The Final CMS Sunshine Rule: Analysis, Interpretation and Implementation

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Sunshine Act Background

- Enacted as Section 6002 of the Patient Protection and Affordable Care Act ("ACA") on March 23, 2010.
- Created significant new legal obligations for drug and device manufacturers.
- Requires every "applicable manufacturer" to file an annual disclosure report with the federal government.
- This annual report must detail the manufacturers' financial relationships with physicians and teaching hospitals ("covered recipients") over the previous year.
- These are known as the "Sunshine Act" provisions, since they were originally proposed in 2007 as the "Physician Payments Sunshine Act" (sponsored by Senators Charles Grassley and Herb Kohl).

Sunshine Act Basics

- **Disclosure**
  - –Requires manufacturers to disclose almost all payments and “transfers of value” made to physicians or teaching hospitals.
  - –Requires manufacturers to disclose specific payments made to physicians and teaching hospitals, rather than simply disclosing aggregate payments.
  - –Disclosures will be made public in a online, searchable database.
- **Penalties**
  - – There is the potential for significant financial penalties on manufacturers for noncompliance.

Key Sunshine Act Milestones

- **March 23, 2010**
  - ACA is signed into law
- **October 1, 2011**
  - *Statutory "deadline" for CMS to promulgate regulations establishing the procedures for submitting disclosure data*
- **January 1, 2012**
  - Statutory preemption of state laws begins
  - *Statutory "deadline" for manufacturers to begin collecting disclosure data*
- **March 31, 2013**
  - *Statutory "deadline" for submission of first annual disclosure reports, covering the 2012 calendar year.*

The New Rule and Key Dates

- Proposed Rule was released by CMS on **December 14, 2011**
- Comments on the Proposed Rule were due **February 17, 2012**
- CMS published the Final Rule on **February 1, 2013**

- The start date for the collecting of data is **August 1, 2013**
- The deadline for reporting of collected data is **March 31, 2014** (for data collected in calendar year 2013)
- CMS plans to release reported data to the public on **June 30, 2014**

Key Statutory Definitions

- **Applicable Manufacturer:** Any "manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States" is subject to the reporting requirements.
- **Covered Device:** "any device for which payment is available under Title XVIII [of the Social Security Act] or under a State plan under Title XIX or XXI of the Act (or a waiver of such a plan)…."
- **Covered drug, device, biological, or medical supply:** "any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan)…."
- **Covered Recipient:** Only physicians and teaching hospitals are "covered recipients." (Physicians employed "in house" by the applicable manufacturer itself are not considered "covered recipients.")

What Is To Be Reported?

- Section 1128G(a) of the Sunshine Act outlines the transparency reporting requirements; it consists of two requirements:
  1) The first outlines the required reports from applicable manufacturers **on payments or other transfers of value to covered recipients**.
  2) The second outlines the reporting requirements for applicable manufacturers and applicable GPOs concerning **ownership and investment interests of physicians**, and their immediate family members, as well as information on any **payments or other transfers of value provided to such physician owners or investors**.
- There is some overlap between these submissions, but the two types of information are to be reported separately "to ensure that the relevant reporting obligations of applicable manufacturers and applicable GPOs are clearly distinguished."

Reporting: payments or other transfers of value to "**covered recipients**"

If:

1) There is any "payment or other transfer of value,"
2) From an "applicable manufacturer"
3) To a "covered recipient"
4) With a value $10 or more

   (or aggregate payments over $100/year)

5) And the payment is not subject to one of the limited statutory exceptions

Such a payment must be disclosed.

Reporting: payments or other transfers of value to **covered recipients**–the details

For each reportable payment or transfer to a covered recipient, the applicable manufacturer must disclose the following information:

- The name of the physician (as listed in the National Plan & Provider Enumeration System, including first and last name, middle initial, and suffix).
- The physician's primary business address of the physician, including: street address, suite or office number, city, state, ZIP code.
- The physician's specialty.
- The physician's National Provider Identifier.
- The physician's state professional license number(s) (for at least one state where the physician maintains a license), and the state(s) in which the license is held.
- The amount of the payment or transfer.
- The date of the payment or transfer.
- A description of the form of the payment or transfer (e.g., cash, in-kind, etc.)
- A description of nature of the payment or transfer (e.g., consulting fees, gift, education, travel, royalty, etc.)
- The name(s) of the related covered drugs, devices, biologicals, or medical supplies
- Categorization of whether the payment or transfer is related to marketing, education, or research specific to a product.

