

## News from our Life Sciences Group

### CMS Publishes Proposed Rule and Requests for Comment on “Sunshine Provisions” of the Patient Protection and Affordable Care Act (“PPACA”)

On December 19, 2011, the Centers for Medicare and Medicaid (“CMS”) published a proposed rule [[federalregister.gov/a/2011-32244](http://federalregister.gov/a/2011-32244)] 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. *See the end of this Alert for our Chart of CMS Requests for Comment.*

#### 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.”

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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 a payment or transfer of value, 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. ■

# Chart of CMS Requests for Comment in Proposed Rule Implementing Sunshine Provisions of the Patient Protection and Affordable Care Act (PPACA)

## *“Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests”*

(42 CFR Parts 402 and 403); 76 Fed. Reg. 78742 (Dec. 19, 2011)

*This chart lists requests for comment or input made by the Centers for Medicare & Medicaid Services (CMS) in its proposed rule implementing the Sunshine Provisions in Section 6002 of the Patient Protection and Affordable Care Act (PPACA) (42 U.S.C. § 1320a-7h). The chart lists the applicable sections of the proposed rule for each CMS request for comment.*

### PROPOSED RULE SUB-SECTION

### CMS REQUESTS FOR COMMENT

## § II. Provisions of the Proposed Regulations

II. Preamble: Provisions of the Proposed Regulations

**Topic: “Preparation period” following publication of the final rule.**

“We seek comment on the amount of time applicable manufacturers and applicable GPOs will need following publication of the final rule in order to begin complying with the data collection requirements of section 1128G of the Act. We are considering a preparation period of 90 days, since we believe that was the time period intended by Congress based on the timeline indicated in the statute and are requesting comments on whether that is a sufficient amount of time.”

II. Preamble: Provisions of the Proposed Regulations

**Topic: Challenges in data collection and reporting.**

“Finally, we also seek input on specific challenges that applicable manufacturers and applicable GPOs may face when setting up the necessary data collection and reporting systems.”

II. Preamble: Provisions of the Proposed Regulations

**Topic: Timing for reporting CY 2012 data in 2013.**

“We seek comments on the feasibility of submitting the required information for part of CY 2012 by March 31, 2013.”

## § II. A. Transparency Reports

II. A.  
Transparency Reports

**Topic: Separate reporting of 1) payments or transfers of value to covered recipients and 2) ownership and investment interests of physicians and their immediate family members—and payments to physician owners or investors.**

“While there is some overlap between these submissions, we propose that these two types of information be reported separately to ensure that the relevant reporting obligations of applicable manufacturers and applicable GPOs are clearly distinguished. We seek comments on this general approach.”

## § II. A. 1. Reports on Payments and Other Transfers of Value Under Section 1128G(a)(1) of the Act

II. A. 1. A. (1)

Manufacturers

**Topic: Definition of “applicable manufacturers.”**

“We interpret these entities as being “engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply.” We seek comment on this interpretation.”

II. A. 1. A. (1)

Manufacturers

**Topic: Definition of “common ownership”—CMS proposes to define common ownership as covering any ownership portion of two or more entities, but CMS is also considering an alternate interpretation that would limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities.**

“We seek comments on our proposed definition of ‘common ownership,’ including, whether a more specific definition is needed and, if a minimum percentage threshold is adopted, whether 5 percent is appropriate.”

II. A. 1. A. (2)

Covered Drug, Device, etc.

**Topic: Definition of “covered drug, device, biological or medical supply”—includes drugs and biologics that require a prescription to be dispensed.**

“We seek comments on the proposal to limit covered drugs and biologics to those that require a prescription to be dispensed.”

II. A. 1. A. (2)

Covered Drug, Device, etc.

**Topic: Definition of “covered drug, device, biological or medical supply”—includes devices and medical supplies that, by law, require premarket approval from the FDA.**

“This would exclude many Class I devices and certain Class II devices, which are exempt from premarket notification requirements under 21 U.S.C. 360(l) or (m), such as tongue depressors and elastic bandages. Some of these devices and medical supplies are so routinely provided in the course of medical care that the Congress may not have intended to capture manufacturers of such items under these reporting requirements... We seek comment on this additional limitation that we are proposing...” [Per § II. A. 2. A. (2): “We believe the device limitation may be appropriate for defining the universe of applicable manufacturers, but are considering that it may be overly limiting for the definition of applicable GPOs, since GPOs often purchase, arrange for, or negotiate the purchase of routine devices and medical supplies.”]

II. A. 1. B.

Covered Recipients

**Topic: Definition of “teaching hospital” as including 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.**

“While we recognize that this definition may not capture hospitals with accredited resident programs that do not receive IME or GME payments, we are unable to include these hospitals since we cannot readily identify them based on Medicare payment data. We seek comment on this proposed definition.”

