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transparency

Overview of CMS Proposed Regulations for U.S. Sunshine

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What is “Sunshine” all about?

Applicable manufacturers now have a legal obligation to report payments or other transfers of value $10 or higher per transaction or $100 in the aggregate for the calendar year made to a covered recipient, which includes physicians or teaching hospitals.

Applicable manufacturers and applicable group purchasing organizations (GPOs) now have a legal obligation to report ownership or investment interests held by physicians or their immediate family members.

Sounds simple . . . right?

Discussion Topics

- CMS Proposed Regulations
  - Applicable Definitions
  - Reportable Information
  - Research Payments
  - Delayed Publication
  - Reporting Exclusions
  - Physician Ownership and Investment Interests
- Implementation, Tracking & Reporting
  - Annual Reporting Requirement
  - Report Submission and Certification
  - Public Availability
  - Penalties
- CMS Requests for Comments
- Questions

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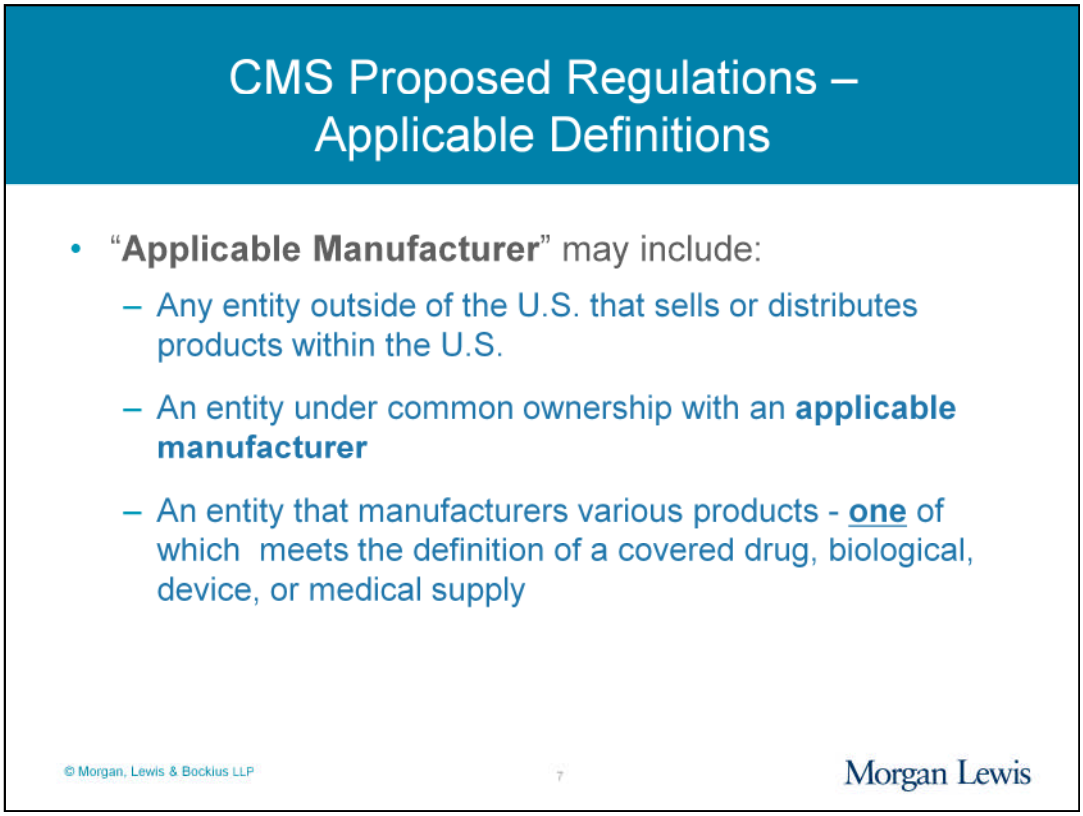
CMS Proposed Regulations – Applicable Definitions

- **Who must report**: "Applicable Manufacturer"
  - Manufacturer of a covered drug, device, biological, or medical supply, for sale or distribution in the U.S., regardless of where the product is manufactured, or where the entity is located or incorporated.
  - An applicable manufacturer also includes an entity that holds FDA approval, licensure, or clearance for a covered drug, device, biological, or medical supply – even if the entity contracts out the physical manufacturing process.



In the preamble, CMS discusses that common ownership is meant to include certain companies that are under 'common ownership' with an entity that meets the definition discussed for applicable manufacturer – even if the company is not involved in the manufacturing process.

CMS is contemplating using a definition for common ownership as an instance where an individual or entity owns 5% or more of the total ownership.

The preamble also suggests that if numerous companies are under common ownership and all companies **independently** meet the definition of applicable manufacturer, **each company would be required to report individually**. So, company A and B are both owned by C and all (A, B, and C) meet the definition of applicable manufacturer, each would report separately.

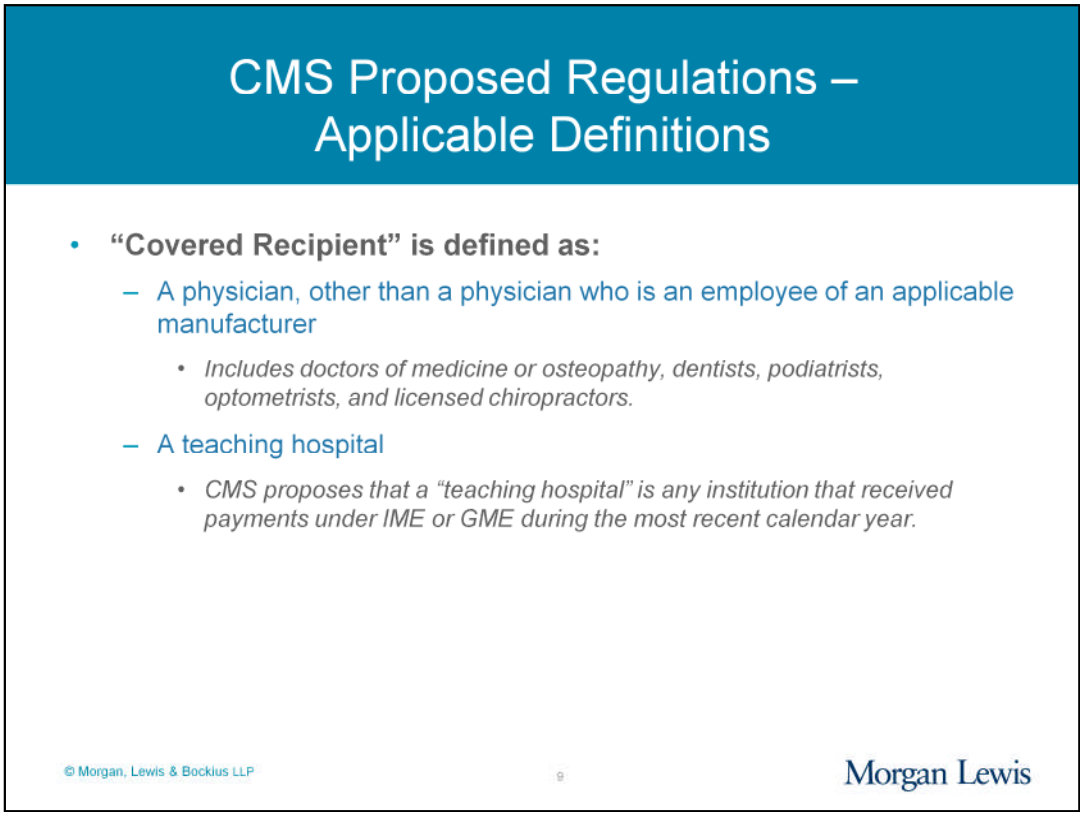
However, if only one company meets the definition of manufacturer and the other companies are required to report as a result of a common ownership scenario, then companies can decide whether or not to report together. CMS is seeking comment on this subject.

