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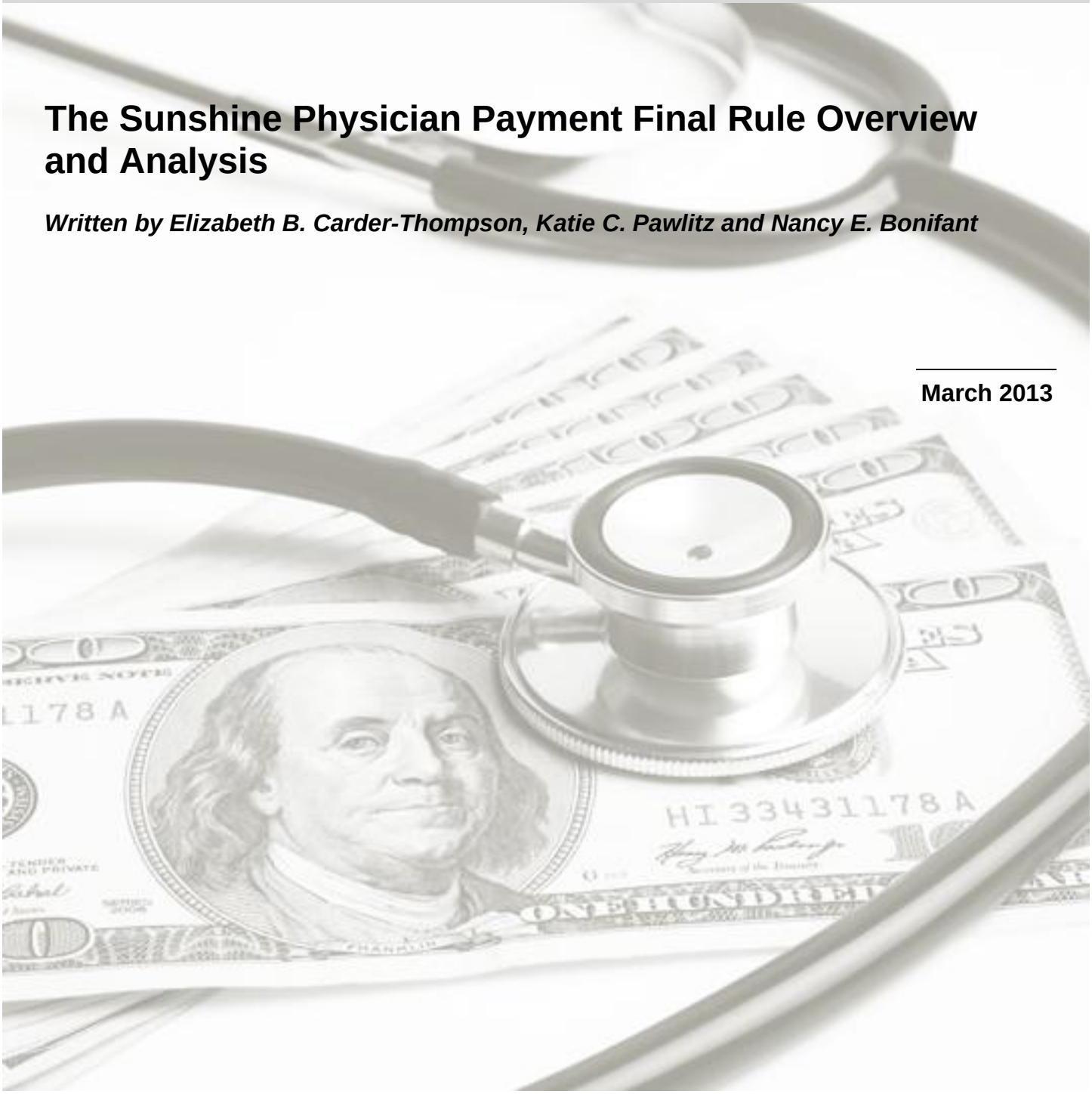
Life Sciences and Health Industry Group

The Sunshine Physician Payment Final Rule Overview and Analysis

Written by Elizabeth B. Carder-Thompson, Katie C. Pawlitz and Nancy E. Bonifant



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OVERVIEW & ISSUES LIST

On February 1, 2013, the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS) released the long-awaited Final Rule (Rule)[1] to implement the "Sunshine" provisions of the Affordable Care Act of 2010 (ACA).[2] These require that certain manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid and CHIP report annually to HHS identified payments or transfers of value they have made to physicians and teaching hospitals. In addition, the Sunshine provisions require manufacturers and certain group purchasing organizations (GPOs) to report to HHS information on physician ownership and investment interests.

The underlying purpose of the Sunshine provisions is to provide increased transparency on the scope and nature of financial and other relationships among manufacturers, physicians, and teaching hospitals, on the theory that such transparency will enable patients to make more informed treatment decisions – and assess possible conflicts of interest. In its 2011 proposed rule,[3] CMS had requested comment on almost every aspect of the new requirements, and the Final Rule is lengthy and complex. It provides needed clarity on some troubling aspects of the proposal, but it leaves a number of questions unanswered. Whether the transparency reports that CMS eventually publishes on a publicly available website will prove enlightening or merely confusing – and potentially susceptible to inaccuracy and misinterpretation – remains to be seen. Of more concern is whether the new reporting mandates will have a chilling effect on the desire of physicians and teaching hospitals to continue to engage in research, educational efforts, and the like.

This Client Alert provides an overview and summary of the Rule, including the important issues below:

1. When manufacturers need to begin collecting and reporting information to HHS;
2. Which types of "applicable manufacturers" will have to file reports;
3. How manufacturers are to identify the physicians and teaching hospitals (known as "covered recipients") that receive the reportable payments;
4. Which general types/categories of payments and transfers of value to physicians and teaching hospitals will need to be reported, and which can be excluded;
5. Special rules for research-related payments;

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[1] 78 Fed. Reg. 9458 (Feb. 8, 2013).

