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E-ALERT | Health Care

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CMS ISSUES FINAL RULE TO IMPLEMENT THE SUNSHINE ACT

On February 1, 2013, the Centers for Medicare and Medicaid Services (CMS) issued a final rule[1] implementing section 6002 of the Patient Protection and Affordable Care Act (ACA), Transparency Reports, and Reporting of Physician Ownership or Investment Interests, known as the "Sunshine Act."[2]

This client alert describes the key provisions of those sections of the final rule related to (1) the reports required to be submitted by manufacturers regarding payments and other transfers of value provided to covered recipients and (2) CMS's publication of the reported data on a public website.[3] It is intended to provide an overview of the rule's most important provisions and thus necessarily does not address all of the rule's nuances and ambiguities.

TIMING

The final rule states that applicable manufacturers must collect data about payments and transfers of value provided to covered recipients on or after August 1, 2013. Their first reports, for the period beginning August 1 and ending December 31, 2013, must be submitted to CMS by March 31, 2014.

DEFINITIONS

Applicable Manufacturers

- **Definition of Applicable Manufacturer:** The statute defines an "applicable manufacturer" as "a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States."[4] The final rule adopts this definition and defines "operating in the United States" to mean having a physical location in the United States or otherwise conducting activities in the United States or in a territory, possession, or commonwealth of the United States.
- **Limitations on "Applicable Manufacturer":** The following are not considered applicable manufacturers: (1) manufacturers of raw materials and (2) hospitals, pharmacies, and laboratories that produce or manufacture materials and products solely for their own use or use by their patients. Distributors and wholesalers (which include repackagers, relabelers, and kit assemblers) that hold title to a covered product are "applicable manufacturers." Contract manufacturers are also applicable manufacturers, but if the following conditions are met, a contract manufacturer is required to report only payments or other transfers of value related to

[1] The final rule was published in the Federal Register on February 8.
[2] Pub. L. No. 111-148, 124 Stat. 119, 689 (2010) (codified at Social Security Act § 1128G (the "statute," or the "Act")).
[3] This summary does not cover those provisions in the final rule related to reporting requirements regarding ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and GPOs.
[4] Social Security Act § 1128G(e)(2).

the covered product (and not all payments or transfers of value): the contract manufacturer (1) does not manufacture a product except pursuant to a written agreement with another entity; (2) does not hold the FDA approval, licensure, or clearance for the product; and (3) is not involved in the sale, marketing, or distribution of the product.

- **Grace Period:** Manufacturers have a grace period of 180 days following a product becoming "covered" to begin complying with the data collection and reporting requirements.
- **"Common Ownership":** The statute defines the term "manufacturer of a covered drug, device, biological, or medical supply" to include "any entity under common ownership with such entity which provides assistance or support to such entity."[5] CMS adopted a five-percent ownership threshold for common ownership. "Assistance or support" means activities that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product. For example, production of the active ingredient for a covered product would be considered provision of "assistance and support," but assistance with human resources functions would not.
- **Consolidated Reporting:** Entities under common ownership are allowed, but not required, to file consolidated reports. Consolidated reports must identify each applicable manufacturer and entity (or entities) under common ownership that the report covers and must state which entity made each payment or transfer of value. Regardless of whether applicable manufacturers file separate or consolidated reports, each single payment or other transfer of value should be reported only once, and each covered recipient included in a consolidated report must be individually and consistently identified.

Covered Drug, Device, Biological, or Medical Supply

- **Definition of Covered Drug, Device, Biological, or Medical Supply:** The final rule provides that a product is covered if payment is available under Medicare, Medicaid, or CHIP *and* requires a prescription (in the case of a drug or biological) or premarket approval by or notification to FDA (in the case of a device or a medical supply that is a device). The final rule includes as covered products those that are reimbursed separately, as well as those that are reimbursed as part of a bundled payment.
- **Manufacturers of Non-Covered Products:** The final rule provides that applicable manufacturers with less than 10 percent of total (gross) revenues from covered products during the previous fiscal year may report only payments or other transfers of value specifically related to covered products, provided they attest that less than 10 percent of their total revenues are from covered products. Applicable manufacturers that have separate operating divisions that produce only non-covered products and do not meet the definition of providing "assistance and support" must report only payments or other transfers of value made by that operating division that are related to a covered product.

