CMS Announces Final Regulations Interpreting the Physician Payment Sunshine Act

On February 1, 2013, the Centers for Medicare & Medicaid Services (CMS) published the final regulations interpreting the physician payment “sunshine” provisions of the Patient Protection and Affordable Care Act (the Act). The “Final Rule” requires drug and device companies to report certain payments, ownership and investment interests, and other transfers of value made to physicians or teaching hospitals. Under the Final Rule, applicable manufacturers must begin to collect relevant physician payment and ownership data on August 1, 2013, in order to meet the first reporting deadline of March 31, 2014. To avoid significant penalties for non-compliance, device and pharmaceutical manufacturers must act quickly to analyze their existing relationships with physicians and researchers and understand the detailed documentation required by the regulation.

Although the Final Rule does not represent a substantial departure from the proposed rule (summarized in Latham's December 19, 2011 Client Alert), affected companies should take note of the additional clarifications and exclusions provided by CMS. As companies develop internal data collection policies and procedures, compliance personnel must also consider the rapidly-evolving state disclosure requirements, some of which may not be pre-empted by the federal reporting required under the Final Rule.

A. Definitions and Exclusions

The Final Rule provides responses to a host of different questions, comments and scenarios submitted by interested parties since the December 2011 publication of the Proposed Rule. Due to the Act’s detailed statutory provisions governing the reporting process, CMS used a significant portion of the 287-page Final Rule to clarify definitions and exclusions that were not entirely clear in the statutory text. Importantly, the Agency’s interpretations alter the universe of entities subject to the Act’s reporting requirements, limit the health care practitioners covered by the Act and illuminate the statutory exclusions to payments or transfers of value.

1. Applicable Manufacturers

Expanding upon the statutory definition, CMS defined “applicable manufacturer” to mean an entity operating in the United States that is engaged in the production, preparation, propagation, compounding or conversion of a covered drug, device,
biological or medical supply, including entities under common ownership (five percent ownership or more) that provide assistance or support with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug or device for sale or distribution in the United States. The Final Rule defines “operating in the United States” as having a physical location or otherwise conducting activities within the United States. CMS further clarified that the definition of applicable manufacturer excludes:

- hospitals, hospital-based pharmacies and laboratories that manufacture a covered product solely for use by or within the entity itself or by an entity’s own patients;
- compounding pharmacies that meet a three-prong test, including that they do not produce or compound drugs or devices for sale other than at retail to individual patients;
- distributors or wholesalers (including repackagers, relabelers and kit assemblers) that do not hold title to any covered drug or device; and
- entities that only manufacture raw materials or components, which are not themselves covered products.

In addition to the above exclusions, CMS limited the reporting requirements of certain entities that would otherwise fall under the definition of "applicable manufacturers." While other applicable manufacturers must report all payments or transfers of value made to covered recipients, the following entities need only report payments to covered recipients that are specifically related to a covered product:

- manufacturers that derived less than 10 percent of gross revenues in the previous fiscal year from covered products;
- contract manufacturers that (i) manufacture a covered product under a written agreement; (ii) do not hold the FDA approval, licensure or clearance for the covered product; and (iii) are not involved in the sale, marketing or distribution of the product; and
- separate company divisions of applicable manufacturers that manufacture only non-covered products.

2. Covered Recipients
In line with the statutory guidance, the Final Rule defines covered recipients to include (1) physicians, other than those who are bona fide employees of the applicable manufacturer reporting the payment and (2) teaching hospitals. While CMS declined to limit the definition of "physicians" solely to physicians enrolled in Medicare, the Agency did not extend the definition to include other non-physician prescribers, such as nurse practitioners. By limiting the definition to physicians holding an active license, the scope of the federal reporting requirements is significantly more narrow than some state reporting laws, such as Vermont and Massachusetts, that require reporting of payments made to other providers such as non-teaching hospitals, nursing homes, laboratories, pharmacists, nurses and other health care practitioners.

To assist applicable manufacturers in determining which hospitals qualify as teaching hospitals, CMS will publish a list of qualifying hospitals (those receiving Medicare direct GME or IME payments) at least 90 days before the end of the year.

3. Covered Products
CMS' Final Rule clarifies that a "covered drug, device, biological or medical supply" is one for which payment is available under Medicare, Medicaid or CHIP — either separately or as part of a bundled payment such as the inpatient or outpatient
prospective payment systems (IPPS and OPPS) — 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). In the Final Rule, CMS finalized its interpretation that manufacturers of “over-the-counter” drugs and biologicals need not report.

An applicable manufacturer whose product becomes covered (e.g., if payment for one of the company’s products becomes available under Medicare) will have a 180-day grace period before it will be required to comply with the Act’s data collection and reporting requirements.

4. Payment or Other Transfer of Value
The Act defines “payment or other transfer of value” broadly to capture anything of value given to a covered recipient, including direct and indirect payments, as well as payments made to a third party at the request of a covered recipient. Importantly, CMS requires applicable manufacturers to report all payments or transfers of value to covered recipients, even if the payment is not related to a specific covered drug, device, biological or medical supply.

