Morgan Lewis

memorandum

Final Sunshine Act Arrives: Now the Hard Part

March 2013

The Centers for Medicare and Medicaid Services (CMS) issued the final regulations on the U.S. Sunshine Act on February 8, 2013. Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458 (Feb 8, 2013) (to be codified at 42 C.F.R. pts. 402, 403), *available at* http://www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf. While there remain implementation questions and challenges, CMS has addressed and clarified many difficult and impractical aspects of the transparency statute. Although the final rule is not long, the public comments and agency responses are lengthy and helpful in understanding some provisions. Notably, CMS appears to have committed to a frequently asked questions (FAQ) process.

Applicable manufacturers and applicable group purchasing organizations (GPOs) must begin to collect the required data on August 1, 2013, and report the data to CMS by March 31, 2014. Failure to timely, accurately, or completely report may result in significant monetary penalties (up to $10,000 per violation or $100,000 for knowing violations).

To aid the review and understanding of the final regulations, Morgan Lewis has updated its U.S. Sunshine chart to capture the statute, the proposed rule, and the final rule with appropriate citations to the statute, Code of Federal Regulations, and relevant *Federal Register* preamble. View the chart at http://www.morganlewis.com/documents/HealthIndustryTransparencyRequirements.pdf.

Threshold Question Answered: What Is an Applicable Manufacturer?

Before entities determine any other requirement or deadline under U.S. Sunshine, it is necessary to assess whether the entity or its divisions, affiliates, or subsidiaries fall within the definition of an "applicable manufacturer." The final rule includes some significant clarification as to what type of entities would meet the definition of an "applicable manufacturer."

An "applicable manufacturer" is defined as an entity that is operating in the United States and that falls within one of the following categories:

- An entity that is 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.
- 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 for sale or distribution in the United States or in a territory, possession, or commonwealth of the United States.

The rule further defines "operating in the Unites States" as having a physical location in the United States or conducting business activities within the United States or in a territory, possession, or commonwealth of the United States. It goes on to clarify that entities based outside the United States that do have operations in the United States are subject to the reporting requirements. Entities that have operations within the United States are not permitted to circumvent the reporting requirements by altering the process to make payments to covered recipients indirectly through a foreign entity that has no operations in the United States.

The final rule also includes some specific examples of entities that are not considered to meet the definition of an "applicable manufacturer." For example, entities that only manufacture raw materials or components, which are not themselves covered products, will not be required to report unless they are considered an applicable manufacturer due to common ownership considerations. In the event a supplier of raw materials is under common ownership with an applicable manufacturer, it will be subject to the reporting requirements for entities under common ownership, including options for consolidated reporting with the applicable manufacturer.

The definition of an "applicable manufacturer" also excludes entities such as hospitals, hospital-based pharmacies, and laboratories that manufacture a covered product solely for use by or within the entity itself or by an entity's own patients.

Additionally, it does not include pharmacies, including compounding pharmacies, that meet all of the following conditions:

- Maintain establishments that comply with applicable local laws regulating the practice of pharmacy.
- Regularly engage in dispensing prescription drugs or devices upon prescriptions from licensed practitioners in the course of their professional practice.
- Do not produce, prepare, propagate, compound, or convert drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail to individual patients.

Further, there is now a bright line on the potential inclusion/exclusion of distributors and wholesalers. The final rule indicates that distributors and wholesalers (which include repackagers, relabelers, and kit assemblers) **that hold the title** to a covered drug, device, biological, or medical supply **meet the definition of an "applicable manufacturer"** for the purpose of this rule and will thereby be subject to the same requirements as all other applicable manufacturers. Wholesalers or distributors that do not hold the title of a covered product will not be subject to the reporting requirements, unless they are under common ownership. Finally, an applicable manufacturer that has product(s) with titles held by distributors does not need to report payments or other transfers of value (TOVs) made by the distributor or wholesaler to covered recipients since these will be reported by the distributor or wholesaler.

