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## Potential for New Federal Device Price Reporting Requirements

### *New Bill Could Significantly Affect Commercial Landscape/ Compliance Obligations of Device Manufacturers*

Pending legislation proposes a federal price reporting requirement on implantable medical devices that could prove to be extremely complicated and costly to device manufacturers. Presented below are a summary of the bill, our thoughts on some of its commercial and operational implications, and our analysis of the likelihood of its passage into law.

#### Background

On October 23, Senators Charles Grassley (R-IA) and Arlen Specter (R-PA) introduced the Transparency in Medical Device Pricing Act of 2007 (S. 2221 or “the Act”). The Act would require that device manufacturers report to the Centers for Medicare and Medicaid Services (“CMS”) the average and median sales prices of their implantable medical devices every quarter. These data would be posted on a publicly accessible website.

Covered medical devices include the implanted device itself and may reach tools or other devices used in the implantation of the primary device. The “average sales price” of a device is defined as a manufacturer’s total sales in the quarter (except to those purchasers that the Secretary of the Department of Health and Human Services (“HHS”) determines are appropriate to exclude), net of most discounts and price concessions, divided by the number of units sold in the quarter. The “median sales price” is defined as the median of all sales in the quarter, net of most discounts or price concessions, excluding sales to those purchasers the Secretary of HHS determines are appropriate to exclude.

Failure to accurately report the average prices or certain other data (regarding the procedure in which the implantable device is used) could result in the imposition of civil money penalties ranging from \$10,000 to \$100,000 per occurrence. The Act calls for reporting to

For more information, contact:

**Edward Basile**  
(202) 626-2903  
ebasile@kslaw.com

**John Bentivoglio**  
(202) 626-5591  
jbentivoglio@kslaw.com

**Laura Loeb**  
(202) 661-7836  
lloeb@kslaw.com

**John Shakow**  
(202) 661-5523  
jshakow@kslaw.com

**Beverly Lorell, M.D.**  
(202) 383-8937  
blorell@kslaw.com

**Anna Weinstein**  
(202) 661-7973  
aweinstein@kslaw.com

**King & Spalding**  
**Washington, DC**  
1700 Pennsylvania Avenue, NW  
Washington, DC 20006-4706  
Tel: (202) 737-0500  
Fax: (202) 626-3737

[www.kslaw.com](http://www.kslaw.com)



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begin with the first quarter of 2009 (initial reports would be due by April 30, 2009).

### Commercial Implications

Price transparency of device implants is likely to have at least three practical commercial consequences. First, many providers are likely to welcome implantable device pricing transparency as an adjunct to their purchasing negotiations. In contrast, there may be confusion about justified differences in prices of implants. Third, physician preference may play a lesser role in purchasing selection of implants.

*Pressure on providers.* It is helpful to think about the Act in the context of Congressional pressure for public disclosure of the prices hospitals charge and the rates that both federal and private payers actually pay for procedures and services. At a March 15, 2006 hearing held by the House Energy and Commerce Health Subcommittee, Representatives Dan Lipinski (D-Ill.) and Rahm Emanuel (D-Ill.) reviewed their separate bills (H.R. 3139 and H.R. 3546, respectively) that would require increased transparency of prices charged by hospitals and ambulatory surgical centers.<sup>1</sup> At least two public websites already publish the prices that hospitals charge for certain procedures and services.<sup>2</sup> Pricing for specific hospital services and procedures is already an important driver in a hospital's competition with other hospitals in its regional market. Thus, hospitals are operating in an environment of increasing pressure to disclose the prices they charge consumers and payers for procedures and services.

Increased transparency of device pricing might especially impact the hospital's purchasing costs of "high sticker price" device implants, allowing the hospital to reduce the publicly posted price charged for specific services and procedures that utilize the device and still maintain a favorable operating margin for that service. In this context, where the hospital's own pricing will be in the spotlight, hospital administrators will look closely at all opportunities to drive down purchasing costs and to negotiate purchasing prices based on market-based pricing information. Hospitals have reported to Senator Specter that implantable devices, for example, represent close to 40% of their expenditures.<sup>3</sup> Clearly these reports influenced Senator Specter's support of S. 2221.