Covered Recipients

- **Definition of Covered Recipient:** CMS revised the definition of "covered recipient" to ensure that only bona fide employment relationships are excluded from the definition. In addition, the final rule clarified that the employee exception applies only to physicians who are employed by the reporting applicable manufacturer and not *any* applicable manufacturer. Board members, prospective employees, and retirees are excluded only to the extent that they meet the IRS definition of "employee" referenced in the statute. The final rule excludes payments and transfers of value provided to residents.

[5] Social Security Act § 1128G(e)(9).

- **Physicians:** Applicable manufacturers should be able to demonstrate that they made a good faith effort to obtain a National Provider Identifier (NPI) for the physician, including specifically requesting an NPI from the physician, checking the National Plan and Provider Enumeration System (NPPES) database, and calling the NPPES help desk. Applicable manufacturers may rely on NPI information in NPPES as of 90 days before the beginning of the reporting year. If an applicable manufacturer cannot, after a good faith effort, determine a physician's NPI, the applicable manufacturer may leave the NPI field blank. However, if CMS later determines that a physician covered recipient has an NPI, the agency may require the applicable manufacturer to re-submit the data, including the NPI, and re-attest to the updated data. Moreover, the report may be considered inaccurate and the manufacturer may be subject to penalties.
- **Teaching Hospitals:** CMS will publish the list of teaching hospitals once annually and make the list available at least 90 days before the beginning of each reporting year.

Payments or Transfers of Value

- **Value of Payment or Transfer of Value:** The final rule defines the value of a payment or transfer of value as the discernible economic value on the open market in the United States.
- **Factors to Determine Value:** The final rule provides the following factors to determine value:
  1. Payments or other transfers of value that do not have a discernible economic value for the covered recipient specifically, but nevertheless have a discernible economic value generally, must be reported.
  2. Even if a covered recipient does not formally request the payment or other transfer of value, it still must be reported.
  3. When calculating value, all aspects of a payment or transfer of value, such as tax or shipping, should be included in the reported value.
  4. All applicable manufacturers must make a reasonable, good faith effort to determine the value of a payment or other transfer of value.
- **Payments or Transfers of Value to Specific Physicians in a Group Practice:** CMS stated that the payment or transfer of value should be attributed to the individual physicians who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value (not necessarily all members of a practice).
- **Payments or Transfers of Value Directed to Another Covered Recipient:** Payments or transfers of value provided to one covered recipient but directed by the applicable manufacturer to another specific covered recipient (e.g., a payment made to a teaching hospital but directed to a specific physician) should be reported in name of the covered recipient that ultimately received the payment or transfer of value because the intermediate covered recipient was merely passing through the payment or transfer of value. If the payment or other transfer of value is not passed through in its entirety, then the applicable manufacturer should report separately the portion retained by the intermediate covered recipient and the portion passed through.
- **Payments of Transfers of Value Made to a Third Party at the Request of a Covered Recipient:** The final rule requires applicable manufacturers to report the name of the entity that received the payment or other transfer of value, as well as the name of the covered recipient. If a payment or transfer of value is provided to an individual, the individual's name does not need to be reported (due to privacy concerns). Instead, the applicable manufacturer should report simply "individual" in the field for entity paid.

REPORT CONTENTS

Data Elements

CMS provided clarity about how to report the following data elements, which must be reported for each payment or transfer of value:

- **Name:** The physician's name, including middle initial if applicable, must be reported as it appears in the NPPES registry.
- **Business Address:** Manufacturers can use whatever address they have on file for the covered recipient. The primary practice location should be reported as the business address, if possible. A full address, including street address, must be provided.
- **Physician Specialty:** In the final rule, CMS stated that manufacturers should be able to use their internal information when reporting specialties. However, the agency added that they should use the NPPES provider taxonomy list as the list of accepted specialties to ensure consistency in the names of reported specialties. Manufacturers may not provide additional information justifying a particular physician specialty.
- **Date:** Manufacturers have flexibility to report payments made over multiple dates either separately or as a single line item for the first payment date. CMS will allow flexibility as to the specific date to report for a nature of payment category, provided that the methodology used to determine the payment date is consistent within a single nature of payment category. CMS encouraged manufacturers to include information in their assumptions document on their methodology for reporting the date of payment or other transfer of value.
- **Context:** CMS will allow applicable manufacturers to voluntarily report a limited amount of contextual information about each payment or other transfer of value and make the information publicly available.
- **Related Products:** Applicable manufacturers must report a related product for all payments or transfers of value, unless the payment or other transfer of value is not related to a covered product. For payments and transfers of value not related to at least one covered product, applicable manufacturers should report "none." Conversely, for payments and transfers of value related to a specific product that is not a covered product, applicable manufacturers should report "non-covered product." For payments and transfers of value related to both a covered product and a non-covered product, applicable manufacturers should report the covered product by name and may include the non-covered product in one of the fields for reporting associated products. CMS further allowed applicable manufacturers to report up to five covered products associated with each payment or transfer of value.
- **Form and Nature of Payment:** The final rule requires a single form of payment and a single nature of payment for each line item. Applicable manufacturers may not report a lump sum payment with multiple forms of payment or multiple natures of payment. If a payment can fit within multiple categories, applicable manufacturers may select the category that best describes the payment, but they may not bundle payments of separate categories into a single payment.

Form of Payment Category

The final rule breaks the category of "stock, stock option, or any other ownership investment interest, dividend, profit or other return on investment" category into two categories: (1) stock, stock options, and other ownership investment interests and (2) dividends, profits, and other returns of investment.

Nature of Payment Category

CMS provided guidance on the nature of payment categories, as follows:

- **Charitable Contributions:** This category should be used only in situations when an applicable manufacturer makes a payment or other transfer of value to a charity on behalf of a covered recipient and not in exchange for any service or benefit.
- **Food and Beverage:**
  - **Attribution of Meals:** For meals in a group setting (other than buffet meals provided at conferences or other similar large-scale settings), applicable manufacturers must report the per-person cost of the food or beverage for each covered recipient who actually partakes in the meals. For example, if a sales representative provides a lunch costing $165 to a 10-physician group practice, and six of the 10 physicians and five support staff participate in the meal, the per-person meal cost is $15 per participant. The meal would be reported only for the six physicians who participated in it, at a value of $15 per person.
  - **Provision of Meals at Conferences:** Applicable manufacturers do not need to report buffet meals, snacks, or coffee at booths at conferences or other similar events. This exemption does not apply to meals provided to individual attendees at a conference where the sponsoring applicable manufacturer can establish the identity of the attendees.
- **Direct Compensation for Serving on the Faculty of or as a Speaker for a Medical Education Program:** This category does not include compensation for accredited or certified continuing education payments. Instead, it includes all instances when an applicable manufacturer provides compensation to a covered recipient for serving as a speaker or faculty at an unaccredited and non-certified education event, regardless of whether the payment was provided directly or indirectly.
- **Consulting Fees:** Consulting services are typically provided under a written agreement and in response to a legitimate need by the applicable manufacturer.
- **Compensation for Services Other than Consulting:** This category is intended to capture compensation for activities or services that are not traditionally considered consulting services. It includes payments or other transfers of value for speaking engagements that are not related to accredited or unaccredited continuing education, such as promotional or marketing activities.
- **Honoraria:** This category is similar to "compensation for services other than consulting," but honoraria are generally provided for services for which custom prohibits a price from being set.
- **Gift:** This category may include items provided to a covered recipient that do not fit into another category.
- **Entertainment:** This category includes, but is not limited to, attendance at recreational, cultural, sporting, or other events that would generally have a cost.
- **Travel and Lodging:** This category includes travel, including any means of transportation, as well as lodging. The report must include the destination, including city, state, and country.
- **Education:** This category includes payments or transfers of value 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 does not include subsidies for registration fees for attendees at accredited or certified continuing education events.
- **Royalty or License:** This category includes, but is not limited to, the right to use patents, copyrights, other intellectual property, and trade secrets, including methods and processes. To

consolidate reporting, applicable manufacturers may report total aggregated payments made under a single agreement.