Another nuance in the preamble is the concept of an "all in" approach. If an applicable manufacturer is selling at least one product that meets the definition of a "covered" product, all payments or transfers of value to a covered recipient must be reported. So, if an entity manufacturers over the counter medicines (which do not meet the definition of covered drug) and ONE pharmaceutical product that does meet the definition of a covered drug, all payments/transfers to a covered recipient must be reported – not just those payments associated with the one pharmaceutical product that is considered a covered drug.

76 Fed. Reg. 78744 (proposed December 19, 2011)

CMS Proposed Regulations – Applicable Definitions

- **Who must report**: "Applicable GPO"
  - An entity that:
    - *Operates in the United States, or in a territory, possession or commonwealth of the United States, and*
    - *Purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.*
    - *Physician owned distributors (PODs) of covered drugs, devices, biologicals, and medical supplies would fall under this definition.*
  - CMS proposes that reporting by **applicable manufacturers** and **applicable GPOs** concerning ownership and investment interests of physicians **be reported separately** to ensure that the reporting requirements are clearly distinguished.
  - CMS seeks comment on this general approach.



In the preamble, CMS proposes that they will publish a list of hospital covered recipients once per year. This list is essential in the eyes of CMS as it may not be immediately apparent to an applicable manufacturer whether a particular hospital meets the CMS proposed definition. Additionally, there is no published database currently available with this information.

The list that is published by CMS is proposed to also include the name and address of each teaching hospital.

CMS seeks comments on this proposal.

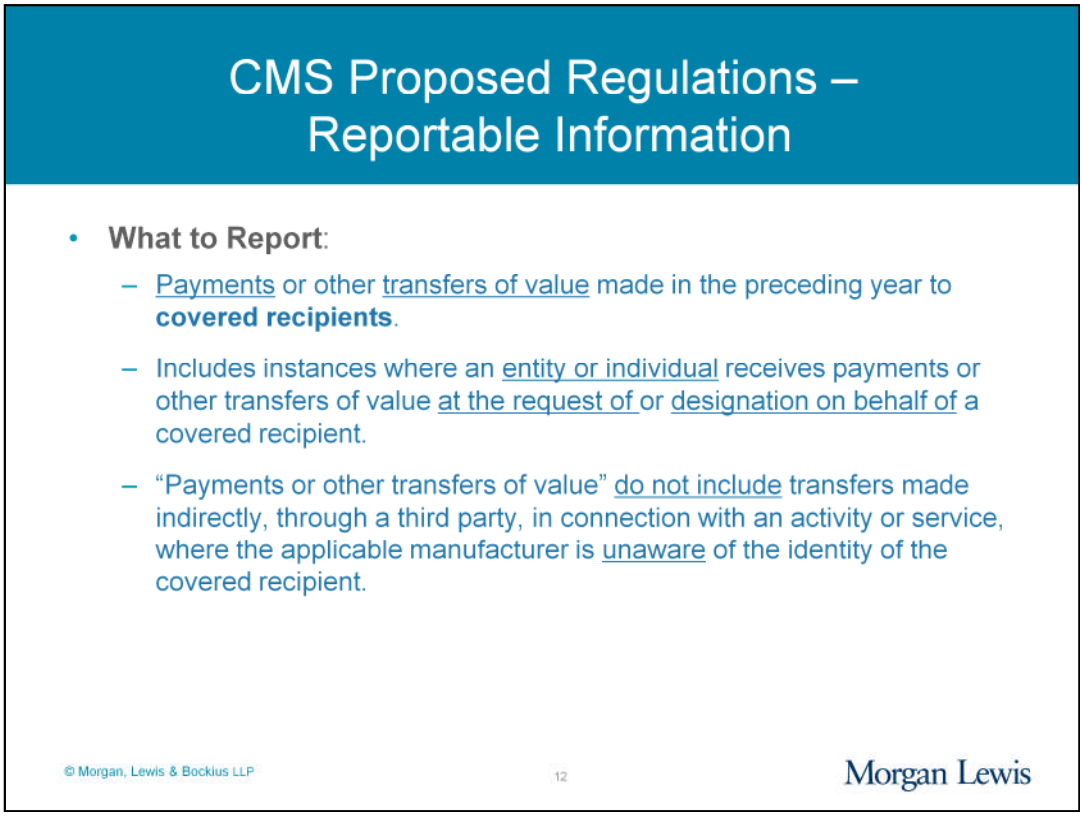
76 Fed. Reg. 78746 (proposed December 19, 2011)

CMS Proposed Regulations – Applicable Definitions

- **"Covered Drug, Device, Biological, or Medical Supply" is defined as:**
  - Any drug, device, biological, or medical supply for which payment is ***available*** under Medicare, Medicaid, SCHIP (or a waiver of such a plan) either separately, as part of a fee schedule payment, or as part of a composite payment rate (prospective payment system).
  - Drug or Biological is limited to those products that, by law, require a prescription to be dispensed; thus excluding over-the-counter drugs.
  - Device or Medical Supply is limited to those products that, by law, require premarket approval by or premarket notification to the FDA.
  - If a manufacturer has at least **one** product that qualifies under the above guidance, all payments/transfers for **covered recipients** must be reported as outlined.

