REGULATORY LAW GROUP PLLC

WHITE PAPER

A Review and Analysis of the Proposed Rules in Support of the Physicians Payment Sunshine Act

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Introduction

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On December 19, 2011, the Centers for Medicare & Medicaid Services (CMS) published the proposed rule implementing the transparency provisions set forth at section 6002 of the Patient Protection and Affordable Care Act (PPACA).[1, 2]

The following summary is intended to serve as an overview of the proposed rule. CMS will receive public comments up until 5:00 p.m Eastern Standard Time on February 17, 2012.

According to the proposed rule, manufacturers will not be required to begin collecting the data until after the final rule is published. CMS is considering requiring manufacturers to begin collecting data 90 days after the date of publication of the final rule. Manufacturers would then be required to submit an interim report on or before March 31, 2013.

Section 1128G of PPACA outlines the transparency reporting requirements as it relates to (1) required reports from applicable manufacturers on payments or other transfers of value to covered recipients[3]; and (2) reporting requirements for applicable manufacturers and GPOs concerning ownership and investment interests of physicians (including immediate family members) as well as information on any payments or transfers of value made to physician owners or investors.[4] In order to clearly distinguish between these two reporting requirements, CMS proposes that these two types of information be reported separately.

In addition to the proposed rule, CMS provided an Addendum consisting of sample reporting templates for payments or other transfers of value (Section 1128G(a)(1)) as well as physician ownership or investment interests (Section 1128G(a)(2)).

The following summary reviews the proposed rule consistent with the delineation set forth above. The various sections of the proposed rule are set forth in full followed by "Commentary" that is intended to serve as a distillation of the rationale and/or interpretation provided by CMS. Because these are proposed rules, CMS is seeking comments from interested parties to help guide the formulation of the final rules. Interested parties are encouraged to submit comments either electronically or via direct mail as follows:

Electronic submission:

http://www.regulations.gov

Regular mail:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
P.O. Box 8013,
Baltimore, MD 21244-8013

Express/Overnight mail:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

[1] 42 U.S.C.A. § 1320a-7h (Transparency Provisions of the Patient Protection and Affordable Care Act).
[2] 76 FR 78742-78771 (December 19, 2011) (Proposed Rules).
[3] Section 1128G(a)(1).
[4] Section 1128G(a)(2).

Reports on Payments and Other Transfers of Value Under §1128G(a)(1)

§ 403.900 Purpose and scope.

The regulations in this subpart implement section 1128G of the Act. These regulations apply to applicable manufacturers and applicable group purchasing organizations and describe the requirements and procedures for applicable manufacturers to report payments or other transfers of value to physicians and teaching hospitals, as well as for applicable manufacturers and applicable group purchasing organizations to report ownership or investment interests held by physicians or immediate family members of physicians.

§ 403.902 Definitions.

Applicable group purchasing organization means an entity that—

(1) Operates in the United States, or in a territory, possession or commonwealth of the United States; and

(2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.

Applicable manufacturer means 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 paragraph (1) of this definition, 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 and distribution in the United States, or in a territory, possession, or commonwealth of the United States.

Charity care means services provided by a covered recipient specifically for a patient who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.

Charitable contribution includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986.

Clinical investigation means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

Common ownership means entities that are owned, in whole or in part, by the same individual, individuals, entity, or entities, directly or indirectly. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.

Covered device means any device for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system).

This definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.

Covered drug, device, biological, or medical supply means any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). With respect to a drug or biological, this definition is limited to those drug and biological products that, by law, require a prescription to be dispensed. With respect to a device or medical supply, this definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.

Covered recipient means—

(1) Any physician, except for a physician who is an employee (as defined in section 1877(h)(2) of the Act) of an applicable manufacturer; or

(2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.

Employee means an individual who is considered to be "employed by" or an "employee" of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).

Immediate family member means any of the following:

(1) Spouse.

(2) Natural or adoptive parent, child, or sibling.

(3) Stepparent, stepchild, stepbrother, or stepsister.

(4) Father-, mother-, daughter-, son-, brother-, or sister-in-law.

(5) Grandparent or grandchild.

(6) Spouse of a grandparent or grandchild.

Know, knowing, or knowingly.
(1) Means that a person, with respect to information—

(i) Has actual knowledge of the information;

(ii) Acts in deliberate ignorance of the truth or falsity of the information; or

(iii) Acts in reckless disregard of the truth or falsity of the information; and

(2) Requires no proof of a specific intent to defraud.

Ownership or investment interest.

(1) Includes, but is not limited to—

(i) Stock, stock option(s) (other than those received as compensation, until they are exercised);

(ii) Partnership share(s);

(iii) Limited liability company membership(s);

(iv) Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) May be direct or indirect and through debt, equity or other means; and

(3) Must not include an ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act, nor any of the following:

(i) An interest in an applicable manufacturer or applicable group purchasing organization that arises from a retirement plan offered by the applicable manufacturer or applicable group purchasing organization to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that applicable manufacturer or applicable group purchasing organization.

(ii) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity.

(iii) An unsecured loan subordinated to a credit facility.

Physician has the same meaning given that term in section 1861(r) of the Act.

Commentary:

Who must submit reports?

Transparency reports required pursuant to section 1128G(a)(1) of the Act must be submitted by "applicable manufacturers."

"Applicable Manufacturer"

The definition of **applicable manufacturer** proposed by CMS is intended to be broad in order to ensure full transparency and comprehensive reporting as envisioned under the statute.

