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A Broader Perspective

Alert

Life Sciences and Health Care Client Service Group

To: Our Clients and Friends March 8, 2013

TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS (SUNSHINE AMENDMENT)

On February 1, 2013, the Centers for Medicare and Medicaid Services (CMS) issued its final rule which will make information publicly available about payments or other transfers of value from certain manufacturers of drugs, devices, biologicals, and medical supplies to physicians and teaching hospitals. Additionally, information will be made publicly available about physician or immediate family members ownership or investment interests in applicable manufacturers and group purchasing organizations. Also called the "National Physician Payment Transparency Program: Open Payments," this rule implements Section 6002 of the Affordable Care Act. The rule was published on February 8, 2013 (78 FR 9457), with the collection of data to begin on August 1, 2013, and data reported to CMS on March 31, 2014. Civil monetary penalties may be imposed for the failure to submit the required reports.

CMS has set up a "National Physician Payment Transparency Program: Open Payments" website that will provide information and updates (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html). Proposed templates for data collection and submission of reports have also been posted by CMS (http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10419.html).

DEFINITIONS – SECTION 403.902

"Applicable group purchasing organization" (GPO) -

1. Operates in the U.S., or in a territory, possession, or commonwealth of the U.S.; and

2. Purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply for resale or distribution to a group of individuals or entities, but not solely for use by the GPO or commonly owned entities of the GPO.

"Applicable manufacturer" - an entity that operates in the U.S., or in a territory, possession, or commonwealth of the U.S., and falls within one of the following categories:

1. 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 U.S., or in a territory, possession, or commonwealth of the U.S.; or

2. Is under common ownership with an entity identified in paragraph 1 and which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply for sale or distribution in the U.S., or in a territory, possession, or commonwealth of the U.S.

An applicable manufacturer does not include the distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that don't hold title to a covered drug, device, biological, or medical supply unless under common ownership with an applicable manufacturer and provide assistance or support with respect to such covered drug, device, biological, or medical supply.

The following entities are excluded as applicable manufacturers:

1. Hospitals, hospital-based pharmacies, and laboratories that manufacture covered drugs, devices, biologicals, or medical supplies for use by or within the entity itself or by the entity's own patients; and

2. Pharmacies, including compounding pharmacies, that:

   (a) Maintain an establishment that complies with laws regulating the practice of the pharmacy;

   (b) Regularly engage in dispensing covered drugs, devices, biologicals, or medical supplies upon receipt of a prescription from a licensed practitioner in the course of their professional practice; and

   (c) Don't produce, prepare, propagate, compound, or convert a covered drug, device, biological, or medical supply for sale other than in the regular course of their business of dispensing or selling covered drugs, devices, biologicals, or medical supplies at retail to individual patients.

Applicable manufacturers include entities that hold an FDA approval, licensure, or clearance for a covered drug, device, biological, or medical supply even if the entity contracts out the manufacturing of the product to another entity. The contracted entity may also be an applicable manufacturer if it manufactures a covered drug, device, biological, or medical supply.

"Assistance and support" - provides a service(s) that is necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply. Producing an active ingredient for a covered drug

is considered assistance and support; providing human resource functions are not assistance and support.

“Covered drug, device, biological, or medical supply” - any drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid, or the Children’s’ Health Insurance Program (CHIP) and which requires a prescription to be dispensed (if a covered drug or biological) or premarket approval from, or notification to, the FDA (covered device or medical supply). The payment can be available through a bundled payment rate (such as IPPS or OPPS) or reimbursed separately (such as through a fee schedule or formulary).

“Covered recipient” -

1. A physician, other than a physician who is an employee of the reporting applicable manufacturer; or

2. A teaching hospital.

“Immediate family member of physician” - spouse; natural and adoptive parent, child, and sibling; stepparent, stepchild, stepbrother, and stepsister; father-, mother-, daughter-, son-, brother-, and sister-in-law; grandparent and grandchild; and spouse of grandparent or grandchild.

“Indirect payments or other transfers of value” - payments or other transfers of value made by an applicable manufacturer to a covered recipient, or by an applicable GPO to 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 other transfer of value, in whole or in part, to a covered recipient or physician owner or investor, as applicable.

