LEONARD STREET AND DEINARD

SUMMARY OF KEY FEATURES OF FINAL SUNSHINE ACT REGULATIONS

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On Friday, February 1, 2013, the Centers for Medicare & Medicaid Services (CMS) released the long-awaited Sunshine Act regulations. The Sunshine Act requires disclosure of payments and other value transfers (Payments) from drug and device, biological or medical supply manufacturers to physicians or teaching hospitals, and disclosure of certain ownership and investment interests in manufacturers and group purchasing organizations (GPOs). Its goal is to implement a national, Internet-based disclosure program for Payments and ownership or investment interests, to promote transparency and decrease the potential for conflicts of interest. The first reports from mandated reporters are due to CMS by March 31, 2014, and must reflect payments made on or after August 1, 2013, through December 31, 2013. Note that registration by mandated reporters is required prior to reporting (within 90 days of the end of the reporting period).

The regulations contain detailed guidance related to who must report and what must be reported, along with guidance on the mechanisms of reporting, including Payment classification and attribution rules. We have listed below some of the key features of the Payment reporting provisions applicable to manufacturers contained in the new regulations, together with some of the responses they engender.

1 **Who Qualifies as an "Applicable Manufacturer"?** *The definition of applicable manufacturer is very broad, and it includes title-taking distributors. It excludes, however, entities that manufacture product solely for internal use or for use by their patients (such as hospitals) and distributors that do not take title. There are also exclusions for some contract manufacturers and separate operating divisions of applicable manufacturers that do not manufacture covered product.*

Only "applicable manufacturers" of a drug, device, biological or medical supply covered by a federal health care program (including a state CHIP plan) are required to report payments. Applicable manufacturers include manufacturers engaged in manufacturing activities (i.e., production, preparation, propagation, compounding or conversion) and entities under common ownership with such an entity, which provide assistance or support to such entity with respect to the manufacturing activities, or with the promotional activities related to the covered product (i.e., marketing, promotion, sale or distribution). The Federal Register commentary indicates that entities that hold the FDA clearance for the product and entities involved in distribution of covered product may all qualify as applicable manufacturers, even absent common ownership. However, hospitals, pharmacies and laboratories that produce or manufacture products solely for their own use or use by their patients are not by reason of that activity "applicable manufacturers". Title-taking distributors and wholesalers are applicable manufacturers, whereas wholesalers or distributors that do not take title to a covered product will not be subject to the reporting requirements solely because they distribute that product. A contract manufacturer is an applicable manufacturer, but may be exempt from the general reporting obligation and, instead, be required to report only those

Payments that relate to the covered product it manufacturers and not payments related to other product. Also, payments made by separate operating divisions of applicable manufacturers that do not manufacture covered product may be exempt.

Most critically, it will be necessary for all parties involved in the manufacture or distribution of health care products to assess whether the Sunshine Act (as interpreted under the rules) is applicable to them. Given the broad definition of applicable manufacturer (including the very low threshold for common ownership and the ambiguities surrounding what constitutes a covered product [see section 3]), some unsuspecting entities may be captured in this net. Once an entity has determined that the Sunshine Act is applicable, reporting in accordance with the Act and regulations is mandatory. Note that the provisions exempting reporting by discrete operating divisions in certain circumstances may suggest that some manufacturers should consider reorganizing their operations to isolate non-covered product from covered product.

2 **Identify Payments to Residents and Manufacturer Employees.** *Payments to physician-residents and bona fide manufacturer employees need not be reported. The traditional Internal Revenue Code test will be used to determine whether someone is a manufacturer employee.*

Payments are reportable only if they are made to "covered recipients." Covered recipients are physicians and teaching hospitals. The term physician is defined to encompass doctors of medicine and osteopathy, dentists, podiatrists, optometrists and chiropractors who are legally authorized to practice by the jurisdiction in which they practice. However, Payments to residents need not be reported. Also, Payments to bona fide employees of the manufacturer (defined with reference to the Internal Revenue Code standard) are excluded.