The "applicable manufacturer" definition was expanded to include not only entities that hold Food and Drug Administration (FDA) approval, licensure, or clearance for a covered drug, device, biological, or medical supply, but also contracted entities conducting the actual manufacturing, as they are actually manufacturing a covered product and clearly are "engaged in the production, preparation, propagation, compounding, or conversion" of a product—even if these contracted entities do not hold the FDA approval, licensure, or clearance. The slight exception is for instances where a contracted entity manufactures a covered drug, device, biological, or medical supply for another entity pursuant to a written agreement; does not hold the FDA approval, licensure, or clearance for the product; and is not involved in the sale, marketing, or distribution of the product. In this situation, the contracted entity is only required to report payments or other TOVs related to the covered product.

Finally, in an attempt to acknowledge the burden for applicable manufacturers whose primary business focus is not the production of covered drugs, devices, biologicals, or medical supplies, or who happen to manufacture one or a few covered products, the final rule included a revenue qualifier. Applicable manufacturers with less than 10 percent of total (gross) revenues from covered drugs, devices, biologicals, or medical supplies during the previous fiscal year need only report payments or other TOVs specifically related to covered drugs, devices, biologicals, or medical supplies. The 10-percent threshold should be calculated based on the company's total (gross) annual revenue. Those entities below the 10-percent threshold that have payments or other TOVs to report must still register with CMS and must also attest that less than 10 percent of total (gross) revenues are from covered products, along with their attestation of the submitted data.

I. Deadlines for Collection and Reporting

Data Collection. The collection of data related to payments and other TOVs must commence as of August 1, 2013. The initial time period for data to be submitted by March 31, 2014, is from August 1 to December 31, 2013. Relevant submission and registration due dates are captured below:

- Reports must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.
- Applicable manufacturers that have reportable payments or other TOVs, ownership or investment interests, or both, are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.
- Applicable GPOs that have reportable ownership or investment interests are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

Registration. Applicable manufacturers and applicable GPOs that are required to report under this rule must register with CMS within 90 days of the end of the calendar year for which a report is required. During registration, two points of contact, with relevant contact information, must be provided. After initial registration, the CMS system will prompt an annual confirmation related to the points of contact on file.

Attestation. Each report, including any subsequent corrections to a filed report, must include an attestation by the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable GPO that the information reported is timely, accurate, and complete to the best of his or her knowledge and belief. For applicable manufacturers choosing to submit a consolidated report, the applicable manufacturer submitting the consolidated report must attest on behalf of itself, in addition to each of the other applicable manufacturers included in the consolidated report.

45-Day Review and Correction Period. Applicable manufacturers, applicable GPOs, 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.

Notification. CMS notifies the applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors when the reported information is ready for review.

- Applicable manufacturers and applicable GPOs are notified through the points of contact they identified during the registration process.
- Physicians and teaching hospitals are notified using an online posting and notifications on CMS's distribution lists and may also register with CMS to receive direct notification about the review processes.

An applicable manufacturer, applicable GPO, covered recipient, or a physician owner or investor may log into a secure website to view only the information reported specifically about itself. Covered recipients and physician owners or investors are able to review data submitted about them for the previous reporting year.

Data Disputes. Following the end of the 45-day review and correction period, applicable manufacturers and applicable GPOs will have **an additional 15 days to correct data** for purposes of resolving disputes, after which they may submit (and provide attestation for) updated data to finalize their data submission. Only data disputed during the 45-day review and correction period **and** resolved within the 15-day period for dispute resolution will be captured in the initial publication of data for the current reporting year. Undisputed data will be finalized for publication after the close of the annual 45-day review and correction period. Other data corrections received throughout the year will be made when the data is updated for the following year.

II. Limitations on Scope of Reporting – 42 C.F.R. § 403.904(b)

There are new and notable limitations on reporting that appear in the final regulations. 42 C.F.R. § 403.904(b). These limitations effectuate a limitation on reporting, although such is not defined in the statute. These limitations do not operate as exclusions from reporting but reduce, potentially, the scope of reporting to covered products.

