The Nuts and Bolts of the Sunshine Act Regulation

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PROGRAM OVERVIEW

- Sunshine Act Basics, Timeline and Background
- Definitions
- Reporting Requirements and Exceptions
- Research and Delayed Publication
- Reports of Physician Ownership
- Review and Dispute Process
- Enforcement and Penalties
- Compliance Takeaways
The Physician Payments Sunshine Act was enacted as section 6002 of the Patient Protection and Affordable Care Act and was codified at 42 U.S.C. § 1302 et seq.

Requires manufacturers of drugs, devices, biologics, or medical supplies covered by Medicare, Medicaid, or CHIP ("Covered Products") to collect and report payments and other transfers of value to physicians and teaching hospitals.

- Also applies to certain entities under common ownership.

Requires such manufacturers ("Manufacturers") and Group Purchasing Organizations ("GPOs") to disclose ownership or investment interests held by physicians or their immediate family members and payments or any other transfers of value to physician-owners.
TIMELINE

- Proposed Rule published on December 19, 2011.
  - CMS received more than 300 comments.
- Final Rule published on February 8, 2013.
- Data collection begins on August 1, 2013.
- CMS will publish data from first annual report no later than September 30, 2014.
- Annual reporting thereafter.
A variety of parties with varying concerns advocated for enactment of the Sunshine Act.

- In 2009, MedPAC and IOM issued reports regarding financial relationships between physicians and industry.
  - Need to balance concerns about interactions with physicians (e.g., increases in costs) vs. benefits of interactions.
- Manufacturers were searching for a way to stem the tide of enforcement actions against Manufacturers based on financial arrangements with physicians.
- Teaching hospitals and academic medical centers (AMCs) were concerned with the impact of financial relationships on clinical research and pushed to be treated similarly to providers.
- Various concerns expressed over the years about GPOs and PODs.
Final Rule: “Financial ties alone do not signify an inappropriate relationship.”

MedPAC and IOM recommended much broader disclosures rules.

Special treatment is given in the Sunshine Act to each of these groups/concerns.

- Special role and responsibilities of AMCs - teaching hospitals are covered recipients like physicians.
- Research is treated in a fundamentally different way than other payment categories.
- GPOs report ownership and investment interests of physicians.
DEFINITIONS

“Applicable manufacturer”

- Excludes distributors or wholesalers that do not hold title to Covered Products.
- Excludes entities that manufacture a Covered Product solely for internal use or for use by their patients.
- Includes entities operating in the U.S.
- Includes an entity under “common ownership” (5% direct or indirect) with a Manufacturer (but see limitations below).

“Applicable group purchasing organization”

- Includes entities that purchase, arrange for, or negotiate the purchase of Covered Products for a group of individuals and entities, but “not for use by the entity itself.”
- Includes entities operating in the U.S.
- Includes physician-owned distributors (“PODs”).
Whether a product is a "covered drug, device, biological, or medical supply" depends partly on whether payments are "available" (part of a fee schedule, formulary, or a bundled payment) from Medicare, Medicaid, or CHIP.

“Covered recipients” include physicians and teaching hospitals.

- CMS will publish a list of “teaching hospitals” 90 days before data collection begins.
- “Physicians” must be authorized to practice and have a current license.

“Payment or transfer of value”: A transfer of anything of value.

- A product has “value” if it has “discernible economic value on the open market . . .”
- CMS rejected OIG’s long-standing definition.
“Indirect payments or other transfers of value”: Payments or other transfers of value made by a Manufacturer (or GPO) to a covered recipient (or a physician owner or investor) through a 3rd party, where the entity “requires, instructs, directs, or otherwise causes the third party” to provide the payment or transfer of value to a covered recipient (or a physician owner or investor).

- Payments need not be reported if the Manufacturer does not know the covered recipient's identity.
- “Know” has the same meaning as under the False Claims Act: actual knowledge of information, deliberate ignorance, or reckless disregard.