*Confusion about justified differences in prices of implants.* Price transparency may lead to confusion about justified differences in price of certain implants with different features, making it more difficult for the high end seller and perhaps creating an advantage for the low end product. Publicly available average prices could lead to improper substitution of cost for quality as the principal determinant of a device's value and quality. In addition, many Class III significant risk devices—particularly those which are implantable and/or have electronic components—are highly complex and require repetitive technical training and

<sup>1</sup> Hearing held March 15, 2006, by The House Energy and Commerce Health Subcommittee, entitled, "What's the Cost: Proposals to Provide Consumers with Better Information About Healthcare Service Costs."

<sup>2</sup> [www.orpricepoint.org](http://www.orpricepoint.org), a site administered by the Oregon Association of Hospital and Health Systems. Also, The State of California Hospital Chargemaster Program (HID) which was developed in response to AB 1045 (Chapter 532, Statutes of 2005) that amended AB 1627 (Chapter 582, Statutes of 2003).

<sup>3</sup> Senator Specter's statement on the Senate Floor, October 23, 2007, is accessible at:

[http://specter.senate.gov/public/index.cfm?FuseAction=NewsRoom.ArlenSpecterSpeaks&ContentRecord\\_id=cf655dfb-1321-0e36-bab2-05c5b6002908&Region\\_id=&Issue\\_id=](http://specter.senate.gov/public/index.cfm?FuseAction=NewsRoom.ArlenSpecterSpeaks&ContentRecord_id=cf655dfb-1321-0e36-bab2-05c5b6002908&Region_id=&Issue_id=)



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education about the product by company personnel who are expert in technical aspects of the device. The safe and effective use of such implants by health care personnel depends in part on these sophisticated technical support and educational services. Currently, these services are usually not an extra charge but are expected to accompany the purchase of the implant. Thus, the price negotiated for an implant and the price that a hospital may be willing to pay may relate not only to the characteristics of the device itself but also to the expertise, reliability, and accessibility of the support services provided for the product and the users of the device.

Devices have different life cycles than do pharmaceuticals, making average price reporting and commercial transparency within a product class less appropriate and potentially damaging to device manufacturers. Unlike a drug or biologic, medical devices undergo multiple iterative changes during the commercial product life cycle. Certain medical devices may have a competitive advantage, and enjoy higher pricing because of favorable design features that permit ease of the addition of enhancements or connectivity with future product accessories. As an example, in today's environment of rapidly changing electronic medical record systems, certain electronic device implants may have advantages related to ease of the adaptation with hospital or office-based electronic record systems. Thus, many types of seemingly similar device implants are not identical exchangeable commodities and a manufacturer's price offering may relate to a favorable match with unique and specific needs of the specific hospital or physician purchaser.

*A lesser role for physician preference.* A separate practical aspect of S. 2221 is that the traditional role of physicians in purchasing decisions is likely to diminish and pricing will play a greater role. The traditional role that physicians play in purchasing decisions of device implants differs from the issue of physician preferences for drugs. Surgeons and interventional physicians may preferentially select specific implants or products from specific implant manufacturers based on the physician's familiarity with hands-on physical use and manipulation of the implant as well as its technical attributes and quality. For this reason, physicians play an important role in hospital purchasing decisions of implantable surgical and interventional devices, such as pacemakers, implantable cardiac defibrillators, orthopedic implants, neuromedical implants, and vascular stents.

However, in some instances, physician-preferred purchasing decisions have the potential to be impacted by other relationships between the manufacturer and/or the hospital, including the company's support of center-of-excellence grants, continuing medical education (CME) grants, or opportunities to participate in clinical investigations and consultant positions. The complexity of such commercial relationships between device manufacturers, hospitals, and physicians has recently been described as a "love triangle" by Robert Burns, professor of health-care systems at the Wharton School.<sup>4</sup> Similar to device pricing, the financial relationships between device and drug manufacturers and physicians are now an area of Congressional scrutiny and proposed legislation.<sup>5</sup>

<sup>4</sup> The Philadelphia Inquirer. November 20, 2007.