II. A. 1. C.

Identification of Covered Recipients

**Topic: Whether to require that applicable manufacturers report another unique identifier, such as State license number, for physicians who are identified, but do not have an NPI.**

“We seek comments on what other unique identifiers could be used, including whether these unique identifiers are readily obtainable by applicable manufacturers.”

## PROPOSED RULE SUB-SECTION

## CMS REQUESTS FOR COMMENT

II. A. 1. C.

Identification of Covered Recipients

**Topic: CMS' proposal, with respect to teaching hospitals, to publish a list of hospital covered recipients (that is, those hospitals that received Medicare direct or indirect GME) on the CMS Web site once per year, including the name and address of each teaching hospital.**

"The list for the reporting year would include the most recent data available. We propose that the list of teaching hospital covered recipients should include the name and address of each teaching hospital. We seek comments on this proposal."

II. A. 1. D.

Payments or Other Transfers of Value

**Topic: CMS' proposal that payments or other transfers of value provided through a group or practice should be reported individually under the name(s) of the physician covered recipient(s).**

"Reporting the entity or individual paid will maximize transparency about the details of the payment or other transfer of value, by allowing end users to discern whether a covered recipient actually received the payment, and if not, where the payment went. We do not believe it is feasible to provide a review period for these entities or individuals before the data is made publicly available on the CMS Web site. Instead, we believe that review by the covered recipient is sufficient. We welcome comment on this approach."

II. A. 1. (e) (4)

Date of Payment

**Topic: For payments or transfers of value provided over multiple dates, CMS' proposal that applicable manufacturers use their discretion over whether to report the total payment on the date of the first payment as a single line item, or to report each individual payment as a separate line item. Under this proposal, either approach would comply with these regulations.**

"We are also considering requiring manufacturers to report multiple payments in a single consistent manner. We seek comments on these proposals."

II. A. 1. (e) (5)

Associated Covered Drug, Device, Biological, or Medical Supply

**Topic: CMS' proposal that applicable manufacturers report only one covered drug, device, biological, or medical supply as related to a payment or other transfer of value, even though there arguably may be multiple products related to the payment.**

"Allowing the reporting of multiple covered drugs, devices, biologicals and medical supplies may be easier for applicable manufacturers since many financial relationships are not specific to one product only, but would make aggregating payments by product difficult. We seek comment on this approach."

II. A. 1. (e) (6)

Form of Payment and Nature of Payment

**Topic: CMS' proposal for requiring reporting payments under a single form of payment and nature of payment.**

"We seek comment on the proposal to require reporting payments under a single form of payment and nature of payment. We welcome comments about the usefulness of this data as well as any operational issues that applicable manufacturers might face in reporting it.

We also solicit comment on an alternative approach of allowing a payment or other transfer of value for an activity that is associated with multiple segregable categories to be reported as a single lump sum, rather than separately by each segregable category. This approach may be more compatible with existing business processes, but it might also make the public disclosure database more confusing for end users. We welcome comment on the costs and relative advantages and disadvantages of this approach."

II. A. 1. F.

Forms of Payments

**Topic: No additions to the forms of payments that applicable manufacturers must use to describe payments or other transfers of value.**

"We do not propose to add any forms of payment beyond those outlined in the statute because we believe what is provided in the statute is sufficient to describe payments and other transfers of value. We seek comments on whether other categories are necessary or would be helpful."

## PROPOSED RULE SUB-SECTION

## CMS REQUESTS FOR COMMENT

II. A. 1. G.

Nature of Payment

**Topic: CMS' proposal to allow applicable manufacturers to submit with their data a document describing the assumptions used when categorizing the natures of payments. Submission of the assumptions document will not be mandatory .... The assumptions documents will not be posted on the public Web site because they may contain information applicable manufacturers would consider proprietary.**

"We recognize that many of these categories are similar, so the assumptions document can also help us understand the assumptions made by applicable manufacturers when classifying payments or other transfers of value. We seek comment on this proposal, including whether we should make submission of the assumptions document mandatory instead of voluntary."

II. A. 1. G. (2)

Food and Beverage

**Topic: CMS' proposals that applicable manufacturers should report the value of any food or beverage items provided to covered recipients, subject to the \$10 minimum threshold for reporting a payment or other transfer of value, and applicable manufacturers should report the cost per covered recipient receiving the meal (even if the covered recipient does not actually partake of the meal).**

"We recognize that this may be difficult for large group practices or hospital-based physicians, where an applicable manufacturer may be bringing bagels for a meeting with two specialists. We are considering whether to adopt a different approach for these situations, such as counting the number of physicians by department. We seek comment on these proposals and whether there is a more equitable, but not overly burdensome, way to report these payments or other transfers of value."