Specifically, applicable manufacturers with total gross revenues from covered products of less than 10% of total gross revenue are only required to report payments or other TOVs related to the covered product.

Entities that fall under the definition of "applicable manufacturers" through the common ownership definition and provide assistance or support in production, preparation, propagation, compounding, marketing, sale, and promotion of a covered product are required to report only payments and TOVs related to the covered product.

Applicable manufacturers with distinct operating divisions that do not manufacture any covered products are only

required to report payments and TOVs if the activities are related to a covered product.

Applicable manufacturers that do not manufacture a covered product except under a written agreement with another entity and that do not participate in the sale, marketing, or distribution of the covered product are required to report only those activities related to the covered product.

III. Categories of Reporting – 42 C.F.R. § 403.904(c)

The general categories of reporting did not materially change in the final regulations, although some changes were made to accommodate issues relating to Continuing Medical Education (CME). Additionally, a new category was included for space rental or facility fees at a teaching hospital. Direct industry funding to compensate a covered recipient for speaking at a continuing education conference, accredited or not, is reportable. The reporting categories include the following:

- Consulting fee
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
- Honoraria
- Gift
- Entertainment
- Food and beverage
- Travel and lodging, including the specified destinations
- Education
- Research
- Charitable contribution
- Royalty or license fee
- Current or prospective ownership or investments interest
- Compensation for serving as faculty or as a speaker at a non-accredited or non-certified CME event
- Compensation for serving as faculty or as a speaker at an accredited or certified CME event
- Grant
- Space rental or facility fees for teaching hospitals only

IV. Exclusions from Reporting: Not Much Changed in the Final Regulations

Section 403.904(i) of the final rule describes those TOVs that are excluded from the reporting requirements. The exclusions in the final rule do not differ materially from what CMS published in the proposed rule. CMS noted in the final rule that it received numerous requests to add additional exclusions to the reporting requirements, but the agency took the position that it did not have the authority to add exclusions beyond what was outlined in the statute. Accordingly, the exclusions outlined in the final rule track the exclusions set forth in the Affordable Care Act (ACA).

The following TOVs are excluded from the reporting requirements:

Section 403.904(i)(1). Indirect TOVs. The final rule discusses numerous types of "indirect" payments, some of which are excluded from the reporting requirements and some of which are not. The final rule excludes from the reporting requirements only those indirect payments or TOVs (as defined in Section 403.902) made to a covered recipient through a third party **when the applicable manufacturer is unaware of the identity of the covered recipient**. As discussed elsewhere in this memorandum, certain indirect payments or other TOVs must be tracked and reported under the final rule, including the following:

- An indirect payment or other TOV made to a covered recipient through an entity under common ownership that is not necessary or integral to the manufacturing process.
- Research-related payments or other TOVs to covered recipients (either physicians or teaching hospitals), including research-related payments or other TOVs made indirectly to a covered recipient through a third party.
- Payments or other TOVs from an applicable manufacturer to non-physician prescribers to be passed through to a physician.
- Any payments or other TOVs made through non-healthcare departments of universities affiliated with teaching hospitals to a covered recipient as indirect payments or other TOVs.

An applicable manufacturer is unaware of the identity of a covered recipient if it does not know the identity of the covered recipient. CMS intends to apply the traditional False Claims Act definition of "knowing" (*see* 31 U.S.C. § 3729(b)(1)) when assessing whether an applicable manufacturer is aware of the identity of a covered recipient—i.e., if the applicable manufacturer has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient (and no intent to defraud must be shown). Note that if the applicable manufacturer is aware of the covered recipient's identity, the TOV must be reported, even if it is provided through a third party.

Section 403.904(i)(2). *De Minimis* TOVs. A TOV that is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 during the calendar year. This *de minimis* threshold is to be increased annually by the same 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. CMS decided to increase the *de minimis* threshold in calendar year 2014, not calendar year 2013, as suggested in the proposed rule. Significantly, CMS clarified that the provision of small incidental items valued at less than $10 (e.g., pens and notepads) provided at "large-scale" events will be excluded from the reporting requirements, and there is no need to track these items for aggregation purposes. Note, however, that any TOV of $10 or more, even when furnished at a large-scale event, must be tracked and reported.