[2] Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act. Pub. L. No. 111-148 (enacted Mar. 23, 2010) (codified at 42 U.S.C. §1320a-7h).

[3] 76 Fed. Reg. 78742 (Dec. 9, 2011). CMS missed the statutory deadline set out in the Act to publish the proposal by October 1, 2011. On May 3, 2012, citing the volume of comments submitted, CMS announced that it would not require any data collection before January 1, 2013, notwithstanding the statutory deadline of January 1, 2012.

6. When reporting can be delayed for payments involving confidential and proprietary research or product development;

7. Which entities will need to report physician ownership and investment interests;

8. How manufacturers, GPOs, physicians, teaching hospitals, and physician owners and investors should handle disputed information; and

9. Penalties for nonreporting and inaccurate reporting.

SUMMARY OF IMPORTANT ISSUES IN FINAL RULE

1. When do manufacturers need to begin collecting and reporting information to HHS?

- "Applicable manufacturers" – defined below – must begin collecting the data to be reported as of *August 1, 2013*, which is 180 days after publication of the Rule.
- The first reporting period – both for reporting transfers of value and physician ownership and investment interests – will be *August 1, 2013 – December 31, 2013*.
- The first reports must be submitted to CMS by *March 31, 2014.*
- CMS will release the reported data on its public website by *September 30, 2014*.

2. What types of "applicable manufacturers" will have to file reports?

Definitions in 42 C.F.R. § 403.902

Applicable manufacturer means an entity that is operating in the United States and that falls within one of the following categories:

(1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.

(2) An entity 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.

Assistance and support means providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Analysis

One of the most challenging aspects of the Rule is determining what entities and affiliated entities have reporting obligations, and for what products. Although the Rule is more narrowly drawn than that proposed by CMS, it is still complex; even CMS recognizes that "it is difficult to anticipate all potential manufacturing arrangements."

U.S. Presence: CMS limits the definition of "applicable manufacturer" to entities that are "operating in the United States," which CMS defines as (1) having a physical location within the U.S. or a U.S. territory, or (2) otherwise conducting activities within the U.S. or a U.S. territory, either directly or through a legally authorized agent. Therefore, foreign entities that have operations in the U.S. (which includes selling a product manufactured outside the U.S.) are subject to the reporting requirements. CMS notes that entities operating in the United States cannot circumvent the reporting requirements by making payments to physicians and teaching hospitals through foreign entities with no U.S. operations. Such payments are considered to be made by the entity operating in the United States as an indirect payment and must be reported, so long as the entity operating in the United States is aware of the identity of the covered recipient receiving the payment (indirect payments and other transfers of value are further discussed below).

Covered Drug, Device, Biological or Medical Supply: Only manufacturers of covered drugs, devices, biological and supplies have reporting obligations. CMS defines these as products (a) for which payment is available under Medicare, Medicaid, or CHIP, and (b) which require a prescription before dispensing – for drugs and biologicals – or premarket approval by or premarket notification to FDA – for devices and supplies. CMS considers payment for devices to be "available" whether they are reimbursed separately or as part of a bundle. Under the Rule, over-the-counter drugs and biologicals are excluded, as are devices and medical supplies that do not require premarket approval by or notification to FDA, including many Class I devices and certain Class II devices.

Common Ownership: With regard to affiliated entities, CMS finalizes a five percent ownership threshold for "common ownership." An entity under "common ownership" with an applicable manufacturer – including but not limited to parent companies and subsidiaries, and brother/sister corporations – is only considered an applicable manufacturer itself *if* it provides "assistance or support" with respect to a covered product. In the Rule, CMS defines "assistance and support" to mean "providing a service or services that are necessary or integral" to the manufacture of the covered product, including sales, marketing, promotion, and distribution. By way of example, CMS states that an affiliate producing the active ingredient of a drug to furnish to the manufacturer would be providing such integral assistance and support – but an affiliate providing human resources administrative functions would not. Finally, while CMS allows common ownership entities to report individually or via a consolidated report, consolidated reports still must break out payments by entity and recipient, and the entity submitting the consolidated report could be liable for penalties applicable to *each* reporting entity. Penalties are discussed further in Section 9 below.

Diversified Manufacturers of Covered & Non-Covered Products: For diversified manufacturers that produce both covered and non-covered products, the analysis is somewhat more complicated. The general rule is that if a manufacturer sells or distributes at least one covered product in the United States, it must report all payments and other transfers of value made to physicians and teaching hospitals regardless of whether the particular payment is associated with a covered or non-covered product. There are, however, notable exceptions to this rule. CMS carves out a narrow group of applicable manufacturers that are only required to report payments and other transfers of value related to *covered* products. Stated differently, this narrow group need not report payments and other transfers of value related to non-covered products:

- Applicable manufacturers with less than ten percent of total (gross) revenue from covered products during the previous fiscal year, provided they register with CMS and attest that less than ten percent of total (gross) revenue are from covered products;

- "Common ownership" applicable manufacturers;

- Applicable manufacturers that have separate operating divisions that only produce non-covered products (e.g., animal health divisions) and do not meet the definition of providing "assistance and support" to other divisions that produce covered products; and

- Applicable manufacturers that manufacture covered products under contract only, do not hold FDA approval, licensure, or clearance for the covered product, and are not involved in the sale, marketing or distribution of the product.

Distributors and Wholesalers: CMS considers distributors and wholesalers – including repackagers and relabelers – to be "applicable manufacturers" subject to all reporting requirements if they hold title to a covered product. In such cases, the manufacturer would not need to report the distributor's payments or transfers of value to physicians and teaching hospitals, because the reporting would be done by the distributor. However, in cases where the distributor does not take title, manufacturers will need to ascertain and report any payments or transfers made by that distributor.