- **Current or Prospective Ownership or Investment Interests:** This category includes ownership or investment interests currently held by a covered recipient, as well those that the covered recipient has not yet exercised.
- **Grant:** This category generally refers to payments to covered recipients in support of a specific cause or activity.
- **Other:** In response to comments that the "other" category would dilute the usefulness of the nature of payment categories, CMS removed this category from the final rule but cautioned that all payments or transfers of value from applicable manufacturers to covered recipients (other than those excluded by statute) must be reported.

Assumptions Document

Manufacturers may submit voluntarily an assumptions document that describes the "assumptions used when categorizing the natures of payments" when they submit their data.

Research

- **Definition of Scope of Research:** CMS defined research based on the definition of research in the Public Health Service Act as set forth in 42 C.F.R. § 50.603: "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." This definition includes pre-clinical research, FDA phases I-IV research, and investigator-initiated investigations. Research must be subject to a research protocol or a written agreement or contract.
- **Reporting Research Payments:** The final rule abandoned the distinction between direct and indirect research set forth in the proposed rule. Instead, applicable manufacturers must use a separate reporting template to report "research-related payments that ultimately are paid, in whole or in part, to a covered recipient (physician or teaching hospital)." Each payment must be reported as a single interaction. The total amount of the research payment should include the aggregated amount of any payments for services included in the written agreement/research protocol but should not include any payments for activities that are separate or segregable from the written agreement or research protocol or are paid through a method different than that of the research.
- **Presentation on the Public Website:** Research payments will be listed separately on the public website, in recognition of the fact that research payments are generally different from other payments and do not necessarily represent a personal payment to physicians.
- **Pre-Clinical Research:** With respect to payments and transfers of value related to laboratory and animal research, applicable manufacturers must report only the name of the research institution, principal investigator(s) (including name, NPI, state professional license number(s), specialty, and business address), and the total amount of the payment.

Exclusions from Reporting

The statute excludes certain types of payments and transfers of value from reporting.

- **Existing Personal Relationships:** As proposed, existing personal relationships do not require reporting. This exclusion covers a situation in which one spouse who is employed by an applicable manufacturer provides a gift to the other spouse who is a covered recipient.
- **Payments or Other Transfers of Value of Less than $10:** The final rule allows flexibility in reporting small payments or transfers of value. An applicable manufacturer may report small payments and transfers of value either individually or combined with other small payments and transfers of value that are in the same nature of payment category. Applicable manufacturers must use consistently their chosen method of reporting and clearly designate the method of reporting that they use. The de minimis reporting thresholds will stay the same throughout an entire reporting period.
- **Educational Materials that Directly Benefit Patients or Are Intended for Patient Use:** The final rule recognizes that "materials" are not limited to written materials, but may take other forms. Overhead expenses, such as printing and time to prepare these materials, should be included in the exclusion, provided they are "directly related" to producing materials that "directly benefit patients or are intended for patient use." The provision of educational materials that "are educational to covered recipients (such as medical textbooks and journal reprints), but are not intended for patient use" does not fall within the statutory exclusion, even though these materials have downstream benefits for patients.
- **Discounts and Rebates:** As proposed, discounts and rebates for covered products are excluded from reporting.
- **In-Kind Items for the Provision of Charity Care:** CMS clarified that the exclusion applies to both patients who are unable to pay and patients "for whom payment would be a significant hardship." CMS also stated that tracking individual items provided to covered recipients is unnecessary, provided there is a written agreement between the covered recipient and the applicable manufacturer stating that the items will be used only for charity care.
- **Product Samples:** This exclusion applies to a drug, device, biological, or medical supply that a covered recipient receives for use by patients. Coupons and vouchers intended to minimize the patient's cost of drugs, devices, or biologicals fall within the exclusion. Products used for research should be included in the larger research payment.
- **Short Term Loans:** Loans for covered devices, including disposable or single use devices, fall within the exclusion, provided the loan is for 90 days or less (regardless of whether the days are consecutive). If the loan is for greater than 90 days, it is subject to the reporting requirements.
- **Contractual Warranty:** Items and services provided pursuant to a contractual service or maintenance agreement are included in the exclusion, as are items and services provided after the warranty expiration period, provided the contract articulated such terms before the expiration and the terms were unchanged.
- **Covered Recipient Acting as a Patient:** This exclusion covers situations in which the covered recipient is participating in a research study as a subject.
- **Provision of Healthcare:** This exclusion applies to "payments to covered recipients for services rendered to family members" who receive care through a self-insured plan and to other situations when an applicable manufacturer makes a payment to a covered recipient for health care services provided to the manufacturer's employees or family members (e.g., an on-site clinic or health care).
- **Nonmedical Professional:** As proposed, the transfer of anything of value to a covered recipient is excluded if the covered recipient is a licensed non-medical professional and the transfer is payment solely for non-medical professional services.

