Morgan Lewis

transparency

The Business of Medicine's 2012 Summit

Everything You Need to Know About the New Transparency Requirements for the Health Industry

Kathleen McDermott
Morgan, Lewis & Bockius
Washington, DC

June 12, 2012
San Diego, CA

www.morganlewis.com

Legal Disclaimer

This document is provided as a general informational service to clients and friends of Morgan, Lewis & Bockius LLP. This information should not be construed as, and does not constitute, legal advice on any specific matter, nor does this message create an attorney-client relationship. These materials may be considered Attorney Advertising in some states.

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

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.

CMS Proposed Regulations – Applicable Definitions

- "**Applicable Manufacturer**" may include:
  - Any entity outside of the U.S. that sells or distributes products within the U.S.
  - An entity under common ownership with an **applicable manufacturer**
  - An entity that manufacturers various products - **one** of which meets the definition of a covered drug, biological, device, or medical supply

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.

CMS Proposed Regulations – Applicable Definitions

- **"Covered Recipient" is defined as:**
  - A physician, other than a physician who is an employee of an applicable manufacturer
    - *Includes doctors of medicine or osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors.*
  - A teaching hospital
    - *CMS proposes that a "teaching hospital" is any institution that received payments under IME or GME during the most recent calendar year.*

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?

CMS Proposed Regulations – Reportable Information

- **What to Report**:
  - Payments or other transfers of value made in the preceding year to **covered recipients**.
  - Includes instances where an entity or individual receives payments or other transfers of value at the request of or designation on behalf of a covered recipient.
  - "Payments or other transfers of value" do not include transfers made indirectly, through a third party, in connection with an activity or service, where the applicable manufacturer is unaware of the identity of the covered recipient.

CMS Proposed Regulations – Reportable Information

- Name and business address of the **covered recipient** (and specialty and NPI number, if the **covered recipient** is a physician);
  - Proposed rule suggests that this information should be obtained from the National Plan & Provider Enumeration System (NPPES) website maintained by CMS
- Amount of the *payment or other transfer of value*;
- Date on which the *payment or other transfer of value* was provided;
- Description of the form of the *payment or other transfer of value*, indicated as:
  - Cash or cash equivalent
  - In-kind item or service
  - Stock, stock option, or other ownership interest, dividend, profit, or other return on investment

CMS Proposed Regulations – Reportable Information

- Description of the nature of the payment or other transfer of value:
  - Consulting fee
  - Compensation for services other than consulting
  - Honoraria
  - Gift
  - Entertainment
  - Food and beverage
  - Travel and lodging (including the specified destination)
  - Education
  - Research
  - Charitable contribution
  - Royalty or license
  - Current or prospective ownership or investment interests
  - Direct Compensation for serving as a faculty or as a speaker for a medical education program
  - Grant
  - Other

CMS Proposed Regulations – Reportable Information

- Name of the covered drug, device, biological, or medical supply, if applicable.
- Indication of whether the payment or other transfer of value is subject to delayed publication.
  - This is meant to be a yes/no field in the report submitted.
  - The absence of this information will result in CMS posting the payment or other transfer of value publicly.
- Indication of whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest in an organization.
  - This is also meant to be a yes/no field in the report submitted.

CMS Proposed Regulations – Reportable Information on Research Payments

- Payments for research must also be designated as:
  - Direct Research; or
    - *Payments made directly to a covered recipient by an applicable manufacturer or through a contract research organization (CRO).*
  - Indirect Research
    - *Payments made to a clinic, hospital, or other institution conducting research. The clinic, hospital, or other institution pays the covered recipient serving as the principal investigator.*

- All research agreements must include a written agreement and a written research protocol between the **covered recipient** and **applicable manufacturer**.

CMS Proposed Regulations – Reportable Information on Research Payments

- Reporting information related to research payments:
  - Direct Research
    - *For physicians, report the full amount individually under the covered recipient name and NPI number.*
    - *For teaching hospitals, report the full amount under the name of the teaching hospital.*
  - Indirect Research
    - *Reported under the covered recipient name and NPI number of the physician acting as the principal investigator. These payments would also include the name of the entity that received the payment (e.g., clinic, hospital).*
    - *When payment is made to a teaching hospital, report under the covered recipient name and NPI number of the physician acting as the principal investigator. Also report under the teaching hospital as a "direct research" payment.*

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)

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 – 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 – 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 <u>not</u> 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.

CMS Proposed Regulations – Physician Ownership or Investment Interest

- Ownership or Investment Interest by Whom:
  - Physicians
    - *Defined as <u>any</u> physician, regardless of whether the physician is an employee of the applicable manufacturer or applicable GPO.*
  - Physician's immediate family member
    - *Defined as:*
      - Spouse
      - Natural or adoptive parents, child, or sibling
      - Stepparent, stepchild, stepbrother, or stepsister
      - Father-, mother-, daughter-, son-, brother-, or sister-in-law
      - Grandparent or grandchild
      - Spouse of a grandparent or grandchild

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

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.

Implementation, Tracking & Reporting – Report Submission & Certification

- **Data Submission:**
  - **Applicable manufacturers** and **applicable GPOs** should submit their data electronically in a comma-separated value (CSV) format.
  - **Applicable manufacturers** can submit an "assumptions" document with annual reporting.
- **45-Day Review Period:**
  - Data will be aggregated by individual **covered recipients** and **physician owners or investors**.
  - CMS will notify **applicable manufacturers**, **applicable GPOs**, **covered recipients**, and **physician owners and investors**.
  - Disputes must be handled directly between parties. If not resolved, CMS will make both versions publicly available.

Implementation, Tracking & Reporting – Report Submission & Certification

- **Errors and Omissions:**
  - If an **applicable manufacturer** or **applicable GPO** discovers an error or omission in its annual report, it must submit corrected information to CMS **immediately upon discovery**.
- **Attestation Requirement**:
  - Each report, or subsequent correction to a filed report, must include a certification as to its accuracy.
  - The certification must be signed by the Chief Executive Officer, Chief Financial Officer, or Chief Compliance Officer.
  - *"...information submitted is true, correct, and complete to the best of his or her knowledge and belief."*

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 Proposed Regulations – Questions

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

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

CMS Proposed Regulations – Questions

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

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?
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?
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?
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?
12. What determines if a research payment is direct or indirect?
13. How must an applicable manufacturer or applicable GPO handle a reporting error?

CMS Proposed Regulations – Questions

14. What does it mean for payment to be "available?"
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?
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?
19. Once data is submitted, will it be available for review?

Contacts

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

Kathleen McDermott *at 202.739.5458; kmcdermott@morganlewis.com;*

Jonathan Havens *at 202.739.5952; jhavens@morganlewis.com;*

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

Morgan Lewis