II. A. 1. G. (3)

Research

**Topic: CMS' proposed method for reporting research payments, which includes, among other things: 1) limiting the research category to bona fide research activities, including clinical investigations that are subject to both a written agreement or contract between the applicable manufacturer and the organization conducting the research, as well as a research protocol; 2) separate reporting of research payments that go indirectly or directly to the covered recipient; 3) when reporting indirect or direct research ... the payment or other transfer of value should be reported individually under the names and NPIs of physician covered recipients serving as principal investigators. ... 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; and 4) research payments provided to teaching hospitals and ultimately to physician covered recipients must be reported for both the teaching hospital covered recipient, and the physician covered recipient(s). (See proposed rule for details)**

"Due to the complexities in the flow of research payments, we have outlined a proposed method for reporting research payments. However, we request comment on whether our proposed method is viable and not overly burdensome, and whether an alternative method would be preferable."

II. A. 1.G. (3)

Research

**Topic: CMS' proposal that for both direct and indirect research, applicable manufacturers must report the entire payment amount for each research payment (whether to the covered recipient or research institution), rather than the specific amount that was provided to the covered recipient. However, on the public Web site, CMS would report the payment amount separately and would not aggregate it into the total for physician covered recipients.**

"For teaching hospitals, we believe end users would understand that the research payment covered all aspects of the research, so we believe it is appropriate to aggregate this into the teaching hospital's total payment amount. However, for physician covered recipients we believe attributing the full research payment to the physician could be misleading, due to the nature of research payments as described. We seek comment on these proposals."

## PROPOSED RULE SUB-SECTION

## CMS REQUESTS FOR COMMENT

II. A. 1. G. (3)

Research

**Topic: Coverage of other circumstances in which applicable manufacturers make payments or other transfers of value to covered recipients for research-related activities.**

“We recognize that the proposed reporting requirements for research payments and transfers of value may not cover all circumstances in which applicable manufacturers make payments or other transfers of value to covered recipients for research-related activities (for example, post-marketing research or other research or studies not conducted pursuant to a written contract between the applicable manufacturer and the organization conducting the research, and those studies without a research protocol). We solicit comments about which existing nature of payment category (previously described) would apply to these other types of research, whether the scope of the “research” nature of payment should be broadened, and/or whether another nature of payment category should be added to address such research.”

II. A. 1. G. (4)

Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program

**Topic: CMS’ proposal that this category be interpreted broadly to encompass all instances in which applicable manufacturers pay physicians to serve as speakers, and not just those situations involving “medical education programs.”**

“Alternatively, we are considering adding another nature of payment category to describe situations when a covered recipient provides speaking services that are outside of medical education programs; however we believe that fewer categories for nature of payment is preferable. Additionally, it is simpler to only have one category for speaker fees to minimize potential inconsistencies in how applicable manufacturers categorize payments. We welcome comment on this proposal and the appropriate distinction between this nature of payment category and other categories, such as honoraria.

We realize that this interpretation does not allow for differentiation between continuing medical education (CME) accredited speaking engagements, and all other speaking engagements. We are considering, and welcome comments on, whether to limit this category to CME-accredited speaking engagements and report other speaking engagements in another category, such as compensation for services other than consulting, or additional category.”

II. A. 1. H.

Exclusions

**Topic: CMS’ intent to exclude purely personal transfers of value.**

“We anticipate that the public may inquire about the treatment of payments or other transfers of value between individuals who happen to have existing personal relationships. It is not our intent to capture purely personal transfers of value (for example, if one spouse, who works for an applicable manufacturer, gives a present to the other spouse who is a covered recipient). We welcome suggestions on how to incorporate this into the codified language of the final rule.”

II. A. 1. H. (2)

Exclusions: Educational Materials That Directly Benefit Patients or Are Intended for Patient Use

**Topic: Which types of educational materials provided to covered recipients should be deemed to “directly benefit patients” [for example, CMS is considering how to handle medical textbooks given to covered recipients but not actually given to patients].**

“We are considering whether certain materials provided by applicable manufacturers to covered recipients to educate the covered recipients themselves, but which are not actually given to patients (for example, medical textbooks), should be interpreted as educational materials that ‘directly benefit patients.’ We seek comments on whether such materials should be included in this exclusion and, if so, which types of educational materials provided to covered recipients should be deemed to ‘directly benefit patients.’”