"Own Use": CMS creates an exception to reporting for "hospitals, pharmacies, and laboratories that produce or manufacture materials and products solely for their own use or use by their patients." However, it provides little detail on the scope or applicability of this exception.

3. How are manufacturers to identify the physicians and teaching hospitals (known as "covered recipients") that receive the reportable payments?

Physicians: CMS requires reports of payments to "any physician," except those employed by the manufacturer making the report. It considers any physician with a current license to fall within this definition – which would exclude residents. It cites to common law rules to identify employer-employee exemptions, refusing to adopt a bright line test excluding reporting for physicians who serve as manufacturer board members or medical directors.

Manufacturers must report the physician's name (including middle initial), full business address (using primary practice address, if applicable), National Provider Identifier (NPI), specialty name and code, state(s), and license number(s). CMS rejected comments to simply publish a list of physicians, putting the onus on manufacturers to "demonstrate that they made a good faith effort" to obtain the NPI number, either by requesting it directly from the physician or by consulting the National Plan and Provider Enumeration System (NPPES). If, after a good faith effort, the manufacturer cannot determine an NPI for a physician, or a physician does not have an NPI, it can leave the NPI field blank. However, if CMS determines that a physician does in fact have an NPI, it may require the manufacturer to re-submit the data including the NPI and re-attest to the updated data. In addition, CMS states that not reporting an NPI for physicians that do have an NPI will be considered inaccurate reporting that may subject manufacturers to penalties.

Teaching Hospitals: Manufacturers must report the teaching hospital's name and business address. CMS plans to publish a list of teaching hospital covered recipients. It will post the list on the CMS website once per year and make it available publicly and for download at least 90 days before the beginning of the reporting year, or for the first reporting year, at least 90 days prior to the start of data collection. The list will include hospital taxpayer identification numbers (TINs) to provide more specific information on hospitals with complex corporate identities.

It is not clear in the Rule whether manufacturers must report a hospital's TIN, but reporting templates released by CMS indicate that TINs will be a required reporting field.

4. What general types/categories of payments and transfers of value to physicians and teaching hospitals will need to be reported, and what can be excluded?

General Rules

Manufacturers must report all "direct and indirect" payments, or transfers of "anything of value," to physicians and teaching hospitals, including those made to third parties at the request of or designated on behalf of physicians and teaching hospitals. They must report both (i) the *form* of payment or transfer of value, and also (ii) the *nature* of the payment or transfer. The first prong involves identifying whether the payment or transfer was cash or cash equivalent; in-kind items and services; stock, stock options, or other ownership interest; or dividend, profit, or other return on investment. The second prong is reporting – separately and on a mutually exclusive basis – the specific type of payment (consulting, honoraria, entertainment, research, and other categories specified in the statute and discussed below). The only types of payments that can be excluded are those specified in the statute (e.g., payment of less than $10, product samples, payments where the manufacturer does not know the identity of the recipient, and others discussed below). Manufacturers may, but are not required to, submit documents setting forth their assumptions in categorizing payments. Note that research payments are covered separately in the section that follows.

Direct or Indirect Payments or Transfers of Anything of Value

Value: CMS defines this term as "discernible economic value on the open market in the U.S." If a manufacturer provides a textbook to a physician who already owns it, it may not have "value" to the physician per se, but it does have economic value that must be reported. It also has value even if the physician does not request it. CMS emphasizes that all aspects of the transfer need to be included in the reported value, including tax and shipping. Finally, CMS requires manufacturers to make "a reasonable, good faith effort" to ascertain value.

Payments to Group Practices: CMS provides manufacturers with flexibility in how to report payments to physician group practices or multiple recipients. Using the example of a set of dermatology textbooks donated to a group practice, CMS states that the payment can be attributed to the individual(s) who requested the payment, the individual(s) on whose behalf the payment was made, or the individual(s) who are intended to benefit – such as all members of the group practice. It will be important, therefore, for manufacturers and physicians to reach an advance understanding on manufacturer attribution of donations in such instances, to avoid attributing payments to physicians who do not agree to such attribution.

Who's the Recipient: Physician vs. Teaching Hospital vs. Individual vs. Third Party?

All aspects of a given transaction involving multiple parties will need to be examined carefully to determine appropriate reporting:

- If a manufacturer makes a payment to one covered recipient (such as a teaching hospital) but it is intended for another (such as a physician employee of that hospital), it is reported in the name of the *ultimate recipient* (in this case, the physician).

- Payments made directly to physician recipients are reported in the name of that physician – even if, for example, the physician recipient also is an employee of a teaching hospital. Payments may need

to be apportioned between recipients in applicable cases, depending on their intended use (e.g., part to a physician and part to a teaching hospital).

- If a physician requests that a payment be directed to a specified third party entity, the manufacturer must report *both* the physician's name and the name of the third party entity (e.g., if the physician specifies a charitable recipient, the manufacturer would report both the name of the physician and the charity – see special note below on characterizing the nature of payment for charitable contributions). However, if the physician directs that payment be directed to an individual, raising confidentiality concerns, the manufacturer would report "individual." (For example, a physician might request that a royalty payment be directed to his or her minor child – the manufacturer would not report the child's name, but only "individual.")

- If a physician waives payment entirely, it will be important for manufacturers to clarify whether the physician does or does not want the payment made specifically "on his behalf." If the physician is named, the manufacturer must report the physician's name in connection with that transfer.