According to the above definition, a manufacturer of a covered drug, device, biological, or medical supply is subject to the requirements of the statute if their products are sold or distributed in the United States, regardless of where the products are manufactured or where the entity is located.[5] In order to meet the definition of an "applicable manufacturer," the manufacturer must only sell or distribute a single

[5] See 76 Fed. Reg. at 78,744.

covered drug, device, biological or medical supply regardless of whether the manufacturer also sells products that are not "covered."[6] Manufacturers that solely produce OTC drugs are not considered "applicable manufacturers" under the proposed rule.[7]

In circumstances where the "applicable manufacturer" sells or distributes both "covered" and non-covered drugs, devices, biological or medical supplies, the proposed rule would require the reporting of "all payments or transfers of value made by an applicable manufacturer to a covered recipient . . . regardless of whether the particular payment or other transfer of value is associated with a covered drug, device, biological or medical supply."[8] As a result, "applicable manufacturers" will be required to track payments as they relate all products, regardless of whether the product is "covered" under Medicaid, Medicare or Children's Health Insurance Programs (CHIP). The requirement to track and report payments or transfers of value extends to those that relate exclusively to OTC products as well, provided the manufacturer otherwise meets the definition set forth above.[9]

The definition of "applicable manufacturer" includes entities that hold FDA approval, licensure, or clearance of a covered drug, device, biological or medical supply regardless of whether the actual product manufacturing is outsourced.[10]

Reporting requirements for entities under common ownership

Entities under **"common ownership"** with an applicable manufacturer that provide assistance or support with respect to the "production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply are also considered "applicable manufacturers." "Common ownership" occurs when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities. "The common ownership definition would apply to a range of corporate arrangements, including, but not limited to, parent companies and subsidiaries and brother/sister corporations." **Please note, CMS is considering adding a 5% threshold of total ownership in the two entities to trigger the "common ownership" definition. The final determination will be based on submitted comments.**[11]

If two entities are under common ownership, and both entities meet the definition of "applicable manufacturer" under paragraph (1) above, CMS proposes that both entities report separately under the Act.

Examples:

Companies A and B are both owned by company C and all meet the definition under paragraph (1) above, all companies must report separately.

Company C meets the definition under paragraph (1) above and companies A and B meet the definition under section (2) above, then the companies can decide whether to report collectively.

If an applicable manufacturer under section (1) above reports for at least one additional entity, the manufacturer may decide whether to identify the payments as arising from the entity under common ownership, or, in the alternative, the manufacturer could combine such payments with their own. In

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[6] See id.
[7] See id. at 78,745.
[8] See id. at 78,744.
[9] See id. at 78,745.
[10] See id.
[11] See id. at 78,744.

addition to payments or transfers of value made directly by applicable manufacturers, such manufacturers are also responsible for reporting payments or transfers of value made on their behalf by 3rd parties if the applicable manufacturer is aware of the identity of the covered recipient.[12]

Who is a covered recipient?

While the definition of "covered recipient" is relatively straightforward as defined in both the Act and the proposed rule, it is worth noting that physicians include doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors.[13] In order to accurately identify the covered recipient, both the Act and the proposed rule require the reporting of the recipient's name and business address. In addition, if the covered recipient is a physician, the applicable manufacturer must also report the NPI number and specialty.[14] In the event that the physician's NPI number is not found within the National Plan & Provider Enumeration System, it is up to the applicable manufacturer to obtain the NPI number from the physician. In the event that the physician does not have an NPI number, CMS is considering whether or not to require the reporting of another unique identifier such as the state license number.[15]

The proposed rule provides much needed clarification with regard to the definition of "teaching hospitals." According to CMS, "teaching hospitals" include institutions that receive payments for direct or indirect graduate medical education. In order to avoid confusion, **CMS proposes to publish a list of teaching hospitals on the CMS website once per year to include the name and address of each institution.**[16]

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[12] See id.
[13] See id. at 78,745.
[14] See id. at 78,746.
[15] See id.
[16] See id.

§ 403.904 Reports of payments or other transfers of value.

(a) General rule. Payments or other transfers of value provided to any covered recipient, including payments to another individual or entity at the request of (or designated on behalf of) a covered recipient, by an applicable manufacturer or a third party (on behalf of an applicable manufacturer) must be reported to CMS by the applicable manufacturer on an annual basis.

(b) Required information to report. A report must contain all of the following information for each payment or other transfer of value:

(1) Name of the covered recipient. If the payment or other transfer of value was provided to another individual or entity at the request of (or designated on behalf of) any covered recipient, the payment or transfer of value must be disclosed in the name of that covered recipient.

(2) Business address of the covered recipient, including street address, suite or office number (if applicable), city, state, and ZIP code.

(3) In the case of a covered recipient who is a physician, the specialty and National Provider Identifier (if applicable) of the covered recipient.

(4) Amount of each payment or other transfer of value to the covered recipient.

(5) Date of each payment or transfer of value to the covered recipient.

(6) Form of each payment or other transfer of value, as described in paragraph (c) of this section.

(7) Nature of each payment or other transfer of value, as described in paragraph (d) of this section.

(8) If a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name under which the covered drug, device, biological, or medical supply is marketed. If the marketed name has not yet been selected, applicable manufacturer must indicate the scientific name. Applicable manufacturers may only report a single covered drug, device, biological or medical supply for each payment or other transfer of value.

(9) The applicable manufacturer must indicate that a payment or other transfer of value is subject to delayed publication, if the payment or other transfer of value is made under any of the following arrangements:

(i) In accordance with a product research or development agreement for services furnished in connection with research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological or medical supply.

(ii) In connection with a clinical investigation regarding a new drug, device, biological, or medical supply.

(10) If the payment or other transfer of value is made to an entity or individual at the request of (or designated on behalf of) a covered recipient, the name of the other individual or entity that receives the payment or other transfer of value.

(11) Whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer.

(c) Reporting the form of payment or other transfer of value. An applicable manufacturer must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms, using the designation that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value. Each of the following terms has its dictionary definition:

(1) Cash or cash equivalent.

(2) In-kind items or services.

(3) Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.

(d) Reporting the nature of the payment or other transfer of value—

(1) General rule. The categories describing the nature of a payment or other transfer of value are mutually exclusive.