- **Civil or Criminal Action or Administrative Proceeding:** Any legal proceeding involving a physician falls within this exclusion.

Indirect Payments or Other Transfers of Value through a Third Party

- **Definition of Indirect Payments or Transfers of Value:** CMS defined "indirect payments or other transfers of value" as payments or transfers of value "that an applicable manufacturer requires, instructs, or directs to be provided to a covered recipient, regardless of whether the applicable manufacturer specifies the specific covered recipient."
- **Definitions of "Unaware" and "Know":** An applicable manufacturer is "unaware" if it does not know the identity of a covered recipient. "Know" means that the manufacturer has actual knowledge of the identity of the covered recipient or acts in deliberate ignorance or reckless disregard of the identity. The applicable manufacturer must be unaware of the covered recipient's identity during the reporting year and the second quarter of the year following the payment or transfer of value.
- **Definition of Deliberate Ignorance or Reckless Disregard:** CMS will not consider an applicable manufacturer to be acting in deliberate ignorance or reckless disregard of a covered recipient's identity in situations when a payment or other transfer of value is made through a third party to ensure that the identity of the covered recipient remains anonymous (e.g., market research).
- **Continuing Medical Education (CME):** CMS will not consider indirect payments to speakers at CME events to be indirect payments or transfers of value if the following conditions are met: (1) the program meets the accreditation or certification requirements and standards of the Accreditation Council for Continuing Medical Education (ACCME), American Osteopathic Association (AOA), American Medical Association (AMA), American Academy of Family Physicians (AAFP), or American Dental Association Continuing Education Recognition Program (ADA CERP); (2) the covered recipient is not selected by the applicable manufacturer nor does the applicable manufacturer provide the third party a set of individuals to be considered as speakers; and (3) the covered recipient speaker is not directly paid by the applicable manufacturer.

REPORT SUBMISSION AND REVIEW[6]

Pre-Submission Review Process

The final rule states that the pre-submission review process is voluntary and that CMS will not administer or manage the pre-submission review process.

Report Submission

- **Registration:** Applicable manufacturers that will submit data as a part of a consolidated report with another manufacturer may indicate during registration that they intend to be part of the consolidated report. Applicable manufacturers must designate two points of contact when they register. Manufacturers must register with CMS within 90 days of the end of the calendar year for which they will submit a report.
- **Deadline:** Initial reports must be submitted by March 31, 2014, and subsequent reports must be submitted by the 90th day of each year. Reports may be submitted on an annual basis only. Submission extensions will not be granted. Late data will be considered failure to report and may be subject to penalties.

[6] For convenience, this section refers only to the submission of information regarding payments and transfers of value, but these provisions of the final rule also apply to reports of physician ownership and investment interests. Likewise, it refers only to applicable manufacturers and not to applicable GPOs.