Special Rules for Indirect Manufacturer Payments Made Through a Third Party

Manufacturers will need to report all indirect payments, as defined in the Rule. The Rule defines an "indirect payment" as a payment where the manufacturer "requires, instructs, directs, or otherwise causes the third party to provide the payment or other transfer of value, in whole or in part" to a physician or teaching hospital. CMS intends this definition to cover circumstances in which a manufacturer makes a payment to a third party and (a) expects that the payment will reach a covered recipient, and (b) knows or should know the recipient's identity. The following examples are helpful in understanding these requirements:

- A reportable indirect payment thus would be a manufacturer's grant to a medical society for the specific purpose of awarding grants to physicians (the manufacturer knows the money will be directed to physicians, and it could consult the society's membership roster to determine their identities).

- Similarly, a manufacturer's payment to a clinic for the services of one of its employed physicians in reviewing materials would be a reportable indirect payment, since the payment is specifically directed to physicians, and the manufacturer could identify the clinic's employees.

- In contrast, a non-reportable indirect payment would be an unrestricted donation to a physician professional organization to be used at the organization's discretion – even if, eventually, that organization decided independently to use the donation for the benefit of physicians. The donation was not earmarked for physicians at the outset.

CMS considers as non-reportable payments through third parties where the identity of the covered recipient remains anonymous.

- For example, a manufacturer's payments to a market research firm to conduct a double-blinded research study involving $50 payments to physicians for responding to questions would not be reportable; while the manufacturer has earmarked a portion of the funds for physicians, there is no way it could know or find out their identities.

CMS defines "unaware" to include a knowledge standard of the manufacturer having actual knowledge or acting in deliberate ignorance or reckless disregard of a covered recipient's identity. CMS intends "to prevent applicable manufacturers from directing payments to a discrete set of covered recipients whose identities the manufacturer may not actually know, but could easily ascertain."

A manufacturer need not report indirect payments for which it is unaware of the identity of the covered recipient – but if the manufacturer discovers the identity within a set time period, it must report the payment for the applicable reporting year. In the Rule, CMS establishes a specific time period during which awareness must be measured in order to determine whether reporting is required. Specifically, indirect payments need only be reported if the applicable manufacturer becomes aware of the identity of the covered recipient during the reporting year and the second quarter of the subsequent year following the transfer of the payment from the third party to the covered recipient. For example, assume a manufacturer provides funds to a medical society in March 2014, directing that the funds be used for physician grants. This is technically an indirect payment since it is earmarked for physicians. If the society awards the grants in October 2014 and notifies the manufacturer of their names in November 2014, the manufacturer is aware of the identities of the physicians who are covered recipients who received the funds during the awareness time period established by CMS and such payments must be reported by the manufacturer for CY2014. Similarly, if the grantees are named and paid in April 2015 and the medical society alerts the manufacturer of the same in June 2015, the manufacturer is aware of the covered recipients' identity during the applicable time period and such payments must be reported for CY2015. However, if the society awards the grants in March 2014, but the manufacturer is not aware of such award until July 2015, the manufacturer need not report the payments because it was not aware of the identity of the covered recipients during reporting year (2014) and the second quarter of the subsequent year following the transfer to the covered recipient (ending June 2015).

Form of Payment

CMS emphasizes that manufacturers must assign each individual payment or transfer of value – or portion thereof – to "one and only one" form of payment category, such as cash, stock option, and the like. It states dictionary definitions are sufficient to identify these forms of payment.

Nature of Payment

Another of the more challenging aspects of manufacturer compliance with the Rule will be identifying the specific category or categories to which payments and transfers of value to physicians and teaching hospitals should be assigned. CMS does not provide extensive detail in this regard, nor does it characterize some categories as more "beneficial or desirable" than others, stating it does not want to be unduly restrictive. Nonetheless, it emphasizes that manufacturers must report *all* payments and transfers made, unless they are specifically excluded, and that manufacturers need to identify the category that "most closely describes the payment." In other words, the absence of a specific category does not excuse non-reporting, and failure to report can subject the manufacturer to penalties. Specific categories are discussed below, though note that research is treated separately throughout the Rule.

Charitable Contribution: The Rule defines this term as including but not limited to a payment or transfer "made to an organization with tax-exempt status under the [IRS Code], which is not provided in exchange for any goods, items or services." The modifier here is an important one: if a manufacturer makes a payment on behalf of a physician in lieu of a consulting fee, the payment must be reported as a consulting fee to the physician.

Food and Beverage: Evidently, CMS' original proposal with respect to the allocation of meals provided to covered recipients created considerable consternation among concerned commenters, and the Rule now reflects a somewhat more balanced approach. Manufacturers need not track and report "buffet meals, snacks, soft drinks, or coffee generally available to all participants of a large-scale conference and similar large-scale event." In contrast, in a group practice or other setting, the manufacturer (1) must first calculate the per person value among those partaking of the meal (e.g., divide the total food/beverage cost by the number of physicians and support staff partaking of it), and (2) then must report that value *only* for the physicians who partook of the meal. For

example, if a manufacturer's sales representative brings a catered lunch costing $165 to a 10-physician group practice and six of the ten physicians and five support staff participate in the meal (a total of 11 participants), the manufacturer must report with respect to each of the six partaking physicians a transfer of value of $15 ($165/11 participants) under the nature of payment category for meals.

Compensation for Serving as Faculty or as a Speaker: CMS states that it wants to shed more light on varied manufacturer payments in this area for the benefit of consumers, with the result that manufacturers will need to focus more closely on distinctions that have not mattered as much in the past. The overarching theory is that manufacturers have little influence over the faculty or content of *accredited* programs in which they have nothing to do with speaker selection, and therefore need not report those payments at all – but where they do have influence over speaker selection or other types of educational programming involving physicians, they must report those payments.

