

Here Comes the Sun: CMS Issues Proposed Physician “Sunshine” Reporting Rule

On December 19, 2011, the Centers for Medicare and Medicaid Services (“CMS”) published in the Federal Register¹ a proposed rule (the “Proposed Rule”) implementing new section 1128G(a) of the Social Security Act (the “Act”), as added by section 6002 of the Patient Protection and Affordable Care Act (“PPACA”).² The Proposed Rule contains two basic sets of requirements, which are identified below by the subsection of Section 1128G(a) that they implement:

Section 1128G(a)(1) Requirements. Certain manufacturers of drugs, devices, biologicals or medical supplies covered by Medicare, Medicaid or the Children’s Health Insurance Program (collectively, the “Manufacturers”)³ must report annually to the Secretary of the Department of Health and Human Services (“DHHS”) certain payments or transfers of value to any physician⁴ who is not an employee of the Manufacturer and/or to any teaching hospitals⁵ (collectively, “Covered Recipients”); and

Section 1128G(a)(2) Requirements. Manufacturers and applicable group purchasing organizations⁶ (“GPOs”) must disclose ownership or investment interests held by a physician, or an immediate family member of a physician⁷, in the Manufacturer or GPO, as well as any payments or other transfers of value to such owners or investors.

Duplicative Reporting Requirements

CMS recognizes that a Manufacturer with ownership interests held by physicians or their immediate family members may have duplicative reporting requirements under Section 1128G(a)(1) and 1128G(a)(2). Therefore, CMS states: “In order to prevent the duplicative reporting, we propose that if an ownership or investment interest is required to be reported under section 1128G(a)(1) of the Act and under section 1128G(a)(2) of the Act, then the applicable manufacturer need only to report under section 1128G(a)(1) and should not report the provision of the ownership or investment interest under the reporting requirements in section 1128G(a)(2)”⁸ Indeed, CMS proposes that “applicable



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¹76 Fed. Reg. 78742 (Dec. 19, 2011).

² Section 6002 of PPACA adds Sections 1128G(a)(1) and (2) to the Social Security Act.

³ Section 1128G(e)(9) defines “manufacturer of a covered drug, device, biological, or medical supply” as—Any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological or medical supply (or any entity under common ownership with such entity 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). The definition also includes entities that hold an FDA approval, licensure or clearance even if they contract out the actual physical manufacturing of the product to another entity.

⁴ “Physician” is defined in §1861(r) of the Social Security Act

⁵ The Act does not define “teaching hospital.” CMS proposes to define “teaching hospital” as, “[a]ny institution that received payments under section 1886(d)(5)(B) of the Act (IPPS Indirect Medical Education (IME)), section 1886(h) of the Act (direct GME), or section 1886(s) of the Act (psychiatric hospitals IME) during the most recent year for which such information is available.” See 76 Fed. Reg. at 78746.

⁶ CMS intends to capture those entities (including physician owned entities) that purchase covered drugs, devices, biologicals or medical supplies, which require a prescription, for resale or distribution to others.

⁷ “Immediate family member” is defined in 42 CFR 411.351

⁸ See 76 Fed. Reg. at 78752

manufacturers submit one file for all their payments and other transfers of value and another for all their physician ownership or investment interests⁹ and even provides Sample Reporting Templates for this purpose at the end of the Proposed Rule (Table A is a Sample Reporting Template for Payment or Other Transfers of Value, and Table B is a Sample Reporting Template for Physician Ownership or Investment Interests).

Note that GPOs, unlike Manufacturers, are required only to submit reports on ownership or investment interests held by physicians or immediate family members of physicians (as well as any other payments or transfers of value to those owners). They are not also required to report on all payments or other transfers of value to non-owner Physicians.

Timelines For Reporting

The Act requires Manufacturers and GPOs (collectively, the “Reporting Entities”) to start collecting the required information for disclosure on January 1, 2012. However, because of the two month delay in publication of the Proposed Rule,¹⁰ CMS notes that Reporting Entities are not required to start collecting the necessary data for reporting until after the final rule is published. Thus, the date that Reporting Entities must start collecting information has not yet been fixed. However, CMS has set the deadline for when the Reporting Entities are required to submit the first, partial year’s worth of information – March 31, 2013 – so presumably the date that Reporting Entities must start collecting information will be prior to that time.