(2) Rules for categorizing natures of payment. An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, in one of the categories listed in this paragraph (d)(2), using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value. Each of the following terms has its dictionary definition:

(i) Consulting fee.

(ii) Compensation for services other than consulting.

(iii) Honoraria.

(iv) Gift.

(v) Entertainment.

(vi) Food and beverage.

(vii) Travel and lodging.

(viii) Education.

(ix) Research.

(x) Charitable contribution.

(xii) Royalty or license.

(xiii) Current or prospective ownership or investment interests.

(xiv) Direct compensation for serving as a faculty or as a speaker for a medical education program.

(xv) Grant.

(xvi) Other.

(e) Special rules for research payments.

(1) Applicable manufacturers must designate each research payment or transfer of value as direct research or indirect research.

(i) Direct research, is a payment or other transfer of value provided to a covered entity directly by an applicable manufacturer or through a contract research organization (or similar entity).

(ii) Indirect research, is a payment or other transfer of value provided by an applicable manufacturer (including through a contract research organization or similar entity) to a clinic, hospital, or other institution conducting the research, and that clinic, hospital, or other institution conducting the research in turn pays the physician covered recipient (or multiple physician covered recipients) serving as the principal investigator(s).

(2) All payments or other transfers of value designated as research (direct or indirect) must be subject to a written agreement and research protocol. Direct or indirect research payments (whether made directly by an applicable manufacturer or through a clinical research organization or similar entity) must be reported as follows:

(i) For indirect research, individually under the name(s) and NPI(s) (if applicable) of the physician covered recipient principal investigator(s). The total amount paid to the clinic, hospital or other institution conducting the research, must be reported for each principal investigator.

(ii) For direct research, individually under the name(s) and NPI(s) (if applicable) of the covered recipient. The total must indicate the amount the covered recipient received.

(3) If payment is made to a teaching hospital, the payment to the teaching hospital must be reported as follows:

(i) Direct research under the name of the teaching hospital.

(ii) Indirect research under the name(s) and NPI(s) (if applicable) of the physician covered recipient serving as principal investigator(s).

(4) For direct or indirect payments provided to physician covered recipients, CMS reports the total payment amount separately from other payments or transfers of value.

(f) Exclusions from reporting. The following types of payments or other transfers of value are excluded from the reporting requirements specified in this section:

(1) 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. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient.

(i) For CY 2012, transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.

(ii) For CY 2013 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (f)(2)(i) of this paragraph must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

(2) Product samples that are not intended to be sold and are intended for patient use.

(3) Educational materials that directly benefit patients or are intended for patient use.

(4) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

(5) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(6) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

(7) Discounts, including rebates.

(8) In-kind items used for the provision of charity care.

(9) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

(10) In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

(11) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

(12) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

Commentary

Payments to Group Practices and Third Parties

Under the broad definition "payment or other transfer of value," CMS proposes to include payments or other transfers of value provided to a physician through a physician group or practice. Payments or transfers of value provided through a physician group or practice would be reported individually under the name of the physician.[17] For payments made to 3rd parties at the request of the covered recipient, CMS proposes that the applicable manufacturer also report the name of the entity or individual receiving the payment at the request of the covered recipient.[18]

Required Information to Report

According to Proposed Rule §403.904(b) and CMS' interpretation thereof, the following information must be reported:

1. **Name** of the covered recipient to include the first name, last name and middle initial.
2. **Business address**:

   Physician – Full street address for the physician's primary practice location. Please note, CMS refers to the "provider business practice location" from the NPPES database as the business address.[19] Utilizing the address provided in the NPPES data file may be problematic for both practitioners and consumers as the address may outdated.

   Teaching hospital – Address listed in the forthcoming CMS-published list
3. **NPI Number and Specialty**:

   NPI – Must report physicians individual NPI (not group NPI)

   Specialty – If using the NPPES, CMS recommends using the "provider taxonomy" field for specialty, and further, CMS proposes that only a single specialty be provided.[20]
4. **Amount** of each payment.
5. **Date** upon which the payment was made. For payments or transfers of value that extend over a range of dates (e.g. monthly consulting payments), applicable manufacturers may use their discretion to report the entire payment on the date of the first payment as a single line item or, in the alternative, report each payment as a separate line item.[21]
6 **Form** of each payment or transfer of value - see Commentary on Section (c) below.
7. **Nature** of each payment or transfer of value – see Commentary on Section (d) below.

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[17] See 76 Fed. Reg. at 78,746.
[18] See id.
[19] See id.
[20] See id.
[21] See id. at 78,746-47.

8. **Name of the product** if related to marketing, education or research. CMS proposes that the applicable manufacturer only report one covered drug, device, biological or medical supply as related to a payment or other transfer of value, even though there may be multiple products related to the payment.[22] Note, CMS is considering an alternative that would allow for the reporting of multiple products related to a payment. If the payment is related to a product for which a trade name is not yet established, the scientific name should be used.[23]

   If an applicable manufacturer is not reporting the name of the drug, device, biological or medical supply as appropriate, then the applicable manufacturer may be subject to penalties under the Act.

9. Indication as to whether the payment is subject to **delayed publication**.
10. Name of **3rd party recipient** of payment or transfer of value (if any).
11. Whether the payment or transfer of value was made to an individual that holds an **ownership interest**.

Defining the "Nature" of the Payment or Transfer of Value

Proposed Rule 42 CFR §403.904(d) sets forth the various categories for reporting the "nature" of the payment. According to the general rule, the various categories are mutually exclusive, and therefore, a payment or transfer of value may only be reported in a single category.[24] To ensure consistency with reporting, CMS will allow manufacturers to submit a document with their data to describe any assumptions used when categorizing the nature of the payments. Any voluntary assumptions submitted by applicable manufacturers will not be subject to public disclosure.