Section 403.904(i)(3). Product Samples. Product samples (including any drug, device, biological, or medical supply) furnished by an applicable manufacturer to a covered recipient that are not intended to be sold and are intended for patient use. CMS clarified that coupons and vouchers for the applicable manufacturer's products intended for patient use are also included in this exclusion. In addition, CMS does not believe an applicable manufacturer should be responsible for tracking what happens to its product samples but suggests that the applicable manufacturer and covered recipient agree in writing that the products will be provided to patients.

Section 403.904(i)(4). Education Materials Benefiting Patients. Educational materials that directly benefit patients or are intended for patient use, including the value of an applicable manufacturer's services to educate patients regarding a covered product. For example, an anatomical model to help explain a procedure, or a flash drive including education materials distributed to patients, would not be reportable. CMS clarified that educational materials furnished to a covered recipient, but which are not intended for patient use (such as a medical textbook), are not covered by the exclusion and must be reported (unless subject to another exclusion).

Section 403.904(i)(5). Short-Term Loans. 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. CMS clarified that this exclusion includes a supply of disposable or single-use devices, including medical supplies, intended to last no more than 90 days.

Section 403.904(i)(6). Contractual Warranties. Items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has expired, 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. Note that the exclusion applies to items and services furnished outside the warranty period, so long as the warranty specified the terms prior to its expiration and the terms did not change.

Section 403.904(i)(7). Covered Recipients as Patients. A transfer of anything of value to a covered recipient when the covered recipient is a patient, a research subject, or a participant in data collection for research, and the

covered recipient is not acting in his or her professional capacity. CMS agreed with a few commenters who recommended that a covered recipient's participation in research be considered the same as being a patient.

Section 403.904(i)(8). Discounts, Including Rebates. Discounts and rebates for covered drugs, devices, biologicals, and medical supplies provided by applicable manufacturers to covered recipients.

Section 403.904(i)(9). In-Kind Items for Charity Care. In-kind items used for the provision of charity care. CMS clarified that this exclusion would not apply to in-kind items furnished to a covered recipient for the care of **all** patients, including both those who can and cannot pay. If the TOV is not an in-kind item for the provision of charity care, it does not meet this exclusion, nor does this exclusion apply to financial support to charitable covered recipients. Similar to CMS's treatment of product samples, the agency does not intend applicable manufacturers to be responsible for tracking each individual item provided to a covered recipient to ensure it is provided to a patient unable to pay. Rather, CMS believes it is sufficient for the applicable manufacturer and covered recipient to agree in writing that a covered recipient will use the in-kind items only for charity care.

Section 403.904(i)(10). Dividends. A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

Section 403.904(i)(11). Provision of Healthcare. In the case of an applicable manufacturer who offers a self-insured plan or is directly reimbursed for healthcare expenses, payments for the provision of healthcare to employees and their families.

Section 403.904(i)(12). Non-Medical Professional. In the case of a covered recipient who is a licensed non-medical professional, a TOV to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

Section 403.904(i)(13). Legal Proceedings. In the case of a covered recipient who is a physician, a TOV 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.

Section 403.904(i)(14). Existing Personal Relationships. A TOV to a covered recipient if the TOV is made solely in the context of a personal, non-business-related relationship (e.g., a gift from a spouse who works for an applicable manufacturer to the other spouse who is a covered recipient).

V. Reporting Format for Payments and Other TOVs

For calendar year 2013, only payments or other TOVs made on or after August 1, 2013, must be reported to CMS. A report must contain all of the following information for each payment or other TOV:

1. **Name of the covered recipient.** For physician covered recipients, the name must be as listed in the National Plan and Provider Enumeration System (NPPES) (if applicable) and include first and last name, middle initial, and suffix (for all that apply).
2. **Address of the covered recipient.** Primary business address (practice location) of the covered recipient, including all of the following:
    a. Street address
    b. Suite or office number (if applicable)
    c. City
    d. State
    e. Zip code
3. **Identifiers for physician covered recipients.** In the case of a covered recipient who is a physician, the following identifiers:
    a. Specialty.
    b. National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider

Identifier cannot be identified for a physician, the field may be left blank, indicating that the applicable manufacturer could not find one.

c. State professional license number(s) (for at least one state where the physician maintains a license) and the state(s) in which the license(s) is(are) held.

