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About PricewaterhouseCoopers

PricewaterhouseCoopers' Global Pharmaceutical and Life Sciences Industry Group (www.pwc.com/pharma) is dedicated to delivering effective solutions to the complex strategic, operational, and financial challenges facing pharmaceutical and life sciences companies. We provide industry-focused assurance, tax, and advisory services to build public trust and enhance value for our clients and their stakeholders. We draw on the knowledge and skills of more than 155,000 people in 153 countries from across our network to share their thinking, experience, and solutions to develop fresh perspectives and practical advice.

Use compliance to increase competitive advantage

The proposed legislation presents manufacturers an opportunity to do more than just implement the basic systems, processes, and controls to achieve compliance. Physician payment reporting is generally reactive and typically viewed by the industry as an administrative burden required to meet regulations. Few companies have actually created a sustainable, enterprise-wide infrastructure that would enable them to have insight into total aggregate spend for all providers and physician practices on an ongoing basis, and even fewer use that information to drive business value. Linking compliance and business operations will drive additional value to the business in the form of improved customer insight and performance metrics.

To integrate compliance into business strategy and drive business value, companies should consider the following actions:

- **Promote a corporate vision for transparency:** Establish a strategy and vision for what transparency can mean to the organization and how it can provide a competitive advantage both from an internal and external stakeholder perspective. Develop a phased roadmap of initiatives (quick wins, short-term, near-term, and longer-term) necessary to achieve the objectives and benefits outlined in an enterprise-wide transparency vision, including process improvement, data integration, technology enablement, and actionable reporting.

- **Streamline and standardize:** Consider aggregate spend in light of other performance improvement initiatives focused on finance effectiveness, healthcare compliance, FCPA, sales and marketing cost reduction, R&D efficiency, corporate reporting and analytics, or IT and data management initiatives. Begin to streamline and standardize end-to-end procure-to-pay and fee-for-service processes across the organization (e.g., advisory boards, speakers bureaus, service agreements); incorporate compliance, privacy, security, and controls; and assess opportunities to improve these processes and functions via technology.

- **Implement proactive monitoring and actionable analytics:** Build and maintain an enterprise-wide framework for transparent monitoring, reporting, and analysis using key performance indicators (KPIs) and dashboards to detect and prevent issues and provide insight and awareness of customer engagement and total spend.

To invest wisely, companies should not undertake this exercise myopically just for the sake of compliance. To drive value to the business with this investment, companies should strongly consider seizing the opportunity to establish a global, integrated, transparent system that will deliver the associated benefits of risk mitigation, cost reduction, efficiency, effectiveness, corporate integrity, and positive public perception. A strategically integrated system for transparency also will provide actionable insight for better business decision making, resource allocation, and avoidance of conflicts of interest.

KnowledgeLine*
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Physician Sunshine Act: Building Value Through Transparency

The life sciences industry should brace for a wave of intensified public scrutiny. Consistent with the transparency theme embraced by the new Obama Administration, a revised Physician Payments Sunshine bill (S. 301) has been introduced in the Senate. The bill places stricter and tougher requirements on the industry to openly share information with the public about its financial investments in, and gifts to, healthcare professionals. These requirements will have sweeping operational and financial impact while simultaneously raising the bar for corporate compliance efforts. For an industry actively seeking to improve its image with consumers, regulators, and other key stakeholders, this bill presents an opportunity to take a major step toward strengthening its relationships and reputation.

Reintroduced January 22, 2009, by Senators Chuck Grassley, R-Iowa, and Herb Kohl, D-Wisconsin, the bill would require drug, device, biological, and medical supply companies to disclose their financial relationships with physicians. Each company's detailed spend information would appear in a national, publicly available registry operated by the Health and Human Services (HHS) secretary.