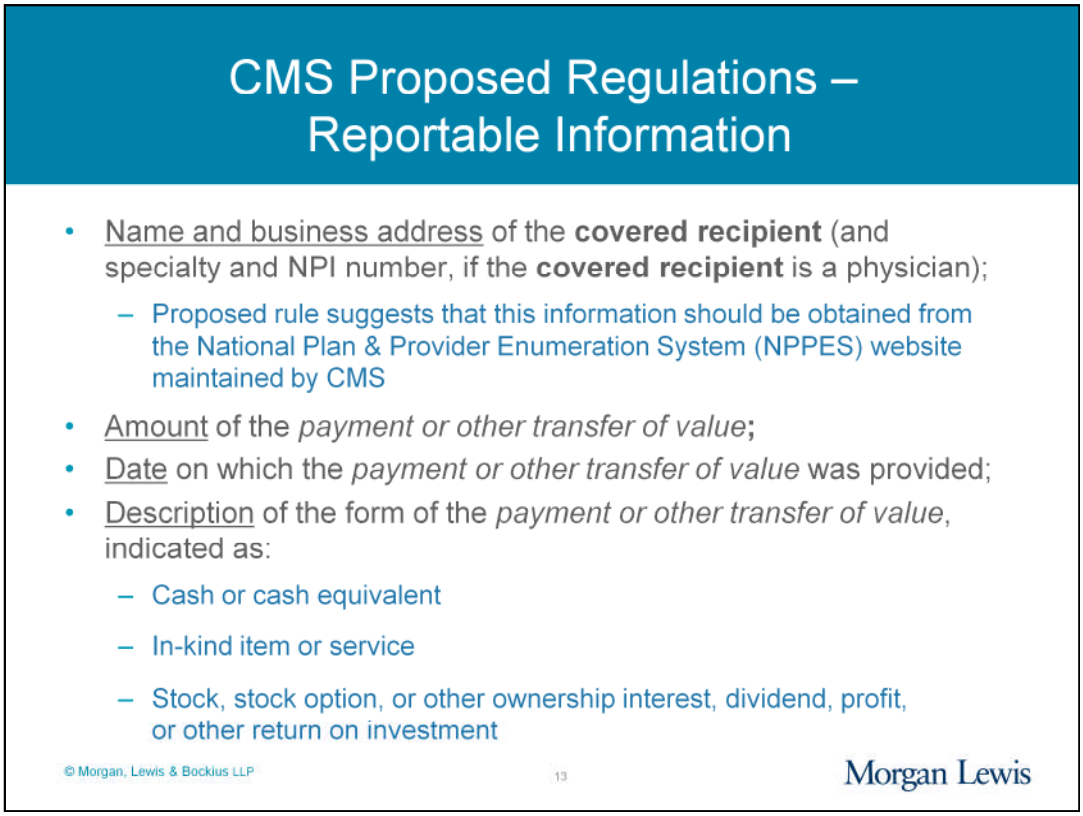
CMS Proposed Regulations – Applicable Definitions

- **Implementation Considerations**
  - In a parent/subsidiary/subsidiary situation, are individual transactions at the corporate level tied to the individual subsidiary with which they are associated?
  - Are there instances where a sales representative incurs expenses associated with more than one subsidiary?
  - If only impacted as a result of common ownership, are there adequate systems in place to ensure that required data is available for all entities? Can such data easily be consolidated?



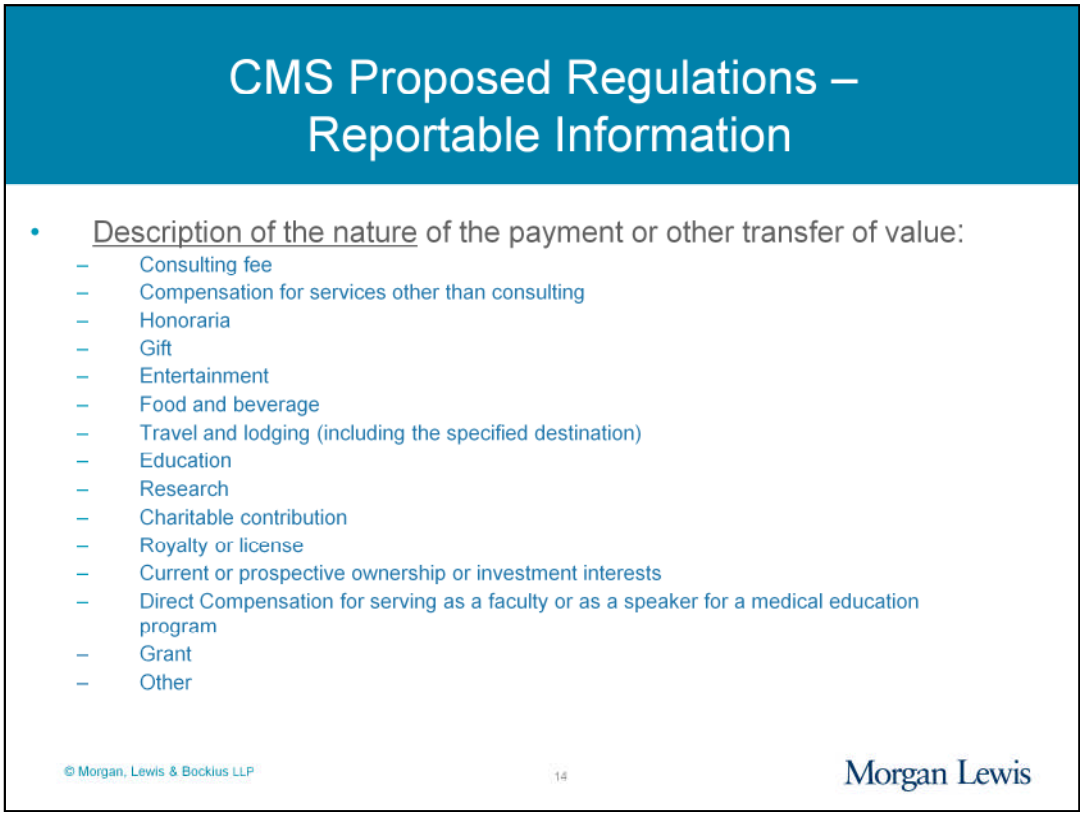
It is outlined in the preamble that payments or other transfers made at the request of or designated on behalf of a **covered recipient** should be reported under the name of the **covered recipient**. Additionally, CMS proposes that applicable manufacturers report the name of the entity or individual that received the payment. So, if Physician Jones requested that payment be made to Jones Family Practice, the transaction would be reported under Physician Jones and would include an additional data field showing that the check was paid to Jones Family Practice.

76 Fed. Reg. 78746 (proposed December 19, 2011)



Within the preamble, CMS talks about the proposal to have applicable manufacturers utilize the NPPES website to identify key data fields. Specifically, this data set would be used to obtain the physician's primary practice location address as the business address; specialty would also be identified using the field named "provider taxonomy"; and the physician's individual NPI number. CMS maintains this NPPES website. This is another area in which CMS seeks comment on the proposed methodology.

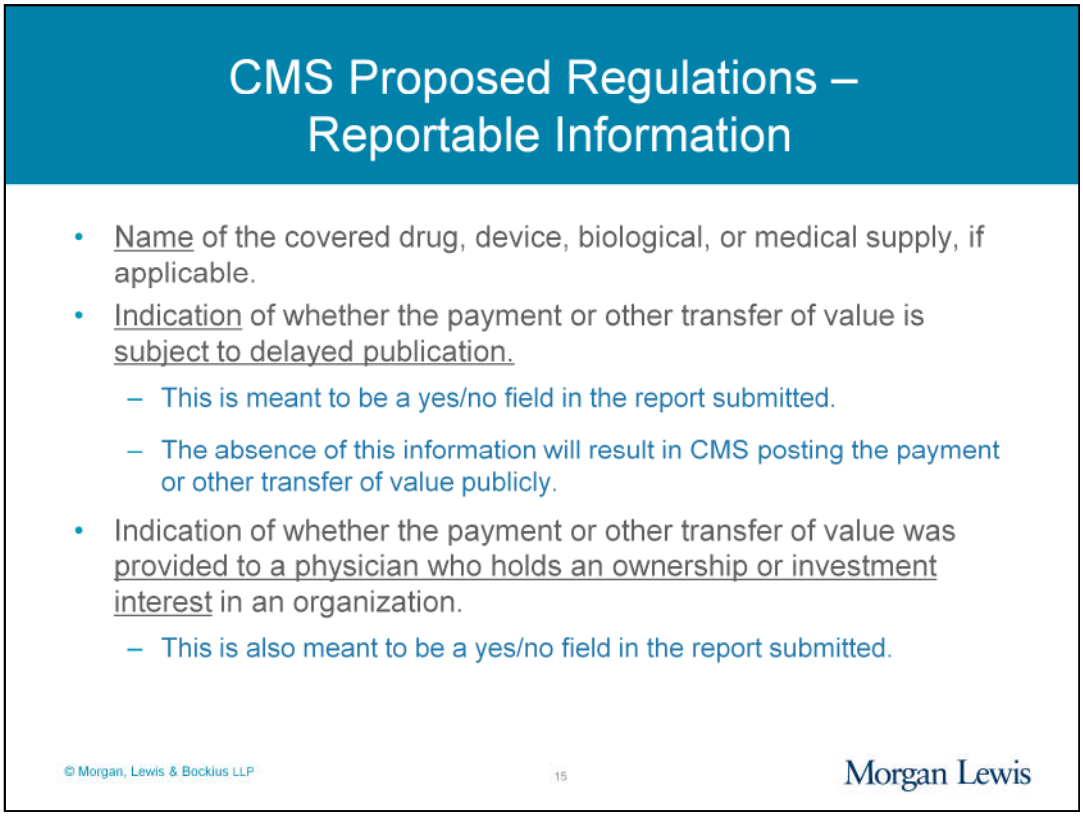
76 Fed. Reg. 78746, 78747 (proposed December 19, 2011)



