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Bioscience Alert

January 19, 2012

CMS Releases Proposed Reporting Requirements for Drug, Device, Biological and Supply Manufacturers and Group Purchasing Organizations

The Centers for Medicare and Medicaid Services ("CMS") recently released proposed regulations to implement the reporting and transparency requirements set forth in the Patient Protection and Affordable Care Act. The proposed regulations (the "Proposed 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 Proposed Rule also requires such manufacturers and certain group purchasing organizations ("GPOs") to report certain ownership and investment interests. Although the Proposed Rule is not final and does not change current law or regulation until a final rule is issued, we are providing this alert to give you a better understanding of what may be expected of you, to help you prepare for the inevitable data collection requirements and to assist you in deciding whether to submit comments to CMS on the Proposed Rule.

1. Who would need to report payments and transfers of value under the Proposed Rule?

"Applicable manufacturers" that transfer anything of value to a physician or teaching hospital would be 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. Applicable manufacturers include entities that hold FDA approval, licensure or clearance for a covered drug, device, biological, or medical supply but contract out the manufacturing of the product to another entity. The obligation to report also applies to entities "under common ownership" with applicable manufacturers, even though such entities may not be involved in the manufacturing process.[2]

2. What payments and transfers would need to be reported under the Proposed Rule?

Any transfer of anything of value to: (i) a physician (other than a physician who is an employee of an applicable manufacturer) or teaching hospital (each a "covered recipient"); or (ii) other individuals or entities at the request of, or designated on behalf of, a covered recipient.

1. A copy of the Proposed Rule is available at: http://www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32244.pdf
2. CMS proposes to define "common ownership" as "when the same individual, individuals, entity or entities, directly or indirectly, own any portion of two or more entities." Alternatively, CMS is also considering a minimum 5% ownership threshold for common ownership.

Questions?
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3. Are there any proposed payments or transfers that would not need to be reported under the Proposed Rule?

Yes, certain payments and transfers would not need to be reported, including, but not limited to: (i) 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); (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.

4. If I am considered an "applicable manufacturer" and have made a transfer or payment to a covered recipient, what kind of specific information is CMS proposing I report under the Proposed Rule?

The Proposed Rule would require an applicable manufacturer to report the: (i) name and business address for the recipient; (ii) specialty and NPI of physician recipients; (iii) amount and date of payment; (iv) name of product (if payment is related to a specific product); (v) form of payment (i.e. cash); and (vi) nature of payment (i.e. contingency fee, honoraria, gift, entertainment).

5. Who would need to report ownership or investment interests under the Proposed Rule?

Applicable manufacturers as described in question 1 above and applicable GPOs. An applicable GPO is a GPO that operates in the United States and purchases, arranges for or negotiates the purchase of a covered drug, device, biological or medical supply (as described in question 1 above) for a group of individuals or entities, and not solely for use by the GPO itself.

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

Certain information concerning ownership and investment interests held by physicians (including physicians who are employees of the applicable manufacturer or GPO) or their immediate family members in such applicable manufacturer or GPO, including, but not limited to, stock, certain stock options, partnership shares, limited liability company memberships, and loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue. Payments or transfers of value to the applicable manufacturer's or GPO's physician owners or investors would also have to be reported.

7. What specific information would need to be reported with respect to ownership and investment interests under the Proposed Rule?

An applicable manufacturer or GPO would need to report: (i) the recipient's name and address; (ii) if a physician, the recipient's specialty and NPI; (iii) interest held by immediate family member; (iv) dollar amount invested; and (v) the value and terms of the interest.

8. What is CMS proposing to do with the reported information?

CMS is proposing to aggregate the data, make the data available for public viewing[3], and may use the data for law enforcement activities. CMS is proposing to give applicable manufacturers, applicable GPOs, covered recipients and physician owners or investors 45 days to review the information before it is made available to the public.

9. When is CMS proposing to have reporting begin under the Proposed Rule?

The collection and reporting obligations set forth in the Proposed Rule will not be effective until publication of a final rule, which is anticipated to be published in 2012. It is anticipated that applicable manufacturers and GPOs will have 90 days from publication of the final rule to begin collecting the required information. Depending on the publication date of the final rule, CMS is considering requiring the collection of data for part of 2012, to be reported to CMS by March 31, 2013 and on the 90th day of each calendar year thereafter.

10. What would the potential penalties be for failure to report under the Proposed Rule?

Applicable manufacturers and GPOs would be subject to civil monetary penalties for failing to comply with reporting requirements. These penalties would range from $10,000 to $100,000 per reportable transfer/investment interest for knowing failures with a maximum penalty of $1,000,000 per annual submission, and $1,000 to $10,000 per reportable transfer/investment interest for unknowing failures with a $150,000 yearly maximum.

11. Would I still be subject to additional reporting requirements imposed by state law requiring disclosure of the same type of information?

No. The Proposed Rule would preempt state laws requiring disclosure of the same type of information by applicable manufacturers and GPOs.

12. Would CMS be able to audit manufacturers and GPOs for compliance with the reporting requirements?

Yes, CMS, the Department of Health and Human Services Office of the Inspector General or their designees would be permitted to audit, evaluate, or inspect applicable manufacturers and GPOs for compliance.

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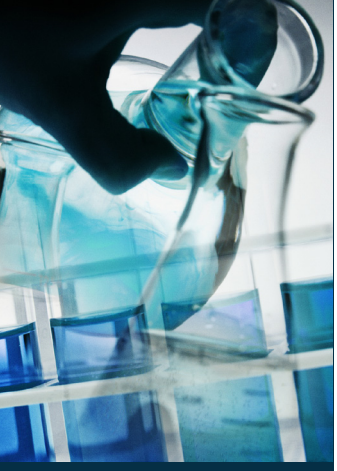
3. Publication of payments or other transfers of value from applicable manufacturers to covered recipients made pursuant to product research or development agreements or clinical investigations may be delayed as set forth in the Proposed Rule.



13. What areas of the Proposed Rule is CMS seeking comments on from manufacturers and GPOs?

CMS is seeking comments on many areas of the Proposed Rule, including but not limited to: (i) the amount of time after a final rule is published entities would need to comply with the final rule; (ii) challenges faced by applicable entities in the set up of data collection/reporting systems; (iii) how to define "applicable manufacturer"; (iv) what identifiers to require manufacturers to use when reporting providers; (v) whether educational materials used for education of covered recipients (as defined in question 2 above) which are not ultimately provided to patients should not be reportable; (vi) whether to require reporting of the name of the immediate family member holding an ownership or investment interest; (vii) the data elements that should be submitted; and (viii) and the structure of the public website listing reported information.

14. I want to provide comments to CMS regarding the Proposed Rule, how and where should I do so?

Pharmaceutical companies, medical device companies and other interested parties can submit comments on the Proposed Rule to CMS no later than February 17, 2012 and may do so electronically, by regular mail, by express or overnight mail or by hand or courier.[4]

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4. Pages two (2) through four (4) of the Proposed Rule contain the relevant addresses and contact information needed to submit comments.

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