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On December 19, 2011, the Centers for Medicare and Medicaid ("CMS") published a **proposed rule** implementing the "sunshine provisions" in Section 6002 of the Patient Protection and Affordable Care Act ("PPACA"). These provisions require (i) applicable manufacturers to report annually to CMS certain payments or transfers of value provided to physicians or teaching hospitals and (ii) applicable manufacturers and applicable GPOs to report annually certain physician ownership and investment interests. The primary effect of the sunshine provisions is to require many life sciences companies to track and make known most of their financial arrangements with physicians. The proposed rule establishes procedures for data collection and reporting to CMS and for publishing by CMS. CMS will publish a final rule in the months ahead, and comments on the proposed rule are due on February 17, 2011. Thus, the rule is subject to change, particularly in those areas in which CMS is seeking comments, although persons may submit comments on any aspect of the proposed rule. ***We have compiled CMS' requests for comment in the proposed rule***.

Overview of the PPACA's sunshine provisions

Applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program are required to report certain payments and transfers of value under the PPACA's sunshine provisions. The proposed rule defines an "applicable manufacturer" as an entity that is:

1. Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or
2. Under common ownership with an entity in [the above] paragraph, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States.

Applicable manufacturers and applicable GPOs must separately report ownership and investment interests held by physicians or their immediate family members in these entities, as well as transfers of value to such physician owner or investors. The proposed rule defines an "ownership or investment interest" to be either direct or indirect and to include, among other things, "stock, stock options (other than those received as compensation, until they are exercised), partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue." Interests in a publicly traded security or mutual fund are excluded, as are securities received as compensation until exercised or converted, and unsecured loans subordinate to a credit facility. The PPACA's sunshine provisions define an applicable GPO as one that "purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply, which is operating in the United States, or in a territory, commonwealth or possession of the United States." The proposed rule clarifies that applicable GPOs include "entities that purchase covered drugs, devices, biological, and medical supplies for resale or distribution to groups of individuals or entities … [such as] physician owned distributors (PODs) of covered drugs, devices, biological, and medical supplies."

Applicable manufacturers must report the form and nature of payments to covered recipients, which include physicians and teaching hospitals. Thirteen types of payments and other transfers of value are excluded from the reporting obligation. CMS will create an electronic system for entities to register and report. Civil monetary penalties under the PPACA range from $1,000-$10,000 for each failure to report the information required by the sunshine provisions (including payments or transfers of value and ownership or

investment interests, as applicable), up to $150,000 per annual submission, and from $10,000-$100,000 up to $1 million per annual submission for each "knowing failure to report." The proposed rule includes and seeks comments on factors to be considered in determining the amount of a penalty. Of course, potential costs associated with the sunshine provisions go beyond the statutory penalties; reported information, as well as failure to report fully or accurately, may prompt government scrutiny of manufacturers, GPOs, and providers, among others, for violations of health care laws. Independent of the PPACA's sunshine provisions, laws in several states regulate drug or drug and medical device manufacturers' marketing behavior and/or disclosure of expenditures.

New requirements

The proposed rule includes a number of new requirements not described in the PPACA's sunshine provisions. The key requirements in the proposed rule include:

- The ability for manufacturers to provide CMS with the assumptions that they used in preparing their disclosures (these assumptions will not be posted online);
- New limitations on the definition of a "covered drug, device, biological or medical supply" to include only drugs or biologics that require a prescription to be dispensed and medical devices or supplies that require FDA premarket approval or notification;
- New reporting guidance for payments made by entities under common ownership;
- Reporting of the form and nature of payments is largely unchanged (with minor changes regarding beverages and multiple payments on multiple dates);
- Simplified definition of research payments;
- Reporting of direct and indirect research payments;
- An unofficial sample of the reporting template in an addendum to the proposed rule;
- Procedures for the 45-day pre-publication period for review of disclosed payments and for the resolution of disputes; and
- Procedures for delayed publication of payments pursuant to product research, development agreements, and clinical investigations.

Pharmaceutical and medical device makers should continue to develop operational capacity as well as compliance policies and procedures to comply with final rules once published.

Immediate concerns

Of immediate concern for all affected parties is when the initial report will be due. The proposed rule clarifies that compliance with the law's data collection elements will not be required until 90 days following CMS' issuance of the final rule (CMS calls this a "preparation period"). Thus, the first date when data collection compliance will be required depends on (i) when CMS publishes the final rule and (ii) the preparation period determined in the final rule. CMS has not proposed delaying the first date when registration with CMS and reporting will be required—by March 31, 2013 and the 90th day of each year thereafter. However, CMS is seeking comments on the proposed timing of the registration and submission process, and it is possible that CMS may delay reporting when it issues the final rule. CMS is seeking comments on the challenges of data collection, which leaves open the possibility that CMS may conclude that a 90-day preparation period is inadequate—thereby further delaying the first date compliance is required.