Essentially, speaker fees involving physicians that are paid by manufacturers must now be attributed to one of four possible categories:

1) Excluded payments for speaking at certain accredited continuing education programs: CMS will not require manufacturers to report indirect payments made for a physician speaker at a medical education program as long as three conditions are met:

a) The program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP or ADA CERP; [4]

b) The manufacturer does not directly pay the physician speaker; and

c) The manufacturer does not select the physician speaker nor does it provide the third party vendor with a distinct, identifiable set of individuals to be considered as speakers.

2) Reportable payments for speaking at certain accredited continuing education programs: CMS will require manufacturers to report payments for accredited and certified programs if prongs (b) and (c) above are not met, i.e., the manufacturer is somehow involved in speaker selection or identification.[5]

3) Payments for speaking at unaccredited and non-certified continuing education programs: CMS will require manufacturers to report payments for unaccredited and non-certified continuing education

[4] The Rule uses Accredited Continuing Medical Education (CME) to refer to CME activities that have been deemed to meet the requirements and standards of a CME accrediting body, as authorized by the Accreditation Council for Continuing Medical Education (ACCME). Certified CME in the Rule refers to CME activities that carry credit offered by the grantors of CME credit (the American Osteopathic Association (AOA), the American Academy of Family Physicians (AAFP), and the American Medical Association (AMA)). Continuing dental education is similarly accredited through the American Dental Association's Continuing Education Recognition Program (ADA CERP). It is unclear if these are the only accrediting/certifying entities that CMS will accept (e.g., sometimes states conduct their own certification activities).

[5] In such cases, the payments are reported as "compensation for serving as faculty or as a speaker for accredited or certified continuing education programs."

programs as required for any other payment or transfer of value. Therefore, if the payment is made indirectly, it will be subject to the same reporting requirements for all indirect payments outlined above.[6]

4) *Payments for other speaking programs:* All other manufacturer payments for physician speaking engagements not related to continuing education (e.g., promotional or marketing activities) should be reported as "compensation for services other than consulting, including speaking at an event other than a continuing education program."

Consulting Fees: CMS states this category covers "services traditionally viewed as consulting," but adds criteria that appear in compliance guidance from the Office of Inspector General, i.e., these are "typically provided under a written agreement and in response to a legitimate [manufacturer] need," and "there is often a connection between the competence of the [physician] paid and the purpose of the arrangement, as well as a reasonable number of [physicians] hired to achieve the intended purpose."[7]

Honoraria: While similar to services "other than consulting," CMS says these fees are distinguishable "in that they are generally provided for services for which custom prohibits a price from being set." This is indeed the term's dictionary definition, but it is doubtful whether most manufacturers view honoraria in this fashion – rather, it is usually just a set price unrelated to an hourly rate.

Gifts and Entertainment: Most manufacturers, adhering to industry codes of ethics and with a desire to avoid anti-kickback issues, have eliminated altogether these types of physician interactions. Nevertheless, reportable gifts are characterized by CMS as "small trinkets (above the minimum [$10] threshold"), while entertainment includes, but is not limited to, physician "attendance at recreational, cultural, sporting or other events that would generally have a cost."

Travel and Lodging: Reportable expenses paid by manufacturers for physicians include means of transportation and lodging, as well as the travel destination (city, state and country).

Education: This category is supposed to cover manufacturers subsidizing physician participation in "classes, activities, programs or events that involve the imparting or acquiring of particular skills or knowledge, such as those used for a profession."

Royalty or License: CMS describes this category as including "the right to use patents, copyrights, other intellectual property and trade secrets, including methods and processes," saying that these "may be pursuant to a written agreement and…entail various payment schedules (such as scheduled or milestone payments)." Manufacturers may report these payments singly or in aggregated form.

Current or Prospective Ownership or Investment Interests: This category includes ownership or investment interests currently held by a covered recipient, as well as ownership or investment interests the covered recipient has not yet exercised.

Grant: CMS states only that this category "generally refers to payments to covered recipients in support of a specific cause or activity."

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[6] In these cases, the payments are reported as "compensation for serving as faculty or as a speaker for unaccredited or non-certified continuing education programs."

[7] 68 Fed. Reg. 23731 (May 5, 2003).

Research: Payments or transfers of value made in connection with an activity that meets the definition of research, discussed in more detail below, must be reported under this nature of payment category.

Space rental or facility fees: In the Rule, CMS adds this new nature of payment category. Interestingly, CMS includes this category generally in its list of approved "nature of payment categories" in the Rule's preamble,[8] but in an earlier section of the preamble[9] and in the actual regulation,[10] it specifies that these payments should be reported only when made by a manufacturer to a teaching hospital. In this regard, it states "we understand that space rental or facility fees are commonly part of hosting an event at a hospital…." CMS thus does not account for instances in which a manufacturer may lease space from a physician. Unless such payments from a manufacturer to a physician are otherwise exempted from reporting, as discussed below, the payment would be reportable, presumably under a different nature of payment category, such as the category for compensation for services other than consulting.

Report Content

The Rule outlines the fields of information manufacturers must include when reporting payments or other transfers of value. The fields are generally consistent with the Sunshine provisions of the ACA and the proposed rule. However, the Rule does include some important clarifications with respect to certain reporting fields, including the following:

- *Date of payment or other transfer of value;*
    - For payments made over multiple dates, manufacturers may report either separately or as a single line item for the first payment date.
    - If multiple payment dates may apply (e.g., for a flight, the date could be either the flight date or the ticket purchase date), manufacturers have flexibility to determine which date to report, but must be consistent in how they report within a nature of payment category (e.g., for all flights, report date of flight).
- *Name(s) and NDCs of the related covered product, as applicable;*
    - Manufacturers may report up to five related products for each interaction.
    - For drugs and biologicals, manufacturers must report the market name of the product and must include the National Drug Code (NDC). If the market name is not yet available, manufacturers should use the name registered on clinicaltrials.gov.
    - For devices and medical supplies, manufacturers should report either the name under which the device or medical supply is marketed, or the therapeutic area or product category.
- *Statement providing additional context for the payment or other transfer of value (optional).*

[8] 78 Fed. Reg. at 9481.