4. **Amount of payment or other TOV.** A payment or other TOV made to a group of covered recipients should be distributed appropriately among the individual covered recipients who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other TOV.
5. **Date of payment or TOV.** The date of each payment or other TOV.
    a. For payments or other TOVs made over multiple dates (rather than as a lump sum), applicable manufacturers may choose whether to report each payment or other TOV as a separate line item using the dates the payments or other TOVs were made or as a single line item for the total payment or other TOV using the first payment date as the reported date.
    b. For small payments or other TOVs reported as a single line item, applicable manufacturers must report the date that the first bundled small payment or other TOV was provided to the covered recipient.
6. **Form of payment or TOV.**
7. **Nature of payment or TOV.**
8. **Related covered drug, device, biological, or medical supply.** The name(s) of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other TOV is not related to a particular covered drug, device, biological, or medical supply. Applicable manufacturers may report up to five covered drugs, devices, biologicals, or medical supplies related to each payment or other TOV. If the payment or other TOV was related to more than five covered drugs, devices, biologicals, or medical supplies, the applicable manufacturer should report the five covered drugs, devices, biologicals, or medical supplies that were most closely related to the payment or other TOV.
    a. For drugs and biologicals, applicable manufacturers must report the name under which the drug or biological is or was marketed and the relevant National Drug Code(s), if any. If the marketed name has not yet been selected, the applicable manufacturer must indicate the name registered on clinicaltrials.gov.
    b. For devices and medical supplies, applicable manufacturers must report at least one of the following:
        i. The name under which the device or medical supply is or was marketed
        ii. The therapeutic area or product category for the device or medical supply
    c. If the payment or other TOV is not related to a covered drug, device, biological, or medical supply, but is related to a specific non-covered product, applicable manufacturers must indicate “non-covered product.”
    d. If the payment or other TOV is not related to any drug, device, biological, or medical supply (covered or not), applicable manufacturers must indicate “none.”
    e. If the payment or other TOV is related to at least one covered drug, device, biological, or medical supply and at least one non-covered drug, device, biological, or medical supply, applicable manufacturers must report the name(s) of the covered drug, device, biological, or medical supply and may indicate “non-covered products” in addition.
9. **Eligibility for delayed publication.** Applicable manufacturers must indicate whether a payment or other TOV is eligible for delayed publication.
10. **Payments to third parties.**
    a. If the payment or other TOV was provided to a third party at the request of or designated on behalf of a covered recipient, the payment or TOV must be reported in the name of that covered recipient.
    b. If the payment or other TOV was provided to a third party at the request of or designated on behalf of a covered recipient, applicable manufacturers must report the name of the entity that received the payment or other TOV (if made to an entity) or indicate “individual” (if made to an individual). If a covered recipient performed a service, but neither accepted the offered payment or other TOV nor requested that it be made to a third party, the applicable manufacturer is not required to report the offered payment or other TOV unless the applicable manufacturer nonetheless provided it to a third party and designated such payment or other TOV as having been provided on behalf of the covered recipient.

11. **Payments or TOVs to physician owners or investors.** An applicable manufacturer must indicate whether the payment or other TOV was provided to a physician or the immediate family of a physician who holds an ownership or investment interest in the applicable manufacturer.
12. **Additional information or context for payment or TOV.** An applicable manufacturer may provide a statement with additional context for the payment or other TOV.

An applicable manufacturer must report each payment or TOV, or separable part of that payment or TOV, as taking one of the following forms of payment that best describes the form of the payment or other TOV, or separable part of that payment or other TOV:

- Cash or cash equivalent
- In-kind items or services
- Stock, stock option, or any other ownership interest
- Dividend, profit, or other return on investment

In the case of consolidated reporting, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers. Additionally, the report must identify the specific entity that provided each payment or TOV.