One important exclusion to the reporting requirements of applicable manufacturers is the exclusion for indirect payments made indirectly to a covered recipient through a third party not subject to the reporting requirements of the Act. While indirect payments are excluded from reporting when the applicable manufacturer does not know the identity of the covered recipient, a number of CMS responses highlight certain payments that must be reported. Indirect payments recognized by CMS as potentially reportable include payments through (i) a manufacturer’s foreign subsidiary that is not operating in the US; (ii) a group practice or clinic that employs multiple covered recipients; (iii) a medical society; (iv) continuing medical education (CME) programs; or (v) a separate department of a teaching hospital’s parent institution.

To clarify when a payment must be reported, CMS states that an indirect payment occurs when an applicable manufacturer requires, instructs or directs an entity to provide payment to a covered recipient, regardless of whether the manufacturer identifies a specific covered recipient. For example, an unrestricted donation to a professional society would not qualify. A donation for the specific purpose of funding awards or grants to physicians would however qualify as an indirect payment and be subject to the reporting requirements. As explained by CMS, the purpose of its definitions related to indirect payments is to prevent applicable manufacturers from directing payments to a discrete set of covered recipients who the manufacturer may not actually know, but could easily ascertain.

One important form of indirect payment addressed by the Final Rule is the exclusion of payments for CME speakers. While payments or other transfers of value associated with attendance at an event (e.g., travel and meals) must continue to be reported, CMS created an exclusion for payments made to a speaker at a CME program if it meets three prongs:

• The program is accredited or certified by certain accrediting bodies (e.g., the American Council for Continuing Medical Education);
• The applicable manufacturer does not select the covered recipient speaker or identify a distinct set of individuals to be considered as speakers; and
• The applicable manufacturer does not directly pay the covered recipient speaker.
Separate from indirect payments, CMS also requires applicable manufacturers to report payments made to a third party at the request of or designated on behalf of a covered recipient. In these instances, the applicable manufacturer must report the identity of the covered recipient as well as the entity or individual receiving the payment.

The Final Rule also provides additional guidance on the reporting of meals. CMS clarified that applicable manufacturers need not report large group meals where the recipients are difficult to identify; CMS also established a reporting process for smaller group meals. For smaller group meals, the Final Rule requires applicable manufacturers to report 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. These same reporting rules also apply to food dropped off at the physician's office.

B. Required Information

CMS' Final Rule refined and explained the categories of information subject to reporting by applicable manufacturers for each payment or transfer of value provided to a covered recipient:

- **Covered Recipient Identity**: Physician's name, primary practice location address, specialty and National Provider Identification (NPI) number.
- **Date of Payment**: The Final Rule gives applicable manufacturers the flexibility to report payments made over multiple dates either separately or as a single line item for the first payment date. CMS clarified that aggregated payments should not cross years.
- **Context**: Applicable manufacturers may, but are not required to, provide brief contextual information for each payment or other transfer of value.
- **Related Covered Drug, Device, Biological or Medical Supply**: Applicable manufacturers may report up to five related covered products for each interaction. If the payment or other transfer of value is not related to at least one covered product, then applicable manufacturers should report "none." If the payment or other transfer of value is related to a specific product that is not a covered product, then applicable manufacturers are to report "non-covered product."
- **Form and Nature of Payment**: Manufacturers must report a single form of payment and nature of payment for each transfer of value. For example, if a physician received meals and travel in association with a consulting fee, CMS requires each separate payment be reported separately in the appropriate category.

C. Separate Reporting for Research Activities

Recognizing the complicated arrangements inherent to research activities, the Final Rule requires manufacturers to report research payments using a different template than other payments or transfers of value. To determine which payments are governed by the separate process, CMS adopted the definition of "research" from the Public Health Service Act as a "systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development."

In response to comments from industry, the Final Rule clarifies that a payment may qualify as a research payment if it is subject to a written agreement or contract or a research protocol. CMS clarified that research arrangements may include an unbroken chain of agreements that link the applicable manufacturer with the covered recipient (e.g., through a contract research organization or site management organization).
Payments from applicable manufacturers for product development or clinical investigations for new products receive preferential treatment under the statute and Final Rule. These payments and associated reports qualify for delayed publication of payments in order to maintain confidentiality for proprietary information relating to the development of new drugs and devices. This treatment does not extend to all investigations, however; CMS explained that payments made in connection with new applications of existing products will not be granted a delay.

Research payment reports need not indicate whether a payment was direct or indirect and should include the following information:

- The entity paid (either directly or indirectly);
- The name of the principal investigator(s);
- The total amount of the research payment. CMS clarified that the total research payment amount includes the “aggregated amount of any payments for services included in the written agreement/research protocol;”
- The name of the study; and
- The name(s) of the related covered drug, device, biological or medical supply and National Drug Code (if applicable). Due to the different nature of pre-clinical research (laboratory and animal research carried out before beginning any studies in humans), the applicable manufacturer does not need to report an associated product or study name.

The applicable manufacturer may also include the context of the research or the clinicaltrials.gov identifier.