- **File Format:** In the final rule, CMS agreed to provide applicable manufacturers with reporting templates, which will be finalized at least 90 days before the first day of data collection for the next reporting year. CMS will allow submission of only a single report covering the entire reporting period.
- **Attestation Process:** In the proposed rule, CMS stated that the chief executive officer, chief financial officer, or chief compliance officer of each applicable manufacturer would be required to annually submit a signed attestation certifying the timeliness, accuracy, and completeness of the data submitted to the best of the signer's knowledge and belief. CMS finalized this attestation requirement, but it stated that other designated company officials may also attest. It also clarified that an applicable manufacturer must provide the attestation when it submits its original submission. An applicable manufacturer must also provide an attestation when the submitted data are changed or updated.
- **Report Content:** The final rule outlined the required information to be included in reports of payments or transfers of value.
  - For each payment and other transfer of value, the report must include:
    1. Applicable manufacturer's name;
    2. Covered recipient's (1) name, (2) specialty, (3) primary business street address, (4) NPI, and (5) state professional license number(s) for at least one state where the physician maintains a license, including the applicable state where the license is held;
    3. Amount of payment or other transfer of value;
    4. Date of payment or other transfer of value;
    5. Form of payment or other transfer of value;
    6. Nature of payment or other transfer of value;
    7. Name(s) of the related covered product, as applicable;
    8. NDCs of related covered drugs and biologicals, if any;
    9. Name of entity that received the payment or other transfer of value, if it was not directly provided to the covered recipient;
    10. A "yes or no response" to whether a payment or other transfer of value was provided to a physician holding ownership or investment interests in the applicable manufacturer; and
    11. Statement providing additional context for the payment or other transfer of value (optional).
  - For each research-related payment or other transfer of value the report must include:
    1. Applicable manufacturer's name;
    2. Name of research institution/entity receiving payment;
    3. Total amount of research payment;
    4. Name of study;
    5. Name(s) of related covered drug, device, biological, or medical supply;
    6. NDCs of related covered drugs and biologicals, if any;
    7. Principal investigators, including name, NPI, state professional license number(s) for at least one state where the physician maintains a license (including the applicable state where the license(s) is held), and specialty and primary business address;

8. Context of research (optional);
9. ClinicalTrials.gov identifier (optional); and
10. A "yes or no response" to question of whether the payment or other transfer of value should be granted a delay in publication because it was made pursuant to a product research agreement, development agreement, or clinical investigation.

45-Day Review Period

- **Notification of Review and Correction Period:** CMS will notify physicians and teaching hospitals of the 45-day review period through (1) email list serves, (2) online postings on CMS's website and the Federal Register, and (3) direct communication, likely by email, to physicians and teaching hospitals that previously registered with CMS. Covered recipients are required to register to review the data attributed to them.
- **Length of Review and Correction Period:** The final rule provides for a 45-day review period, but adds an additional 15-day period for applicable manufacturers to correct disputed data at the end of the 45-day period. CMS stated that it plans to encourage covered recipients to register with the CMS system, review their data, and if necessary, initiate disputes as soon as possible within the 45-day review and correction period to maximize the likelihood of successful resolution and accurate data available for publication. CMS will provide only one review and correction period annually.
- **CMS-Secure Website:** The review and correction process will take place on a CMS-secure website. Applicable manufacturers will be able to review only the data they submit, and covered recipients will be able to view only the data submitted on their behalf. All data from the previous reporting year, including data eligible for delayed publication, will be available for review and correction.
- **Dispute Resolution:** CMS will not take an active role in resolving disputes over submitted data. CMS will provide covered recipients with the opportunity to review data submitted on their behalf and correct the data if needed. When the submitted data are corrected by a covered recipient, CMS's system will automatically flag the data as disputed and notify the applicable manufacturer that there is a dispute over the submitted information. The applicable manufacturer and the covered recipient will then have 15 days to resolve the dispute. If the dispute is not resolved within 15 days, CMS will publish only the original data submitted by the applicable manufacturer, but it will identify the data as disputed. CMS intends to monitor the volume and terms of disputes and resolutions and plans to provide additional guidance regarding situations when the cost of resolving a dispute may outweigh the benefits of doing so.
- **Updating of Public Website:** The public website will be updated at least once a year after the initial publication of the data to reflect corrected data. CMS will also allow covered recipients to review and contest data throughout the year, and corrected data will be published the next time CMS updates the website.

PUBLIC AVAILABILITY

- The statute requires CMS to publish the data submitted by applicable manufacturers. CMS will publish the data submitted for 2013 in 2014. In the final rule, CMS emphasized that it will incorporate stakeholder input into the design and content of the website. The final rule provides only general information about the public website.

