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Understanding the New U.S. Sunshine Act and Its Impact on Health Care Providers and Industry

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Sunshine Act Background

- Enacted as Section 6002 of the Patient Protection and Affordable Care Act ("ACA") on March 23, 2010.
- Creates 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.
- 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**
  - Imposes significant financial penalties on manufacturers for noncompliance.

Key Sunshine Act Timelines

- **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 set to begin
  - 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.

Sunshine Act: Newly Proposed Rule and Key Deadlines

- Proposed Rule was released by CMS on **December 14, 2011**
- Comments on the Proposed Rule are due **February 17, 2012**
- Data collection requirements will be stayed until at least **90 days** after a Final Rule is issued:
  - This is likely in June/July 2012.
- Deadline for reporting of collected data remains **March 31, 2013** (for data collected in calendar year 2012).

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 a State plan under title XIX or XXI (or a waiver of such a 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.")

- **Manufacturer of a Covered Drug, Device, Biological, or Medical Supply.** Any "entity which is engaged in the production, preparation, propagation, compounding, or conversation of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity [regarding the same]."

What Needs to be Disclosed

- If there is any "payment or other transfer of value,"
- From an applicable manufacturer to a covered recipient,
- With a value greater than $10,
- And not subject to one of the limited statutory exceptions,
- Must be disclosed.

Reporting Requirement Details

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

- The name and address of the covered recipient
- The amount and 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.)
- Whether the payment or transfer is related to marketing, education, or research specific to a product (and the name of the product, if applicable).

Reporting 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.

Other Notable Requirements

- **Physician Ownership.** Manufacturers must report ownership or investment interests in the manufacturer that are held by physicians.

- **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 states that the "dictionary definition" will be used. The CMS commentary on the Proposed Rule elaborates on how CMS will interpret this definition.

Proposed Rule: Interpretation of "Research"

- CMS proposed to limit the "research" reporting category to "bona fide research activities, including clinical investigations that are subject to both a written agreement or contract between the applicable manufacturer and the organization conducting the research, as well as a research protocol."

- One reason CMS proposes this particular definition is to remain consistent with its proposed definition of "research" in the context of payments for certain clinical investigations that may be eligible (as proprietary information of the manufacturer) for delayed publication in the online public database.

- CMS acknowledges that due to the complexity of "research" activities, defining how it should be reported is a "complicated" issue. CMS seeks comments about whether its proposed approach is "viable and not overly burdensome, and whether an alternative method would be preferable."

"Direct" vs. "Indirect" Research Payments

- CMS proposes to create two subcategories of "research" payments – "**direct**" and "**indirect**".

- CMS proposes that a "**direct**" research payment would occur "when a research payment or other transfer of value was provided directly to a physician covered recipient or teaching hospital covered recipient by an applicable manufacturer or CRO [contract research organization] entity"

- CMS proposes that an "**indirect**" research payment would occur "when a research payment is made to a clinic, hospital (other than a teaching hospital), or institution conducting the research (either by an applicable manufacturer or a CRO entity) and that organization in turn pays the physician covered recipient (or multiple physician covered recipients) serving as a principal investigator(s)."

Potential Reporting Complications

Indirect Payments

- CMS acknowledges that attributing the entire amount of an indirect research payment to a single physician — rather than just the amount that that individual physician received — could be "misleading" to the public.

- CMS therefore proposes that in its public online database, indirect research payments made to a given physician will be reported separately from all other types of payments made to that physician.

Direct Payments

- Where the principal investigator receiving a direct research payment is a physician, CMS is "considering" attributing the total amount of that direct research payment to the individual physician, as opposed to allowing the reporting only of the amount personally retained by that individual physician.

Potential Expansion of Proposed Definition

- CMS notes that its proposed definition of research "may not cover all circumstances in which applicable manufacturers make payments or other transfers of value to covered recipients for research-related activities"

- CMS gives examples such as research not conducted pursuant to a written contract, or studies without a research protocol.

