

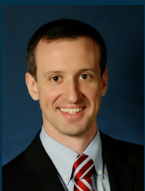
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CMS Issues Physician Payments Sunshine Act Final Rule: *Reporting Requirements for Manufacturers of Drugs, Devices, Biologicals and Medical Supplies and Group Purchasing Organizations*

The Centers for Medicare and Medicaid Services (“CMS”) recently issued final regulations to implement the reporting and transparency requirements set forth in the Patient Protection and Affordable Care Act, also known as the Physician Payments Sunshine Act. The final regulations (the “Final Rule”)¹ require certain manufacturers of drugs, devices, biologicals or medical supplies to report to CMS certain payments or transfers of value to physicians and teaching hospitals. The Final Rule also requires such manufacturers and certain group purchasing organizations (“GPOs”) to report certain ownership and investment interests. We have prepared this alert to provide an overview of the requirements imposed by the Final Rule.

Part I: Reporting Transfers of Value

Applicability

1. Who needs to report payments and transfers of value under the Final Rule?

“Applicable manufacturers” that transfer anything of value to a physician or teaching hospital are required to report. “Applicable manufacturers” are entities that are “engaged in the production, preparation, propagation, compounding, or conversion of” (i) drugs and biologicals that require a prescription to be dispensed; or (ii) medical devices and supplies that require premarket approval by, or notification to, the FDA (each a “covered product”). Payment for a drug, biological, device or medical supply must be available under Medicare, Medicaid or CHIP in order for it to be a covered product.

¹ A copy of the Final Rule is available at: http://shipmangoodwin.com/files/19251_2013-02572.pdf

The obligation to report also applies to entities “under common ownership” with applicable manufacturers, when the entity provides “assistance and support” to the applicable manufacturer with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product. “Under common ownership” refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5% or more of two entities, including parent corporations, direct and indirect subsidiaries and brother/sister corporations.

2. *For purposes of determining common ownership, what does CMS mean by “assistance and support?”*

An entity provides “assistance and support” when it provides services necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product. The Final Rule notes that an entity under common ownership that produces an active ingredient for a covered product would be considered to provide “assistance and support” but an entity under common ownership that provides only human resources administrative support would not.

3. *I am a manufacturer based outside of the United States. Am I subject to the data collection and reporting requirements of the Final Rule?*

An applicable manufacturer, foreign or not, which has operations, a physical location or is otherwise conducting activities in the United States (including holding a clearance or approval from the FDA) must comply with the Final Rule’s data collection and reporting requirements, regardless of where the product is physically manufactured.

4. *Are hospitals, hospital-based pharmacies and laboratories that produce or manufacture materials and products solely for their own use or use by their patients subject to the Final Rule?*

No. 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, are not subject to the Final Rule.

5. *Are pharmacies and compounding pharmacies subject to the Final Rule?*

Pharmacies and compounding pharmacies are not subject to the Final Rule if the pharmacy meets all of the following conditions: (i) maintain establishments that comply with applicable local laws regulating the practice of pharmacy; (ii) regularly engage in dispensing prescription drugs or devices upon prescriptions from licensed practitioners

in the course of their professional practice; and (iii) do not produce, prepare, propagate, compound or convert drugs or devices for sale other than in the regular course of business of dispensing selling drugs or devices to individual patients.

6. *Are distributors and wholesalers, including repackagers, relabelers and kit assemblers subject to the Final Rule?*

Distributors and wholesalers, including repackagers, relabelers and kit assemblers, are considered “applicable manufacturers” and are thus subject to the Final Rule if the entity holds title to a covered product during the production/distribution process. Such entities are subject to the data collection and reporting requirements in the same manner as the actual manufacturer of the product.

7. *My firm holds the FDA clearance for a covered product but contracts out the actual manufacturing of it. Are we considered an “applicable manufacturer” for purposes of the Final Rule?*

Yes, the Final Rule’s definition of “applicable manufacturer” includes entities that hold FDA approval, licensure or clearance for a covered product even when the manufacturing is contracted out to another entity.

Reporting Requirements

1. *What payments and transfers need to be reported under the Final Rule?*

Any transfer of anything of value to: (i) a physician (other than a resident or a physician who is an employee of an applicable manufacturer) or teaching hospital (each a “covered recipient”); or (ii) other individuals or entities to be passed through to a physician. Non-physician prescribers are not covered.

2. *How does an applicable manufacturer identify a “teaching hospital?”*

CMS will publish a list of all hospitals that CMS considers to be “teaching hospitals” for purposes of the Final Rule. CMS will publish the list once annually and make it available publically at least 90 days prior to the start of a reporting year. For 2013, CMS anticipates publishing the list by May 1, 2013.