Currently the proposed rule lays out that each payment must be reported under one of these categories. One of the challenges may be in the instance where a physician is paid a flat fee – which includes consulting, travel, meals, etc. As proposed, an applicable manufacturer will be required to 'un-bundle' these payments to reach each area separately. The thought is that this will help to ensure greater consistency with the database because applicable manufacturers will separate all payments, rather than each applicable manufacturer combining payments differently.

In the preamble, CMS seeks comment on an alternative approach of allowing a payment or other transfer of value for an activity that is associated with multiple segregable categories to be reported as a single lump sum acknowledging that this may be better aligned with certain existing business processes, although it might make the public disclosure database more confusing for end users. CMS is also requesting comment on the costs that may be associated with this approach.

76 Fed. Reg. 78747 (proposed December 19, 2011)

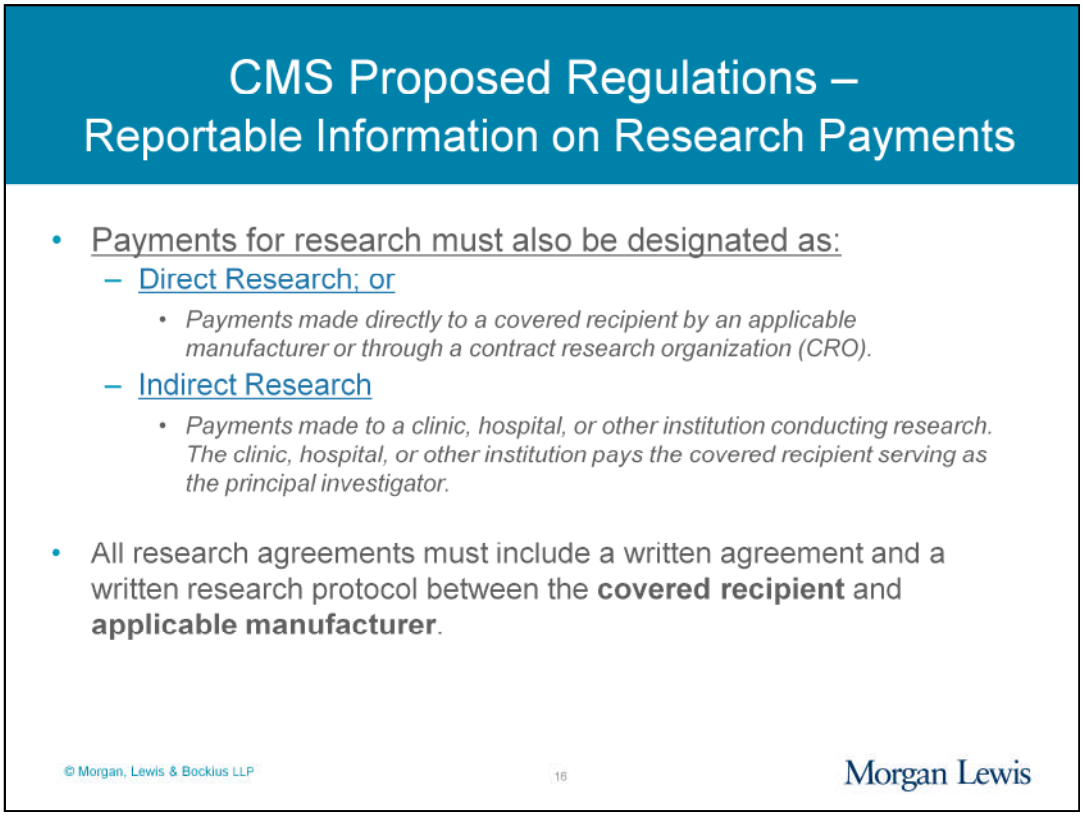


The name of the covered product would be included if the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply. The name would be the name under which this covered product is marketed. If the marketed name has not yet been selected, the applicable manufacturer must indicate the scientific name. It is recommended that only a single product name can me associated with an individual payment.

CMS is considering allowing an applicable manufacturer to report multiple product names related to a single payment as this may be less burdensome on manufacturers given that financial relationships are not specific to one product only – but this would make aggregating payments by product difficult for CMS. CMS is seeking comment on this approach.

The preamble does highlight that if an applicable manufacturer is not reporting the name of the drug, device, biological, or medical supply as appropriate, then the applicable manufacturer may be subject to penalties.

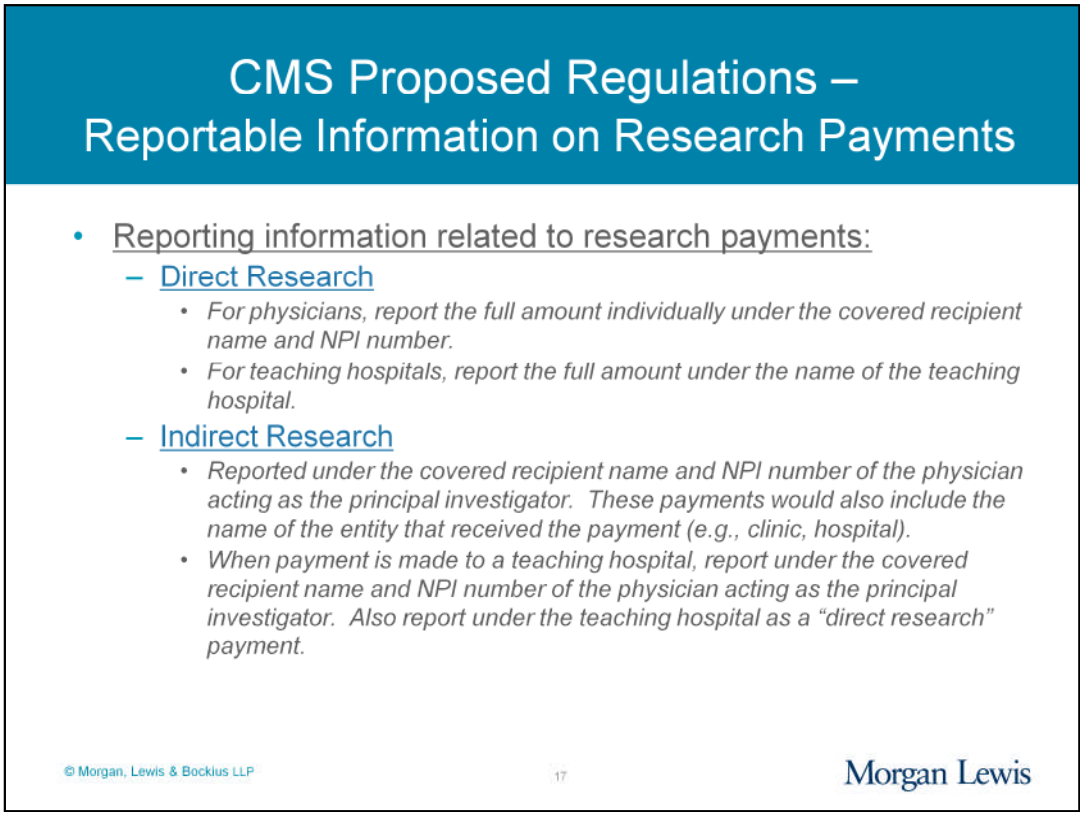
76 Fed. Reg. 78747 (proposed December 19, 2011)