Reporting: payments or other transfers of value to **covered recipients-**-exemptions

The following transfers of value to covered recipients are exempt from the reporting requirements:

- Product samples that are not intended to be sold;
- Discounts, including rebates;
- Payments to employees under a manufacturer's self-insured plan;
- In-kind items for charity care;
- Educational materials that directly benefit patients;
- Short-term loans of certain devices for evaluation by the recipient;
- Items or services provided under a contractual warranty;
- Dividends or profit distributions from a publicly traded security and mutual fund;
- Transfers to covered recipients as patients (when not acting in their professional capacity);
- Transfers to a covered recipient for non-medical professional services which that individual is licensed to provide; and
- Payments to a physician solely for services with respect to a civil or criminal action or an administrative proceeding.

Exemption for Certain Patient Use Items

- The Act exempts manufacturers from the reporting requirements in situations when manufacturers provide covered recipients with certain specific items that are intended for patient use.
- One key exclusion for the reporting requirement is for "product samples that are not intended to be sold and are intended for patient use"; interestingly:
  - "we do not believe the applicable manufacturer should be responsible for tracking what actually happens to samples. Instead, we believe that as long as the applicable manufacturer and covered recipient agree in writing that the products will be provided to patients, which is commonplace in the industry, the provision of samples can be excluded."
- A second key exclusion from the reporting requirement is for "educational materials that directly benefit patients or are intended for patient use."
  - CMS originally proposed a definition of "educational materials" limited to materials (including written or electronic materials).
  - CMS has reconsider and expanded this definition slightly in the Final Rule to also exempt materials that "educate the covered recipients themselves" (such as medical textbooks, flash drives or anatomical models for patients).
  - However, educational materials provided to covered recipients for their own education, but that do not ''directly'' benefit patients, do not fall within the exclusion and are therefore subject to the reporting requirements.

Reporting: ownership/investment interests and payments/transfers of value to **physician owners or investors**

- The name of the physician (as listed in the National Plan & Provider Enumeration System, including first and last name, middle initial, and suffix.
- An indication of whether the ownership or investment interest was held by the physician or an immediate family member of the physician.
- The physician's primary business address of the physician, including: street address, suite or office number, city, state, ZIP code.
- The physician's specialty.
- The physician's National Provider Identifier.
- The physician's state professional license number(s) (for at least one state where the physician maintains a license), and the state(s) in which the license is held.
- The dollar amount invested by each physician or immediate family member of the physician.
- The value and terms of each ownership or investment interest.

What is status of CME expenditure reporting?

- An indirect payment made to a speaker at a continuing education program is not an indirect payment or other transfer of value for the purposes and does not need to be reported, provided all of the following conditions are met:
  - the program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP or ADA CERP;
  - The applicable manufacturer does not select the covered recipient speaker nor does it provide the third party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing education program; and
  - the applicable manufacturer does not directly pay the covered recipient speaker. Applicable manufacturers will not be responsible for reporting payments made to CME vendors that are used to subsidize attendees' tuition fees for continuing education events.
- Payments or other transfers of value associated with attendance of an event (such as travel and meals) must be reported.

Delayed Reporting for Research

Delayed Reporting of Payments for Product Research, Development Agreements, or Clinical Investigations.

- A payment or transfer made to a covered recipient relating to product research, development agreements, or clinical investigations is reportable.
- However, that information remains confidential (and is not disclosed to the public) until the earlier of
  a) the date of FDA approval or clearance, or
  b) four calendar years after the payment was made.

Reportable Information and "Research"

- The Act defines what **categories** of information must be reported by a manufacturer for each specific payment or transfer of value made to a "covered recipient" (defined as a physician or a teaching hospital). One reportable category is "a description of the nature of the payment or other transfer of value."
- The Act enumerates fourteen different types of descriptors, as well as authorizing the Secretary to add further descriptors at her discretion. One of the enumerated descriptors is where the payment is for "research."
- Because the Act does not define what constitutes "research" for reporting purposes, the Proposed Rule stated that the "dictionary definition" will be used.
- The Final Rule goes further: "[W]e have decided to define research based on the Public Health Service Act definition of research in 42 CFR 50.603; this definition defines research as: ''a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. This term encompasses basic and applied research and product development.''