In its commentary, CMS further clarifies the reporting of separable payments. For example, if a physician receives meal and travel in conjunction with a consulting arrangement, the applicable manufacturer should report 3 distinct transactions ((1) Food and beverage; (2) Travel; and (3) Consulting Fees).[25]

Each payment or transfer of value must be classified as one of the following:

1. Consulting fee
2. Compensation for services other than consulting
3. Honoraria
4. Gift
5. Entertainment

[22] See id. at 78,747.
[23] See id.
[24] 42 CFR §403.904(d),
[25] See 76 Fed. Reg. at 78,747.

6. Food and beverage

   CMS recognizes the difficulty of identifying specific covered recipients when meals are provided in group settings (ex. Buffet style lunch provided in physician's office). In this type of scenario, CMS proposes that applicable manufacturers should report the cost per covered recipient receiving the meal, even if the covered recipient does not partake in the meal.[26]

   Example: $25 of bagels to sole practitioner's office. Office staff partakes in the food. All $25 gets reported to the sole practitioner.

   Example: $25 of bagels to group practice with 5 practitioners. Each practitioner receives $5 in value regardless of whether they consume the food.

   CMS proposes to exclude from reporting snacks, refreshments and buffet meals that are provided at conferences where it is difficult to ascertain the identify of all participants.[27]

7. Travel and lodging
8. Education
9. Research - (please see special rules for research payment below)
10. Charitable contribution - A charitable contribution is any payment or transfer of value made to an organization with a tax-exempt status under the IRS code.
11. Royalty or license
12. Current or prospective ownership or investment interests
13. Direct compensation for serving as a faculty or a speaker for a medical education program

    CMS propose that this category be interpreted broadly to include all instances where applicable manufacturers pay covered recipients to serve as speakers, and not just situations involving "medical education programs."[28] Presumably, this would encompass payments related to promotional speaker programs. In the alternative, CMS may seek to add an additional category.

14. Grant
15. Other

The "Other" category is designed to capture all payments or transfers of value that do not fall in the above categories and are not specifically excluded.[29]

[26] See id.
[27] See id.
[28] See id. at 78,750.
[29] See id.

Special Rules for Research Payments

CMS seeks to limit "Research" to bona fide research activities, including clinical investigations that are subject to a written agreement or contract between the applicable manufacturer and the organization conducting the research, as well as a research protocol.[30] As a result, if research did not include a protocol (e.g. post-market research), the payment would not fit within the definition of "Research" and would need to be reported under a different "nature." Research payments are eligible for delayed publication to protect proprietary interests of applicable manufacturers.

CMS proposes to separate the classification or research payments as either "indirect research" or "direct research." When reporting either "indirect research" or "direct research" as those terms are described below, the payments or other transfers of value would be reported under the names and NPIs of physician covered recipients serving has principal investigators who would ultimately receive payments from the clinic, hospital or research organization (assuming the applicable manufacturer is aware of the identify of the principal investigator).

Like payments made to 3rd parties at the request or direction of the covered recipient, Indirect Research payments would be reported under the name of the principal investigator and would also include the name of the entity receiving the payment.

"Indirect research" would be used when a research payment is made to a clinic, hospital (other than a teaching hospital), or institution conducting the research (either by an applicable manufacturer or a CRO) and that organization in turn pays the physician covered recipient (or multiple covered recipients) serving as principal investigator(s).[31]

"Direct research" would be used when a research payment or other transfer of value was provided directly to a physician covered recipient or teaching hospital covered recipient by and applicable manufacturer or CRO entity.[32] For a direct research payment to a physician, the name of the physician and the NPI number must be included. Research payments to teaching hospital covered recipients should be reported as "Direct research" payments to the teaching hospital and "Indirect research" to the physician covered recipient(s).[33]

For both direct and indirect research, applicable manufacturers must report the entire payment amount for each research payment (whether to the covered recipient or to the research institution), rather than the specific amount that was provided to the covered recipient.[34]

Due to the complexity surrounding research payments, CMS is seeking comments on the categorization as described above as well as the display of such payments in the publicly available database. Moreover, CMS seeks comment on the classification of research payment that do not meet the requirement set forth above (i.e. written agreement and research protocol) such as marketing studies.

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[30] See id. at 78,749.
[31] See id.
[32] See id.
[33] See id.
[34] See id.

Statutory Reporting Exclusions

1. "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." An applicable manufacturer is unaware of the identify of a covered recipient if the applicable manufacturer does not know (as defined in §403.902) the identity of the covered recipient."[35]

   An applicable manufacturer will be considered "aware" of the identify of the covered recipient if the applicable manufacturer has "actual knowledge of, or acts with deliberate ignorance or reckless disregard of, the identify of the covered recipient." Note, according to CMS, the awareness of the identity of a covered recipient by the applicable manufacturer's agent will be imputed to the manufacturer.[36]

2. Transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.

   Pursuant to CMS' commentary, applicable manufacturers should not individually report any payments or other transfers of value less than $10. Rather, if the covered recipient has exceeded the $100 annual threshold, and there are multiple transactions under $10 in the same category (ex. 5 lunches valued at $9 each), the applicable manufacturer should aggregate the payments and report as a single transaction ($45 – Food and beverage).[37]

3. Product samples that are not intended to be sold or are intended for patient use.

4. Educational materials that directly benefit patients or are intended for patient use. According to CMS, this exclusion is limited to "materials" and does not include services or other items. CMS is considering whether to include, within this exception, educational materials provided directly to covered recipients that are intended to educate the covered recipient (i.e. text books). This exclusionary item will be finalized based upon comments received.[38]

5. The loan of a covered device for a short-term trial period not to exceed 90 days, to permit evaluation of the covered device by the covered recipient. Presumably, if the loan of the covered device exceeded the 90 day evaluation period, the transaction would then be reported as "In-kind items or services" and "Other." According to CMS, any payment or transfer of value that is not specifically excluded must be reported under "other."

6. Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

7. A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

8. Discounts, including rebates.

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[35] Proposed 42 CFR §403.904(f)(1).
[36] See 76 Fed. Reg. at 78,751.
[37] See id. at 78,750.
[38] See id. at 78,751.

9. In-kind items for the provision of charity care.

   CMS proposes the following definition of "charity care" - "items provided to a covered recipient for one or more patients who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay." Note, the proposed definition does not include the provision of in-kind items (ex. donation of an imaging machine) to a covered recipient for use with all of the covered recipient's patients (those who can and cannot pay), regardless of whether the covered recipient is a charitable organization.[39]

10. A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

11. In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

12. In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

13. In the came of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

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[39] See id.

Reports of Physician Ownership and Investment Interests under §1128G(a)(2)

§ 403.906 Reports of physician ownership and investment interests.

(a) General rule. Each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership or investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding year.

(b) Identifying information. Reports on physician ownership or investment interests must include the following identifying information:

(1) Name of the physician, and whether the ownership or investment interest is held by an immediate family member of the physician.

(2) Business address of physician, including street address, suite or office number (if applicable), city, State, and ZIP code.

(3) The physician owner's specialty and NPI (if applicable). If the ownership or investment interest is held by the immediate family member of a physician, the physician's specialty and National Provider Identifier must be reported.

(4) Dollar amount invested by each physician or immediate family member of the physician.

(5) Value and terms of each ownership or investment interest.

(6) For any payment or other transfer of value provided to a physician holding an ownership or investment interest (or to an entity or individual at the request of, or designated on behalf of, a physician holding such an ownership or investment interest), an applicable manufacturer or applicable group purchasing organization must report the information requested in § 403.904(b). The same exclusions from reporting in § 403.904(f) apply to payments or other transfers of value made by applicable manufacturers and applicable group purchasing organizations to physician owners or investors under this section.

Commentary

Defining an "applicable group purchasing organization."

Pursuant to section 1128G(e)(1) of the Act, the Secretary has the authority to define a GPO for purposes of the statutory reporting requirements. CMS interprets the statute to cover traditional GPOs that negotiate contracts for their members, as well as entities that purchase covered drugs, devices, biologics and medical supplies for resale or distribution to groups of individuals or entities. As a result, it is arguable that the definition, as interpreted by CMS, includes distributors.

For purposes of defining "applicable manufacturers," under 1128(G)(a)(1) of the Act, CMS limits the definition to those manufacturers of drugs or biologics or medical devices that require a prescription or premarket approval. CMS is seeking comment as to whether the device limitation (premarket approval) is too limiting for purposes of defining a GPO.

Defining "Physician" for purposes 1128G(a)(2)

Section 1128G(a)(1) of the Act requires the reporting of payments or transfers of value to "Covered Recipients," the definition of which specifically excludes physician employees of the applicable manufacturer. In contrast, Section 1128G(a)(2) uses the term "physician," and therefore the requirements to report physician ownership and investment interests includes any physician, regardless of whether they are an employee of the applicable manufacturer or GPO.[40] In addition, ownership or investment interests of "immediate family members" of physicians must also be reported. The proposed definition of "immediate family member" includes:

- Spouse
- Natural or adoptive parent, child, or sibling
- Stepparent, stepchild, stepbrother, or stepsister
- Father-, mother-, daughter-, son-, bother- or sister-in-law
- Grandparent or grandchild

Defining Ownership or Investment Interests

CMS proposes to define an ownership or investment interest in an applicable manufacturer or GPO in a manner similar to the definition set forth in the self-referral regulations (42 CFR 411.354(b)) to include direct or indirect interests through debt, equity or other means. In general, an ownership interest will include stock, stock options (other than those received as compensation until such time as the are exercised), partnership shares, membership interests in limited liability companies as well as loans and bonds.[41] Items excluded from the definition include:

- Ownership or investment interests in publicly traded securities or mutual funds;
- An interest in an applicable manufacturer or GPO that arises from a retirement plan offered to the physician or his or her immediate family members by virtue of the physicians employment by the applicable manufacturer or GPO; and
- Stock options and convertible securities received as compensation, until such stock options are exercised or securities are converted to equity; and
- An unsecured loan subordinated to a credit facility.

In order to avoid duplicative reporting, CMS proposes that if an ownership or investment interest is reportable under both 1128G(a)(1) and 1128G(a)(2) of the statute, that applicable manufacturers need only report under 1128G(a)(1) of the statute.[42]

Physician Ownership or Investment Report Content

As proposed by CMS, the content of the report should include the name, address, NPI, and specialty of the physician owner or investor. In addition, if the ownership or investment interest is held by an immediate family member, the applicable manufacturer or GPO would be required to report the aforementioned as it relates to the physician as well as an acknowledgement that the ownership or investment interest is held by an immediate family member.

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[40] See id. at 78,752.
[41] See id.
[42] See id.

In order to provide further transparency with regard to the relationship, CMS is considering whether to require the reporting of the immediate family members relationship with the physician as well as their name. CMS is seeking comment on this proposed requirement. When comparing the additional burden on applicable manufacturers and GPOs to track this information as well as the privacy concerns of immediate family members, it is doubtful that the disclosure of the relationship and name of the immediate family member would further the goals of the legislation in any meaningful way.[43]

Pursuant to Section 1128G(a)(2)(C) of the Act, applicable manufacturers and GPOs must report all payments or transfers of value to physicians holding an ownership or investment interest as required under Section 1128G(a)(1) as described above.