Within the preamble, CMS acknowledges that the proposed rule may not cover all circumstances in which applicable manufacturers make payments or other transfers of value to covered recipients for research-related activities (for example, post-market research, other research or studies not conducted pursuant to a written agreement, or those studies without a research protocol).

CMS solicits comment regarding which existing category or nature of payment would apply to these other types of research.

76 Fed. Reg. 78749, 78750 (proposed December 19, 2011)



This proposed methodology results in redundant reporting when payment is made to a teaching hospital. The preamble lays out that research payments provided to teaching hospitals and ultimately to physician covered recipients (as principal investigator) must be reported for **both** the teaching hospital covered recipient, **and** the physician covered recipient. The payment to the teaching hospital will be reported as a direct research payment in the full amount. The payment will also be reported as an indirect research payment to the physician covered recipient in the full amount – even though CMS acknowledges that the physician is known to be receiving only a portion of the payment.

Given that the exact amount received by the physician as an indirect research payment, CMS will report this amount separately and will not include this amount in an aggregated totals for the physician.

These payments will be aggregated for any teaching hospital covered recipients as the teaching hospital received the funds as a direct research payment.

CMS is seeking comment in regards to this proposal.

76 Fed. Reg. 78749 (proposed December 19, 2011)

CMS Proposed Regulations – Delayed Publication

- Delayed publication is allowed for research-related services as indicated below:
  - Research and Development
    - *New drugs, devices, biologicals, and medical supplies*
    - *New applications of existing drugs, devices, biologicals, and medical supplies*
  - Clinical
    - *Limited to new drugs, devices, biologicals, and medical supplies*
- CMS proposes continued annual report of delayed publication data and any updated information.
- Following FDA approval, licensure or clearance, applicable manufacturers will indicate in their next annual report that the payment(s) should no longer be granted a delay and should be published.

CMS Proposed Regulations – Delayed Publication

- For reports including a date of payment four years prior to the current year, the payments or other transfers of value will be automatically published – regardless of whether the **applicable manufacturer** indicates that the payment should be delayed.
- All product research or development agreements must include a written agreement and a written research protocol between the **covered recipient** and **applicable manufacturer**.
- Clinical investigations are defined as any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used. These investigations must be memorialized in a written research protocol between the **covered recipient** and **applicable manufacturer**.

CMS Proposed Regulations – Sample Reporting Template

Reporting Entity	Recipient Name	Recipient Business street address	Recipient Specialty *physician only	Recipient National Provider Identifier (NPI) *physician only	Amount of Payment (US dollars)	Date of Payment	Form of Payment	Nature of Payment	Name of Associated Drug, Device, Biological, or Medical Supply *if necessary	Entity Paid Name	Physician Owner or Investor (y/n)	Delayed Publication (y/n)

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CMS Proposed Regulations –
Reportable Information, Research, Delayed Publication

- **Implementation Considerations**
  - Do current tracking systems capture sufficient detail related to the covered recipient?
    - *Middle initial*
    - *Specialty*
    - *NPI number*
    - *LLC or other entity receiving payments on behalf of, or as designated by the covered recipient*
    - *Teaching hospital designation*
  - Do current tracking systems include all "other transfers of value" or in-kind remuneration?

CMS Proposed Regulations –
Reportable Information, Research, Delayed Publication

- **Implementation Considerations**
  - Are consulting payment types such as research or development used within current systems consistent with the CMS proposed categories and/or definitions?
  - Does your system store data to the level of granularity required (e.g., indirect/direct research, product name)?
  - Does your system include principal investigator information for payments made to a clinic, hospital, or other institution?
  - Are you able to track whether an item or consulting agreement is eligible for delayed reporting?

CMS Proposed Regulations – Reporting Exclusions

- A transfer of value less than $10, as long as the aggregate amount to a covered recipient **is less than $100** during the calendar year.
- Product samples that are not intended to be sold and are intended for patient use.
- Educational materials that directly benefit patients or are intended for patient use.
  - CMS is considering whether or not materials provided to covered recipients to educate themselves (e.g., medical textbooks) should be considered educational materials that "directly benefit patients."
  - CMS is seeking comment in this area.

CMS Proposed Regulations – Reporting Exclusions

- 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**.
- Items or services provided under a contractual warranty, including replacement, if the terms of the warranty are set forth in the agreement.
- A transfer of anything of value to a **covered recipient** when the **covered recipient** is a patient and not acting in the professional capacity of a **covered recipient**.
- Discounts (including rebates).

CMS Proposed Regulations – Reporting Exclusions

- In-kind items used for the provision of charity care.
  - CMS proposes to define "charity care" as items provided to a **covered recipient** for one or more patients who cannot pay, where the **covered recipient** neither receives, nor expects to receive, payment because of the patient's inability to pay.
  - Provision of items to a **covered recipient** for the care of all of their patients (both those who can and cannot pay) are not excluded.
    - *For example – the donation of an imaging machine to a **covered recipient** that would be used for both paying and non-paying patients would not be excluded – even if the covered recipient is a charitable organization.*

CMS Proposed Regulations – Reporting Exclusions

- A dividend or other profit distribution from, or ownership or investment interest in, a publicly-traded security or mutual fund.
- Payments for the provision of health care to employees under a self-insured plan offered by an **applicable manufacturer.**
- A transfer of value if the transfer is payment solely for non-medical professional services provided by a **covered recipient** who is a licensed non-medical professional.
- A transfer of value if the transfer is payment solely for services, provided by a **covered recipient** who is a physician, with respect to a civil or criminal action or an administrative proceeding.

CMS Proposed Regulations – Reporting Exclusions

- Possible additional exclusions under consideration by CMS:
  - Offerings of buffet meals, snacks, or coffee at booths at conferences or other similar events where it would be difficult for applicable manufacturers to definitively establish the identities of the individuals who accept the offerings.
  - Personal transfers of value (e.g., if one spouse, who works for an applicable manufacturer, gives a gift to the other spouse who is a **covered recipient**).
- CMS is seeking suggestions on how to incorporate these concepts into the final rule.