How is clinical trial expenditure reporting handled?

- All payments or other transfers of value that are related to “research” made pursuant to a written research agreement for research related to new products will be granted a delay.
  - However, payments or other transfers of value related to research for new applications of products already on the market will be treated differently due to the statutory distinction between new products and new applications of existing products.
  - Pursuant to the statute, payments related to research on new applications of existing products will be granted a delay only if the research does not meet the definition of ‘‘clinical investigation.’’
  - Why?
    “We believe that the statute clearly differentiates them for purposes of delayed publication from research and development, and indicates that payments or other transfers of value made in connection with clinical investigations related to new applications of existing products should not be granted a delay.”
- ‘‘Clinical investigation’’ includes Phases I through IV clinical research for drugs and biologicals, and approval trials for devices (including medical supplies).

How does the 45 day period for correction by physicians & teaching hospitals work?

- Section 1128G(c)(1)(D) of the Act requires that CMS provide a review and correction period of ‘‘not less than 45 days.’’
- CMS proposed a 45-day review period “to maximize the time for the agency to aggregate and publish the data.
- To facilitate the review, CMS proposed that applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors would sign into a secure Web site to view the data submitted.
- Only the current year and preceding year will be available for review and correction:
  - For example, during the 45-day review period in 2015, applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors would be able to review and amend the data submitted for 2013 and 2014.
  - Data cannot be corrected the year it is submitted.
  - After two years, the data is final and not subject to correction.

How does the 45 day period for correction work: once you find an error, how do you fix it?

- Once the data is made available, covered recipients and physician owners and investors may register and then sign into the CMS secure Web site and review the data submitted by applicable manufacturers and GPOs.
- Covered recipients and physician owners and investors choose to dispute certain payments or other transfers of value, or ownership of investment interests.
- Once a dispute is initiated, applicable manufacturers or applicable GPOs may begin resolving the dispute and correcting the data.
- Following the end of the review and correction period, applicable manufacturers and applicable GPOs will have an additional 15 days to correct data for purposes of resolving disputes, and after which they may submit (and provide attestation for) updated data to CMS to finalize their data submission. Undisputed data will be finalized for publication after the close of the annual 45-day review and correction period.

How does the 45 day period for correction work: what happens in the 15 days?

- CMS acknowledges that "15 days is not much time for applicable manufacturers and applicable GPOs to resolve disputes submitted late in the review and correction period."
- Only data changes initiated during the 45-day review and correction period and resolved by the end of the 15-day period for dispute resolution will be captured in the initial publication of the current reporting year of data on the public Web site.
  - "There is no limit to the number of times a particular transaction can be reviewed and disputed."
- Stating the obvious: "Disputes submitted earlier in the review and correction period will have more time to be resolved."
- CMS will not play any role in resolving disputes.
- Is there a form of sanction for an entity that improperly refuses to cooperate?
  - Sanction for incomplete reporting?
  - A private cause of action to force correction?

How is public access to data going to work?

- The reported data will be available on a “public web site” starting June 30, 2014.
- There may still be some “public engagement” about the site’s capabilities, but it will be “searchable across multiple fields and available for downloads.”
- There will be a one-year lag in review of the data, so erroneous data could exist for a long time without correction.
  - Disputed transactions will be labeled as such, but only the original reported account will be listed until the dispute is resolved.
  - CMS will update the current and a previous year’s data at least once annually, beyond the initial data publication following the submission of the data.
- NPIs will not be on the public web site.
- Assumptions documents about classification of payments will not be on the public web site.

Penalties Remain Unchanged

- Manufacturers can face two types of noncompliance penalties – one for unknowing failures to report, and one for knowing failures to report.
- **Unknowing Failures to Report**
  - Subject to a penalty of between $1,000 and $10,000 for each unreported payment, transfer, or ownership interest.
  - Total penalties for unknowing omissions are capped at $150,000 annually.
- **Knowing Failures to Report**
  - Subject to significantly steeper penalties: between $10,000 to $100,000 per each unreported payment, transfer, or ownership interest.
  - Total penalties for knowing omissions are capped at $1,000,000 annually.