[9] 78 Fed. Reg. at 9477.

[10] 42 C.F.R. 403.904 (e)(xvii).

- The Rule allows manufacturers to provide brief contextual information for each payment or other transfer of value, but does not require manufacturers to provide this information.

Assumptions Document: Manufacturers and GPOs

CMS finalizes its proposal to permit manufacturers voluntarily to submit an "assumptions document" setting out assumptions and methodologies used to categorize payments made to physicians and teaching hospitals. GPOs (discussed further below in Section 7) also can submit assumptions documents concerning their reporting on physician owners or investors. Although CMS states its belief that the contents of such documents "should not be made public," it nevertheless acknowledges that (a) it may be requested under FOIA, in which case CMS will follow its predisclosure notification procedures and seek the manufacturer's or GPO's input on the applicability of certain FOIA exemptions, and (b) it could provide access to the document during an audit or investigation by other HHS divisions, the Office of Inspector General, or the Department of Justice. The only discernible benefit to submitting such a document cited by CMS is that it may decide – based on the information submitted – to issue more detailed guidance to manufacturers generally, or to the individual manufacturer, to assist in classifying payments.

Excluded Payments

Manufacturers need not report payments or transfers of value of certain categories of payment specified in the Sunshine provisions of the ACA. Such exclusions also apply to reporting physician investment or ownership interests.

Existing Personal Relationships: CMS will not require reporting of "purely personal transfers of value," providing the example of a circumstance in which "one spouse, who works for a [manufacturer], gives a present to the other spouse who is a physician…."

Payments of Other Transfers of Value of Less Than $10: The Sunshine provisions of the ACA state that manufacturer payments or transfers of less than $10 need not be reported, unless the total annual value to a physician exceeds $100. CMS will permit manufacturers to report small payments separately or bundle them, so long as they employ a consistent methodology. CMS also plans to update the dollar thresholds for subsequent calendar years. Finally, CMS states that manufacturers need not track, identify, or aggregate the value of "small incidental items that are under $10 (such as pens and notepads) that are provided at large-scale conferences and similar large-scale events," though items over $10 do need to be tracked even when provided at large-scale conferences.

Educational Materials that Directly Benefit Patients or Are Intended for Patient Use: Educational items provided by manufacturers that are intended to be used with patients need not be reported. CMS provides as express examples of such excluded materials wall models and anatomical models, along with overhead expenses associated with these items including printing and time. Note that these excluded items need to be distinguished from educational materials manufacturers provide to physicians for *their* education, but that do not "directly" benefit patients, such as medical textbooks and journal reprints. Manufacturers must report these items. Further, CMS stresses that the exception applies to educational materials only – not to marketing or promotional materials.

Discounts and Rebates: Manufacturers need not report discounts and rebates furnished to physicians.

In-Kind Items for the Provision of Charity Care: CMS states that manufacturers need not report in-kind items provided by manufacturers to covered recipients for their patients who cannot pay for them – including patients for whom co-insurance amounts pose significant financial hardship. This exclusion has some important limitations,

however: it is not intended to cover items provided for the care of *all* patients, even if the recipient is a charitable organization; it is not intended to cover financial support; and, CMS anticipates that manufacturers will enter written agreements with recipients to ensure the provided in-kind items are used only for charity care. Finally, CMS includes a somewhat ambiguous statement in this section of the preamble to the effect that it recognizes "some payments made to charitable third parties may at some point indirectly benefit a covered recipient," and that these should be reported as indirect payments or transfers of value.

Publicly Traded Fund Payments: Manufacturers need not report payments or transfers to physicians or teaching hospitals in the form of dividends or other profit distributions from, or ownership or investment interests in, a publicly traded security or mutual fund.

Product Samples: This exclusion from reporting includes drugs, devices, biologicals, and medical supplies intended to be provided to patients, along with single use or disposable devices, demonstration devices or evaluation equipment *intended for patient use*, and coupons and vouchers. Again, CMS anticipates the manufacturer and covered recipient will enter into a written agreement that the products will be provided to patients. Note that some types of samples and evaluation equipment – i.e., those to be evaluated by the covered recipient as opposed to the patient – are better characterized under the exclusion for short term loans.

Short Term Loans: The operative words here are "short term," defined in the statute as 90 days. CMS states that manufacturer loans of equipment up to 90 days/year (which need not be consecutive) and provision of a 90-day supply of disposable and single use devices (including medical supplies) can be excluded from reporting, but items furnished beyond these thresholds will have to be reported.

Contractual Warranty: CMS expands the scope of this exclusion to apply to manufacturer items and services provided pursuant to a warranty – both during and after the warranty period – or as part of a service and maintenance agreement. It also permits exclusion of replacement products following a recall.

Covered Recipient Acting as a Patient: Manufacturers need not report providing items or services to physicians when they are patients, including as a subject in a research study.

Provision of Healthcare: Manufacturers need not report providing health care items and services to employee physicians and their family members as part of a self-insured plan, or at an on-site clinic or health fair.

Nonmedical Professional: If a physician is also a "licensed nonmedical professional," then manufacturers may provide and need not report transfers of value related to services of the nonmedical professional.

Civil or Criminal Action or Administrative Proceeding: Manufacturers need not report payments for physician services furnished as part of legal proceedings.