3. *I manufacture covered and noncovered products. Does the Final Rule require me to report all payments and transfers of value to covered recipients or only payments and transfers of value particular to the covered products I manufacture?*

An applicable manufacturer must report all payments or transfers of value to covered recipients and not only those related to a covered product, unless one of the following exceptions apply:

- If an applicable manufacturer does not manufacture a covered product except pursuant to a written agreement to manufacture the covered product for another entity, does not hold the FDA approval, licensure or clearance for the product and is not involved in the sale, marketing or distribution of the product, then the manufacturer is only required to report payments or other transfers of value related to the covered product it manufactures.
- The Final Rule permits applicable manufacturers with less than 10% of total (gross) revenues from covered products during the previous fiscal year to report only payments or other transfers of value specifically related to covered products.

4. *While our entity qualifies as an applicable manufacturer, we have separate operating divisions that do not produce any covered products. Must these divisions report all payments and transfers of value to covered recipients?*

Separate operating divisions of applicable manufacturers that produce only non-covered products and which do not qualify as applicable manufacturers themselves under the common ownership rules are required to report only payments or transfers of value that are related to a covered product.

5. *If I am considered an “applicable manufacturer” and have made a transfer or payment to a covered recipient, what kind of specific information must I report to CMS?*

The Final Rule requires an applicable manufacturer to report the: (i) name and business address for the recipient; (ii) specialty, NPI and at least one state professional license number of physician recipients; (iii) amount and date of payment; (iv) information regarding ownership or investment interests of the recipient; (v) name of product (if payment is related to a specific product); (vi) form of payment (i.e. cash); and (vii) nature of payment broken down by category (i.e. contingency fee, honoraria, research, gift, entertainment, food, travel); and (viii) name of entity paid. The Final Rule also permits (but does not require) applicable manufacturers to provide brief contextual information for each payment or transfer of value.

6. *Are there any proposed payments or transfers of value that do not need to be reported under the Final Rule?*

Yes, certain payments and transfers do not need to be reported, including, but not limited to: (i) for calendar year 2013, payments of less than \$10 (except when the total annual value of payments or other transfers of value provided to a covered recipient

exceeds \$100)²; (ii) product samples that are not intended to be sold and are intended for patient use; (iii) educational materials that directly benefit patients or are intended for patient use; (iv) discounts, including rebates; (v) in-kind items used for the provision of charity care; and (vi) transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient. Offerings of buffet meals, snacks or coffee at booths at conferences or other similar events where it would be difficult for applicable manufacturers to definitively establish the identities of the individuals who accept the offerings also need not be reported. However, for meals in group settings, 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 must be reported.

Part II: Reporting Ownership or Investment Interests

1. Who needs to report ownership or investment interests under the Final Rule?

Applicable manufacturers (as described above) and applicable GPOs must report ownership or investment interests. An “applicable GPO” is an entity that operates in the United States, and purchases, arranges for or negotiates the purchase of a covered product for a group of individuals or entities, and not solely for use by the entity itself.

2. What ownership and investment interests need to be reported by applicable manufacturers and GPOs?

Applicable manufacturers and GPOs must report ownership or investment interests of physicians³ and their “immediate family members”⁴ in such applicable manufacturers and GPOs. Under the Final Rule, an “ownership or investment interest” may be direct or indirect, and through debt, equity, or other means, including but not limited to, stock, certain stock options, 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. Ownership or investment interest in a publicly traded security or mutual fund, or through employee retirement plans and unsecured loans to credit facilities do not need to be reported. Applicable manufacturers and GPOs are not required to report indirect ownership or investment

2 For calendar year 2014 and subsequent years, CMS will increase the \$10 and \$100 amounts by the same percentage as the percentage increase in the consumer price index for all urban customers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

3 The term “physician” in this case includes any physician, regardless of whether the physician is an employee of the applicable manufacturer or GPO.

4 The Final Rule defines an “immediate family member” as one of the following: (i) a spouse; (ii) a natural or adoptive parent, child, or sibling; (iii) a stepparent, stepchild, stepbrother, or stepsister; (iv) a father-, mother-, daughter-, son-, brother-, or sister-in-law; (v) a grandparent or grandchild; or (vi) a spouse of a grandparent or grandchild. Applicable manufacturers and GPOs are not required to report the name or relationship for an immediate family member holding an ownership or investment interest in such entity.

interests held by physicians or their immediate family members if they did not know about such interests.

3. *What specific information must be reported with respect to ownership and investment interests under the Final Rule?*

Applicable manufacturers and GPOs must report (i) the name, business address, NPI, state license number, and specialty of the physician, (ii) whether the interest is held by an immediate family member, and (iii) the dollar amount invested and the value and terms of the ownership or investment interest.

