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Physician Payment Sunshine Act – A Brief Summary

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Basic Requirements:



- Company must report “payment or other transfer of value” to 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
 - Name of drug/device to which payment relates
- Information will be posted on searchable and downloadable website

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 the first reporting period after the date of product 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 or guidance 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 [required to be disclosed under federal law] 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

Open Questions (for starters...)



- What part of HHS will be responsible for implementation, including drafting proposed rule, consulting with stakeholders, and administering website?
- What definitions – beyond those in statute – will be promulgated regarding substance and format of required disclosures?
- Appropriate disclosure/allocation of clinical trial payments, e.g., payments made to CRO's or institutions?
- Scope of preemption?
- What additional information will be provided on federal website to put payments into context?
- Unintended consequences when payments are posted?