“Related to a covered drug, device, biological, or medical supply”: A payment or other transfer of value is made in reference to or in connection with one or more Covered Products.
General Rule on Reporting

- Manufacturers must disclose direct and indirect payments or other transfers of value to covered recipients, including payments to a 3rd party by an applicable manufacturer on behalf of a covered entity.

- CMS kept to its basic position that as long as a Manufacturer manufacturers at least one covered product, it must disclose all payments or other transfers of value whether or not related to a covered product.
Limitations on Reporting

- Less than 10% of total gross revenue from Covered Products – only report payments related to Covered Products.

- Manufacturer by common ownership – only report payments or transfers of value where entity provided “assistance or support.”

- Manufacturers with separate operating divisions that do not manufacture any Covered Products – only report payments made by these divisions if payments relate to a Covered Product from another division.
14 exceptions to reporting requirement in the Final Rule. Certain exceptions are likely to be used frequently.

Payments of less than $10.

- Need not be reported unless payments to a covered recipient exceed $100 annually.
- The $10 threshold will increase every year according to the consumer price index.
- Manufacturers do not have to track incidental items worth less than $10 (e.g., pens and note pads) provided at large-scale conferences.
- Similarly, although not a defined exception, Manufacturers do not have to track or report food or drinks, such as buffet meals or coffee, made generally available at a conference or large-scale event.
REPORTING EXCEPTIONS (Cont.)

➤ Educational materials and items.
  - These materials and items (CMS added “items” in the Final Rule) intended for use by or with patients are not subject to the reporting requirements.

➤ Product samples.
  - Samples not intended to be sold and intended for patient use are exempt.
  - The Final Rule clarifies that the term “product samples” is reasonably broad and includes devices and medical supplies, as well as coupons and vouchers that patients can use to obtain samples.
Discounts and rebates.

- Excluded from the reporting requirements.
  - A discount or rebate on a product purchased by a physician from a Manufacturer technically is something of value flowing from a Manufacturer to a physician covered recipient.

- The Final Rule fails to define either term.
  - CMS did not make clear whether value in the form of a credit or a charge-back qualifies a discount.
Payments related to speaking at accredited or certified CME programs.

- According to CMS, such programs include safeguards “designed to reduce industry influence.”

- Stringent requirements for exception:
  - The Manufacturer cannot have selected the speaker.
  - The payment cannot have been made directly to the speaker.

- Other rules related to CME programs establish are stated in the nature of payment categories for reporting of speaking fees.
Examples of specific reporting requirements:

- **Related covered products** (which meet the definition “related to a covered drug, device, biological, or medical supply”) must be reported, if the Manufacturer can tie the payments directly to certain covered products.

- The **covered recipient’s name** must be reported and must include the middle initial and suffix of the individual.

- The **covered recipient’s office suite or office number**

- The **covered recipient physician’s national provider identification** (“NPI”).

- The **covered recipient physician’s state license number**.

- **Travel-related** payments must specify the destination to which the covered recipient traveled.
Details about the context of the payment may be provided (but are not required).

"Form" of payment—one of four categories:

- Cash;
- In-kind items or services;
- Stock, stock option, or any other ownership interest; or
- Dividend, profit, or return on investment.
"Nature" of payment or transfer of value—or any separable part of that payment—that "best describes" the payment or transfer of value.

- Final Rule has 17 nature categories; Manufacturers must assign only one to each payment or separable part of a payment.

- Additions in the Final Rule:
  - space rental or facility fees (for teaching hospitals only), and
  - CME programs.