Part III: General Requirements

1. *What is the procedure for submitting reports to CMS?*

Applicable manufacturers and GPOs with reportable payments or interests must register with CMS and submit the required reports to CMS electronically. CMS encourages (but does not require) applicable manufacturers and GPOs to include an assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or interests. The reports must include an attestation by the chief executive officer or another company officer that the information reported is timely, accurate and complete to the best of his or her knowledge and belief.

2. *What will CMS do with the reported information?*

At a minimum, CMS will aggregate the data and make the data available for public viewing.

3. *Will applicable manufacturers and GPOs, covered recipients, and physician owners and investors have an opportunity to review the reported information prior to it being made public?*

Yes. Applicable manufacturers, GPOs, covered recipients and physician owners and investors will have a 45-day review and correction period in which they may review the data submitted to CMS. To facilitate this review, CMS will provide a secure website where each individual or entity may log-in and review information specific to it.

4. *May a covered recipient or physician owner or investor dispute information submitted to CMS by an applicable manufacturer or GPO?*

Yes. A covered recipient or physician owner or investor may initiate a dispute if it disagrees with information reported by an applicable manufacturer or GPO.

5. *What if an applicable manufacturer or GPO discovers an error or omission in its report to CMS?*

If an applicable manufacturer or GPO discovers an error or omission in its report, it must submit corrected information to CMS immediately upon confirmation of the error or omission. CMS will update the website at least once annually with corrected information.

6. *When must applicable manufacturers and GPOs begin to collect and report the data required by the Final Rule?*

Applicable manufacturers and GPOs must begin to collect the required data on August 1, 2013 and report the data to CMS by March 31, 2014. Thereafter, reports must be submitted to CMS by the 90th day of each calendar year.

7. *What are the potential penalties for failure to report under the Final Rule?*

Civil monetary penalties (“CMPs”) may be imposed on an applicable manufacturer or GPO for failure to report information in a timely, accurate, or complete manner.

The Final Rule establishes two penalty tiers based upon the reporting entity’s knowledge or lack thereof. Under the first tier, if an applicable manufacturer or GPO fails to submit the required information in a timely, accurate or complete manner, the applicable manufacturer or GPO may be subject to a CMP of at least \$1,000, but no more than \$10,000, for each payment or other transfer of value or ownership or investment interest not reported as required. The maximum total CMP with respect to each annual submission for failure to report is \$150,000. Penalties for a knowing failure to submit required information include at least \$10,000, but no more than \$100,000, for each payment or other transfer of value or ownership or investment interest knowingly not reported as required. The maximum total CMP with respect to each annual submission for a knowing failure to report is \$1,000,000. The penalties imposed for failures to report and knowing failures to report will be aggregated separately and are subject to separate aggregate totals, with a maximum combined annual total of \$1,150,000. The following table illustrates both penalty tiers.

| Type of Violation | Range of Penalty | Annual Maximum Aggregate Penalty |
|---------------------------------------|-------------------------|---|
| Failure to Report as Required | \$1,000 - \$10,000 | \$150,000 |
| Knowing Failure to Report as Required | \$10,000 - \$100,000 | \$1,000,000 |



8. *What factors will CMS consider in determining the amount of a CMP?*

The factors CMS will consider in determining the amount of a CMP include, but are not limited to: (i) the length of time the applicable manufacturer or GPO failed to report, including the length of time the applicable manufacturer or GPO knew of the payment or other transfer of value, or ownership or investment interest; (ii) the amount of the payment or other transfer of value or the value of the ownership or investment interest the applicable manufacturer or GPO failed to report; (iii) the level of culpability; (iv) the nature and amount of information reported in error; and (v) the degree of diligence exercised in correcting information reported in error.

9. *Will CMS be able to audit manufacturers and GPOs for compliance with the reporting requirements?*

Yes, CMS is permitted to audit, evaluate or inspect applicable manufacturers and GPOs for compliance with the reporting requirements. Accordingly, applicable manufacturers and GPOs must maintain all books, records, documents and other materials sufficient to enable such an audit, evaluation or inspection of compliance for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published by CMS.

10. *Am I still subject to additional reporting requirements imposed by state law requiring disclosure of the same type of information?*

No. The Final Rule preempts state laws requiring disclosure of similar types of information by applicable manufacturers and GPOs. States may still require reporting of information for payments or other transfers of value not reported to CMS.

If you have any further questions regarding the Final Rule or reporting requirements generally, please feel free to contact any member of our **Life Sciences and Medical Products Team**.

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