5. What are the special rules for research-related payments?

In the Rule, CMS recognizes that research payments are unique and should be reported differently than other payments or transfers of value. CMS also acknowledges that reporting research-related payments or other transfers of value is extremely complicated. As such, the Rule provides additional information regarding what constitutes research and what research-related payments must be reported.

Definition in 42 C.F.R. § 403.902

> *Research* includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-science research. This term encompasses basic and applied research and product development.

According to CMS, the term research includes pre-clinical research and FDA Phases I-IV research, as well as investigator-initiated investigations. In addition, CMS finalizes that in order to fall within the nature of payment category for research, the payment need only be subject to a written agreement or contract *or* a research protocol. CMS previously proposed that research payments would require both a written agreement or contract *and* a research protocol but later acknowledged that such a requirement would be limiting to some types of research.

Reporting Research Payments

Any payments reported under the nature of payment category of research should be made in connection with an activity that meets the above definition. Research-related payments that do not meet the definition of research should be reported using the other nature of category payments available.

In General. The Rule finalizes that manufacturers must report each research-related payment that ultimately is paid, in whole or in part, to a covered recipient separately in a different template than that used for other payments. Each research payment should be reported only once as a single interaction and the report should include the following information:

- Name of research institution/other entity or individual receiving payment (regardless of whether a covered recipient);
    - If paid directly to a physician covered recipient, list the individual's name, NPI, state license number(s)/state name(s), specialty, and primary business address).
    - If paid directly to a teaching hospital covered recipient, list name and primary business address of the teaching hospital.
    - If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list name and primary business address of the entity.
- Total amount of research payment;
- Name of study;
- Name(s) of related covered product and NDC (if any).
- Principal investigator(s) (including name, NPI, state license number(s)/state name(s), specialty, and primary business address);
- Context of research (optional); and
- ClinicalTrials.gov identifier (optional).

Pre-Clinical Research. CMS finalizes modified reporting requirements for pre-clinical research, which includes laboratory and animal research that is carried out prior to beginning any human studies. Specifically, for pre-clinical research, manufacturers only have to report the name of the research institution; principal investigator(s) (including name, NPI, state license number(s), specialty, and business address); and the total amount of the payment. Manufacturers need not report an associated product or study name.

Research Payment Amount. The total research amount should include the aggregated amount of any payment for services included in the written agreement/research protocol (e.g., costs associated with patient care, time spent by health care professionals treating patients and managing the study, and the provision of study products or other in-kind items). The payment should not include any payments for activities that are separate from the written agreement/protocol or are paid through a method different than that of the research.

For example, if a manufacturer makes a payment to a physician for medical research writing, such payment would be included in the research payment if such activity was included in the written agreement or research protocol and paid as part of the research payment. However, if medical research writing was not covered under the research agreement/protocol, payment for such service should be reported separate from the research payment, under a different nature of payment category, such as the category for payments for services other than consulting.

Similarly, with respect to meals and travel, CMS clarifies that such expenses should be reported separately (under the food and travel nature of payment categories) unless included in the written agreement or research protocol and paid through the large research contract.

Public Availability of Research Payment Information

CMS finalizes in the Rule how reported research payments will be presented to the public on CMS' website. For physician covered recipients who are paid by a third party and not directly by the manufacturer, CMS will list research studies separately from all other payments provided to the covered recipient and will not aggregate the research payment with other payments. This separation is important since research payments are generally different than other payments and may not represent a payment to the covered recipient. Therefore, CMS recognizes that it would be misleading to attribute an entire research payment to the physician principal investigator.

For teaching hospitals, CMS will publish all research payments that went to the hospital as a research institution. These payments will be listed separately from other payments to the hospitals, but will include both the study amount and the study name.

6. When can reporting be delayed for payments involving confidential and proprietary research or product development?

Under the Rule, certain payments or other transfers of value related to research (as defined above) may be delayed from publication on CMS' website. Payments or other transfers of value subject to delay will not be published until (i) the covered product receives FDA approval, licensure, or clearance, or (ii) four years after the date of the payment or other transfer of value, whichever occurs first. Such delay is intended to balance a manufacturer's need to maintain confidentiality of proprietary information with the public's need for transparency of payments to covered recipients.

In order to qualify for delayed publication, the payment or transfer of value must be made under a written product research or development agreement and/or a research protocol in connection with one of the following:

- Research on or development of a new product;
- Research on or development of a new application of an existing product;
- Clinical investigations regarding a new product.

Delayed publication is not available for payments and transfers of value made in connection with clinical investigations related to new applications of existing products.

The distinctions the Rule makes between new products and new applications, and between research and clinical investigations, may create practical challenges for manufacturers in determining which payments and transfers of value are eligible for delayed publication. Underscoring these practical challenges, neither "new product" nor "new application" is defined in the Rule, and, as CMS recognizes, clinical investigations are a subset of research.

CMS does offer some limited guidance with respect to both of these issues. First, CMS notes that "clinical investigation" includes Phase I through IV clinical research for drugs and biologicals, and approval trials for devices (including medical supplies). Second, CMS provides that for purposes of delayed publication, new generic products will be considered new products, including drugs receiving approval under an Abbreviated New Drug Application and devices receiving approval under the 510(k) process.

For each payment or other transfer of value that a manufacturer determines is eligible for delayed publication and for which it intends to seek delayed publication, the manufacturer must indicate on its report that such payment is eligible for delayed publication. The manufacturer must continue to include the payment or transfer of value on subsequent reports, with a continued indication of eligibility, for each year that delayed publication is available.

Information reported by manufacturers subject to delayed publication will be considered confidential and will not be subject to disclosure under FOIA or any other similar federal, state, or local law, until after the date on which the information is made available to the public on the public website.

7. What entities will need to report physician ownership and investment interests?

Applicable manufacturers (discussed above in Section 2) and applicable GPOs must report certain information regarding ownership and investment interests held by physicians or their immediate family members, as well as payments or other transfers of value to such physician owners or investors.