CMS Proposed Regulations – Reporting Exclusions

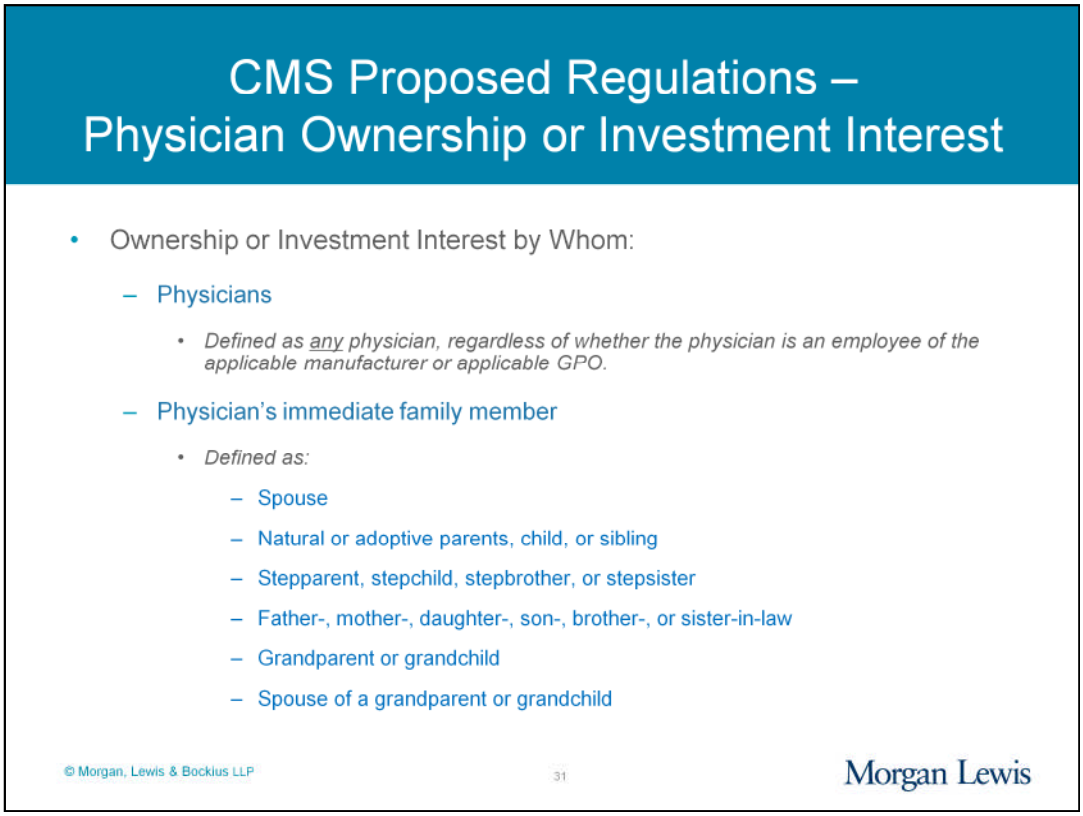
- **Implementation Considerations**
  - Does the system or tracking mechanism in place incorporate all payments (regardless of dollar amount) in order to determine when the $100 reporting threshold is triggered?
  - How do these reporting exclusions align with other transparency/marketing codes when implementing internal tracking mechanisms (e.g., state transparency laws)?
  - Does your system have the ability to differentiate product donations to a charitable organization from those that meet the definition of the provision of charity care?

CMS Proposed Regulations – Physician Ownership or Investment Interest

- **"Ownership or Investment Interest" is defined as:**
  - An ownership or investment interest that may be direct or indirect and through debt, equity, or other means.
  - Includes, but is not limited to:
    - *Stock, stock options (other than those received as compensation, until they are exercised);*
    - *Partnership shares;*
    - *LLC memberships; and*
    - *Loans, bonds, or other financial instruments that are secured with an entity's property or revenue, or a portion of that property or revenue.*

CMS Proposed Regulations – Physician Ownership or Investment Interest

- **"Ownership or Investment Interest" does not include:**
  - An ownership or investment interest in a publicly-traded security or mutual fund;
  - An interest in an **applicable manufacturer** or **applicable GPO** that arises from a retirement plan offered by that **applicable manufacturer** or **applicable GPO** to the physician (or immediate family member) through their employment with that **applicable manufacturer** or **applicable GPO**;
  - Stock options and convertible securities received as compensation, until the stock is exercised or the convertible securities are converted to equity; and
  - An unsecured loan subordinated to a credit facility.



As noted in the preamble, CMS is considering whether to require the reporting of the immediate family member's relationship to the physician, as well as the immediate family member's name, in order to bring additional transparency to the nature of the relationship.

CMS is cautious in this regard due to privacy concerns. If the information will not be made public, is it worth the additional collection of information?

CMS is seeking input regarding this item.

76 Fed. Reg. 78752 (proposed December 19, 2011)

CMS Proposed Regulations – Physician Ownership or Investment Interest

- Information that must be reported:
  - The dollar amount invested by each physician.
  - Whether the ownership or investment interest is held by the physician or an immediate family member.
  - The value and terms of each ownership or investment interest.
  - Any payment or other transfer of value provided to a physician holding such ownership or investment interest.
  - Physician-specific identifier information (e.g. business address, specialty, NPI number).

CMS Proposed Regulations – Sample Reporting Template

Reporting Entity	Recipient Name	Recipient Business street address	Recipient Specialty *physician only	Recipient National Provider Identifier (NPI) *physician only	Interest Held by Immediate Family Member (y/n)	Dollar Amount Invested	Value of Interest	Terms of Interest