Avoiding Duplicative Reporting

Since Sections 1128G(a)(1)(A) and 1128G(a)(2)(C) both require the reporting of payments to transfers of value to "covered recipients" (Section 1128G(a)(1)(A)) and "physicians"(1128G(a)(2)(C), there is the potential for duplicative reporting to the extent that a "covered recipient" also holds an ownership or investment interest in an applicable manufacturer. Therefore, in order to avoid duplicative reporting, CMS proposes that applicable manufacturers file one report under 1128G(a)(1)(A) reporting all their payments and transfers of value and another report under 1128(G)(a)(2) disclosing ownership or investment interests. To the extent that a physician owner or investor is also a "covered recipient," applicable manufacturers should note that the covered recipient receiving the payment or transfer of value is also a physician owner or investor.[44]

Since applicable GPOs are not subject to the reporting requirements under 1128G(a)(1)(A), they should file a single report required under 1128G(a)(2) utilizing the same data elements required under 1128G(a)(1)(A) as they relate to "physician" owners or investors.

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[43] See id.
[44] See id. at 78,753.

Miscellaneous Provisions

§ 403.908 Procedures for electronic submission of reports.

(a) File format. Reports required under this subpart must be electronically submitted as comma separated value (CSV) files to CMS by March 31, 2013, and by the 90th day of each subsequent calendar year.

(b) General rules.

(1) If an applicable manufacturer made no reportable payments or transfers of value in the previous calendar year, nor had any reportable ownership or investment interests held by a physician or a physician's immediate family member (as defined in § 403.902) during the previous calendar year, the applicable manufacturer is not required to file a report.

(2) If an applicable group purchasing organization had no reportable ownership or investment interests held by a physician or physician's immediate family member during the previous calendar year, the applicable group purchasing organization is not required to file a report.

(c) Registration. Any applicable manufacturer or applicable group purchasing organization that is required to report under this subpart must register with CMS before March 31, 2013. During registration, applicable manufacturers and applicable group purchasing organizations must name a point of contact with appropriate contact information.

(d) Other rules. (1) An applicable manufacturer under paragraph

(1) of the definition of "applicable manufacturer" in § 403.902 and an entity (or entities) under common ownership with the applicable manufacturer under paragraph

(2) of the definition of "applicable manufacturer" may, but are not required to, file a consolidated report of payments or other transfers of value to covered recipients, and physician ownership or investment interests.

(3) If an applicable manufacturer and an entity (or entities) under common ownership choose to file a consolidated report, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers. It is up to the discretion of the applicable manufacturer and entity (or entities) under common ownership whether or not specific payments need to be identified to the entity that provided the payment.

(4) If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, the payment or other transfer of value must be reported—

(i) In the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers; and

(ii) Only once by one applicable manufacturer.

(e) Errors or omissions. If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon discovery of the error or omission.

(f) Attestation. Each report, including any subsequent corrections to a filed report, must include a certification by the Chief Executive Officer, Chief Financial Officer, or Chief Compliance Officer of the applicable manufacturer or applicable group purchasing organization that the information submitted is true, correct, and complete to the best of his or her knowledge and belief.

(g) 45-day review period for review and error correction—

(1) General rule. Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45-days before CMS makes the information available to the public. In no case may this 45-day period for review and submission of corrections prevent the information from being made available to the public.

(2) Notification. CMS notifies the applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors when the reported information is ready for review.

(i) Applicable manufacturers and applicable group purchasing organizations are notified through the point of contact the applicable manufacturer or applicable group purchasing organization identified during registration.

(ii) Physicians and teaching hospitals—

(A) Are notified using a CMS' list serve and through a posting.

(B) May also register with CMS to receive notification about the review processes.

(iii) The 45-day review period begins on the date of this notification, but in no case may the 45-day review period begin later than August 16, 2013, or May 16 of any subsequent year.

(3) Process.

(i) An applicable manufacturer, applicable group purchasing organization, covered recipient, and a physician owner or investor may log into a secure Web site where each applicable manufacturer, applicable group purchasing organization, covered recipient, and physician owner is able to view the information reported specific to it.

(ii) If the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor agrees with the information reported, the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor may electronically certify that the information reported is accurate.

(4) Data disputes.

(i) Upon request by a covered recipient, physician owner or investor, CMS provides the point of contact information for the applicable manufacturer or applicable group purchasing organization in the event that the covered recipient or physician owner disputes the reported data.

(ii) The covered recipient or physician owner or investor must directly contact the applicable manufacturer or applicable group purchasing organization to attempt to resolve any dispute regarding a reported payment or other transfer of value or an ownership or investment interest.

(iii) At the discretion of the parties involved, one entity must notify CMS that a specific payment or other transfer of value, or ownership or investment interest is disputed and the outcome of the dispute at the end of the 45-day review period.

(iv) If the dispute is not resolved by the end of the 45-day review period, CMS publicly reports both the applicable manufacturer's or applicable group purchasing organization's version of the payment or other transfer of value, or ownership or investment interest data, as well as the covered recipient's or physician owner's version of the payment or other transfer of value, or ownership or investment interest data.

Commentary

Pre-submission Review and Post –Submission Review Process

In order to ease the post-submission review process (see below), CMS recommends that applicable manufacturers and GPOs establish a "pre-submission review" process to share the spend data with covered recipients and physicians prior to submission to CMS.[45]

Pursuant to Section 1128G(c)(1)(C)(ix) of the Act, the Secretary is required to allow applicable manufacturers, GPOs, covered recipients and physician owners and investors the opportunity to review data submitted prior to disclosure of such data to the public. The statutory review period is a minimum of 45 days.