VI. Reportable Physician Ownership and Investment Interests

For calendar year 2013, only ownership or investment interests held on or after August 1, 2013, must be reported to CMS. Each applicable manufacturer and applicable GPO must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable GPO that were held by a physician or an immediate family member of a physician during the preceding calendar year.

Reports on physician ownership and investment interests must include the following identifying information:

1. **Name of the physician** as listed in the NPPES (if applicable), including first and last name, middle initial, and suffix (for all that apply) and an indication of whether the ownership or investment interest was held by the physician or an immediate family member of the physician.
2. **Primary business address** of the physician, including the following:
    a. Street address
    b. Suite or office number (if applicable)
    c. City
    d. State
    e. Zip code
3. **The following information for the physician** (regardless of whether the ownership or investment interest is held by an immediate family member of the physician):
    a. Specialty
    b. National Provider Identifier (if applicable and as listed in the NPPES)
    c. State professional license number(s) (for at least one state where the physician maintains a license) and the state(s) in which the license(s) is(are) held
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. **Direct and indirect payments or other TOVs** provided to a physician holding an ownership or investment interest, and direct and indirect payments or other TOVs provided to a third party at the request of or designated by the applicable manufacturer or applicable GPO on behalf of a physician owner or investor, must be reported by the applicable manufacturer or applicable GPO in accordance with the requirements for reporting payments or other TOVs. The terms “applicable manufacturer” and “applicable group purchasing organization” must be substituted for “applicable manufacturer,” and “physician owner or investor” must be substituted for “covered recipient” in each place they appear.

CMS recently released the various reporting templates (i.e., research payments, non-research payments, and physician ownership) along with a supporting statement providing context for the data submission processes. The templates provide detailed information on properly formatting data prior to submission, including data component field values (e.g., text, numeric, alphanumeric, set value), data field character length, whether each data component is required or optional, and whether each field will be publicly displayed. To download the supporting statement as well as the data submission templates from the CMS website, visit http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10419.html.

VII. Research-Related Payment Provisions Have Material Changes

The final rule attempts to provide clarity and ease some of the administrative burden for research-related payments by adopting a definition for the term "research" and developing a separate reporting template for research-related payments. In an attempt to give clear direction on what constitutes bona fide research, the rule adopts the definition of "research" from the Public Health Service Act (42 C.F.R. § 50.603) as "a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development." CMS further elaborates that this definition includes pre-clinical research and FDA Phases I–IV research as well as investigator-initiated investigations.

Additionally, CMS has broadened its interpretation to allow for various types of research in different industries by allowing payments that meet the definition of "research" as now defined to be reported within the research nature of payment category if the payment is subject to a written agreement or contract or a research protocol. The final rule takes a step further to include what is referred to as "an unbroken chain of agreements" that link the applicable manufacturer with the covered recipient through use of a contract research organization (CRO) or site management organization (SMO). So, applicable manufacturers must expand their tracking and reporting systems to ensure that they are knowledgeable of the ultimate recipient of the funds (e.g., principal investigator, teaching hospital, non-teaching hospital, clinic).

The final rule does not require an applicable manufacturer to indicate whether a payment is categorized as indirect or direct. The final rule also eliminates the redundant reporting initially outlined in the proposed rule. Applicable manufacturers must report each research payment only once as a single interaction. They must report the following information for each research payment:

1. Name of the individual or entity that received the payment for research services—receiving payment either directly from the applicable manufacturer or indirectly through a CRO or SMO, regardless of whether the individual or entity is itself a covered recipient.
2. If the payment is paid directly to a physician covered recipient, identifying information must also be provided, including the following:
    a. Physician's name
    b. NPI
    c. State professional license number(s) and the state name(s) for at least one state in which the physician maintains a professional license
    d. Specialty
    e. Primary business address for the physician
3. Name of the principal investigator (including the identifying information detailed above).
4. Total amount of the research payment.
5. Name of the study.
6. Name of the related covered drug, device, biological, or medical supply and the National Drug Code, if any.
7. Context for research (optional).
8. ClinicalTrials.gov identifier (optional).