## § II. A. 2. Reports on Physician Ownership and Investment Interests Under Section 1128(G)(a)(2) of the Act

II. A. 2. a. (2)

Applicable Group Purchasing Organizations

**Topic: CMS' proposal that the definition will not include entities that buy covered drugs, devices, biologicals, or medical supplies solely for their own use.**

"We propose that the definition will not include entities that buy covered drugs, devices, biologicals, or medical supplies solely for their own use, such as some large practices or hospitals (including those owned by physicians). Rather, it is our intent to capture entities (including physician-owned entities) that purchase covered drugs, devices, biologicals, or medical supplies for resale or distribution to others. We solicit comments on this proposal."

II. A. 2. a. (2)

Applicable Group Purchasing Organizations

**Topic: Definition of "covered drug, device, biological or medical supply"—includes devices and medical supplies that, by law, require premarket approval from the FDA. (See § II. A. 1. a. (2) above)**

"We believe the device limitation may be appropriate for defining the universe of applicable manufacturers, but are considering that it may be overly limiting for the definition of applicable GPOs, since GPOs often purchase, arrange for, or negotiate the purchase of routine devices and medical supplies. We seek comment on whether to include the proposed limitation on devices and medical supplies in the definition of covered drug, device, biological, or medical supply."

II. A. 2. d.

Physician Ownership or  
Investment Report Content

**Topic: Whether CMS should report the relationship and/or the name of the immediate family member holding the ownership and investment interest in cases when an ownership or investment interest in an applicable manufacturer or applicable GPO is held by an immediate family member of a physician.**

"We are considering whether to require the reporting of the immediate family member's relationship to the physician, as well as the immediate family member's name, in order to bring additional transparency to the nature of the relationship. We believe this would provide additional details on the nature of the relationship; however, we wonder whether this information is worth the additional collection of information, particularly since we believe, due to privacy concerns, that the name of the immediate family member should not be made public. We seek comment on whether to report the relationship and/or the name of the immediate family member holding the ownership and investment interest."

## § II. B. Report Submission & Correction

II. B.

Report Submission & Correction

**Topic: CMS proposes standardized procedures for applicable manufacturers and applicable GPOs to submit the required information.**

"Based on our stakeholder outreach and analysis of the data systems available, we are proposing a potential system for the submission of data to CMS. We seek comments on the proposed approach and whether an alternative system would be preferable."

II. B. 1.

Prior to Submission

**Topic: A way for applicable manufacturers and applicable GPOs to make necessary corrections prior to submission to CMS.**

"We are considering ways to ease the post-submission review process of this information and facilitate early resolution of conflicts between applicable manufacturers, applicable GPOs, covered recipients and physician owners or investors. We seek comments on a way for applicable manufacturers and applicable GPOs to make necessary corrections prior to submission to CMS, thus lessening potential changes during the statutory review and correction period, and thereby strengthening the accuracy of the data."

## PROPOSED RULE SUB-SECTION

## CMS REQUESTS FOR COMMENT

II. B. 1.

Prior to Submission

**Topic: CMS recommendation (but not requirement) that applicable manufacturers and applicable GPOs provide for a “presubmission review” according to which applicable manufacturers, prior to submitting data to CMS, provide each covered recipient with information regarding the payments or other transfers of value that the applicable manufacturer plans to report to CMS as having made to the covered recipient. Similarly, applicable manufacturers and applicable GPOs could provide to each physician owner or investor the information they plan to report regarding the ownership and investment interests held by the physician owner or investor.**

“While CMS is not proposing to require this type of pre-review, we recommend that applicable manufacturers and applicable GPOs provide for a ‘presubmission review,’ and we seek comment on whether a pre-review of this nature would be useful.”

II. B. 2.

Report Submission

**Topic: Timing of registration and report submission process for applicable manufacturers and applicable GPOs beginning on January 1, 2013 and by March 31, 2013 and the 90th day of each year thereafter.**

“We are proposing to open the registration process at the beginning of the calendar year, giving applicable manufacturers and applicable GPOs time to register and submit their data. The first opportunity for registration and the data submission would be January 1, 2013. We seek comment on the proposed timing of the registration and submission process.”

II. B. 2.

Report Submission

**Topic: Potential requirement that all applicable manufacturers and applicable GPOs register with CMS, regardless of whether they have information to report.**

“We believe this may help us better understand the extent of these relationships (including which types of entities have financial relationships with covered recipients and physician owners and investors and which do not). Additionally, we believe such a requirement would ensure that applicable manufacturers and applicable GPOs perform a more thorough evaluation to determine whether they have any reportable information. However, we are seeking input on whether requiring registration for all entities and an attestation from entities with no reportable information would be more burdensome than beneficial. We seek comment on both the benefits and burdens of this consideration and intend to finalize the agency’s position on this in the final rule based on comments received.”