Once CMS has received the data from applicable manufacturers and GPOs and aggregated the data by individual covered recipient or physician owner or investor, CMS will notify the relevant parties as to the review process. CMS intends to notify applicable manufacturers, GPOs, covered recipients and physician owners or investors as follows:

- Allow (but not require) the relevant parties to register with CMS
- Notify physicians and hospitals through CMS' list serves as well as publicly posting the information

The relevant parties would be provided with instructions on the post-submission review process which would include the ability for a covered recipient or physician owner or investor to log into a secure

[45] See id. at 78,753.

website to review the data reported about them. In addition, CMS is considering an alternative method whereby applicable manufacturers and GPOs would be required to collect and report whether the covered recipient or physician owner or investors would like to be notified via USPS or e-mail. If e-mail is selected, the applicable manufacturer would be required to provide the relevant email address. CMS is seeking comment on the above outlined approaches.[46] While it is often beneficial to provide individuals with multiple avenues to seek redress, requiring applicable manufacturers and GPOs to solicit the preferred method from covered recipients and physician owners and investors would be unduly burdensome. Moreover, each covered recipient and physician owner or investor will be receiving requests from multiple applicable manufacturers and/or GPOs.

While CMS is not going to participate in the dispute resolution process by and between covered recipients, physician owners or investors and applicable manufacturers or GPOs, they are establishing a process for reporting disputes and changes. CMS is proposing that covered recipients and physician owners or investors request from CMS the contact information for a specific applicable manufacturer or GPO, in the event or a potential dispute over the reported data. It would then be the responsibility of the covered recipient or physician owner or investor to contact the applicable manufacturer or GPO to resolve the dispute or inquiry. To the extent that the covered recipient, physician owner or investor and the applicable manufacturer or GPO are unable to resolve the dispute, CMS will publish the original information as well as the contradictory information and acknowledge the existence of the dispute.[47] Upon expiration of the 45-day review period, CMS will publish the data, including any disputed information, and maintain the database as-is for a year. Neither the covered recipients, physician owners or investors, applicable manufacturers or GPOs will have the ability to alter or amend the data until the following annual 45-day review period.

Report Submission Process

Prior to the submission of annual reports, applicable manufacturers and GPOs with reportable spend and/or ownership or investment interests will be required to register with CMS and designate a point of contact for communication purposes. CMS is currently seeking comment as to whether to require registration by all applicable manufacturers and/or GPOs, regardless of whether they have reportable transactions.

The report submission process is as follows:

- Applicable manufacturers and GPOs will be required to submit data electronically in a comma-separated value (CSV) format;
- Each line item should represent a unique payment or transfer of value, or unique ownership or investment interest;
- Following the submission of one or more files, either the CEO, CFO or COO of the applicable manufacturer must file an attestation certifying the truth, correctness and completeness of the submitted data.

[46] See id. at 78,753-54.
[47] See id. at 78,755.

Required Information

For each payment or transfer of value, CMS is proposing the following information be provided:

- Name of applicable manufacturer or GPO.
- The following information with regard to a covered recipient or physician owner;
- Name (for physicians include first, last and middle initial);
  - Specialty (physician only);
  - Business street address (practice location);
  - NPI # (physician only);
- Amount of payment or other transfer of value in US dollars.
- Date of payment or other transfer of value.
- Form of payment or other transfer of value.
- Nature of payment or other transfer of value.
- Name of the associated covered drug, device, biological, or medical supply, as applicable.
- Name of the entity that received the payment or other transfer of value, if not provided to the covered recipient directly.
- Whether the payment or other transfer of value was provided to a physician holding ownership or investment interests in the applicable manufacturer (yes or no response).
- Whether the payment or other transfer of value should be granted a delay in publication because it was made pursuant to a product research agreement, development agreement, or clinical investigation (yes or no response).

For each physician or ownership interest, the following information is required:

- Applicable manufacturer or GPO name.
- The following information for physicians with ownership or investment interests:
  - Name (for physicians include first, last and middle initial);
  - Specialty;
  - Business and street address (practice location);
  - NPI #
- Whether the ownership or investment interest is held by the physician or an immediate family member.
- Dollar amount invested.
- Value and terms of each ownership or investment interest.

For applicable GPOs only, the following information with regard to any payments or transfers of value made to a physician owner or investor:

- Amount of payment or other transfer of value in US dollars.
- Date of payment or other transfer of value.
- Form of payment or other transfer of value.
- Nature of payment or other transfer of value.
- Name of the associated covered drug, device, biological, or medical supply, as applicable.

§ 403.910 Delayed publication for payments made under product research or development agreements and clinical investigations.

(a) General rule. In the case of payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement, or in connection with a clinical investigation, payments may be delayed from publication on the Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances:

(1) Research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological, or medical supply.

(2) Clinical investigations regarding a new drug, device, biological, or medical supply.

(b) Research or development agreement. The research or development agreement must include a written agreement and research protocol between the applicable manufacturer and covered recipient.

(c) Date of publication. Payments must be reported to CMS on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following:

(1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

(2) Four calendar years after the date the payment or other transfer of value was made.

(d) Notification of delayed publication. It is the responsibility of the applicable manufacturer to notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, with which the payment is associated, is approved by the FDA.

(1) An applicable manufacturer must indicate on its report to CMS whether a payment or other transfer of value is eligible for a delay in publication. The absence of this indication in the report results in CMS posting all payments publicly in the first year of public reporting.

(2) An applicable manufacturer must continue to indicate annually in its report that FDA approval of the new drug, device, biological or medical supply, with which the payment is associated, is pending.

(3) Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.

(4) If, after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.

Commentary

Section 403.910 of the proposed regulations and CMS' interpretation of the Section 1128G(c)(1)(E) of the Act creates a convoluted policy as it relates to the delayed publication of payments made pursuant to product research or development agreements and clinical investigations.

Specifically, the Act refers to various circumstances giving rise to delayed publication including "research," "development" or "clinical investigations. Furthermore, the Act refers to the following circumstances (emphasis below added):

1. Services furnished in connection with "research" on a potential **new** medical technology or a new application of an **existing** medical technology, or
2. the "development" of a **new** drug, device, biological or medical supply, or
3. a "clinical investigation" regarding a **new** drug, device, biological, or medical supply.