In response to these rules, reporting entities will want to adjust their payee lists to exclude residents from the report to CMS, and to establish a process for ensuring residents are included on the Payment list after they matriculate. In addition, reporting entities will want to develop robust processes for ensuring that only bona fide employees are excluded under the employment exception.

3 **What Is "Covered Product"?** *Together with product reimbursed separately (e.g. under a fee schedule), covered product is defined broadly to include product reimbursed under bundled payments. Thus, at least in some circumstances, it may be difficult to identify whether a particular product will be deemed to be covered.*

Covered product is defined to mean a drug, device, biological or medical supply for which payment is available under Medicare, Medicaid or CHIP and which requires a prescription to be dispensed (in the case of a drug or biological) or premarket approval by or notification to the FDA (in the case of a device or a medical supply that is a device). A manufacturer's compliance obligation kicks in 180 days after its first product is covered. Products are "covered" if they are reimbursed separately or as part of a bundled payment. The term "bundled payment" means payments made under the IPPS, OPPS and other prospective payment systems.

In response to this approach, entities will have to determine whether or not they manufacture covered products. This determination will not always be easy, in that outside of product that is separately reimbursed or product that is integral to a procedure and thus is described by a covered code, it may be difficult to determine if it is covered product. For example, it is difficult to know if external defibrillators are considered covered product, in that they are clearly an element

of general overhead for inpatient hospitals but are not normally used as part of a procedure for which reimbursement is available. For a single product contract manufacturer, in particular, such a determination may be critical, as it will determine whether or not it has any reporting obligations.

4 **Corporate Relationships Triggering Reporting Obligations.** *A 5% (direct or indirect) common interest can transform an entity that provides assistance and support to an applicable manufacturer into an applicable manufacturer with independent reporting obligations. It is not entirely clear what types of assistance and support will trigger this classification.*

Common ownership is defined to include any circumstance where "the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities." "Assistance and support" is defined as activities that are "necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product." Whether or not a particular activity will be deemed to be necessary or integral is not entirely clear. The government explains that producing the active ingredient for a covered drug and providing it to the applicable manufacturer would be considered necessary to the manufacturing of that product, since the applicable manufacturer could not produce the drug without the active ingredient. However, the provision of human resources administrative functions would not qualify as necessary or integral, since human resources functions are not directly involved with any of the named manufacturing processes. it strikes us that many activities could be seen as falling between these two examples. This ambiguity, coupled with the fact that it may be very difficult to identify common ownership, makes this feature of the regulatory scheme particularly burdensome. Suffice it to say that any entity that thinks that it may be involved in providing "assistance and support" to a manufacturer should consider making an inquiry into the possibility of common ownership.

5 **Tracking Indirect Payments.** *Indirect manufacturer Payments made through a distributor or wholesaler are reportable.*

An applicable manufacturer that manufactures product and transfers title to a distributor or wholesaler does not need to report payments or other transfers of value made by the distributor or wholesaler to covered recipients. Rather, these payments must be reported by the distributor or wholesaler (see Section 1 above). However, Payments related to the product made by the manufacturer either independently from the distributor or wholesaler, or through the distributor or wholesaler, are reportable by the manufacturer.

Reporters will have to develop standards for determining, and processes for tracking, what payments to third parties will be deemed to be Payments by the manufacturer and, therefore, reportable.

6 **Valuation of Payments.** *Payments are to be reported at their market value (and not adjusted to their value to the particular recipient).*

No specific valuation methodology is required. In response, reporters will want to develop robust and consistent valuation methodologies.

7 **Characterizing What Is Reportable.** *Manufacturers must report "payments and other transfers of value" (which is defined to include simply "a transfer of anything of value") provided to a covered*

recipient or provided to another party at the request or designated on behalf of a covered recipient.

This standard will require that manufacturers develop systems to facilitate attribution to the applicable covered recipient of disbursements made to payees that are not covered recipients. Notably, it does not appear that expenditures that result in incidental value to a covered recipient—but that are not made to the covered recipient, nor provided to another party at the request, or designated on behalf, of a recipient—are reportable.