“Know,” “knowing,” or “knowingly” - a person, with respect to information:

1. Has actual knowledge of the information;

2. Acts in deliberate ignorance of the truth or falsity of such information; or

3. Acts in reckless disregard of the truth or falsity of such information.

No proof of specific intent to defraud is required.

“Operating in the U.S.” - having a physical location or otherwise conducting activities in the U.S., or a territory, possession, or commonwealth of the U.S., or selling a covered drug, device, biological, or medical supply in the U.S.

“Payment or other transfer of value” - the transfer of anything of value.

1. Must have a discernable economic value generally even if it is not of value to a specific covered recipient.

2. The total of the payment or other transfer of value includes all aspects of the payment or other transfer of value, such as shipping and taxes.

"Physician" - includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors who are legally authorized to practice. Residents are excluded.

"Research" - a systemic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. It encompasses basic and applied research and product development.

"Teaching hospital" - an institution that receives payments for indirect medical education (IME), graduate medical education (GME), or psychiatric hospital IME during the most recent year for which such information is available. CMS will publish the list of teaching hospitals annually at least ninety days prior to the beginning of the reporting year.

REPORTS OF PAYMENTS OR OTHER TRANSFERS OF VALUE TO COVERED RECIPIENTS – SECTION 403.904

Direct and indirect payments and other transfers of value provided by an applicable manufacturer to a covered recipient or to a third party at the request of or as designated by the applicable manufacturer on behalf of the covered recipient during the preceding calendar year must be reported by the applicable manufacturer on an annual basis. Section 403.904(a). An applicable manufacturer that has separate operating divisions that don't manufacture a covered drug, device, biological, or medical supply and that don't meet the definition of "assist and support" only needs to report payments and other transfers of value, directly and indirectly, related to a covered drug, device, biological, or medical supply. Section 403.904(b)(3). An applicable manufacturer that only manufactures a covered drug, device, biological, or medical supply under a written contract with another entity, does not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and isn't involved in the sale, marketing, or distribution of the covered drug, device, biological, or medical supply is only required to report payments and other transfers of value related to the covered drugs, devices, biologicals, or medical supplies manufactured under the agreement. Section 403.904(b)(4).

All payments and other transfers of value are to be reported only one time. All covered recipients must be individually, uniquely, and consistently identified. Applicable manufacturers have a grace period of 180 days after a product becomes "covered" before the applicable manufacturer has to begin complying with the data collection and reporting requirements.

The information required to be reported to CMS includes:

1. Name of the covered recipient

   (a) For a physician covered recipient, the name must be as listed in the National Plan and Provider Enumeration System (NPPES), if applicable, and include the physician's first and last names, middle initial, and suffix.

(b) If a payment or other transfer of value is made to one covered recipient, but is directed to or benefits another covered recipient, it should be reported in the name of the covered recipient who ultimately receives the payment or other transfer of value.

(c) If the payment or other transfer of value is provided to an individual, at the request of or on behalf of a covered recipient, report "individual" in the field for the entity paid.

(d) If a covered recipient directs an applicable manufacturer to provide a payment or other transfer of value to another individual or entity rather than receiving it personally, it must be reported in the name of the covered recipient and provide the name of the entity or report as "individual" in the field indicating who received the payment or other transfer of value.

2. Address

Primary business address is to include:

(a) Street address;

(b) Suite or office number;

(c) City;

(d) State; and

(e) Zip code.

3. Identifiers for physician covered recipients

(a) Specialty name and code;

(b) National Provider Identifier (NPI), as listed in the NPPES; if none, leave blank; and

(c) State professional license number(s) and State(s) in which the license is held (for at least one State).

(NPPES databases:

http://nppes.viva-it.com/NPI_Files.html;

https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions)

4. Amount of payment or other transfer of value

   If the payment or other transfer of value is made to a group of covered recipients, allocate it among the individual covered recipients who requested the payment or other transfer of value, on whose behalf the payment or other transfer of value was made, or who are intended to benefit from the payment or other transfer of value.