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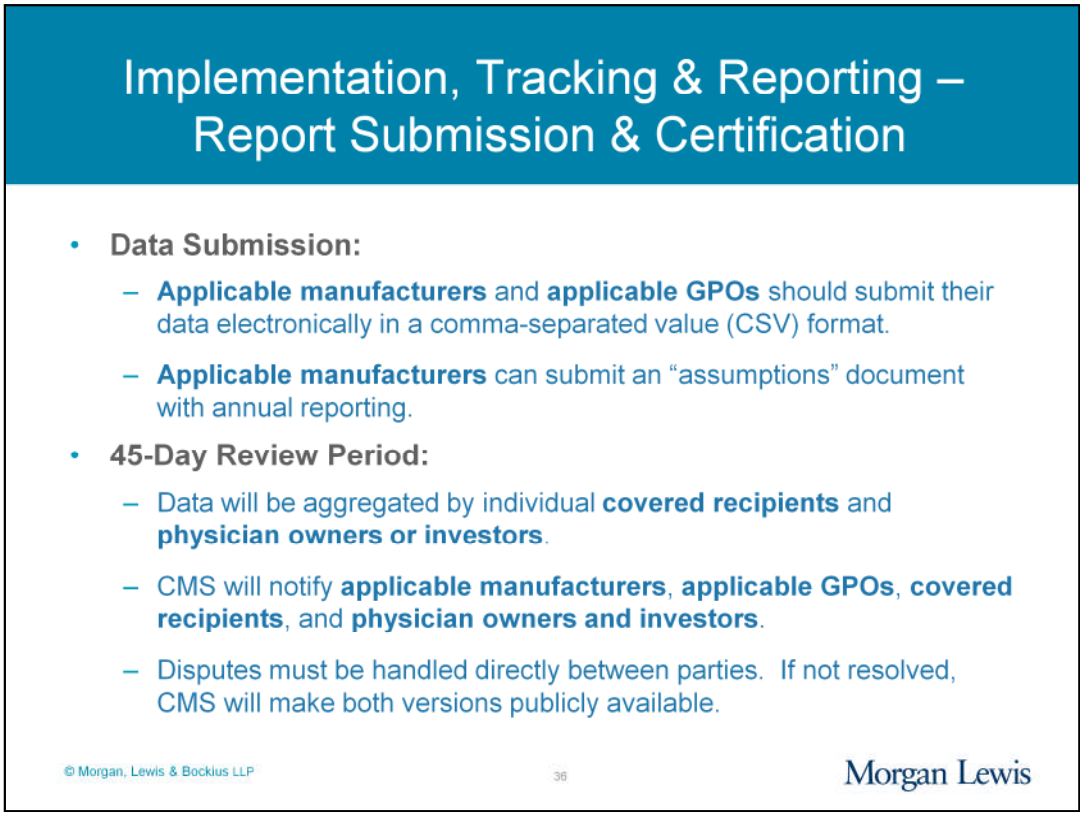
Implementation, Tracking & Reporting – Annual Reporting Requirement

- **When to Report**:
  - First report due March 31, 2013.
  - Time period for reporting will be determined based on when CMS issues the final rule.
  - CMS is considering a 90 day implementation period after it issues the final rule.
  - Companies may submit comments regarding whether or not 90 days is sufficient for implementation.
  - Allowed to submit data to CMS voluntarily during the interim period.

Implementation, Tracking & Reporting – Report Submission & Certification

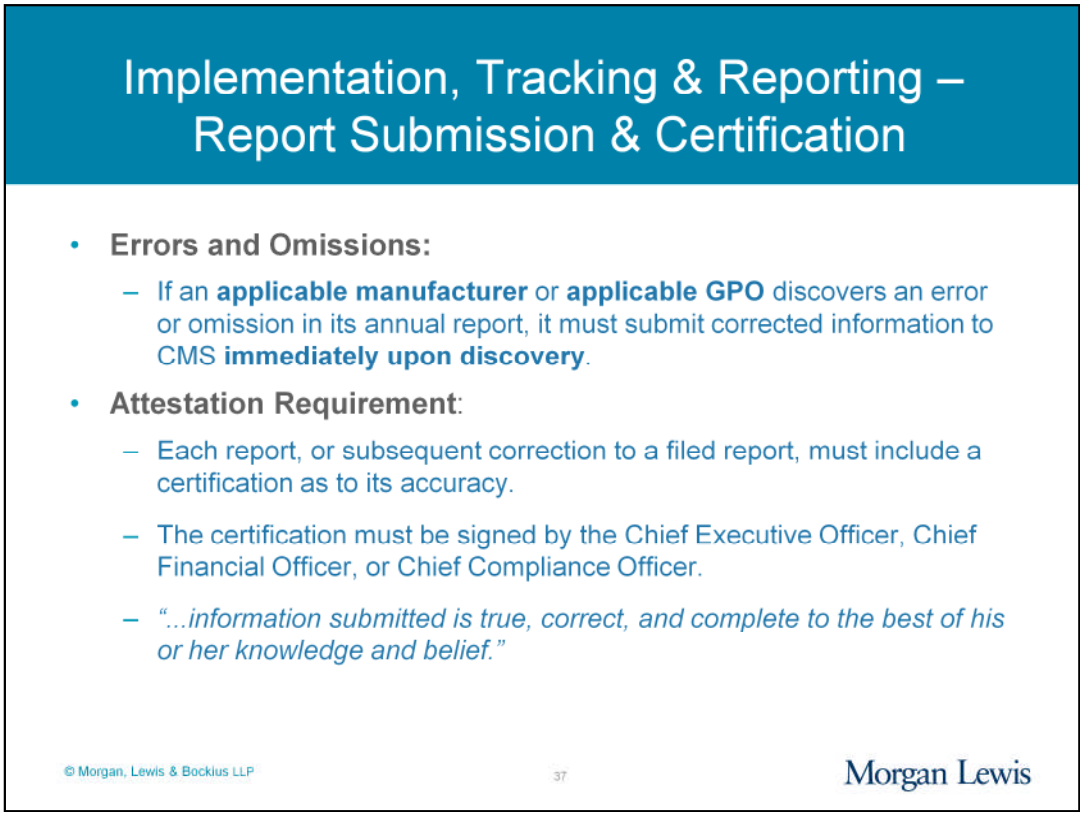
- **Registration**:
  - Any **applicable manufacturer** or **applicable GPO** must register with CMS before March 31, 2013.
  - Must designate a point of contact to receive detailed information from CMS on the report submission process.
  - The first opportunity for registration and data submission will be January 1, 2013.
- **Consolidated Reporting**:
  - Applicable manufacturers under common ownership may, but are not required to, file a consolidated report.
  - If an organization is submitting consolidated reporting, it must still register each entity name under common ownership.



The preamble suggests that CMS will allow applicable manufacturers to submit a document describing the assumptions used when compiling the data. This document is not mandatory and may be submitted with the CSV file. These documents will not be posted on the public website in order to alleviate any concerns regarding proprietary information.

CMS is considering and seeks comment on whether or not they should make the submission of this assumptions document mandatory. CMS has acknowledged that many of the categories are similar, therefore the assumptions document can help CMS to understand any assumptions made by the applicable manufacturer when classifying payments or other transfers of value.

76 Fed. Reg. 78748 (proposed December 19, 2011)



CMS is considering requiring that all applicable manufacturers and applicable GPOs register with CMS, regardless of whether they have information to report. This would be coupled with the requirement that for applicable manufacturers and applicable GPOs that have NO payments or transfers of value and/or ownership or investment interests to report would still be required to submit an attestation signed by the CEO, CFO or CCO.

CMS seeks comment on both the benefits and burdens of this consideration and intends to finalize the rule based on comments received.

76 Fed. Reg. 78753, 78754 (proposed December 19, 2011)

Report Submission & Certification – Public Availability

- Except where confidentiality applies, data reported will be made publicly available through an Internet website that:
  - Is searchable and in a format that is clear and understandable;
  - Contains key reportable information; and
  - Is easily aggregated and downloadable.

Report Submission & Certification – Penalties

- Failure to submit the required information may result in:
  - a civil monetary penalty (CMP) of $1,000 to $10,000 for each payment or other transfer not reported
  - not to exceed $150,000 annually.
- A knowing failure to submit the required information may result in:
  - a CMP of $10,000 to $100,000 for each payment or other transfer of value not reported.
  - not to exceed $1,000,000 annually.