D. Reports on Physician Ownership and Investment Interests

The Act requires applicable manufacturers, as well as applicable group purchasing organizations (GPOs), to report information concerning ownership and investment interests held by physicians (or their immediate family members) in such applicable manufacturers and applicable GPOs, as well as payments or other transfers of value to such physician owners or investors. An applicable GPO is an entity that operates in the United States and 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. Significantly, unlike the reporting requirement for payments and transfers of value, the Final Rule does not exclude physician employees of manufacturers and GPOs from the reporting requirements related to physician ownership and investment interests.

In defining “ownership or investment interest,” CMS looked to the definition found in the physician self-referral regulation, which includes but is not limited to stock, stock options, partnership shares, LLC memberships and other secured instruments. Ownership interests do not include (i) ownership or investment interest in a publicly traded security or mutual fund; (ii) ownership that arises from a retirement plan offered by the manufacturer or GPO that employs the physician; (iii) stock options or convertible securities received as compensation and not yet converted to equity; and (iv) an unsecured loan subordinated to a credit facility.

E. Penalties for Non-Compliance and Record Retention

Penalties imposed for failures to report and knowing failures to report will be aggregated separately. Therefore, CMS and the Office of Inspector General are authorized to impose penalties of up to US$1,150,000 per applicable manufacturer or applicable GPO, per each annual submission, for failing to timely, accurately
or completely submit the documentation required pursuant to the Final Rule. Applicable manufacturers or applicable GPOs will be subject to a penalty of at least US$1,000, but no more than US$10,000, for each payment or other transfer of value, or ownership or investment interest not reported as required (capped at US$150,000 per annual submission). For knowing failures to report, applicable manufacturers or applicable GPOs will be subject to a penalty of at least US$10,000, but no more than US$100,000 (capped at US$1 million per annual submission).

Applicable manufacturers and GPOs may be required to retain certain records to enable an audit or inspection of compliance with the Act for up to 9 years. While CMS requires applicable manufacturers and GPOs to maintain such documentation for at least 5 years, certain payments or other transfers of value may be eligible for delayed publication, as explained above. The retention period will begin on the date of publication of the payment by CMS.

F. State Preemption

The Act preempts any state or local laws requiring reporting of the same type of information concerning payments or other transfers of value made by applicable manufacturers to covered recipients. No state or local government can require separate reporting of any information regarding a payment or transfer of value that is required to be reported under the Act unless the applicable information is requested for public health purposes. State and local entities may require reporting of non-required categories of information for payments or other transfers of value reported to CMS, including the exclusions from the Act summarized above or information not required to be reported at all under the Act.

Specifically, applicable manufacturers and GPOs subject to state law reporting requirements in the District of Columbia, Maine, Massachusetts, Minnesota and Vermont should be aware that certain state requirements to report gifts or payments may be preempted. Applicable manufacturers and GPOs should consider, however, that the Act does not preempt all aspects of state disclosure requirements covering payments to physicians and other health practitioners. For example, Vermont’s comprehensive disclosure statute requires manufacturers of prescribed products to annually disclose all product samples provided to health care providers during the preceding calendar year, including the product, recipient, number of units and dosage. Because the Act excludes product samples from its disclosure requirements, Vermont’s broader requirement is not preempted. In Massachusetts, regulations require disclosure of payments and other transfers of value by pharmaceutical and medical device manufacturers to Massachusetts health care practitioners, defined to include nurse practitioners and physician assistants. As explained above, because Massachusetts’ definition of covered recipients is broader than the Act, the broader disclosure requirement is not preempted.

Applicable manufacturers and GPOs should actively monitor state-law developments in this area, as the finalization of CMS’ implementation of the Act may lead to revisions of applicable state laws. Shortly after the announcement of the Final Rule, the Minnesota Board of Pharmacy announced that it would not require manufacturers or wholesale drug distributors to disclose payments to physicians and other healthcare professionals, as required by Minnesota law, because the majority of Minnesota’s law is preempted by the Act. The Board of Pharmacy will also ask that the legislature repeal the annual disclosure requirement related to such payments in 2013. As the Final Rule is reviewed by state legislatures and agencies, Latham expects further changes to the state regulatory scheme governing payments or transfers of value to healthcare practitioners.
G. Conclusion

Although CMS clarified — and in some cases limited — the reporting requirements for applicable manufacturers and GPOs under the Act, the implementation of the Final Rule is expected to cost approximately US$269 million in the first year and US$180 million each year thereafter. Entities may seek to shift costs among the various stakeholders responsible for reporting payments, as CMS states that joint ventures and other cooperative services arrangements between multiple entities may specify the party responsible for reporting physician payment information. Affected companies may also reduce long-term reporting costs through the timely development of a comprehensive internal tracking and compliance system. CMS has committed to publishing a series of frequently asked questions (FAQs) and other resources to assist applicable manufacturers and GPOs as additional issues arise during implementation of the Rule’s requirements.

Endnotes

1 H.R. 3590, section 6002.
2 42 CFR 50.603
3 See 18 V.S.A. § 4632.
4 Pharmaceutical and Medical Device Manufacturer Code of Conduct, 105 CMR 970.000.

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