BERKELEY CENTER
FOR HEALTH TECHNOLOGY

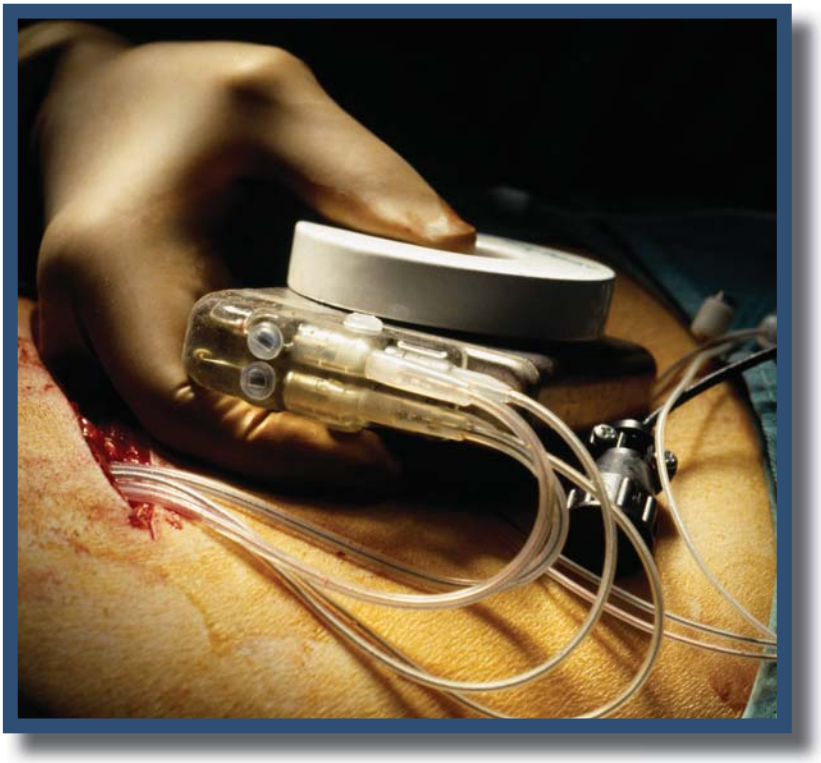
Issue Brief

Confidentiality and Transparency in Medical Device Prices: Market Dynamics and Policy Alternatives

The larger context for the debate over price transparency for device prices is the rising cost of health care, the hospitals' desire to forge closer relationships with the surgeons who practice in their facilities but who often have consulting contracts with device manufacturers, and the trend towards increased transparency in a health care system that places ever more responsibility onto individual consumers for choosing cost-effective treatment.

Hospital and medical device manufacturers are embroiled in an acrimonious debate over the hospitals' right to compare prices charged to other hospitals before purchasing artificial knee and hip joints, spine surgery components, coronary stents, implantable defibrillators and other high-cost surgical devices. The debate has spilled over into the courts, with two lawsuits against data intermediaries that work with hospitals to benchmark supply costs, and into Congress, where legislation mandating price disclosure by device firms was proposed in 2007 but ultimately not enacted.

In the lawsuits, which precipitated the proposed federal legislation, Boston Scientific (then Guidant) brought claims against two data intermediaries alleging that they had misappropriated Guidant's trade secrets and interfered in its contractual relationships with hospitals. The legal claims were based on the



intermediaries' generation of comparative price information using prices disclosed to them by their hospital clients in violation of the hospitals' purchasing contracts with Guidant, which contained confidentiality clauses. Because both cases settled out of court before any decision was reached over the merits of Guidant's trade secret claims, a cloud now hangs over price benchmarking for MediCal devices, and intermediaries have been reluctant to provide comparative information.

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This Issue Brief describes the dynamics of the market for medical devices and the controversy over price confidentiality and then analyzes alternative management and policy responses. It considers the merits of federal legislation that would mandate price disclosure and concludes that there are more effective ways to promote transparency in the device market.

Implantable Devices in the Health Care Marketplace

In their efforts to manage the cost of the care they provide, hospitals have a strong interest in comparing medical device prices across hospitals and manufacturers and discussing these prices with their affiliated physicians in order to negotiate favorable rates. Conversely, manufacturers of these devices prefer to keep prices confidential so as to limit comparison shopping by hospitals, preferring that physicians make device selections without regard to price. Despite their interest in price transparency, many hospitals have signed confidentiality agreements with device manufacturers that prohibit them from disclosing prices to any third party, including independent (e.g., non-employed) physicians, insurers, and patients. However, confidentiality clauses are most directly targeted at hospitals' desires to disclose device prices to intermediary entities engaged in comparing data across device manufacturers and hospitals. To the extent that hospitals cannot provide price data to these intermediaries, the intermediaries cannot develop benchmarks to evaluate the performance of particular hospitals relative to their peers.