- CMS therefore seeks comments on:
  - which other existing "nature of payment" categories might apply to these types of research
  - whether the scope of the "research" subcategory should be broadened, and/or
  - whether another "nature of payment" category should be added to address these types of research activities.

Proposed Reporting Procedure

- Direct or indirect not relevant for reporting:
  - Regardless of whether research payments are "direct" or "indirect," CMS proposes that the payment be reported "individually under the names and NPIs of physician covered recipients serving as principal investigators."

- Regulations require double counting:
  - Because teaching hospitals are also "covered recipients," CMS proposes that payments made to teaching hospitals for research ultimately conducted by a principal investigator who is a physician should be reported twice – once as a "direct" payment to the teaching hospital, and again as an "indirect" payment to any PI physician.

Definition of "Physician"

- The Act adopts the very broad definition of "**physician**" used in the Medicare statute (§1861(r)).
- That definition generally defines a "physician" (for the purpose of "the performance of any function or action") as a doctor of medicine, osteopathy, dentistry, podiatry, optometry, or chiropractic medicine who is "legally authorized to practice by the State in which he performs such function or action"
- Note that this definition does **not** clearly distinguish between practicing and non-practicing physicians, or limit the definition only to physicians who bill Medicare.
- Commenters **could** request that CMS clarify that the definition of "physician" for Sunshine purposes is limited to "practicing" or "billing" physicians. However, the Proposed Rule does not make such a proposed distinction at present.

Definition of "Food and Beverage"

- 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 category that must be reported for each transaction is "a description of the nature of the payment or other transfer of value."

- The Act enumerates fourteen different types of descriptors (and authorizes the Secretary to add further descriptors at her discretion). One of the enumerated descriptors is where the payment or in-kind transfer is for "food."

- The Act does not define the term "food" for reporting purposes. CMS proposes to expand the definition to include "food and beverage," and states that the "dictionary definition" will be used. The CMS commentary on the Proposed Rule elaborates on how CMS will interpret this definition.

Interpretation of "Food and Beverage"

- CMS proposes that manufacturers report the value of any food and beverages provided to covered recipients.
- Although not specified, CMS presumably will interpret "value" to mean the fair-market value of the item if the physician were to purchase the item at retail. This definition could be clarified in the Final Rule.
- CMS also proposes to exempt from the reporting requirement "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."

Complications in the Buffet Line

- In situations where allocating the precise value of "food and beverages" to a specific covered recipient is difficult (such as in buffet-style situations), CMS proposes that manufacturers report the cost-per-covered-recipient present, even if a given individual covered recipient did not actually partake.
  - For example, if five physicians are present at an event where $100 of food is provided, manufacturers would be required to report $20 of food for each physician, regardless of whether each physician actually consumed food.

- However, CMS recognizes that this proposal may be "difficult" to implement in certain situations (such as when food is being brought to large practices), and is thus "considering whether to adopt a different approach for these situations, such as counting the number of physicians by department."

Food & Minimum Reportable Values

- The Act does not required the reporting of items with a value of less than $10.
  - Example 1: An applicable manufacturer takes a physician to lunch four times during the year and each lunch costs $9. The applicable manufacturer has no other relationships with the physician. Since the aggregate cost of the four meals is $36 for the year, these payments would not need to be reported.
- However, the Act does require the reporting of all items of value (regardless of their individual value) if the aggregate value of all the items provided to a given covered recipient in a calendar year exceeds $100.
  - Example 2: An applicable manufacturer provides a physician with four meals, each worth $9, and a speaker fee of $150. The aggregate amount is greater than $100, so all the payments need to be reported.
- As a result, if an applicable manufacturer expects to provide food (or other transfers of value) to the same covered recipient on several occasions throughout the year, it will be advisable for the manufacturer to retain records of each transaction, regardless of size.