<sup>5</sup> On September 6, 2007, Senator Charles Grassley (R-IA) and Senator Herbert Kohl (D-WI) introduced The Physicians Payments Sunshine Act of 2007 (S. 2029)The bill is accessible at:  
<http://www.senate.gov/~finance/press/Gpress/2007/prg090607d.pdf>



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### Operational and Compliance Challenges

For the first time, manufacturers of devices would be forced by the Act to identify, manipulate and report complex pricing data to CMS. The pharmaceutical industry has been confronting these types of requirements for many years, so it is appropriate to look to the drug industry for insight. Five issues stand out:

- First, device manufacturers will likely have to develop and implement robust standard operating procedures to satisfy the price reporting requirements of S. 2221. Furthermore, they will likely have to invest in price and discount tracking computer systems and in training and personnel to perform the calculations. In 2005 a mid-size generic drug manufacturer named King Pharmaceuticals paid \$124 million to settle allegations *not* that it had intentionally misreported its products' pricing data, but that it had negligently failed to have adequate systems, training and processes in place to accurately calculate its reported prices. It would not be surprising if CMS held the device industry to the same rigorous standard.
- Second, assuming the HHS Secretary exercises his option to exclude certain types of purchasers from the calculations (presumably to encourage greater discounting to those purchasers), device manufacturers will have to develop and adopt class of trade tracking systems that will allow them to accurately identify and filter the appropriate sales by customer type. This will undoubtedly include tracking beyond the wholesaler level, and may prove complicated and contentious. Currently, there is no provision for separate averages or medians to be reported for different classes of purchasers (*e.g.*, hospitals or outpatient clinics), but one could see the potential for such a requirement and all its attendant complexities.
- Third, device manufacturers will have to have the capability to track every price concession to the ultimate purchaser, and to be able to identify the proper quarter in which the "sale" took place. This can be difficult if the direct sale, indirect sale, chargeback and rebate payment all happen in different quarters. The Act permits CMS to develop a methodology to deal with lagged price concessions (like the 12 month rolling averages in the drug world for Average Sales Price and Average Manufacturer Price); perhaps something similar will be adopted for devices if the Act becomes law.
- Fourth, the Act is silent as to the treatment of bundled sales. Where price concessions for one product are triggered by the purchase of another, how will this cross-subsidization be treated under a device price reporting regime? For drugs, the discount is allocated proportionally across all the drugs in the bundle before average or best prices are calculated. The same may be required of devices.
- Fifth, other issues are percolating in the drug price reporting world that may be implicated for devices by S. 2221. For instance, the identification of true service fees and how they are to be treated differently than normal price concessions; the definition of fair market value in identifying excludable service fees; the treatment of returns, free products and replacement goods; how



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discounts made available to the patient (not the provider) are to be accounted for; and finally, the possibility of a certification requirement as is now required for all drug reports.

Any of these issues could present significant operational compliance challenges for device manufacturers.

### **Status of the Bill**

Activity related to S. 2221 has been gaining momentum in Congress over the past week. Senator Grassley is making a strong effort to attach the bill to the Medicare “physician fix” package that is slated to be marked up by the Senate Finance Committee this week, but we understand he is having a difficult time. At present, the situation is very fluid.

### **Conclusion**

The Act presents numerous very significant commercial, operational and regulatory concerns for manufacturers of implantable devices. Manufacturers should very closely monitor the status of S. 2221 as it moves through the legislative process. Should it become law, there will be opportunities to influence the nature and scope of its implementing regulations. In the meantime, manufacturers would be well advised to take an inventory of the effects passage of this legislation would have on their business and compliance functions, and be prepared to engage legislators and regulators accordingly.

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If you have any questions or concerns relating to these or any other medical device regulation or price reporting issues, please contact any of us on the King & Spalding team for assistance.

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