Because the Act seemingly distinguishes between "research" on new or existing "medical technology" and "development" and "clinical investigation" on a new drug, device, biological, or medical supply, CMS proposes the following rule:

> Given these interpretations, we propose that delayed publication should only apply to payments to covered recipients for services in connection with research on, or development of new drugs, devices, biologicals, or medical supplies, as well as new applications of existing drugs, devices, biological or medical supplies. Conversely, we propose limiting delayed publication for payments in connection with clinical investigations for new drugs, devices, biological, or medical supplies, and not new applications of existing drugs, devices, biological or medical supplies.[48]

In order to maintain the confidentiality of proprietary information relating to the development of new drugs, devices, biologics or medical supplies, Section 1128G(c)(1)(E) of the Act provides for the delayed publication of payments or other transfers of value made pursuant to product research or development agreements and clinical investigations.

Payments and transfers of value that meet the prerequisites for delayed publication under Section 1128G(c)(1)(E), must be made publicly available on the first publication date after the earlier of the following:

1. The approval, licensure or clearance by the FDA of the covered drug, device, biological or medical supply; or
2. Four (4) calendar years after the date of payment.

While this section delays public disclosure in order to protect confidential or proprietary information relating to research, it does not affect an applicable manufacturer's obligation to disclose the payments to CMS in accordance with the requirements of Section 1128G(a)(1). It is up to the manufacturer to identify those transactions set forth in its annual report that are subject to delayed publication on the public website. Furthermore, CMS proposes that applicable manufacturers continue to report delayed payments on an annual basis indicating that publication should remain delayed as well as providing any updated information on the payment or transfer of value as necessary.[49]

Upon receipt of approval by the FDA, the applicable manufacturer must indicate in their next annual submission that the payment or transfer of value is no longer subject to delayed publication. The failure of an applicable manufacturer to notify CMS in a timely fashion that a payment is no longer eligible for delayed publication may subject the manufacturer to monetary penalties under Section 1128G(b) of the Act.

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[48] See 76 Fed. Reg. at 78,757.
[49] See id. at 78,756.

In order to meet the requirements of this subsection, CMS proposes that the "product research or development agreement" referenced in the statute include a written statement or contract between the applicable manufacturer and the covered recipient as well as a written research protocol. In the event that the applicable manufacturer conducts research through a CRO, the applicable manufacturer must have a written agreement with the CRO and the CRO may maintain the written research agreement with the covered recipient.[50]

Note: CMS is seeking comments with regard to the proposed treatment of "research," "development" and "clinical investigations" as set forth above. Specifically, they are considering whether or not to treat clinical investigations in the same manner as research and development activities.

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[50] See id. at 78,756-57.

§ 403.912 Penalties for failure to report.

(a) Failure to report.

(1) Any applicable manufacturer or applicable group purchasing organization that fails to accurately and completely submit the information required in accordance with the rules established under this subpart in a timely manner is subject to a civil monetary penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported.

(2) The total amount of civil monetary penalties imposed on an applicable manufacturer or applicable group purchasing organization under this subpart with respect to each annual submission of information will not exceed $150,000.

(b) Knowing failure to report.

(1) Any applicable manufacturer or applicable group purchasing organization that knowingly fails to accurately and completely submit the information required in accordance with the rules established under this subpart in a timely manner is subject to a civil monetary penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported.

(2) The total amount of civil monetary penalties imposed on an applicable manufacturer or group purchasing organization for knowing failure to report under this subpart with respect to each annual submission of information will not exceed $1,000,000.

(c) Determinations regarding the amount of civil monetary penalties. In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the following:

(1) The length of time the applicable manufacturer or applicable group purchasing organization 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.

(2) Amount of the payment the applicable manufacturer or applicable group purchasing organization failed to report.

(3) Level of culpability.

(4) Nature and amount of information reported in error.

(5) Degree of diligence exercised in correcting information reported in error.

(d) Record retention and audits—

(1) Maintenance of records.

(i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer's or applicable group purchasing organization's compliance with the requirement to accurately and

completely submit information in a timely manner in accordance with the rules established under this subpart.

(ii) The items described in paragraph (d)(1)(i) of this section must be maintained 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.

(2) Audit. HHS, CMS, OIG or their designees may audit, inspect, and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to accurately and completely submit information in a timely manner in accordance with the rules established under this subpart.

(3) The record retention and audit requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.

Commentary

Applicable manufacturers and GPOs may be assessed a CMP for failure to report information in a timely and accurate manner. Pursuant to section 1128G(c)(1)(c)(ix), applicable manufacturers and GPOs have a 45 day period to review their data prior to publication. According to CMS, any additions or oversights beyond the 45-day period would be considered late and subject to penalties.

For purposes of determining whether an applicable manufacturer or GPO "knowingly" fails to comply with the requirements of the Act, CMS will apply the following definition:

"The terms 'knowing' and 'knowingly' mean that a person, with respect to the information has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information."[51]

In determining the amount of the CMP, CMS may consider, among others, the following factors:

- The amount of the payment or other transfer of value or ownership interest that the applicable manufacturer or GPO failed to report.
- Level of culpability.
- The nature and amount of information that was erroneously reported.
- The degree of diligence that was exercised in correcting the erroneous information.

Applicable manufacturers and GPOs will be subject to audit. In order to facilitate an audit, applicable manufacturers and GPOs are required to maintain books and records for a minimum of 5 years from the date the payment or transfer of value or ownership interest is published on the public website.

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[51] 31 U.S.C.A. § 3729(b)(1)

§ 403.914 Preemption of State laws.

(a) General rule. In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.

(b) Information collected for public health purposes.

(1) Information required to be reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes must still be reported to appropriate Federal, State, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart.

(2) Governmental agencies include, but are not limited to, the following:

(i) Agencies that are charged with preventing or controlling disease, injury, disability.

(ii) Agencies that conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

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