



PRAXIS
management
international, llc.

Physician Payments Sunshine Act of 2009

Summary of the Proposed Act

August 15, 2009



Use of This Presentation

- The Physician Payments Sunshine Act is currently under consideration by the Congress. The Act (if passed) will directly impact business processes and information systems of pharmaceutical, medical device and biologics companies
- This presentation summarizes the current contents of the Act. Individuals and companies should use the information in this presentation only after completing their own review of the legislation and any proposed regulations.
- This Presentation (presentation) is being provided by Praxis Management International, LLC (Praxis) for the "fair use" by you, the User, as that term is defined under the U.S. Copyright Laws. All other use, reproduction or re-transmission in any form or by any means, electronic or mechanical, including photocopying and recording, or by any information storage or retrieval system, without prior written permission from Praxis is prohibited. ©2009 Praxis Management International, LLC. All rights reserved.



What is the Sunshine Act?

- An amendment to title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.
- Effort by Senators Chuck Grassley (Iowa) and Herb Kohl (Wisconsin) to achieve public disclosure of financial relationships between physicians and the drug, device and biologic industry.



Senator's Comments

- Grassley
 - “Shedding light on industry payments to physicians would be good for the system,” Grassley said. “Transparency fosters accountability, and the public has a right to know about financial relationships.”
- Kohl
 - “Since we first introduced the bill, there has been a groundswell of support from every corner. Patients want to know that they can fully trust the relationship they have with their doctor.”



Summary of the Act

- Requires pharmaceutical, medical device and biologics companies to report payments to physicians annually
- Requires companies to report physician ownership interests in their companies outside of publicly traded securities
- Preempts existing state laws with the same information requirements. Does not preempt new state requirements.
- Penalties for non-compliance
- Information to be posted to a public web site



Who is Covered

- Any applicable manufacturer that provides a payment or other transfer of value to a covered recipient
 - Applicable manufacturer means
 - Manufacturer of a covered drug, device, biological, or medical supply
 - Covered recipient means
 - A physician
 - A physician medical practice
 - A physician group practice



What Must Be Reported?

- The name of the covered recipient
- The business address of the covered recipient and Medicare billing number of the covered recipient (if applicable)
- The value of the payment or other transfer of value.
- The dates on which the payment or other transfer of value was provided to the covered recipient.
- A description of the form of the payment or other transfer of value, indicated as
 - cash or a cash equivalent;
 - in-kind items or services;
 - stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
 - any other form of payment or other transfer of value (as defined by the Secretary).



What Must Be Reported (cont'd)

A description of the nature of the payment or other transfer of value including:

- consulting fees
- compensation for services other than consulting
- honoraria
- gift
- entertainment
- food
- travel
- education
- research
- charitable contribution
- royalty or license
- current or prospective ownership or investment interest
- compensation for serving as faculty or as a speaker for a continuing medical education program
- grant
- any other nature of the payment or other transfer of value (as defined by the Secretary)



What Must Be Reported (cont'd)

- If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.
- Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.



Aggregate Reporting

- Information submitted shall include the aggregate amount of all payments or other transfers of value provided by the applicable manufacturer to covered recipients (and to entities or individuals at the request of or designated on behalf of a covered recipient) during the preceding year.



When and How to Report

- Annual Reporting
 - Due to the Secretary of Health and Human Services annually starting March 31, 2011
 - Reports in any such electronic form as the Secretary shall require



Physician Ownership Reporting

- Applicable manufacturer or applicable group purchasing organization shall submit the following information regarding any ownership or investment interest (*other than an ownership or investment interest in a publicly traded security and mutual fund*) held by a physician (*or an immediate family member of such physician*) in the applicable manufacturer or applicable group purchasing organization



Physician Ownership Reporting Requirements

- The dollar amount invested by each physician holding such an ownership or investment interest.
- The value and terms of each such ownership or investment interest.
- Any payment or other transfer of value provided to a physician holding such an ownership or investment interest
- Any other information regarding the ownership or investment interest the Secretary determines appropriate.



Penalties for Non-Compliance

- Civil money penalty of
 - not less than \$1,000, but not more than \$10,000,
 - for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection
- The total amount of civil money penalties imposed with respect to each annual submission of information shall not exceed \$150,000.



Penalties for Failure to Report

- Failure to submit information required in a timely manner in accordance with rules or regulations shall be subject to a civil money penalty of
 - not less than \$10,000, but not more than \$100,000, for each payment
 - The total amount of civil money penalties imposed shall not exceed \$1,000,000



Knowing Failure to Report

- Knowingly failing to submit information in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than \$10,000, but not more than \$100,000, for each payment
- The total amount of civil money penalties imposed with respect to each annual submission of information shall not exceed \$1,000,000.



Information Must be Posted

The Secretary must post submitted information to an internet site that:

- is searchable and is in a format that is clear and understandable;
- contains information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment and the name of the covered drug, device, biological, or medical supply;
- **contains information that is able to be easily aggregated and downloaded;**
- **contains a description of any enforcement actions taken, including any penalties imposed during the preceding year;**
- **contains background information on industry-physician relationships;**
- **contains any other information the Secretary determines would be helpful to the average consumer; and**
- **provides the covered recipient an opportunity to submit corrections to the information made available to the public with respect to the covered recipient.**



State Laws

- Effective on January 1, 2010, subject to subparagraph (B), the 26 provisions of this section shall preempt any law or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer (as defined in subsection (g)) to disclose or report information (as described in subsection (a)) regarding a payment or other transfer of value provided by the applicable manufacturer 30 to a covered recipient (as so described).
- **NO PREEMPTION OF ADDITIONAL REQUIREMENTS.**—Subparagraph (A) shall not preempt any law or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information not required to be disclosed or reported under this section.