II. B. 2.

Report Submission

**Topic: CMS’ proposal that applicable manufacturers and applicable GPOs submit their data electronically in a comma-separated value (CSV) format. Each line item in the dataset should represent a unique payment or other transfer of value, or a unique ownership or investment interest.**

“We seek comments on the appropriateness of the CSV format for data submission, and suggestions for alternative formats.”

II. B. 3.

Report Format

**Topic: CMS proposed fields of information to be included when reporting payments or other transfers of value and physician ownership and investment interests.**

“We seek comment on our proposed requirements regarding the data elements that should be submitted and plan to finalize them in the final rule based on comments received.”

II. B. 4.

45-Day Review Period for Applicable Manufacturers, Applicable GPOs, and Covered Recipients

**Topic: CMS proposed procedures for data submission and the 45-day review period (See proposed rule for details).**

“We seek comments on the procedures outlined for data submission and the 45-day review period, particularly the best way to contact covered recipients and physician owners or investors to ensure they receive notification of the review period.”

## PROPOSED RULE SUB-SECTION

## CMS REQUESTS FOR COMMENT

II. B. 4.

45-Day Review Period for Applicable Manufacturers, Applicable GPOs, and Covered Recipients

**Topic: CMS' proposal to notify physicians and hospitals through CMS' list serves and posting the information publicly about the procedures for the review the data submitted for a period of at least 45-days prior to the data being made available to the public.**

"We are considering a posting either on the CMS Web site or on the *Federal Register*, and seek comment on which would be most useful to physicians and teaching hospitals."

II. B. 4.

45-Day Review Period for Applicable Manufacturers, Applicable GPOs, and Covered Recipients

**Topic: CMS' proposal on its proposed method of notification, as well as the alternative method provided, for these notifications to be provided annually to announce the covered recipient and physician owner and investor review and correction period and including the specific instructions for performing this review.**

"For example, we are considering that covered recipients and physician owners and investors would sign in to a secure Web site to see the information reported about them. We are also considering an alternative method, in which we would require applicable manufacturers and applicable GPOs to collect and report whether the covered recipient, or physician owner or investor would like to be notified by USPS or email of the processes for their review, as well as the individual's email address, if indicated. We seek comment on our proposed method of notification, as well as the alternative method provided. We solicit comments on other ways that CMS, applicable manufacturers, or applicable GPOs can provide timely, adequate, and cost-effective notice to covered recipients and physician owners or investors of their opportunity to review the collected data."

II. B. 4.

45-Day Review Period for Applicable Manufacturers, Applicable GPOs, and Covered Recipients

**Topic: CMS' proposal that if an applicable manufacturer or applicable GPO, and covered recipient, or physician owner or investor have contradicting information that cannot be resolved by the parties involved, then the data would be identified as contradictory and both the original submission from the applicable manufacturer or applicable GPO, and the modified information provided by the covered recipient, or physician owner or investor would appear in the final publicly available Web site.**

"We believe that this is preferable since the covered recipient and physician owner or investor stakeholders have expressed concern about the accuracy of information submitted by the applicable manufacturer or applicable GPO. However, we are also considering aggregating the original information, as submitted by the applicable manufacturer and applicable GPO. We seek comment on this proposal and suggestions for how best to handle instances where there are outstanding disagreements."

## § II. C. Public Availability

II. C.

Public Availability

**Topic: CMS' proposals for publishing on a publicly available Web site the data reported by applicable manufacturers and applicable GPOs for CY 2012 by September 30, 2013 and for each year thereafter, publishing the data for the preceding calendar year by June 30th.**

"The public Web site must be searchable, understandable, downloadable, and easily aggregated on various levels, as stated in the statute. In addition, section 4 of Executive Order 13563 calls upon agencies to consider approaches that 'maintain flexibility and freedom of choice for the public,' including the 'provision of information to the public in a form that is clear and intelligible.' We request comments on how to structure this Web site for ultimate usability... We welcome comment regarding the details and format for how this information should be displayed on the Web site."

## § II. D. Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements and Clinical Investigations

II. D.

Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements and Clinical Investigations

**Topic: CMS' proposals regarding delayed publication for payments made pursuant to product research or development agreements and clinical investigations. (See proposed rule for details)**

"We seek comment on these proposals and solicit comment on whether there are better ways to distinguish among these categories for the purposes of delayed publication, including treating payments and transfers of values made in connection with clinical investigations the same as those made in connection with research and development."

II. D.

Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements and Clinical Investigations

**Topic: CMS' proposals for implementing delayed 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.**

"The statute requires that information about payments and other transfers of value that are delayed from publication must be made publicly available on the first publication date after the earlier of either: (1) The approval, licensure or clearance by the FDA of the covered drug, device, biological or medical supply; or (2) 4-calendar years after the date of payment.... We seek comment on these proposals [implementing these requirements]."