- Final Rule eliminates the catchall category "other."
Four "nature" categories related to speaking and education:

- Compensation for serving as faculty or as a speaker at an accredited or certified CME program (applies only if the payment cannot meet the terms of the related exception);
- Compensation for serving as faculty or as a speaker at an unaccredited and non-certified CME program;
- Compensation for speaking at an event other than a CME program; and
- Education, unrelated to speaking.
Other Nature of Payments Categories:

- Consulting fee,
- Honoraria,
- Gift,
- Entertainment,
- Food and beverage,
- Travel and lodging (including the specified destinations),
- Research,
- Charitable contribution,
- Royalty or license,
- Current or prospective ownership or investment interest, and
- Grant.
"Research" is one of the "nature" categories, but is subject to special reporting rules.

- Payments will be reported on a separate template.

Manufacturers need not specifically identify the amount of payments to physician covered recipients when the money is paid to another party (e.g., a teaching hospital).

Amounts paid to physicians for research will be listed separately from other payments or transfers of value.
Payments and transfers of value made under a product research or development agreement may qualify for delayed publication.

- Payments related to *new products* will qualify.
- Payments related to *new applications of existing products* will *not* qualify if payments are part of a "clinical investigation."

Qualifying payments must be timely reported but will not be published until the earlier of:

- The date the product receives FDA approval, or
- The 4th calendar year after the date of the payment.
Manufacturers and GPOs must submit an annual report to CMS regarding all ownership and investment interests held by physicians or immediate family members of physicians during the preceding year.

- Ownership or investment interest is defined similarly under the Stark Law.
- GPOs generally are not required to report payments to covered recipients, but must report direct and indirect payments and transfers of value to physicians with an ownership or investment interest.
45-day period after report submission to review, dispute, and propose corrections to reported data.

Disputes must be resolved without CMS’s participation.

CMS will make changes to reported information if provided to CMS no later than 15 days after the end of the 45-day review period.

- Unresolved disputed reports will be published but will be noted as disputed.
- If the dispute is later resolved, a corrected report will not be published until the next annual reporting cycle.
Applicable Manufacturers and GPOs may submit a voluntary assumptions document with their annual report.

- Assumptions document will not be publicly available.
- Enforcement agencies may obtain the document from CMS or directly from the Manufacturer or GPO.
ENFORCEMENT AND PENALTIES

- Reports must contain an attestation that the report is timely, accurate, and complete.

- Civil Monetary Penalties (CMP)
  - $1,000 to $10,000 for each payment not reported (up to $150,000)
  - $10,000 to $100,000 for each knowing failure to report (up to $1,000,000)

- For errors corrected during the review and correction period, Manufacturers will not be “subject to penalties for failure to report in instances when the original submission was made in good faith.”
State law preempted as of January 1, 2012.

Manufacturers should continue to assess the extent to which the Sunshine Act preempts applicable state laws, such as those in effect in Massachusetts and Vermont.

- The Sunshine Act will likely not preempt state “gift bans”; no such prohibition in Sunshine Act.
- The Sunshine Act may not preempt state laws requiring disclosure of payments to health care practitioners other than physicians.
Total Burden: $269 million in the first year; $180 million in second and subsequent years

Average Labor Costs for Manufacturers: $160,000 in the first year; $136,000 in the second and subsequent years.
- Estimated first-year implementation costs will only be $24,000 for each average Manufacturer.

Average Labor Costs for Covered Recipients (First Year):
- $250 per physician.
- $3,500 per teaching hospital.
Initial Priorities for Manufacturers:

- Parse the regulations.
- Assess potential automated solutions for tracking payments.
- Create new internal reporting process.
- Conduct compliance training.

Open Questions:

- Many questions unanswered by the Final Rule.
- CMS did not use “Interim Final Rule With Comments.”
- CMS may use Q&A documents to address open issues.
Considerations for Manufacturers:

- Create an internal record of all assumptions and methodologies applied.
- If relying on an exemption, determine if all requirements are met.
  - Potential for enforcement for failure to report.
- Consider whether to elaborate on the context of a payment or transfer of value.
- Engage in internal auditing and monitoring activities early and often.

Considerations for Providers:

- Review internal policies to determine if disclosure is sufficient to address conflicts of interest.
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