implementing the Physician Payment Sunshine Act (section 6002 of the Affordable Care Act). Although the Act requires reporting of payments that are made beginning January 1, 2012, CMS purports to delay the need to begin tracking payments until after the final rule is promulgated. Further, the Proposed Rule answers some questions about manufacturer tracking and reporting responsibilities, but it leaves scores of other questions unanswered. Comments on the Proposed Rule will be accepted until February 17, 2012.

Significant issues upon which CMS is actively soliciting comment include the following:

- **Delayed Data Tracking.** CMS is seeking comments from stakeholders as to the feasibility of collecting the required data for a portion of calendar year 2012 and reporting this information to CMS by the initial statutory deadline of March 31, 2013. CMS proposes a 90-day “preparation period,” following the issuance of the final rule to afford manufacturers additional time to comply with the Act’s data collection requirements. CMS also seeks input on the specific operational challenges manufacturers may face in establishing data collection and reporting mechanisms.
- **Submission of Assumptions Letters.** CMS seeks comment on its proposal to permit applicable manufacturers to submit assumptions letters with their annual reporting form to describe the manufacturer’s practices with regard to categorizing the nature of the various payments and transfers of value it reports. In particular, CMS seeks comment on whether the submission of assumptions letters should be mandatory.
- **Definition of Applicable Manufacturer.** CMS is soliciting comments on its proposal that any manufacturer that meets the definition of applicable manufacturer by selling or distributing in the United States at least one covered product is considered an applicable manufacturer, even though it may also manufacture non-covered products. Under this proposal, CMS would require that all payments or transfers of value made by an applicable manufacturer to a covered recipient be reported regardless of whether the particular payment or other transfer of value is associated with a covered product.
- **Definition of Common Ownership.** With potentially significant implications for entities that have operations, affiliates, or partners outside of the United States, CMS is considering two alternative definitions of the term “common ownership” as it is used in the definition of “applicable manufacturer.” Depending on the relationships among affiliated entities, a manufacturer may be required to submit separate annual reports for each affiliated entity or may be permitted to submit combined reports.

This **Sidley update** has been prepared by Sidley Austin LLP for informational purposes only and does not constitute legal advice. This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship. Readers should not act upon this without seeking advice from professional advisers.

Attorney Advertising - For purposes of compliance with New York State Bar rules, our headquarters are Sidley Austin LLP, 787 Seventh Avenue, New York, NY 10019, 212.839.5300 and One South Dearborn, Chicago, IL 60603, 312.853.7000.

Prior results do not guarantee a similar outcome.

- **Definition of Covered Drug, Device, Biological, or Medical Supply.** CMS solicits comment on its proposals to exclude over-the-counter drugs and biologicals from the reporting requirements (unless the manufacturer is otherwise an applicable manufacturer, as discussed above). CMS also seeks comment on its proposal to limit covered devices and medical supplies to those that, by law, require premarket approval by or notification to the Food and Drug Administration (unless the manufacturer is otherwise an applicable manufacturer, as discussed above).
- **Date of Payment.** CMS seeks comment on whether applicable manufacturers should be able to use their discretion in reporting payments provided over multiple dates related to a single activity as a single item (for example, a consulting arrangement), or to report each individual payment as a separate line item. CMS also seeks input on whether manufacturers should be required to report multiple payments in a consistent manner.
- **Nature of Payment.** CMS seeks comment on its proposal to require manufacturers to report each segregable payment associated with a particular activity (for example, consulting fees, consultant meals, and consultant travel). CMS also solicits comments on an alternative approach that would permit applicable manufacturers to report lump sum payments for an activity that is associated with multiple segregable categories.
- **Payments Related to Multiple Products.** CMS is seeking comments on its proposal to require applicable manufacturers to report only one product as related to any particular payment or transfer of value, regardless of whether multiple products may be related to such payment or transfer of value. CMS is also soliciting comments on an alternative proposal that would permit applicable manufacturers to attribute multiple products to a single payment or transfer of value.
- **Reporting Food and Beverages.** CMS proposes that in instances where an applicable manufacturer provides a meal in a group setting (*e.g.*, buffet-style food in a physician's office), the manufacturer should report the cost per covered recipient receiving the meal, even if the covered recipient is not actually partaking in the meal. Acknowledging that such an approach may be difficult for large group practices, CMS is soliciting comments on whether this approach is feasible, or whether an alternative approach should be adopted.
- **Reporting Educational Materials.** CMS seeks input on whether the educational material exclusion should extend to materials, such as textbooks, provided by applicable manufacturers to educate covered recipients themselves.
- **Reporting Research.**
 - CMS proposes that research payments must be reported in a timely manner as with all other payments covered by the Act, but that CMS will delay publication of research payments to covered recipients for services in connection with research on, or development of new covered products, as well as new applications of existing covered products. In an alternative proposal, CMS proposes limiting delayed publication for those payments in connection with clinical investigations for new covered products only.
 - CMS seeks input on the definitions for "research," "development" and "clinical investigations." CMS also solicits comments on its proposal to classify research payments as direct or indirect depending on whether the payment is made directly by a manufacturer (or a clinical research organization ("CRO") on the manufacturer's behalf) to a covered recipient, or indirectly by a manufacturer or its CRO to an entity that then makes the payment to a covered physician.
 - CMS also seeks comment on whether its proposed definition of "research" or another payment category would cover payments or other transfers of value to covered recipients for research-related activities (examples given in the Proposed Rule include post-marketing research, studies without research protocols, or research or studies not conducted pursuant to a written contract). For those providing comments who indicate that the foregoing types of research-related activities are not covered by an existing proposed payment