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"
- A second key exclusion from the reporting requirement is for "educational materials that directly benefit patients or are intended for patient use."
  - CMS proposes to clarify that the definition of "educational materials" is limited to materials (including written or electronic materials), and does not include services or other items.
  - CMS is considering whether to expand this definition slightly in the Final Rule to also exempt materials that "educate the covered recipients themselves" (such as medical textbooks).

Penalties

- 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 unknowing omissions are capped at $1,000,000 annually.

Preemption Provisions of the Sunshine Act

Overview: Federal Preemption

- Preemption- Legal term for when federal law supersedes a similar (or conflicting) state law on the same issue
- The Sunshine Act preempts those state-level reporting requirements that either
  - Duplicate the new federal reporting requirements OR
  - Require the reporting of covered transfers valued at LESS than $10
- The Sunshine Act does not preempt any additional reporting requirements that states may choose to impose
  - States may continue to require manufacturers to disclose additional information about transfers of value not otherwise covered under Sunshine
  - States could also continue to require the disclosure of transfers of value to medical professionals who are NOT physicians or teaching hospitals
- "Gift Ban"-type regulation not pre-empted by Sunshine

Basic Preemption Provisions

- What is preempted? Any type of payment required to be reported under the Act, or any other covered payment under $10
  - The statute shall preempt any statute or regulation of a State that requires a manufacturer to disclose or report the type of information covered by the federal law regarding any payment or other transfer received by a covered recipient on or after January 1, 2012.
    - Exceptions: Information that is collected by a Federal, State or local government agency for public health surveillance, investigation or public health oversight.
  - States can require reporting of any other information not covered by the Act, with the exception of covered payments less than $10 individually or $100 in the aggregate.

States Affected by Preemption

- Five states currently require reporting of pharmaceutical marketing expenses at some level
  - District of Columbia
  - Massachusetts
  - Minnesota
  - Vermont
  - West Virginia

- All of these states will likely adjust state level reporting requirements to deal with Sunshine preemption

- Massachusetts example

Sunshine – Narrow Categories as compared to State Law

- Sunshine will not totally pre-empt most state reporting requirements because of
  - Limited definition of Covered Recipient
    - "Physicians"
    - Teaching hospitals
  - List of Reporting Exemptions

"Covered Recipients" under Sunshine

- Under Sunshine, the range of covered recipients is fairly limited as compared to some existing state requirements (two groups)
  - Only "Physicians" and "Teaching Hospitals" are covered
  - Both definitions are NARROWER THAN THE FULL RANGE OF PRESCRIBERS or PROVIDERS
  - Physicians
    - Uses the definition in the Social Security Act, which includes "doctors of medicine and osteopathy, dentists, optometrists and licensed chiropractors."
  - Teaching Hospitals
    - Undefined in the Social Security Act. CMS proposes the definition of institutions that receive Medicare graduate medical education ("GME") payments. CMS Plans to publish a list of teaching hospitals.

Sunshine's Reporting Exemptions

- Numerous Sunshine exemptions that are not included in some existing state level reporting laws
  - Product samples not for sale
  - Discounts and rebates
  - In-kind items for charity care
  - Educational materials benefiting patients
  - Short term loans of certain devices for evaluation

Massachusetts Reporting Requirements

- Covered recipients:
  - Teaching and Non-teaching hospitals,
  - All purchasers, prescribers or dispensers of drugs, biologics or medical devices, including physicians, nurse practitioners, physician assistants, pharmacists, dentists, clinics, clinical laboratories, all hospitals, nursing homes.
- Certain exemptions under the MA reporting regulation similar to Sunshine, and include
    - Drug samples for use by patients
    - Demonstration or evaluation units
    - In-kind items for the provision of charity care
    - Confidential price concessions (rebates and discounts) between manufacturers and insurers/pharmacies

Massachusetts- What impacts?