CMS Requests for Comment

- CMS is soliciting substantial comments on the proposed regulation.
- To be considered, comments must be received no later than 5 p.m. EST on **February 17, 2012**.
- Please refer to file code **CMS-5060-P** when submitting comments.
- Comments can be submitted electronically or in written form.
- Visit our website for a list of items for which CMS is requesting comment:
  http://www.morganlewis.com/documents/HealthIndustryTransparencyRequirements.pdf

CMS Proposed Regulations – Questions

1. Are applicable manufacturers required to begin tracking on January 1, 2012?

CMS Proposed Regulations – Questions

2. What determines if a drug or device is "covered"?

CMS Proposed Regulations – Questions

3. How is “teaching hospital” defined in the proposed rule?

CMS Proposed Regulations – Questions

4. Can an entity that does not manufacture anything be considered an "applicable manufacturer"?

CMS Proposed Regulations – Questions

5. Is it reportable if a covered recipient requests that payment be made to his/her LLC? If so, under what name must it be reported?

CMS Proposed Regulations – Questions

6. What types of payments require the disclosure of a specific product name?

CMS Proposed Regulations – Questions

7. If an entity holds a conference for which it charges a registration fee, and at which it provides meals, are the meals reportable?

CMS Proposed Regulations – Questions

8. How long following publication of the final rule will entities have to comply with its data collection requirements?

CMS Proposed Regulations – Questions

9. If an entity primarily manufacturers consumer products, but also manufactures one product that requires 510k clearance, what are its reporting obligations?

CMS Proposed Regulations – Questions

10. Is it necessary to track payments or other transfers of value to non-physician health industry workers that are affiliated with a teaching hospital?

CMS Proposed Regulations – Questions

11. Are transactions involving medical textbooks reportable?

CMS Proposed Regulations – Questions

12. What determines if a research payment is direct or indirect?

CMS Proposed Regulations – Questions

13. How must an applicable manufacturer or applicable GPO handle a reporting error?

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CMS Proposed Regulations – Questions

14. What does it mean for payment to be "available?"

CMS Proposed Regulations – Questions

15. Does a manufacturer that hires a contract research organization (CRO) have to report the amounts that it pays the CRO for medical monitoring services as indirect research?

CMS Proposed Regulations – Questions

16. How does an entity categorize meals, travel and/or other payments of value to physicians or institutions made during clinical trials?

CMS Proposed Regulations – Questions

17. What are the reporting obligations of distributors?

CMS Proposed Regulations – Questions

18. How would an applicable manufacturer report the delivery of meals to hospital staff?

CMS Proposed Regulations – Questions

19. Once data is submitted, will it be available for review?

Additional Questions

If you have any questions, or would like more information on any of the issues discussed today, please contact:

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Becky Osowski *at 202.739.5009; rosowski@morganlewis.com; or*

Michele Buenafe *at 202.739.6326; mbuenafe@morganlewis.com.*

Additional Resources

Morgan Lewis Transparency Compliance Team email:
TransparencyCompliance@morganlewis.com

Transparency Compliance Resource Center Website:
http://www.morganlewis.com/topics/transparencycompliance

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Transparency Compliance Team

Kathleen McDermott is a partner in the Washington, D.C. office of Morgan Lewis and has been involved in government enforcement and compliance matters for 20 years. She has served as an Assistant U.S. Attorney and DOJ Health Care Fraud Coordinator, and is a recipient of the HHS-OIG Inspector General's Integrity Award for her work in government healthcare fraud matters.

Ms. McDermott has a national corporate defense practice devoted exclusively to health industry matters in a broad array of government enforcement and litigation representations and has handled investigations in diverse jurisdictions, relating to allegations of off-label promotion, anti-kickback, reimbursement, privacy, and quality of care violations. She has been recognized as a leading False Claims Act practitioner with both government and defense experience in this unique practice area and designated as one of the top fraud and abuse compliance attorneys in the country by Nightingale's and as a D.C. Super Lawyer in white collar corporate matters.

Ms. McDermott also represents various health industry sectors on government voluntary disclosures, mandated compliance matters, including OIG-CIAs and DOJ consent decrees, compliance policy development for global operations, and fraud and abuse, transparency, and codes of ethics counseling. She frequently conducts training and internal reviews for corporate boards and related corporate operations.

Ms. McDermott teaches and publishes on corporate compliance and enforcement developments and has served as Chair of the American Health Lawyers Association's Fraud and Abuse Practice Group and as a board member for the BNA Medical Devices Law and Industry publication. She has served as faculty for many years for the Seton Hall Health Care Compliance Program and as adjunct faculty for Catholic University Columbia School of Law, teaching on health care fraud and compliance issues.

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Transparency Compliance Team

Becky Osowski is the director of healthcare compliance for Morgan Lewis's FDA and Healthcare Practice. Morgan Lewis's compliance representations encompass HHS OIG corporate integrity agreements for CIA implementation; Board and IRO compliance resources; DOJ deferred prosecution agreements; voluntary corporate compliance effectiveness reviews; healthcare professional arrangement reviews; corporate compliance policy development; and federal and state transparency and marketing compliance.

Ms. Osowski's corporate compliance engagements focus on assisting clients in developing and implementing practical and sustainable global compliant business practices, complying with government mandated requirements under CIAs and DPAs, voluntary arrangements reviews, compliance effectiveness assessments and corporate policy development. Ms. Osowski has deep industry knowledge, including involvement within AdvaMed, to help shape industry guidelines governing interactions between industry and health care professionals.

She also has experience in the area of health industry transparency requirements (e.g., Physician Payment Sunshine Act) as well as similar state requirements (e.g., Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct, Vermont Gift Ban and Disclosure Law). Ms. Osowski's compliance career has involved serving as a healthcare compliance officer for a large international device company under both a DPA and CIA and as a consultant assisting clients in the development and implementation of corporate compliance best practices for a broad range of health industry sectors.

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Transparency Compliance Team

Jonathan A. Havens is an associate in Morgan Lewis's FDA and Healthcare Practice. His practice focuses on FDA and healthcare regulatory, compliance, and enforcement issues. In this capacity, Mr. Havens assists in the representation of clients in matters relating to FDA regulatory compliance, including marketing, promotion, and advertisement. Mr. Havens has spoken on health industry transparency compliance and is well versed on the procedural and substantive requirements of transparency reporting.

Prior to joining Morgan Lewis, Mr. Havens was a regulatory counsel with the U.S. Food and Drug Administration. While at the FDA, Mr. Havens received an FDA Group Recognition Award for Compliance and Enforcement of Tobacco Product Regulations and a Center for Tobacco Products Team Excellence Award. Before his legal career, Mr. Havens was a legislative aide in the U.S. Senate and U.S. House of Representatives, as well as a legislative specialist with a national law firm.

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Michele L. Buenafe is an associate in Morgan Lewis's FDA and Healthcare Practice. Her practice focuses on FDA regulatory, compliance, and enforcement issues pertaining to medical devices and pharmaceuticals. As part of her practice, Ms. Buenafe regularly advises clients on issues related to the development, manufacturing, and marketing of medical devices, pharmaceuticals, biologics, and combination products; labeling and advertising; post-market requirements; and compliance with FDA's bioterrorism regulations. In addition, Ms. Buenafe has assisted clients in navigating the state regulatory requirements (including licensure requirements) applicable to drug and device manufacturers and distributors, pharmacies, DME suppliers, and healthcare providers. Ms. Buenafe also has experience advising clients on the regulatory requirements and emerging legal issues related to health information technology.

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