II. D.

Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements and Clinical Investigations

**Topic: CMS' proposal to consider "medical technology" broadly as any drug, device, biological, or medical supply.**

"We propose this interpretation because we believe that the rationale underlying the statutory inclusion of the delayed publication provision—protecting an applicable manufacturer's legitimate proprietary and competitive interests in research and development—should apply to all applicable manufacturers under this statute. Moreover, it is difficult to fairly carve out certain applicable manufacturers or certain products for differing standards of delayed publication. Alternatively, we are considering defining "medical technology" more narrowly as a subset of drugs, devices, biologicals, and medical supplies. We seek comments on both approaches, including suggestions for a narrower definition of "medical technology."

II. D.

Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements and Clinical Investigations

**Topic: Given that the statute distinguishes between the scope of delayed publication permitted for payments related to "research" versus payments related to "development" or "clinical investigations," CMS' proposal to treat them similarly in this provision.**

"It is difficult to meaningfully separate research and development due to the overlap in the activities associated with them, and the fact that they are commonly used synonymously. Given this close association between the terms, we propose to treat them similarly in this provision. However, we are also considering the possibility of assigning different meanings to "research" and "development," and we seek comments on this approach and suggestions for meaningful distinctions for the two terms."

## § II. E. Penalties

II. E.  
Penalties

**Topic: CMS' proposed factors to be considered in determining the amount of a Civil Monetary Penalty (CMP) authorized by Section 1128G(b) of the Act.**

"In determining the amount of the CMP, we propose that the factors to be considered include, but are not limited to, the following:

- The length of time the applicable manufacturer or applicable GPO failed to report, including the length of time the applicable manufacturer and applicable GPO knew of the payment or other transfer of value, or ownership or investment interest.
- Amount of the payment or other transfer of value or the value of the ownership or investment interest the applicable manufacturer or applicable GPO failed to report.
- Level of culpability.
- Nature and amount of information reported in error.
- Degree of diligence exercised in correcting information reported in error.

We seek comments on these proposals."

II. E.  
Penalties

**Topic: CMS' proposal that the HHS Secretary, CMS, OIG, or their designees may audit, evaluate, or inspect applicable manufacturers and applicable GPOs for their compliance with timely, complete and accurate submission of information required in section 1128G of the Act and the implementing regulations. CMS' proposal that applicable manufacturers and applicable GPOs must maintain these books, records, documents, and other materials 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 publicly on the Web site.**

"Access to this information is implicit in the statute in order to enforce the requirements outlined.... We believe that 5 years from the date of publication is sufficient for all audit, inspection, or evaluation activities. The requirements set forth in this proposed rule are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable GPOs to retain and allow access to records. We seek comments on these proposals."

## § III. Collection of Information Requirements

III.  
Collection of Information Requirements—  
Information Collection Requests (ICRs)

**Topic: Solicitations for comments, as required by the Paperwork Reduction Act of 1995.**

"In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques."

## PROPOSED RULE SUB-SECTION

## CMS REQUESTS FOR COMMENT

III. A.

ICRs Regarding Reports of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904, § 403.906 and § 403.908(a) Through (g))

**Topic: CMS estimate of the total number of device manufacturers that are applicable manufacturers.**

"For device manufacturers, we used data from the FDA to identify the total number of manufacturers to use as a ceiling for our estimate. We seek comment on whether there are any other sources of data available."

III. A.

ICRs Regarding Reports of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904, § 403.906 and § 403.908(a) Through (g))

**Topic: Costs of 5-year records retention requirement.**

"As a technical point, we note that we propose a 5-year records retention requirement. We believe the costs of this are negligible for electronic record keeping, but solicit comment on this approach."

III. A.

ICRs Regarding Reports of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904, § 403.906 and § 403.908(a) Through (g))

**Topic: With respect to the burden of collection of information requirements, specific problems or timesaving options, particularly with respect to the burden of collecting and recording information for each payment or transfer of value by the staff and identifying whether individuals with ownership or investment interests have physicians as immediate family members.**

"We welcome more detailed and disaggregated information that would help us improve the overall estimate or better craft the final rule to deal with specific problems or timesaving options. We are particularly interested in the burden of collecting and recording information for each payment or transfer of value by the staff and identifying whether individuals with ownership or investment interests have physicians as immediate family members."

III. A.

ICRs Regarding Reports of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904, § 403.906 and § 403.908(a) Through (g))

**Topic: The burden of collection of information requirements on applicable manufacturers of various sizes.**

"We welcome comments that can provide empirical data on the costs to implement the requirements in firms of varying sizes and product portfolios, on the extent to which systems already in place meet the proposed requirements in firms of various kinds and sizes, and on the extent to which firms would modify their practices to avoid reporting costs."