5. Date of payment or other transfer of value

   For payments and other transfers of value made over multiple dates, the applicable manufacturer may choose whether each payment or other transfer of value is reported as a separate line item using the dates of each payment or other transfer of value, or as a single line item for the total payment or other transfer of value, using the first payment or other transfer of value date as the reported date.

6. Form of payment or other transfer of value

   Each payment or other transfer of value, or separable part of that payment or other transfer of value, shall be reported as taking one of the following forms of payment that best describes the payment or other transfer of value:

   (a) Cash or cash equivalent;

   (b) In-kind items or services;

   (c) Stock, stock option, or any other ownership interest; or

   (d) Dividend, profit, or other return on investment.

7. Nature of payment or other transfer of value

   See Section, "Categorizing Nature of Payment or Other Transfer of Value."

8. Related covered drugs, devices, biologicals, or medical supplies if a payment or other transfer of value is related to a particular covered drug, device, biological, or medical supply

   (a) Up to five covered drugs, devices, biologicals, or medical supplies may be reported as related to each payment or other transfer of value. If a payment or other transfer of value is related to more than five covered drugs, devices, biologicals, or medical supplies, report the five that are most closely related to the payment or other transfer of value.

   (b) For drugs and biologicals, report the name under which the drug or biological is/was marketed and the relevant National Drug Code(s), if any. If it is marketed but the name has not yet been selected, indicate the name registered on clinicaltrials.gov.

(c) For covered devices and medical supplies, report at least one of the following:

(1) Name under which marketed; or

(2) Therapeutic area or product category.

(d) If a payment or other transfer of value is not related to a covered drug, device, biological, or medical supply, indicate "non-covered product."

(e) If a payment or other transfer of value is not related to any drug, device, biological, or medical supply, covered or not, indicate "none."

(f) If a payment or other transfer of value is related to at least one covered drug, device, biological, or medical supply and one non-covered drug, device, biological, or medical supply, report the name of the covered drug, device, biological, or medical supply and also indicate "non-covered product" in addition.

9. Eligibility for delayed publication

   See Section, "Delayed Publication for Product Research."

10. Payment or other transfer of value to third party

    (a) If a payment or other transfer of value is to a third party at the request of, or designated on behalf of, a covered recipient, the payment or other transfer of value must be reported in the name of that covered recipient.

11. Payments or other transfers of value to physician owners or investors

    See Section, "Reports of Physician Ownership and Investment Interests."

12. Additional information may be provided for context of the payment or other transfer of value

Section 403.904(c).

CATEGORIZING NATURE OF PAYMENT OR OTHER TRANSFER OF VALUE - SECTION 403.904(e)

Each payment or other transfer of value must be categorized into one of the following categories that best describes the nature of the payment or other transfer of value:

1. Consulting fees

2. Compensation for services other than consulting, including serving as faculty or as speaker at an event other than a continuing education program

3. Honoraria

4. Gift

5. Entertainment

6. Food and beverage

    (a) Meals in group settings

        (1) Calculate the per-person cost for each person who actually partakes, not just for covered recipients.

        (2) If the per-person cost exceeds the incidental threshold (currently $10.00), report the meal cost for each participating covered recipient.

    (b) Buffet meals, snacks, and drinks

        (1) If buffet meals, snacks, and drinks are provided at a conference or large-scale event, these don't need to be reported unless the identity of the actual covered recipients who partake in the meal/snack can be identified.

7. Travel and lodging

8. Education

    (a) This does not include attendees whose fees have been subsidized by an applicable manufacturer.

9. Research

    (a) A payment or other transfer of value falls into the research category if it is subject to a written contract or research protocol.

    (b) An unbroken chain of contracts can link an applicable manufacturer with a covered recipient (e.g., a contract between an applicable manufacturer and a contract research organization (CRO); a contract between the CRO and a site management organization (SMO); and a contract between the SMO and a teaching hospital).

10. Charitable contribution

    (a) This includes, but is not limited to, any payment or other transfer of value made to an organization with a tax-exempt status under the IRS and which isn't provided in exchange for any goods, items, or services.

