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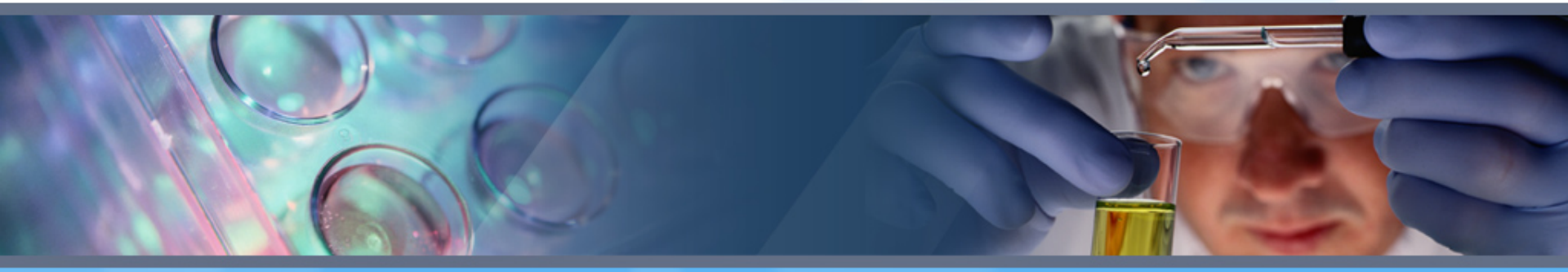

Sunshine Act Implementation

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Pharmaceutical Compliance Forum

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Sunshine Act

- Passed as part of Affordable Care Act
- Section 6002
- Sens. Grassley/Kohl key proponents

Basic Requirements

- Company must report “payment or other transfer of value” to “covered recipients”
  - physician or teaching hospital (or to other entity/individual at physician or teaching hospital’s request, OR ON THEIR BEHALF)

- Must report:
  - Name and address of recipient
  - Amount and form of payment
  - Nature of payment (14 categories)
  - Name of “covered” drug/device to which payment relates

- Information will be posted on the Internet, searchable, clear and understandable, easily aggregated, AND DOWNLOADABLE

Basic Requirements , cont.

- Includes a description of any enforcement actions taken
- Contains background information on industry-physician relationships
- Any other information “helpful to the average consumer”
- Opportunity to review and correct no less than 45 days prior to public posting; but no impact on public availability of information

Basic Requirements, cont.

- Exemptions from reporting certain items, e.g.,:
  - Payment of less than $10 (unless aggregate payments exceed $100 in calendar year)
  - Discounts and rebates
  - Product samples; in-kind items for “charity care”
  - Educational materials that benefit or are used by patients
  - 90-day “trial period” for medical device
- Penalties for non-compliance:
  - Failure to report = $1,000 to $10,000 per payment not reported, with $150,000 cap
  - Knowing failure to report = $10,000 to $100,000 per payment not reported, with $1,000,000 cap
- Delayed publication of payments for R&D or clinical trials until REPORTING PERIOD AFTER date of approval or four years after payment

Implementation Timeline

- First report due: **March 31, 2013**, with annual reports thereafter
- Report based on data from preceding calendar year (so 2013 report based on **2012 payments**)
- By **October 1, 2011**, HHS must establish procedures for manufacturers' submission of information and HHS' publication of information, as well as definition of terms
  - In establishing procedures, HHS required by statute to consult with OIG, manufacturers, consumers and other interested parties
  - HHS mechanism for meeting these obligations likely will be a proposed rule published for comment

Preemption

- After January 1, 2012, federal law preempts “any statute or regulation of a State or of a political subdivision of a State that requires [a manufacturer] to disclose or report, in any format, the type of information … regarding such payment or transfer of value.”

- Not preempted:
  - Requirement to disclose information “not of the type required to be disclosed” under federal law;
  - Requirement to disclose information exempted from federal disclosures (except payment of less than $10, unless aggregate payments exceed $100 in calendar year)
  - Requirement to disclose information by any person or entity other than covered manufacturer or covered recipient
  - Requirement to disclose information to federal, state or local authority for public health surveillance or as part of oversight or investigation

Current Activities

- March 24 CMS Open Door Forum
- Stakeholder Comments
- Proposed Rules?
- Final rule by end of 2011?

Open Questions (for starters…)

- What definitions – beyond those in statute – will be promulgated regarding substance and format of required disclosures?
- WHAT WILL BE THE SCOPE OF THE REQUIREMENTS FOR CLINICAL TRIAL PAYMENTS, WHEN LUMP SUM PAYMENTS MAY BE MADE TO CROs OR TO INSTITUTIONS?
- Impact on physicians and health care providers?
  - -interactions with companies
  - -interactions with patients/patient care
- Impact on clinical research?
- Open meetings/exhibit halls?

Open Questions (for starters…)

- What additional information will be provided on federal website to put payments into context?
- What additional information may be required?
  - Regulatory or statutory?
- Unintended consequences when payments are posted?
- Disclosures by others?
  - Sen. Grassley urging voluntary disclosure by disease and medical advocacy groups
    - American Diabetes Association disclosures
- Media and public scrutiny
  - ProPublica

Questions?

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