The proposed legislation's objective is clear: to enhance compliance with applicable laws, regulations, and industry guidelines while discouraging the perception of inappropriate financial influence. The revised bill brings the concept of transparency to the forefront and puts the industry on notice that identifiable (manufacturer and physician) and detailed payment information will be accessible to the average consumer, Congress, the press, state governments, consumer advocates, and other interested parties. With the Obama

administration and Democratic Congress focused on implementing sweeping changes to the US healthcare system, including better transparency, cost reduction, health information technology, personalized medicine, and public health programs, there is significant momentum behind the bill.

Subsequent to the initial release of this bill, many leading industry organizations, including Pharmaceutical Research and Manufacturers of America (PhRMA), American Medical Association (AMA), and AdvaMed, voiced their support for appropriate disclosure and a national reporting standard. Many pharmaceutical and medical device manufacturers also support the transparency initiative. The industry's support of the standard does not necessarily equate to full support of the bill and, as such, it will be important to continue to monitor reaction to the proposed legislation as it progresses through Congress. Despite broad support for its intent, the bill raises critical questions: How will this information be used? How will this information influence public perception? How will it impact reputations of manufacturers, physicians, and medical institutions?

Revised bill strengthens accountability requirements

The recently introduced Physician Payments Sunshine bill contains significant revisions to the original September 2007 Senate bill. Changes include:

- **Broader applicability across the industry:** The revised bill requires more companies to report payments to individual healthcare professionals. The original Senate bill applied to large pharmaceutical, device, and medical supply companies with annual gross revenues of $100 million or more. The current proposal expands disclosure requirements to apply to any manufacturer of a covered drug, device, biologic, or medical supply, regardless of size or revenue. In addition, the revised language also requires applicable group purchasing organizations (GPOs) to disclose physician ownership interests and payments.

- **Additional payment disclosures:** In the current version of the bill, companies would be required to report payments that exceed an aggregate of $100 provided to a physician, physician medical practice, physician group practice, or an entity or individual at the request of or on behalf of a physician. The original Senate bill excluded payments or other transfers of value made for general funding of a clinical trial. Now payments made in connection with the development of a new product or in connection with a clinical investigation are reportable. In addition to previous payment disclosures required for consulting fees, compensation for services, honoraria, gifts, food, entertainment, travel, and education, the revised bill includes disclosure of current or prospective ownership and investment interest, grants, charitable contributions, royalties, and licenses.

- **New payment exemptions:** The revised bill exempts the following types of payments: educational materials intended for patient use, the loan of devices for short-term trial periods, and items or services covered under contractual warranty. As they were under the original bill, product samples and transfers of any value to a physician who is a patient also are exempt. The aggregate financial trigger increased from $25 to $100 per calendar year.

- **Additional reporting attributes:** Companies would still be required to report the physician's name, address, and the value, date, and description of the payment, using a standard list of payment types. In addition, if the recipient is a physician, the revised bill proposes including the specialty, Medicare billing number, and form of payment (e.g., cash, service, stock, dividend, profit). If the payment is related to marketing, education, or research specific to a covered product, the name of the product must also be disclosed. When a physician has ownership interest in the manufacturer or GPO (outside of a publicly traded security or mutual fund), additional information related to the amount invested, value and terms of the investment, and description of all applicable payments to the covered recipient are required.

- **Adjusted reporting timeline:** The bill adjusts the reporting timeline from quarterly to annual. Manufacturers must submit their first aggregate reports electronically March 31, 2011, and include all applicable payments or transfers of value provided during the preceding calendar year. The bill, however, does allow for delayed reporting to protect a manufacturer's proprietary information. Payments related to clinical trial investigations and product development may be delayed until the first reporting period after FDA approval or clearance or two calendar years after the date of payment, whichever occurs first.

- **Significantly stronger penalties:** The bill revises penalties for non-compliance from fines of $10,000 to $100,000 per instance of failure to report, with no annual cap, to fines of up to $10,000 for each payment, transfer of value, or ownership/investment interest not reported in a timely manner and in accordance with the rules and regulations (with an annual cap of $150,000). In addition, the fine for knowingly failing to report is set at $10,000 to $100,000 for each instance, not to exceed $1 million annually. Penalties imposed would be posted on the public website and included in annual reports to Congress.