11. Royalties/License

    (a) This includes any rights granted to use patents, copyrights, other intellectual property, and trade secrets, including methods and processes.

12. Current or prospective ownership or investment interest

13. Compensation for serving as faculty or speaker for an unaccredited and non-certified continuing education program

14. Compensation for serving as faculty or speaker for an accredited or certified continuing education program

    (a) If the following conditions are met, the payment or other transfer of value is for speaking at a certified continuing education program:

        (1) The event meets the accreditation or certification requirements and standards of one of the following:

            (1) The Accreditation Council for Continuing Medical Education;

            (2) The American Academy of Family Physicians;

            (3) The American Dental Association Continuing Education Recognition Program;

            (4) The American Medical Association; or

            (5) The American Osteopathic Association;

        (2) The applicable manufacturer doesn't pay the covered recipient speaker directly; and

        (3) The applicable manufacturer doesn't select covered recipient speakers or provide the third party with a distinct, identifiable set of individuals to be considered as speakers.

15. Grant

16. Space rental or facility fees (teaching hospital only)

EXCLUDED FROM REPORTING - SECTION 403.904(i)

The following payments or other transfers of value are excluded from reporting:

1. Indirect payments or other transfers of value where an applicable manufacturer does not know of the identity of the covered recipient during the reporting year or by the end of the second quarter following the reporting year.

2. For calendar year 2013, payments or other transfers of value less than $10.00 ("incidental threshold"), unless an aggregate amount transferred to, requested by, or designated on behalf of a covered recipient is greater than $100.00 in the calendar year.

    (a) For calendar year 2014 and subsequent years, the incidental threshold dollar amount will be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers for the 12-month period ending with June of the previous year.

    (b) Small incidental items with a value less than the incidental threshold may be provided at large-scale conferences and events, as well as events open to the public, and don't need to be reported nor included for purposes of an aggregate threshold.

3. Product samples, including coupons and vouchers to be used by patients to obtain samples, which are not intended to be sold and are intended for patient use.

    (a) This includes single-use or disposable devices, demo devices, or evaluative equipment.

    (b) Applicable manufacturers and covered recipients should agree in writing that product samples will be provided to patients.

4. Educational materials and items that directly benefit patients or are intended to be used by or with patients, including an applicable manufacturer's services to educate patients regarding covered drugs, devices, biologicals, or medical supplies.

    (a) This includes materials such as wall and anatomical models.

5. Loan of a covered device or a device under development, or the provision of limited quantities of medical supplies for short-term trial periods, not to exceed 90 days or quantities of 90 days of average use, to permit the evaluation of the device or medical supply.

    (a) The 90-day period does not have to be consecutive for the limit to apply; it will be based on the total number of days in the calendar year.

    (b) If a covered recipient receives a covered device or medical supply after the ninetieth day, it shall be reported as if the loan began on Day 91.

6. Items or services provided under a contractual warranty (includes service or maintenance agreement), whether the warranty period has expired, including replacement covered devices, where the terms of the warranty are set forth in the purchase or lease agreement.

7. Transfer of anything of value to a physician covered recipient when the physician is an actual patient, research subject, or participant in data collection for research, and is not acting in a professional capacity as a physician.

8. Discounts, including rebates.

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

    (a) "Charity care" means services provided by a covered recipient for patients who are unable to pay for such services, or for whom payment would be a significant hardship, where the covered recipient neither receives nor expects to receive payment because of the patient's inability to pay.

    (b) An applicable manufacturer and covered recipient should agree in writing that the covered recipient will use in-kind items only for charity care.

10. Dividends or other profit distributions from, or ownership or investment in, a publicly traded security or mutual fund.

11. If an applicable manufacturer offers a self-insured plan or directly reimburses for health care expenses, payments for the provision of health care to employees and their families.

12. If a covered recipient is a physician, a payment or other transfer value solely for the services of the covered recipient with respect to administrative proceedings, legal defense, prosecution, or settlement or judgment of a civil or criminal action or arbitration.

13. Payment or other transfer of value made solely in the context of personal, non-business-related relationship.

    (a) For example, between family members.