III. A.

ICRs Regarding Reports of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904, § 403.906 and § 403.908(a) Through (g))

**Topic: The burden of collection of information requirements on applicable GPOs.**

"Also again, we have not found any empirical studies to better inform this estimate. Accordingly, we estimate that on average, an applicable GPO would dedicate 10 percent of an FTE employee to reporting under this section for year 1, followed by 7.5 percent for year 2 and annually thereafter. We welcome any comments or data that would improve this estimate."

III. B.

ICRs Regarding Review and Correction by Physicians and Teaching Hospitals (§ 403.908(h))

**Topic: The burden of collection of information requirements on applicable covered recipients and physician owners or investors.**

"An additional burden associated with section 1128G of the Act is the time and effort spent by covered recipients, and physician owners or investors reviewing, and if necessary, correcting the data before it is reported publicly. Neither the statute, nor this proposed rule, contains a record keeping requirement for physicians or teaching hospitals. Therefore, while we evaluated the burden associated with the review and correction process, we do not include an estimate of the burden for keeping records. We seek comments on this assumption, and on the extent to which physicians and teaching hospitals will keep records in the absence of a requirement to do so."

## PROPOSED RULE SUB-SECTION

## CMS REQUESTS FOR COMMENT

III. B.

ICRs Regarding Review and Correction by Physicians and Teaching Hospitals (§ 403.908(h))

**Topic: The burden of collection of information requirements on teaching hospitals.**

"We believe that teaching hospitals would have to review more payments or other transfers of value and have more complex relationships, so we estimate that, on average, it would take a representative from a teaching hospital 10 hours to review the submitted data, ranging from 3 hours for small teaching hospitals that receive few payments or other transfer of value, to 60 hours for teaching hospitals that have lengthy disputes. We welcome comment and data on these estimates, and particularly welcome data from physicians and institutions in States that have required similar reporting in the past."

III. B.

ICRs Regarding Review and Correction by Physicians and Teaching Hospitals (§ 403.908(h))

**Topic: The burden of collection of information requirements on applicable covered recipients and physician owners or investors.**

"We emphasize that these estimates are, by necessity, uncertain, and that we particularly solicit comments providing us a better basis for final estimates.

If you comment on these information collection and record keeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or
2. Submit your comments to:

Office of Information and Regulatory Affairs, Office of Management and Budget  
Attention: CMS Desk Officer, CMS- 5060-P.  
Fax: (202) 395-5806; or  
Email: OIRA\_submission@omb.eop.gov."

III. B.

Overall Impact

**Topic: All assumptions and estimates in CMS' regulatory impact analysis.**

"We estimate that this rulemaking is "economically significant" as measured by the \$100 million threshold. Accordingly, we have prepared a Regulatory Impact Analysis that presents estimated costs and benefits of the rulemaking. We solicit comments on all assumptions and estimates in this regulatory impact analysis."

III. B.

Overall Impact

**Topic: CMS' assumption that the majority of teaching hospitals and physicians, and most applicable manufacturers and applicable GPOs are small entities under either the size or not-for-profit standard.**

"For purposes of the RFA, we estimate that the majority of teaching hospitals and physicians, and most applicable manufacturers and applicable GPOs are small entities under either the size or not-for-profit standard. We seek comment on our assumptions and estimations regarding the RFA."

III. C.

Anticipated Effects

**Topic: CMS' assumptions, data, estimates, and anticipated effects of the regulatory impact of this provision.**

"Because of a paucity of existing data on which to base these estimates they are very uncertain. We solicit comments on the assumptions, data, estimates, and anticipated effects described throughout this analysis and section III. of this proposed rule."

III. 1.

Effects on Applicable Manufacturers and Applicable GPOs

**Topic: Whether it is possible to approximate the lessened burden for entities already reporting under state laws and/or in order to comply with Corporate Integrity Agreements (CIAs) with HHS OIG.**

"However, given the differing requirements for each State and CIA, and broad scope of section 1128G of the Act, we do not believe it is possible to approximate the lessened burden for entities already reporting. We seek comment on this interpretation and whether there is a more precise way to quantify these estimates. Further, we estimate that applicable manufacturers and applicable GPOs may face significant first year costs in scaling and staffing up to meet the reporting requirements."