As to specific types of payments:

All payments are to be classified by form and nature. While the "other" category has been eliminated from the nature list, CMS cautions that the absence of a category does not negate the need to report the payments.

Payments made to a charity but that represent remuneration for services (directed by the contractor to the charity) are to be classified as consulting fees and not as charitable contributions.

With respect to meals in a group setting (other than buffet meals provided at conferences or other similar large-scale settings), the final rules (in contrast to the proposed rules) direct the reporting of "the per person cost (not the per covered recipient cost) of the food or beverage for each covered recipient who actually partakes in the meals (that is, actually ate or drank a portion of the offerings)." Food and beverage provided at conferences, or in other settings where it would be difficult to establish the identities of people partaking in the food, need not to be reported.

Similarly, gifts that are under $10 in value (such as pens and note pads) that are provided at large-scale conferences (and similar large-scale events) will be exempted from the reporting requirements, so they need not be tracked for aggregation purposes. Note also that the exclusion threshold for small gifts remains at $10 (for a single item) and $100 (in aggregate, annually) per covered recipient. These exclusions will be increased in future years.

A great deal of attention is paid to the reporting of research-related payments. Research is broadly defined, and the final rules have dispensed with the requirement of a protocol to qualify. Research payments will be reported separately with a very granular approach that is intended to more accurately identify the beneficiaries of the payment than did the approach taken in the proposed regulations. The commentary notes that additional guidance on reporting of research payments will be forthcoming. Research payments on new products (including new generic drugs) are granted a delay in reporting, but payments related to research on new applications of existing products will be granted a delay only if the research is not a "clinical investigation."

The exclusions (those payments that need not be reported) have been further developed and rationalized. Interesting features include:

- The exclusion for short-term (90 days per year) equipment loans now includes supplies needed for the loan period and covers both covered product and product under development.
- The warranty exclusion has been expanded to include extended warranties, service and maintenance agreements, and replacement products in the case of a product recall.
- The exclusion for indirect payments made through third parities is not available if the manufacturer knows or should know the identity of the party at the time during the reporting

year or the second quarter of the subsequent year following the transfer of the payment from the third party to the covered recipient. Note, however, that a payment is not considered an indirect payment unless the manufacturer directed the use of the payment to pay a covered recipient (even though no particular recipient need be designated). Further, indirect payments to presenters at accredited CME programs are largely excepted from the reporting requirement, so long as the manufacturer does not suggest the speakers.

8 **Avoiding Disputes with Recipients.** *There will be no mandatory pre-submission review process by which recipients may contest a report, although ongoing reporting to recipients is recommended. CMS will not adjudicate post-submission disputes.*

Covered recipients may register for access prior to public release of the data, and there will be a mechanism for registered recipients to dispute the reported data with the reporter. Reports that are disputed and that are not resolved by the time of final public release of the data will be marked as contested. Once a dispute is resolved, the manufacturer is obliged to submit any required updates or corrections and to attest to the veracity of the submission. The correction of an error during the stipulated correction period should not draw penalties, so long as the original submission was in good faith.

Manufacturers may want to develop a program for vetting data prior to submission, in order to promote good will among covered recipients. They will also need to develop a protocol for timely resolving, and reporting the resolution of, disputes.

9 **Reported Data Attestations Required.** *An officer-level attestation (CEO, CFO, CCO or other officer) as to the accuracy of the data will be required, and records related to the reports must be maintained for five years.*

This feature has implications related to what level of due diligence will be required in order for a person to be willing and able to make the required attestation. It may also militate against consolidated reports. Supporting data must be maintained for a period of five years.

Manufacturers will need to establish policies and protocols for assuring the accuracy of data and for maintaining the records that support their conclusions and reports.

10 **Reporting Ownership & Investment Interests.** *The regulations also provide guidance to manufacturers and GPOs related to reporting ownership and investment interests.*

The section of the Sunshine Act dealing with reporting of physician ownership and investment interests is applicable to both manufacturers and GPOs. GPOs are defined broadly to include both physician-owned distributors (PODs) and traditional GPOs. Specifically, the definition includes any entity that: "(1) operates in the United States; and (2) 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."*