For pre-clinical research, the reporting requirement **does not** include the name of the related covered drug,

device, biological, or medical supply or the study name since early-stage research is often not connected to a specific product. The final rule notes that pre-clinical research is intended to include laboratory and animal research that is carried out prior to beginning any studies in humans, including FDA's defined phases of investigation.

The final rule does allow for delayed publication for research or clinical investigation activities. All payments or other TOVs that are related to **new** products are eligible for delayed publication. However, those related to research for a new application of a product already on the market will be eligible for delayed publication only if the research **does not** meet the definition of "clinical investigation" as clinical investigations related to new applications of existing products are not eligible for delayed publication. The rule further clarifies that clinical investigation includes Phases I through IV clinical research for drugs and biologicals and approved trials for devices (including medical supplies). For purposes of determining eligibility for delayed publication, new generic products will be considered new products, including drugs receiving approval under an Abbreviated New Drug Application and devices under the 510(k) process.

The data indicated as eligible for delayed reporting will be included in the data set reviewed by applicable manufacturers and covered recipients during the 45-day review and correction period, but the data will not be published on the website for the public until the appropriate time for release. As outlined in the final rule, CMS will publicly post the payment on the first annual publication date after the earlier of the following:

- The date of the approval, licensure, or clearance of the covered drug, device, biological, or medical supply by the FDA

  or

- Four calendar years after the date the payment or other TOV was made

However, if a manufacturer does not indicate that a payment or other TOV is eligible for delayed publication, it will be published immediately on the next publication date.

VIII. Special Issue of Note: CME

Relevant Definitions:

- **Indirect payments or other TOVs** refer to payments or other TOVs made by an applicable manufacturer (or an applicable GPO) to a covered recipient (or a physician owner or investor) through a third party, where the applicable manufacturer (or applicable GPO) requires, instructs, directs, or otherwise causes the third party to provide the payment or TOV, in whole or in part, to a covered recipient(s) (or a physician owner or investor).
- **Accredited CME** refers 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 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).

CMS stated in the final rule that it believes the category of "Education" generally includes payments or TOVs for classes, activities, programs, or events that involve the imparting or acquiring of particular knowledge or skills, such as those used for a profession. It is not the agency's intention to capture the attendees at accredited or certified continuing education events whose fees have been subsidized through the CME organization by an applicable manufacturer (as opposed to payments for speakers at such events). However, CMS believes that any travel or meals provided by an applicable manufacturer to specified covered recipients associated with these

events must be reported under the appropriate nature of payment categories.

Under the final rule, an indirect payment made to a speaker at a continuing education program is not an indirect payment or other TOV for purposes of this rule and, therefore, does not need to be reported when **all** of the following conditions are met:

- The program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP, or ADA CERP.
- The applicable manufacturer does not select the covered recipient speaker nor does it provide the third-party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing education program.
- The applicable manufacturer does not directly pay the covered recipient speaker.

Applicable manufacturers will not be responsible for reporting payments made to CME vendors that are used to subsidize attendees' tuition fees for continuing education events. However, payments or other TOVs associated with attendance at an event (such as travel and meals) must be reported as required.

IX. Penalties

The final rule imposes civil penalties on applicable manufacturers and applicable GPOs that fail to timely, accurately, or completely report the information required in accordance with the regulations. Specifically, violative applicable manufacturers and applicable GPOs may face a civil monetary penalty of $1,000 to $10,000 for each payment or other TOV or ownership or investment interest not reported timely, accurately, or completely. The penalty amount increases to a range of $10,000 to $100,000 for knowing failures. The maximum total amount of civil monetary penalties imposed on each applicable manufacturer or applicable GPO for failures related to a particular annual submission is $150,000 or $1,000,000 for knowing failures.

Contacts

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