- Basic preemptions:
  - Without changes in MA law or regulation, reporting will continue for
    - Non-teaching hospitals as covered recipients
    - Prescribers and purchasers of drugs NOT included in Sunshine's definition of "physician" (including nurse practitioners, physician assistants, dentists, and clinics)

- New Federal Reporting Requirements for Massachusetts
  - Any payments covered under Sunshine over $10 (as compared to the Massachusetts $50 limit)
  - Clinical trial expenses
  - Licensing and royalty fees

Residual Reporting in Massachusetts

- Impacts based on reported data from June 1- Dec 31, 2009
  - Majority of transfers and dollars already Sunshine reportable
    - Just over 75% of all transfers and 65% of overall dollars went to physicians and teaching hospitals
    - Transfers to non-"physician" individuals are of very low value

    (nurses, pharmacists and all other non-physicians made up just over 20% of all reported transfers, but only 6% of all total dollars)
  - Covered Recipients under MA regulation include Stem Cell Research and Clinical Laboratories
    - Drug purchasers under the MA law, but are they prescribers?

- Is there a need for continued MA reporting?
  - Are company costs associated with "dual reporting" worth the data value?

What now in Massachusetts?

- No comprehensive formal guidance.
  - DPH appears to be waiting for promulgation of CMS Final Rule
  - But, DPH has advised companies that, pending final rule "pharmaceutical and medical device manufacturing companies must continue to collect and submit disclosures on all covered recipients as currently defined under the [MA] law."

- Regardless of the CMS regulatory deferral, Sunshine prohibits pre-empted data requirements for covered transfers made as of January 1, 2012.
  - Can states require manufacturers to "collect" pre-empted marketing data after January 1, 2012?

Understanding the New U.S. Sunshine Act and Its Impact on Health Care Providers and Industry

A Medical Device Perspective

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The materials and views expressed during this session are those of the presenter, which may not reflect the views of DePuy Spine, Johnson & Johnson, or any other medical device manufacturer.

This presentation is based on the preliminary implementing regulations published in December 2011, which are subject to change and are still under review by Johnson & Johnson.

Applicable Manufacturers

- ***Complexity***. In large, global organizations, capturing all applicable entities can be a significant effort. Mix of Sunshine-covered and non-covered products adds to complexity
- ***Third Parties***. Manufacturer needs input from others who make payments or act on its behalf (CROs, sales agents, etc.)
- ***Applicability***. Need for correct interpretation of the regulations to drive appropriate and comprehensive tracking systems
- ***Tracking***. Ability to capture both domestic and cross border transactions (e.g., US physicians engaged by/paid by a covered entity outside the US)
- ***Awareness***. Compliance needs to be kept informed of corporate structure and reorganizations, as well as changes in manufacturing

Covered Recipients

- **Teaching hospitals:**
  - Proper identification of covered recipient
  - Matching internal records to CMS-published list
  - Capturing appropriate related entities if required
  - Treatment of newly published teaching hospitals

- **Physicians:**
  - Proper identification of covered recipient
  - Physician's first and last name *and middle initial*
  - Appropriate address
  - NPI number
  - Physicians with multiple state licenses (if no NPI number)

Physician Practices & Other 3rd Parties

- Payment made to a physician group practice attributable to the name(s) of the individual physician(s)
  - Allocation of cost across all physicians, some of whom may not have actually received the payment (e.g., a consulting fee paid to the practice)?
  - Manufacturer needs to know all the physicians in the practice
  - Could result in relatively small allocations if the practice is large
  - Could attribute payment to physicians who are not part of the approved called-on audience ("off label" concerns?)