Definitions in 42 C.F.R. § 403.902

> *Applicable group purchasing organization* means an entity that:
>
> (1) Operates in 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, but not solely for use by the entity itself.

Ownership or investment interest

(1) Includes but is not limited to stock, stock option(s) (other than those received as compensation, until they are exercised); partnership share(s); limited liability company membership(s); 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.

(3) Excludes (i) an ownership or investment interest in a publicly traded security or mutual fund; (ii) an interest in an applicable manufacturer or applicable GPO that arises from a retirement plan offered by the applicable manufacturer or applicable GPO 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 GPO; (iii) stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity; (iv) an unsecured loan subordinated to a credit facility; (v) an ownership or investment interest if an applicable manufacturer or applicable GPO did not know about such ownership or investment interest.

Analysis

Ownership or Investment Interest. "Any ownership or investment interest" encompasses both direct and indirect interests, since, according to CMS, indirect ownership or investment interests are also true interests. However, CMS does limit this interpretation by finalizing that manufacturers and GPOs need not report indirect ownership or investment interests held by physicians or immediate family members of physicians about which they do not know.

Physician Owned Distributors (PODs). In the Rule, CMS defines applicable GPOs to include entities that purchase covered products for resale or distribution to groups of individuals or entities, which includes PODs. While CMS intends to require reporting by "as many PODs as possible," it declines to limit the exclusion for entities that purchase the products for their own use to only those entities that are end users of the product based on billing under the same provider or supplier number as the entities that purchased the product. Interestingly, CMS estimates that 260 PODs currently operate in the United States.

8. How do manufacturers, GPOs, physicians, teaching hospitals, and physician owners or investors handle disputed information?

According to CMS, the Sunshine provisions of the ACA require applicable manufacturers and GPOs to resolve disputes with physicians, teaching hospitals, and physician owners or investors regarding the accuracy of reported data. To allow for dispute resolution, the Sunshine provisions provide that manufacturers, GPOs, physicians, teaching hospitals, and physician owners or investors must be afforded with at least 45 days to review the data reported to CMS prior to the data being made available to the public. To address concerns that 45 days is not a sufficient amount of time to review, correct *and resolve disputes*, the Rule also affords an additional 15-day period for manufacturers and GPOs to correct disputed data.

Notification of Review and Correction Period. CMS will notify physicians and teaching hospitals about the 45-day review and correction period. To do so, CMS will use email list serves, online postings (including both the CMS website and the Federal Register) and direct notices (likely by email) for any physicians or teaching hospitals that have registered with CMS in advance. During the review and correction period, physicians and teaching hospitals

will be able to login to a CMS-secure website, review the information submitted by applicable manufacturers or GPOs on their behalf, and initiate any disputes.

Dispute Resolution. To initiate disputes, physician and teaching hospitals will identify a transaction on the CMS-secure website and fill out electronic fields detailing the dispute, including the proposed corrections. The system will automatically flag the transaction and notify the appropriate manufacturer or GPO. The manufacturer or GPO is then responsible for resolving the dispute with the physician or teaching hospital and submitting corrected information and re-attesting to the new data. Disputed transactions that remain unresolved after the 15-day correction period for disputed data, will be labeled as "disputed" on the public website, but the manufacturer's or GPO's version of the transaction will be made public. While CMS does not believe it should be actively engaged in mediating disputes, it plans to monitor the rate of disputes and resolutions, including whether a manufacturer or GPO has an abnormally high number of disputes or has an abnormally high rate of unresolved disputes.

9. What penalties could apply for nonreporting and inaccurate reporting?

The Sunshine provisions of the ACA provide that if a manufacturer or GPO fails to timely, accurately, or completely report the required information, then it will be subject to a civil monetary penalty (CMP) of at least $1,000, but no more than $10,000, for each payment or other transfer of value, or ownership or investment interest not reported as required. With respect to each annual submission, the maximum CMP for failure to report is $150,000. Additionally, if a manufacturer or GPO *knowingly* fails to timely, accurately, or completely report the required information, then it will be subject to a CMP of at least $10,000, but no more than $100,000, for each payment or other transfer of value, or ownership or investment interest not reported as required. The annual maximum CMP for knowing failures to report is $1 million.

Significantly, CMS clarifies in the Rule that penalties imposed for failure to report and knowing failures to report will be aggregated separately, such that a manufacturer or GPO could be subject to a maximum combined annual total of $1,150,000.

Inaccurate Reporting. CMS considers the failure to timely, accurately, or completely report to include omissions and errors. Such errors could include, for example, the failure to accurately report an entire transaction, as well as the failure to accurately report certain fields related to a transaction. With regard to corrections made during the review and correction, and dispute resolution periods, CMS does not intend for the errors corrected to be subject to penalties for failure to report provided that the original submission was made in good faith. Outside of this period, however, any errors or omissions will be considered failures to report timely, accurately, or completely and ***will be subject to penalties***.

Consolidated Reports. While CMS affords manufacturers under common ownership with other applicable manufacturers the flexibility to submit consolidated reports, the manufacturer actually submitting the report will be subject to maximum penalties ***for each individual manufacturer included in the consolidated report***. Because the manufacturer submitting the consolidated report is the entity attesting to the data, CMS believes it is fair that it be subject to the CMPs for each manufacturer included in the consolidated report.

Relevant Factors. CMS will consider the following factors in determining the amount of a CMP:

- Length of time the manufacturer or GPO failed to report, including the length of time the manufacturer or 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 manufacturer or GPO failed to report;

- Level of culpability;
- Nature and amount of information reported in error; and
- Degree of diligence exercised in correcting information reported in error.