HHS expected to issue compliance procedures by November 1, 2009

The HHS secretary will issue detailed procedures for manufacturer submission and public access to this information no later than November 1, 2009. Details include:

- **Public availability:** The manufacturer reports submitted to the secretary will be made accessible to the public through a searchable and downloadable Internet site. The goal is to display detailed information, including:
  - Name of the manufacturer or GPO
  - Name, address, and specialty of the physician recipient
  - Value, date, nature of the payment
  - Enforcement actions taken
  - Background information on industry-physician relationships
  - Separately listed information related to funding for clinical research

The secretary will provide a report to Congress each year summarizing manufacturers' information and any enforcement actions and will submit to the states a summary report of information about covered recipients within their borders.

- **Impact to state laws:** To date, several states, including Minnesota, Vermont, Maine, West Virginia, Nevada, California, the District of Columbia, and, most recently, Massachusetts have enacted similar physician sunshine laws setting limits on industry payments to physicians and/or requiring disclosure of payments. The revised Senate bill suggests preempting any law or regulation of a state that requires manufacturers to disclose or report information covered under the Federal Physicians Payment Sunshine Act. However, the bill does not preempt additional or stricter state disclosure or reporting requirements.

- **Extended considerations:** Grassley and Kohl are also considering MedPAC's recommendation to extend industry reporting requirements to include payments to medical organizations, hospitals, pharmacy benefit managers, pharmacists, pharmacies, continuing medical education groups, and medical schools.

What manufacturers need to do now

A majority of manufacturers have already taken steps to address individual state reporting requirements. Many have implemented short-term, semi-automated solutions resulting in manually intensive, cumbersome processes to gather, consolidate, validate, and report total physician spend from disparate systems. Most of the data that is required to be reported (e.g., gifts, meals, entertainment, consulting fees, honoraria, travel expenses), is either manually captured, duplicated in multiple systems and needing to be reconciled, and/or resident in stand-alone applications or data repositories across the organization.

Although manufacturers have begun to make good strides in bridging the gaps in information and data exchange across sales and marketing functions, a large portion of higher-value payments originate from outside the commercial organization and reside in separate systems and contracts within various other functions, such as medical affairs, finance, legal, and research and development (e.g., scientific advisory board payments, contractual agreements, continuing medical education, and clinical trial spend). Complicating these efforts, manufacturers also find it challenging to obtain and manage relevant financial data from third-party vendors.

The effort to gather and align the data to individual healthcare professionals often proves difficult because each business unit usually has a separate profile for the same physician. Few companies have achieved the ideal state of an enterprise-wide customer master system to match profiles and establish a unique healthcare provider ID across business functions. In addition, more stringent reporting requirements require an understanding of organizational hierarchy and affiliations among healthcare providers—as in physician group practices, among providers and institutions, and between institutions themselves.

These challenges, and the proposed federal requirements, will prompt companies to expand their compliance efforts by taking the following steps:

- **Current state assessment:** Transition from reporting spend on healthcare providers in several states to national aggregated reporting of payments to all healthcare providers, physician practices, and potentially institutions is a major undertaking. Manufacturers should begin to address this challenge with an assessment of the impact of the Physician Payments Sunshine requirements and how they differ from existing state requirements. The assessment should identify necessary changes and additions to current interpretation, processes, organization, data integration, supporting applications, reporting, communication, and training.

- **Data access, integration, and reporting:** Map the new required payment types (e.g., clinical investigation payments, ownership and investment interest, and grants) to existing data sources and applications to define the best strategy for extracting and aligning the data to report total aggregate healthcare provider spend. In many cases this new information is captured manually or embedded in contracts contained in legacy applications or those from which the information is not easily extracted.

- **Customer master enhancements:** Assess existing customer master repositories and determine a phased strategy to establish a single consistent view of the customer across the company via a consolidated unique physician profile with additional required attributes (e.g., Medicare billing number) and cross-references to various business units, applications, and customer affiliations (organization, prescriber, institution, nonprescriber).