- **Data Elements:**
  - The information on the public website regarding payments and other transfers of value will include:
    1. Applicable manufacturer's name;
    2. Covered recipient's (1) name, (2) specialty, and (3) primary business street address;
    3. Amount of payment or other transfer of value in US dollars;
    4. Date of payment or other transfer of value;
    5. Form of payment or other transfer of value;
    6. Nature of payment or other transfer of value;
    7. Name(s) of related covered drugs, devices, biologicals, or medical supplies;
    8. NDCs of related covered drugs and biologicals, if any;
    9. Name of the entity that received the payment or other transfer of value, if not provided to the covered recipient directly; and
    10. Statement providing additional context for the payment or other transfer of value (optional).
  - The information available on the public website regarding research payments or other transfers of value will include:
    1. Name of research institution or entity receiving payment;
    2. Total amount of research payment;
    3. Name of study;
    4. Name(s) of the related covered drugs, devices, biologicals, or medical supplies;
    5. NDCs of related covered drugs and biologicals, if any;
    6. Principal investigator(s), including name, specialty, and primary business address;
    7. Context of research; and
    8. ClinicalTrials.gov identifier (optional).

Delayed Publication for Research Payments

- **Payments or Transfers of Value Subject to Delayed Publication:** The final rule clarifies that publication of a payment or transfer of value will be delayed if the payment or transfer of value (1) concerns research and (2) is made under a written research agreement that concerns a new product. If the payment or transfer of value concerns research on new applications of existing products, CMS will delay publication only if the research is not a "clinical investigation." A "clinical investigation" includes Phases I-IV clinical research for drugs and biologicals and approved trials for devices. New products will include new generic products, including drugs "receiving approval under an Abbreviated New Drug Application, and devices under the 510(k) process."
- **Written Agreement and Research Protocol:** The final rule states that the requirements for the written agreement and research protocol for purposes of delayed publication are the same as those articulated in the research section of the rule.

- **Requesting Delay in Publication:** The final rule states that while an applicable manufacturer is not required to state that publication should be delayed, CMS will automatically publish a payment or transfer of value on the next publication date if the report does not indicate that publication should be delayed.

PENALTIES

- **Factors for the Imposition of CMPs:** CMS finalized the factors for the imposition of CMPs in the final rule as follows: (1) length of time an applicable manufacturer failed to report; (2) amount that the applicable manufacturer failed to report; (3) level of culpability; (4) nature and amount of information reported in error; and (5) degree of diligence exercised in correcting information reported in error.
- **Penalties for Inaccurate Reporting:** CMS will impose penalties for inaccurate reporting. Errors in a submission made in good faith that are corrected during the review period will not be subject to penalties.
- **Consolidated Reports:** When an applicable manufacturer submits a consolidated report, it will be required to attest for all the entities included in the report. Consequently, the applicable manufacturer that submits the consolidated report is subject to the maximum penalties for each individual manufacturer included in the report.
- **Retention Period:** The retention period starts on the date of publication.

ANNUAL REPORTS

- **Annual Report to Congress:** The final rule states that CMS's annual report to Congress will include information that applicable manufacturers submit in the preceding year. CMS will submit its first annual report to Congress on April 1, 2015, and the report will contain aggregated information submitted by applicable manufacturers in the preceding year (i.e., the 2015 report will contain 2013 data), enforcement actions taken, and penalties paid.
- **Annual Report to States:** CMS will submit its first report to the states by September 30, 2014, and by June 30 of each year thereafter. Reports will be state-specific and will include data collected during the previous calendar year, which were submitted in the current year (i.e., the 2014 report will contain 2013 data).

RELATION TO STATE LAWS

The statute preempts state or local law requirements that require reporting of the same "type of information" about payments or transfers of value from applicable manufacturers to covered recipients. The final rule clarifies that "type of information" for preemption purposes concerns the information that must be reported for payments or other transfers of value under 42 U.S.C. § 1320a-7h(a)(1)(A)(i)-(viii) and 42 C.F.R. § 403.904(c). Local and state governments may not require separate reports unless the governmental agency is collecting the information for public health surveillance, investigation, other public health purposes, or health oversight. CMS urged manufacturers to continue to report under state or local disclosure laws until the requirements under the federal rule take effect.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Health Care Practice Group:

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