- If payment is redirected by a physician to a third party, both parties are reportable by the manufacturer
  - Manufacturer's reporting system needs to be able to track not only the actual recipient but also the name(s) of the covered physician(s)

Associated Covered Drug, Device, Biological or Medical Supply

- Product name may not be known at early stages of development, particularly with devices
- Need for adequate system to capture necessary information
- Patients are not always aware of brand names (esp. devices)
- Often times a single payment is attributable to multiple products (e.g., meal where several products are discussed, consulting fee that spans products, etc.)
- Possible misperception that more $ is being spent to market a named product than is actually the case

Payment Categories

- Segregation of a payment into multiple categories requires additional effort for manufacturers who may otherwise classify the entire payment on a single line in a purchase order or general ledger account.

- "Dictionary" definition may still result in inconsistent application by different manufacturers (e.g., "honoraria")

Food & Beverage

- Allocation across multiple physicians of meals provided to non-physician attendees
  - Similar challenges as physician practice payment
- Manufacturer must track all items, even those <$10
- Buffet meals, snacks or coffee at booths at conferences

Research

- One of the more complex parts of the proposed regulation
  - "Direct" vs. "Indirect" payments
  - "Clinical Investigation" vs. "Product Development" efforts
  - May involve several covered recipients
- Manufacturer needs to capture data on payments made by contract research organizations (CRO) on its behalf
- Attribution of payment to principal investigator, who may not have actually received part of that research payment
- Dual reporting of payment remitted to a teaching hospital

Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program

- Proposal to use this category broadly for all "speaking" and not just for those involving "medical education programs"
  - Could result in inconsistent interpretation/treatment by manufacturers (e.g., how to define "medical education programs")
  - CMS seeks input on this and whether another category should instead be added
- Given that ACCME rules prohibit direct payment to faculty for CME speaking, it would be preferable to see CMS distinguish between company-controlled programs and independent third party programs
- Public may confuse company-controlled speaker programs (including device product training) vs. manufacturer funding of independent programs

Exclusions

- Purely personal transfers of value
  - Example: one who works for an applicable manufacturer and provides a gift to his/her spouse who is a covered recipient
  - Extrapolate to other types of “social” interactions?
- Payments <$10
  - Still reportable if aggregate exceeds $100
  - “Small” payments can be bundled and not reported separately. Is “small” defined as <$10?
  - If aggregate >$100 and small payments cannot be bundled, they are reported individually (e.g., $5 gift cited in example within the draft regulations)
  - If payments are aggregated, what payment date must be reported to CMS?

Exclusions, con't

- ***Loaners.*** Evaluation equipment loaned <90 days is not reportable.
  - Manufacturer must have a system in place to track
  - How to value loaners > 90 days?
- ***Medical textbooks***. Should they be excluded along with other "educational materials that directly benefit patients or are intended for patient use?"
  - How to track
- ***Donated products***. Could they potentially be used for non-charitable purposes?

Prior Review of Data

- Manufacturer may be required to provide advance notice to covered recipients of information it intends to report to CMS
  - CMS seeks input on this proposal
- While burdensome, this may be the easiest way to satisfy the law's requirement of 45 days' advance notice to covered recipients
- Manufacturers may need more than 90 days to accommodate this additional effort

Delayed Publication for Certain Payments

- Manufacturer must correctly interpret and apply the regulations to know what payments may and may not be delayed
  - Research “protocol” required
  - New product vs. New application of existing product
- Internal tracking systems must accommodate requirements over a period of years
- Need to track timing of FDA approval/clearance (to release flag and designate the payment as disclosable by CMS)

Pre-Emption of State Laws

- Manufacturer still needs to comply with surviving requirements of state laws
- Reporting system(s) must allow for appropriate tracking of different requirements
- Timing and due dates of various state and federal submissions can present challenges
- How to treat an allowable “payment” (e.g., a meal in a hospital setting) to a non-physician that was attributed to a physician for Sunshine?

Recap

- Regulations are helpful in clarifying many points left unanswered in the law itself
- CMS is seeking comments on a number of its proposals and open items
- There continue to be implementation challenges that manufacturers need to address, and certain areas will need legal input in the absence of clearer guidance from CMS

Questions?

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