## PROPOSED RULE SUB-SECTION

## CMS REQUESTS FOR COMMENT

<p>III. D. Alternatives Considered</p>	<p><b>Topic: Assessment of the alternatives considered by CMS.</b></p> <p>“These examples demonstrate our effort to minimize the regulatory burden of this proposed rule and we solicit comments on all the alternatives considered in this section or elsewhere in the preamble.”</p>
<p>III. D. Alternatives Considered</p>	<p><b>Topic: The potential cost and transparency implications of including covered drugs and biologicals other than those that require a prescription to be dispensed and covered devices (including medical supplies) other than those that require premarket approval by or notification to the FDA.</b></p> <p>“These limitations may reduce the number of entities meeting the definition of applicable manufacturer and applicable GPO. However, we do not expect that removing these limitations would significantly change the regulatory burden because we do not expect many companies that manufacture only these exempt products to have significant relationships with physicians and teaching hospitals. As a result, if the companies were included as applicable manufacturers, they would likely not be required to file a report, or would only have a few relationships to report, thus minimizing the burden. We request information on the potential cost and transparency implications of including these products.”</p>
<p>III. D. Alternatives Considered</p>	<p><b>Topic: The potential implications of CMS’ proposed definition of “common ownership” or of variations for ease of implementation, scope of covered entities or transparency implications.</b></p> <p>“We propose to define “common ownership” as covering any ownership portion of two or more entities, but are also considering an alternate interpretation that would limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities. We solicit information on the potential implications of this option or of variations for ease of implementation, scope of covered entities or transparency implications.”</p>
<p>III. D. Alternatives Considered</p>	<p><b>Topic: CMS’ proposal that applicable manufacturers may leave the NPI blank for physicians that do not have an NPI.</b></p> <p>“We are also considering whether we should require that applicable manufacturers report another unique identifier, such as State license number, for physicians who are identified but do not have an NPI. Such an approach would provide additional information by which to cross-reference physicians who do not have an NPI, but it may be confusing to interpret if it is not captured in a consistent manner. Instead, we are proposing that applicable manufacturers may leave the NPI blank for physicians that do not have an NPI. We seek comments on this alternative.”</p>
<p>III. D. Alternatives Considered</p>	<p><b>Topic: CMS’ proposal to include physician owned distributors (PODs) of covered drugs, devices, biologicals, and medical supplies in its interpretation of its definition of a GPO.</b></p> <p>“We therefore interpret the statute to encompass entities that purchase covered drugs, devices, biological[s], and medical supplies for resale or distribution to groups of individuals or entities. This would include physician owned distributors (PODs) of covered drugs, devices, biological[s], and medical supplies. We welcome comment on this interpretation and on whether there is some variation that would reasonably distinguish entities according to potential for improper influence.”</p>

## PROPOSED RULE SUB-SECTION

## CMS REQUESTS FOR COMMENT

III. D.

Alternatives Considered

**Topic: An alternative time period for the 45-day review period during which applicable manufacturers and GPOs, covered recipients, and physician owners or investors can review the data before it is made available to the public—as well as possible alternatives to this approach that might better serve the interest of all concerned in publication of accurate information.**

“We request comments on alternative time periods and, especially, on possible alternatives to this approach that might better serve the interest of all concerned in publication of accurate information. For example, should there be a two-step process, in which the information when first released is labeled provisional, and ‘final’ data is labeled as such after a second opportunity for correction? As previously discussed, what about mail or email options? Should applicable manufacturers and applicable GPOs be required to inquire of covered recipients and physician owners or investors of their opportunity to review the data? We welcome comments on any approach that minimizes costs or improves accuracy of the information. We also would welcome information on the likely frequency of cases in which additional communication methods would be necessary, useful, costly, inexpensive, or otherwise better or worse.”

III. D.

Alternatives Considered

**Topic: Ideas on how to improve the quality and utility of the program, while minimizing unnecessary costs—particularly comments that provides ways to quantify the potential savings from proposed methods.**

“As these alternatives suggest, we welcome ideas on how to improve the quality and utility of the program, while minimizing unnecessary costs. We particularly welcome comments that can provide not only better methods, but also ways to quantify the potential savings from those methods.”

III. E.

Accounting Statement (Table 7)

**Topic: The burden of the rule in future years and CMS’ assumptions for the burden beyond year two.**

“We assume that future outlay costs may be similar to those costs experienced in year two. We envision that the number of financial relationships required to be reported will remain similar, so the cost of reporting the information will not change significantly. However, we welcome information on the burden in these future years and seek comment on our assumptions for the burden beyond year two.”

III. F.

Conclusions

**Topic: Analysis and assumptions provided throughout this preamble and in the alternatives section of the regulatory impact analysis in particular.**

“Nonetheless, we believe that the public comment period offers an excellent opportunity for all stakeholders to consider alternatives and to present quantitative or qualitative information that will enable us to both improve the effectiveness and lower the costs of the final rule. Therefore, we solicit comments on the analysis and assumptions provided throughout this preamble and in the alternatives section of the regulatory impact analysis in particular.”