DELAYED PUBLICATION FOR PRODUCT RESEARCH - SECTION 403.910

The publication on the website of payments or other transfers of value made under a product research or development agreement may be delayed under the following scenarios and guidelines:

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

2. Clinical investigation regarding a new device, drug, biological, or medical supply.

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

3. The research or development agreement must include a written agreement, a research protocol, or both, between the applicable manufacturer and the covered recipient.

4. Payments and other transfers of value eligible for delayed publication must be reported to CMS on the first reporting date following the year in which the payment or other transfer of value occurs, but CMS will not publicly post the payment or other transfer of value until the first annual publication date after the earlier of the following:

   (a) Date of the approval, licensure, or clearance of the covered drug, device, biological, or medical supply by the FDA; or

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

5. The applicable manufacturer must continue to indicate annually in its report that FDA approval, licensure or clearance of a new drug, device, biological, or medical supply to which the payment or other transfer of value is related is still pending or whether it has been approved, licensed, or cleared.

6. Information submitted and eligible for delayed publication is considered confidential and not subject to disclosure under any Federal, State, or local law until on or after the date on which the information is made available to the public.

REPORTING RESEARCH PAYMENTS AND OTHER TRANSFERS OF VALUE - SECTION 403.904(f)

Payments and other transfers of value related to research will be reported separately to CMS in a different template. Each research payment or other transfer of value will be reported as a single interaction. For each research payment or other transfer of value, the following information shall be reported:

1. Name of the research institution, individual, or entity receiving the payment or other transfer of value.

   (a) If the payment or other transfer of value is made to a physician covered recipient, all of the following must be provided:

      (1) Name as listed in the NPPES;

      (2) NPI;

      (3) State professional license number(s) and State(s) in which the license is held (for at least one State where a license is maintained);

(4) Specialty; and

(5) Primary business address.

(b) If the payment or other transfer of value is made to a teaching hospital covered recipient, list the name and primary business address of the teaching hospital.

(c) If the payment or other transfer of value is made to a non-covered recipient, list the name and primary business address of the entity.

2. Total amount of the payment or other transfer of value, including all research-related costs for activities outlined in the written contract, research protocol, or both.

(a) This includes costs associated with patient care, including diagnostics, examinations, laboratory expenses, time spent by health care professionals treating patients and managing the study, and the provision of study drugs, devices, biologicals, and medical supplies or other in-kind items.

(b) Payments for medical research writing and/or publication should be included in the research payment if the activity was included in the research protocol or written agreement, and paid as part of the research payment.

(c) Payment for meals and travel should be reported separately, unless they are included in the written contract or research protocol and are paid as part of the research payment.

3. Name of the research study.

4. Name(s) of any related covered drug, device, biological, or medical supply, unless the payment or other transfer of value is not related to that particular covered drug, device, biological, or medical supply. For drugs and biologicals, include the relevant National Drug Code(s) (NDCs), if any.

5. Information about each physician covered recipient principal investigator (if applicable), as set forth in paragraph 1 above.

6. (Optional) Contextual information for the research.

7. (Optional) Clinicaltrials.gov identifier.

For pre-clinical studies (before any human studies have begun) an applicable manufacturer only needs to report the following:

1. The research entity name and primary business address;

2. The total amount of the payment or other transfer of value (as set forth in paragraph 2 above); and

3. The principal investigator (as set forth in paragraph 5 above).

REPORTS OF PHYSICIAN OWNERSHIP AND INVESTMENT INTERESTS - SECTION 403.906

Each applicable manufacturer and applicable GPO must report to CMS annually all ownership and investment interests in the applicable manufacturer or applicable GPO that were held by a physician or an immediately family member of the physician during the preceding calendar year.

"Ownership and investment interests" includes, but is not limited to:

1. Stock and stock options (other than those received as compensation until exercised);
2. Partnership shares;
3. LLC memberships; and
4. Loans, bonds, or other financial instruments that are secured with an entity's property or revenue, or a portion of property or revenue.

Ownership or investment interests may be direct or indirect, and through debt, equity, or other means.