category, CMS asks whether the proposed definition of research should be broadened, or if another payment category should be added to address such research related activities.

- **Reporting Compensation for Speaking Arrangements.** CMS seeks comments on its proposal to broaden the payment category for direct compensation for serving as a faculty member or speaker for a medical education program to encompass all instances where the applicable manufacturer may pay a covered physician to serve as a speaker.
- **Indirect Payments through a Third Party.** The Act excludes indirect payments made by an applicable manufacturer to a covered recipient through a third party when the applicable manufacturer is unaware of the covered recipient's identity. CMS proposes to interpret the awareness standard as when an applicable manufacturer has "actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient."
- **Report Submission and Correction.** CMS has expressed interest in receiving comments on its proposed procedure for the submission of payment and ownership and investment interest data, while stating that it understands the need for flexibility in the reporting process. Topics of particular interest include whether covered recipients should be afforded the opportunity to review and correct data prior to submission, whether a senior executive would be required to sign an attestation that no reports need to be filed and / or attest to the accuracy of any reports that are filed, whether applicable manufacturers should have the opportunity to review and correct data prior to publication, the adequacy of the proposed report template and spreadsheet, providing covered recipients and physician owners and investors access to information reported about them through a secure website or through mail or email notice in advance of the publication date, establishing a process for reviewing data that is disputed by the covered recipient or physician owner or investor, and amending previously reported information.
- **Recordkeeping.** CMS seeks comments on its proposal that manufacturers maintain all books, records, documents, and other materials for a period of at least five years from the date of the payment, indicating that the costs should be negligible for electronic recordkeeping.

If you have any questions regarding this update, please contact the Sidley lawyer with whom you usually work.

Healthcare Practice

Our Healthcare Practice represents participants in all facets of the healthcare industry, including pharmaceutical, biotech and device companies, DME suppliers, hospitals, skilled nursing facilities, physician-owned companies, professional associations and research institutions. Our lawyers combine a strong background in the complexities of healthcare financing and delivery, including coding, reimbursement, and coverage issues, privacy and security, trade regulation, and competition. We have extensive experience representing clients on enforcement and regulatory matters before federal and state enforcement agencies.

For further information on the Healthcare Practice, please contact:

Paul E. Kalb, M.D.
+1.202.736.8050
pkalb@sidley.com

Sidley Global Life Sciences Practice

On three continents, Sidley's Global Life Sciences Practice team offers coordinated cross-border and national advice on Food, Drug and Medical Device Regulatory, Life Sciences Enforcement, Litigation and Compliance, Healthcare Regulatory, Products Liability, Intellectual Property, Corporate and Technology Transactions, Securities and Corporate Finance, International Trade and Arbitration, FCPA/Anti-Corruption, Antitrust/Competition, Environmental/Nanotechnology.

Globally rated as one of the top life sciences practices, our team includes former senior government officials, medical doctors and leaders in various life sciences fields.

For further information on the Global Life Sciences Practice, please contact:

Scott Bass James C. Stansel
+1.202.736.8684 +1.202.736.8092

+1.212.839.5613
sbass@sidley.com jstansel@sidley.com

To receive future copies of this and other Sidley updates via email, please sign up at www.sidley.com/subscribe.

BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG LONDON LOS ANGELES NEW YORK
PALO ALTO SAN FRANCISCO SHANGHAI SINGAPORE SYDNEY TOKYO WASHINGTON, D.C.

www.sidley.com

Sidley Austin LLP, a Delaware limited liability partnership which operates at the firm's offices other than Chicago, London, Hong Kong, Singapore and Sydney, is affiliated with other partnerships, including Sidley Austin LLP, an Illinois limited liability partnership (Chicago); Sidley Austin LLP, a separate Delaware limited liability partnership (London); Sidley Austin LLP, a separate Delaware limited liability partnership (Singapore); Sidley Austin, a New York general partnership (Hong Kong); Sidley Austin, a Delaware general partnership of registered foreign lawyers restricted to practicing foreign law (Sydney); and Sidley Austin Nishikawa Foreign Law Joint Enterprise (Tokyo). The affiliated partnerships are referred to herein collectively as Sidley Austin, Sidley or the firm.