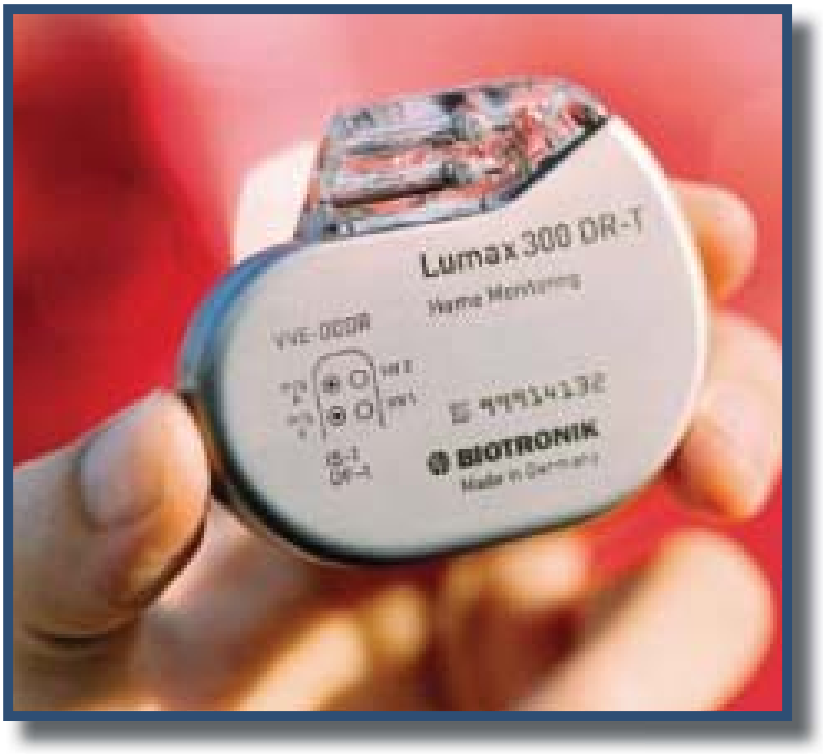
Price confidentiality clauses have been inserted into purchasing contracts by device firms often without the explicit knowledge of senior hospital leadership (e.g., they can be printed on the bottom of a purchasing invoice that is signed by a hospital

clerk who has no understanding of the larger issues). Historically, these have not been enforced, but in recent years, hospitals have become more aggressive in seeking to reduce the rate of growth in medical device prices by comparing their rates with those charged to other hospitals locally and across the nation.

Device firms have sought to prevent this price comparison by enforcing pricing confidentiality clauses, but rather than sue the hospitals who actually sign (consciously or inadvertently) these clauses, they have focused their attention on data intermediaries that provide price benchmarking, as the Guidant litigation demonstrated.

Some hospitals and hospital systems in California, such as St. Joseph of Orange, have consciously removed price confidentiality clauses from all of their purchasing contracts with medical device firms. Some public hospitals, such as those owned by the University of California, question the enforceability of the clauses since their contracts are subject to freedom of information and other disclosure requests from the public. Most hospitals in California, however, continue to have confidentiality clauses in at least some of their medical device purchasing contracts.

Hospital executives express concern that efforts to delete these clauses and move towards more aggressive negotiation of device prices will result in countervailing pressures from surgeons, who have close personal ties with device firms. In the contemporary environment of competition between physicians and hospitals for ownership of ambulatory surgery centers, diagnostic testing centers, and short-stay orthopedic and cardiac facilities, traditional hospitals are more reluctant than ever to alienate their surgical staffs. Most surgeons tend to use devices developed by one particular manufacturer, often due to having trained in a hospital that used that vendor's products, and are reluctant to switch vendors and learn to use another set of instruments and implants. Many also have consulting contracts with device manufacturers that provide substantial payments. Their loyalties are thus divided between hospitals and manufacturers, and it is often not clear that the hospitals are favored. These payments have received substantial scrutiny in recent years from the media, from federal and state regulators and legislators, and from the U.S. Department of Justice, as they are seen as a potential inducement for surgeons to use particular brands of devices (similar to the issues raised with respect to pharmaceutical payments in exchange for physician prescription of particular drugs). To the extent that different surgeons in the same hospital have affinities with different device vendors, which typically is the case, it is difficult for the hospital to obtain volume discounts by consolidating its purchases from particular vendors.



