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The Sunshine Act: Still Partly Cloudy

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The Big Questions

- Who's in charge here?
- When are you going to tell me what I have to do?
  - "No later than October 1, 2011, the Secretary shall establish procedures…"
- What say do I have in this?
  - Statute requires that, "in establishing the procedures under Paragraph (1)," the Secretary must consult with OIG, "affected industry, consumers, consumer advocates, and other interested parties"
  - "Paragraph (1)" refers to procedures for submitting information and for public disclosure (includes definitions of terms)

Applicable Manufacturer

- Manufacturer – “any entity which is engaged in the production, preparation, propagation, compounding, or conversion” of a covered product
  - However, definition includes “any entity under common ownership with such entity which provides assistance or support to such an entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution” of a covered product
- Research entities working on unapproved products? On approved products? Other affiliates?
- Any room to exclude separate legal entities or separate divisions that do not provide “assistance or support”?

Covered Recipients – Physicians

- "The term 'physician' has the same meaning as under section 1861(r) of the Social Security Act (42 U.S.C. § 1395x(r)).
  - doctor of medicine or osteopathy;
  - doctor of dental surgery or dental medicine;
  - doctor of podiatry;
  - doctor of optometry;
  - a chiropractor.
- What spend would be considered to be "on behalf of" or "at the request of" a covered recipient?
  - Training of staff?

Covered Recipients – Teaching Hospital

- Undefined
- Cross-reference existing statutory or regulatory definitions?
- Medicare regulations regarding physician services in teaching settings define a “teaching hospital” as “a hospital engaged in an approved [graduate medical education (GME)] residency program in medicine, osteopathy, dentistry, or podiatry” (42 C.F.R. § 415.152)
  - But, some entities receive GME payments and are not “teaching hospitals”
- How will we know? Where’s the list?
- How are teaching hospital employees treated?
- What of hospital foundations?

Indirect Payments

- Statute covers payments "to" a covered recipient
  - Payments made to an entity or individual "at the request of" or "on behalf of" a covered recipient are reported by covered recipient
- What of payments to entity that selects the covered recipient? E.g., CROs
- "Payment or other transfer of value" does not include "payments made indirectly to a cover recipient through a third party in connection with an activity or service in the case where the manufacturer is unaware of the identity of the covered recipient."
- What does it mean to be "unaware"?
- Target list of physicians to include? List of 5? 50? 5,000?
  - Physician types?
- What if we subsequently become aware?

Meal Allocation

- How are business courtesy meal costs brought into a physician's office to be allocated for purposes of the reporting requirement?
- Simple, pro-rata allocation (divide total cost by number of attendees and report costs for only covered recipients)?
- Will regulators take position that meal to office staff is "at the request of or designated on behalf of" a covered recipient?
- Regulators likely not unaware that states have provided guidance (and taken various positions) in this regard
- What of meals provided as part of consulting relationships? Reported separate from other payments?

Open Exemption Issues

- PhRMA Code vs. Educational Items Exemption
  - PhRMA Code permits "items designed primarily for the education of patients or healthcare professionals"
  - Statute exempts "educational materials that directly benefit patients or are intended for patient use"
    - Textbooks? Reprints?
- Exemption for payments for the provision of health care to employees under a self-insured plan
  - How narrow is this? What of employee health screen?
  - Perhaps not a payment "to" a covered recipient depend on how physician is retained
- Transfer of value to "licensed non-medical professional" solely for "non-medical professional services." JD/MD? Others?

Preemption – The Basics

- "Preempts" any provision of state law that requires a manufacturer "to disclose or report, in any format, the type of information" described under federal disclosure requirement
- That is: information required under both a state law and federal law would be reported to HHS and not to the state
- Federal law does not preempt any provision of state law that requires disclosure:
  - by other entities
  - to other covered recipients (i.e., other than "physicians" or "teaching hospitals"); or
  - of different information not required (or specifically excluded) under the federal law
- Federal law does not alter state gift bans

Preemption – The Questions

- Statute doesn't preempt items excluded "except in the case of information described" under SSA 1128F(e)(10)(B)(i):
  - "A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100."
  - What happens where state sets a higher floor? E.g., $25/$50/$100
  - What happens where state sets no floor, such as Vermont?
    - Vermont gift ban may make inquiry mostly moot, but consider $5 market research survey payment
  - What if payment calculation is different under state and federal law?
- Who determines what is the same "type" of information?
  - E.g., state asks for information on institutional affiliation

Reporting Challenges

- When does a transfer of value occur?
- Joint marketing efforts?
- How to track/report items less than $10 where aggregate amount exceeds $100 for that covered recipient?
- Report product if a marketing, education or research payment is “specific” to a covered product. What’s specific? What about multiple “products”? (Big concern for device industry.)
- How will data corrections be handled?
  - Statute requires that manufacturers and covered recipients have an “opportunity to review and submit corrections” to the information submitted “for a period of not less than 45 days prior to such information being made available to the public.”
  - Data due March 31 and must be posted publicly by June 30

Next Steps

- Industry should help set the tone for the working relationship with the regulators
  - HHS may be more receptive than some states regulators to being educated about implementation challenges/transparency best practices
- Don’t ask… tell. Assess internal capabilities and advocate for your best solution and/or a solution that allows flexibility.
  - E.g., When does transfer of value occur? What does your system do now? Secondary solution: allow for summary of methodology?
- Continue to develop systems/procedures that capture data at granular level
- Expanding reporting requirements will expose you to even greater web of company operations and expenditures
  - Don’t forget to continue to ask the compliance questions: Is this an FDA / Kickback / FCA / PhRMA Code problem?

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