Format For Reporting

The Proposed Rule sets forth detailed instructions on the required format for reporting information, the specific information that must be included with each report, and also certain payment exclusions from the reporting requirement. According to the Proposed Rule, the reported information must be submitted in an electronic format and will become publicly available via a searchable website.

For each payment and transfer of value to Covered Recipients, the Manufacturer must include the Covered Recipient’s name, business address, specialty and NPI number, date of payment or transfer, associated covered drug, device, biological, or medical supply¹¹ (if payment is linked to a specific item[s]), and form (e.g., cash or cash equivalent, in-kind, stock or stock option) and nature of payment (e.g., gift, honoraria, charitable contribution, research, speaking engagements or faculty). If applicable, the Proposed Rule allows Manufacturers to report multiple covered drugs, devices or medical supplies as related to a single payment or transfer since most financial relationships are not specific to one item only. Also, if the nature of the payment is for research, CMS proposes that research payments should be classified to clarify whether the payment or other transfer of value was paid directly or indirectly to the Covered Recipient (note that there does not seem to be a data field for this item in the Sample Reporting Tables) and also to delay the publication of certain research payments until the Food and Drug Administration (“FDA”) has approved the product or four years after the payment, whichever is earlier. With respect to speaking engagements, CMS is seeking comments on whether to limit the “speaking engagement” payment category to Continuing Medical Education (“CME”) accredited speaking engagements. If limited, CMS would require that payments for

⁹ See 76 Fed. Reg. at 78753

¹⁰ Section 6002 required HHS to issue proposed regulations by October 1, 2011.

¹¹ CMS proposes to limit this category to only those covered drugs, devices, biologicals and medical supplies that require a prescription.

other speaking engagements be reported as another category.

Entities reporting ownership or investment interests should report the name, address, NPI and specialty of the physician and, if applicable, that the ownership or investment interest is held by an immediate family member of the physician. CMS is seeking comment on whether to require more specific information on behalf of the immediate family member, such as name and relationship to the physician.

Exclusions

The following payments and other transfers of value are excluded from the reporting requirements: (i) transfers of value less than \$10, (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) loan of a covered device for a short term trial period, not to exceed 90 days, to permit evaluation of the covered device, (v) items or services provided under a contractual warranty, (vi) when the Covered Recipient is not acting in a professional capacity but as a patient, (vii) discounts, including rebates, (viii) in-kind items used for charity care, (ix) dividend or other profit distribution from ownership in a publicly traded security or mutual fund, (x) payments for the provision of healthcare under a self-insured plan, (xi) payments to a Covered Recipient who is a licensed non-medical professional if the payment is solely for non-medical professional services, (xii) payments for services related to a civil or criminal or an administrative proceeding, and (xiii) transfers of value made indirectly to a Covered Recipient through a third party when the applicable manufacturer is unaware of the identity of the Covered Recipient.

Process for Reporting

The Rule requires CMS to give Covered Recipients, as well as physicians and immediate family members of the physicians who hold ownership or investment interests, 45 days to review the information submitted by the Reporting Entities. Disputes regarding the accuracy of information submitted should be resolved between the Reporting Entity and the individual who is being reported. Failing to submit required reports can result in civil monetary penalties of up to \$150,000 annually. Reporting Entities are subject to a \$1 million penalty for knowingly failing to report. CMS proposes that all Reporting Entities register with CMS, and thereby acquire the capacity to report, even if there is currently no applicable information to disclose.

Conclusion

The Proposed Rule represents another move by the federal government toward promoting transparency within the healthcare delivery system. CMS representatives reason that Manufacturers' payments and transfers of value to physicians, as well as physician ownership and investment interests, should be available for patients to assess when trying to choose a physician and/or making a decision regarding a recommended course of treatment.

Reporting Entities should consider developing internal information-gathering protocols to ensure that all applicable information is being obtained and subsequently reported. Physicians should be prepared to disclose personal and practice-specific information if they are subject to financial relationships with Reporting Entities. The Rule has the potential to create significant administrative hurdles for Reporting Entities and Physicians, but based on the recent enforcement actions against pharmaceutical companies and medical device manufacturers, efforts

toward transparency as demonstrated in the Rule continue to “shine” and are unlikely to “sunset” anytime soon.

If you have any questions about this issue of *Health Reform IMPACT*, please contact any of the attorneys in our Healthcare Practice Group listed below.

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