The following are not ownership or investment interests:

1. Ownership or investment interests in a publicly traded security or mutual fund;
2. Interest in an applicable manufacturer that arises from a retirement plan offered by the applicable manufacturer to the physician or immediate family member of the physician through the physician's or immediate family member's employment with that applicable manufacturer;
3. Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to equity;
4. Unsecured loan subordinated to a credit facility; and
5. An ownership or investment interest if the applicable manufacturer did not know about such ownership or investment interest.

The reports must include the following information:

1. The name of the physician as listed in the NPPES (if applicable), including the physician's first and last names, middle initial and suffix, and whether the ownership investment interest is held by the physician or an immediate family member of the physician;

2. The primary business address of the physician, including street address, suite or office number, city, state, and zip code;

3. The physician's specialty, NPI, and State professional license number(s) and State(s) in which the license is held (for at least one State where a license is maintained);

4. The dollar amount invested by the physician and/or each immediate family member of the physician;

5. The value and terms of the ownership or investment interest; and

6. All direct and indirect payments or other transfers of value provided to the physician owning the ownership or investment interest, and direct and indirect payments or other transfers of values provided to a third party at the request of or designated by the applicable manufacturer or applicable GPO on behalf of the physician owner or investor (must be reported in accordance with the requirements for reporting payments and other transfers of value in Section 403.904(c) through (i), substituting the terms "applicable manufacturer" and "applicable GPO" for "applicable manufacturer," and "physician owner and investor" for "covered recipient.").

SUBMISSION OF REPORTS - SECTION 403.908

Reports must be electronically submitted to CMS by March 31, 2014, and by the ninetieth day of each subsequent calendar year. CMS will provide reporting templates and will create an electronic system to accept the data. Each applicable manufacturer and applicable GPO shall only submit a single report for a calendar year. Late data submitted will be considered a failure to report and subject to a civil monetary penalty (CMP).

All applicable manufacturers that have a reportable payment or other transfer of value or ownership or investment interest, and all applicable GPOs that have a reportable ownership or investment interest, must register with CMS within 90 days of the end of the calendar year for which the report is required (October 2nd). During the registration process, two points of contact with appropriate contact information must be identified.

Applicable manufacturers that are under common ownership with separate entities that are also applicable manufacturers may, but are not required to, file a consolidated report for all of the entities. The report must provide the name of each applicable manufacturer that is under common ownership and that the report covers, and the report must identify the specific applicable manufacturer that provides each payment or other transfer of value. The applicable manufacturer submitting a consolidated report on behalf of multiple applicable manufacturers is liable for any civil monetary penalties imposed on each of the applicable manufacturers included in the consolidated report up to an annual maximum for each applicable manufacturer.

If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, report:

1. In the name of the applicable manufacturer that actually furnished the payment or other transfer of value to a covered recipient, unless the terms of a written contract specifically require otherwise, provided the contract requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers; and

2. Only once by one applicable manufacturer.

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 reporting entity that the information reported is timely, accurate, and complete to the best of his/her knowledge and belief. If submitting a consolidated report, the attestation must be on behalf of all included applicable manufacturers.

Applicable manufacturers and applicable GPOs may submit an assumptions document explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value or ownership or investment interests. The assumptions document will not be made available to covered recipients, physician owners or investors, or the public.

Applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors have an opportunity to review and submit corrections to report information for a period of not less than 45 days prior to CMS making the information available to the public. CMS will notify applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors when reported information is ready for review. They will be notified using email list serves, online posting (CMS website and Federal Register), and directly to covered recipients or physician owners or investors who have registered with CMS. Covered recipients and physician owners or investors are granted access only to data submitted on their behalf. A secure website with verification will be used.

If a covered recipient or a physician owner or investor disagrees with information reported, the designated electronic fields detailing the dispute and proposed correction are to be completed. The system will flag the transaction and notify the submitter of the report of the dispute. Disputes must be resolved and CMS notified of any changes to the information no later than 15 days after the end of the 45-day period. If disputes are not timely resolved, CMS will publicly report the originally submitted information but will mark it as disputed. Any changes from disputes resolved after the sixtieth day may be reported during the next time data is refreshed.