Also of immediate concern is the opportunity to comment on and to anticipate the focus of CMS' attention as it develops the final rule. CMS has requested a wide range of comments on all of its analysis and assumptions and its specific requests for comment indicate areas in which CMS will most likely be most responsive to comments and make changes in the final rule. In Section III.D. of the proposed rule, CMS notes, "we solicit comments on the analysis and assumptions … in the alternatives section of the regulatory impact analysis in particular." CMS seeks numerous comments on how it can better estimate the burdens of compliance

on affected parties, so it is unsurprising that CMS will "particularly welcome comments that can provide not only better methods [for the implementing law's reporting requirements], but also ways to quantify the potential savings from those methods."

A third area of immediate concern is reporting requirements that already exist and are unaffected by the proposed rule. Various state laws, such as Massachusetts, Vermont, and Minnesota, already require reporting of payments. In addition, Section 6004 of the PPACA is independent of Section 6002 and requires that prescription drug manufacturers and authorized distributors of record make annual reports by April 1 of each year beginning with 2012 to CMS, which reports must contain aggregated information regarding the identity and quantity of drug samples requested and distributed.

Impact on the health care industry

Now that CMS has published its proposed rule, it is even more apparent that these sunshine provisions will have a significant impact across the health care industry. Although the "rays of sun" will reach almost everyone in the health care system, the following are among those most directly affected by the law:

1. **Pharmaceutical and medical device manufacturers.** Those that qualify as applicable manufacturers under the statute and regulations will require the operational capacity to perform accurate and timely data collection and reporting to CMS. They will also be subject to scrutiny from the government for violations of reporting requirements as well as violations of federal health care laws revealed through investigation of the reported data, potentially adverse publicity from the media, and possible private sector litigation. In the proposed rule, CMS estimates that approximately 1,150 applicable manufacturers, (150 drug and biologic manufacturers, and 1,000 device and medical supply manufacturers) will submit reports.
2. **GPOs.** Those that qualify as applicable GPOs under the statute and regulations will be required to report annually physician ownership and investment interests, including those of physicians' immediate family members. CMS estimates that approximately 420 applicable GPOs will submit reports.
3. **Physicians.** The proposed rule leaves standing the statute's definition of "physician" to include doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors. Physicians will not be required to report any information to CMS, but the payments they receive and their ownership and investment interests will receive new potentially adverse publicity. CMS has proposed and seeks comments regarding procedures for a 45-day review period during which physicians may seek to correct data before it becomes public—and for handling disputes between physicians and reporting entities. CMS has also proposed and seeks comments on procedures for identifying physicians according to their National Provider Identifier (NPI) number—CMS suggests using the National Plan & Provider Enumeration System (NPPES)—and specialty.
4. **Teaching hospitals.** Like physicians, teaching hospitals will not be required to report any information to CMS, but the payments they receive and their ownership and investment interests will receive new potentially adverse publicity. The proposed rule defines teaching hospitals to include any institution that received Indirect Medical Education (IME), direct Graduate Medical Education (GME), or psychiatric hospital IME payments during the most recent year for which such information is available. CMS proposes to publish a list of hospital covered recipients on the CMS Web site once per year, including the name and address of each teaching hospital.
5. **Contract research organizations (CROs).** While CROs are also not required to report information to CMS, the proposed rule includes research payments or transfers of value made by CROs directly to a physician covered recipient or teaching hospital or indirectly to an organization that pays physician principal investigators. Applicable manufacturers and CROs will need to collaborate to track these payments.
6. **Third parties performing research.** The proposed rule requires the identification of payments to a clinic, hospital, or institution conducting research, which organization in turn pays a physician covered recipient (or

multiple physician covered recipients) serving as a principal investigator(s). Per the proposed rule, "Payments or other transfers of value reported as indirect research should also include the name of the entity or individual that received the payment or other transfer of value." Accordingly, these institutions will not be required to report any information to CMS, but the payments they receive and their ownership and investment interests will receive new potentially adverse publicity.

7. **Other.** Various other players in the health care system will be affected by the PPACA's sunshine provisions, such as early-stage companies attempting to determine whether they will qualify as applicable manufacturers, companies that manufacture products outside the U.S. but sell products in the U.S. (they are applicable manufacturers according to the proposed rule), physicians' administrative staff, and independent sales force contractors.

For questions about preparing for compliance with these sunshine provisions in the PPACA, as well as state laws, or for assistance submitting comments to CMS, please contact one of the attorneys listed above.