If an applicable manufacturer or applicable GPO discovers an error or omission in its report, it must submit corrected information to CMS immediately. CMS will notify any affected covered recipients or physician owners or investors that additional information has been submitted and is available for review. CMS will update the website at least once annually with the corrected information.

Data will be published by CMS no later than June 30th. A statement will be included that disclosures of payments and other transfers of value do not indicate legitimate transactions nor do they indicate any conflict of interest or any wrongdoing. The data will be published on a public website and will be in a format that is searchable, downloadable, understandable, and able to be aggregated. The data on the public website includes the following:

1. Applicable manufacturer's name;
2. Covered recipient's name, specialty, and primary business address;
3. Amount of payment or other transfer of value in U.S. 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 the related covered drugs, devices, biologicals, or medical supplies, as applicable;
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).

For research payments or other transfers of value, the following research-related information will be available on the public website:

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. Clinical trials.gov identifier (optional).

For physician ownership and investment interests, the following information will be included on the public website:

1. Applicable manufacturer's or applicable GPO's name;

2. Physician owner's or investor's name, specialty, and primary business address;

3. Whether the ownership or investment interest is held by the physician or an immediate family member of the physician;

4. Dollar amount invested;

5. Value and terms of each ownership or investment interest; and

6. Any payment or other transfer of value provided to the physician owner or investor, including:

   (a) Amount of payment or other transfer of value in U.S. dollars;

   (b) Date of payment or other transfer of value;

   (c) Form of payment or other transfer of value;

   (d) Nature of payment or other transfer of value;

   (e) Name(s) of the related covered drugs, devices, biologicals, or medical supplies, as applicable;

   (f) NDCs of related covered drugs and biologicals, if any;

   (g) Name of the entity that received the payment or other transfer of value, if not provided to the physician directly; and

   (h) Statement providing additional context for the payment or other transfer of value (optional).

PENALTIES FOR FAILURE TO REPORT – SECTION 403.912

Any applicable manufacturer or applicable GPO that fails to timely, accurately, or completely report required information is subject to a civil monetary penalty (CMP). The range for a CMP is $1,000-$10,000 for each payment or other transfer of value or ownership or investment interest that is not reported timely, accurately, or completely, or a CMP of $10,000-$100,000 may be imposed for each payment or other transfer of value or ownership or investment interest that is knowingly not reported timely, accurately or completely. The total CMP that can be imposed on an applicable manufacturer or applicable GPO annually is not greater than $150,000, unless if there is a knowing failure to report a total annual penalty not to exceed $1,000,000 may be imposed.

In determining the amount of the CMPs the following factors are to be considered including, but not limited to:

1. Length of time the applicable manufacturer or applicable GPO failed to report, including the length of time the applicable manufacturer or applicable GPO knew of the payment or other transfer of value or ownership or investment interest;

2. The amount of payment or other transfer of value that was not reported;

3. Level of culpability;

4. Nature and amount of the information reported in error; and

5. The degree of diligence exercised in correcting the information reported in error.

CMPs are subject to the provisions set forth in 42 C.F.R. Part 402.

RECORD RETENTION AND AUDITS – SECTION 403.912(e)

Applicable manufacturers and applicable GPOs must maintain all books, contracts, records, documents, and other evidence to enable the audit, evaluation, and inspection of their compliance with their requirements to timely, accurately, and completely submit information. Items must be maintained at least five years from the date from which the information was published publicly on the website. HHS, CMS, and the OIG may audit, inspect, investigate, and evaluate any books, contracts, records, documents, and other evidence that pertain to compliance with these laws.

PREEMPTION OF STATE LAWS – SECTION 403.914

These regulations preempt any statute or regulation of a State that requires an applicable manufacturer to disclose or report the type of information regarding the payment or other transfer of value required to be reported under these regulations.

MOVING FORWARD

For questions or further information, please speak to your regular Bryan Cave contact, a member of our Life Sciences and Health Care Client Service Group, or the author of this client alert:

Sheryl Feutz-Harter
Kansas City
816-374-3245
Sheryl.FeutzHarter@bryancave.com