Strategies for Resolving the Problems Posed by Device Price Confidentiality

Hospital Initiatives: Refusal to Sign Confidentiality Clauses

Price confidentiality clauses exert a chilling effect on hospitals' ability to work with data intermediaries to evaluate relative prices, and to work with their affiliated surgeons to improve the efficiency of orthopedic and cardiac service lines. The most straightforward solution to this problem is for hospitals to refuse to sign these clauses and to insist that they be removed from invoices and other documentation of the purchasing process. As hospital executives have become more aware of the existence and effects of these clauses, some have done just that. Moreover, the topic of medical device price transparency has been the subject of considerable discussion among individual hospitals and at meetings of health sector associations in California and elsewhere. While antitrust concerns limit hospitals from cooperating directly with one another to change contracting practice, these discussions have raised the level of understanding among senior hospital executives concerning medical device prices, the issues of confidentiality and transparency, and their interaction with strategic goals such as improved collaboration with physicians and improved efficiency in surgical service lines.

The 'just say no' strategy for resolving the challenge of device price confidentiality is difficult for hospitals in contexts where device manufacturers push back hard in negotiation and indirectly encourage surgeons to demand that hospital purchasing departments not risk a contractual termination that would require the surgeons to switch device vendors (and, potentially, consulting arrangements). Nevertheless, it is the best solution to the problem— one that allows hospitals to retain confidentiality of their prices if they wish (it does not mandate disclosure, but permits it), while letting others disclose their prices to physicians and data intermediaries if they so desire. It is likely to impose lower administrative costs than any legislative or regulatory initiative mandating disclosure. Rejection of confidentiality clauses symbolizes a hospital's assertion of its right to use its data as it sees fit and, in particular, to share price data with affiliated surgeons.

Legislative Initiatives: Non-Enforceability of Price Confidentiality Contracts

Rather than revquiring device makers to disclose average price information, which the federal legislation proposed in 2007 would do, legislation could be enacted at the state level declaring void any provision in a device sales contract that limits

communication concerning the price of devices between hospitals and their patients, affiliated physicians, or third-party advisors. Statutory limits on private bargaining are a common policy lever for preventing the enforcement of contractual provisions that operate in restraint of trade, or that otherwise contravene the public's interest. Some examples include state statutes that make noncompete agreements in most employment contracts void as a matter of law and, more directly relevant to the health care context, statutes that declare void so-called gag clauses in managed care agreements between HMOs and providers that limit the information providers can share with patients concerning treatment options and reimbursement.

A statutory nullification of contractual promises by hospitals to keep device prices secret would lift the legal cloud that now hangs over intermediaries that deliver comparative price information to hospitals. While no hospital would be required by such a statute to reveal its prices to any third party, those seeing an advantage in sharing prices with physicians or data intermediaries could do so without exposing themselves or any third party to legal liability. A shift in regulatory focus from mandatory to permissive disclosure also would avoid the administrative costs of compliance with a legislative mandate for price disclosure.

Conclusion: Enhancing Efficiency Through Transparency

The debate over confidentiality and transparency of pricing for implantable medical devices ultimately needs to be understood within a larger framework where performance comparisons, mutual learning, and continual process improvement represent the way off the path of rising cost and decreasing access. Hospitals are engaged in benchmarking their performance against that of their peers, not only in terms of clinical quality but also in terms of supply prices and financial sustainability. Eliminating barriers to sharing cost and quality information with their affiliated physicians, who are responsible for the important decisions of where to admit their patients, which procedures to perform, and which devices to use, is an important component. Such a change would facilitate a more balanced relationship between medical device firms, hospitals and surgeons to improve both the devices themselves and the entire course of care. Hospitals, physicians, and device manufacturers should foster a culture of cooperation that permits them to continually rethink and redesign their processes in light of changing technological opportunities.

The acrimonious debate and litigation over device price disclosure have served to fragment rather than coordinate the surgical service lines. Public policy has a role to play both in the immediate context, by limiting the enforceability of confidentiality clauses, and in the larger context, by promoting the values of transparency throughout the health care system. Price data on implantable devices are only one form of performance data, but efforts to promote transparency in this one domain can have symbolic as well as practical effects in promoting transparency throughout the health care system.

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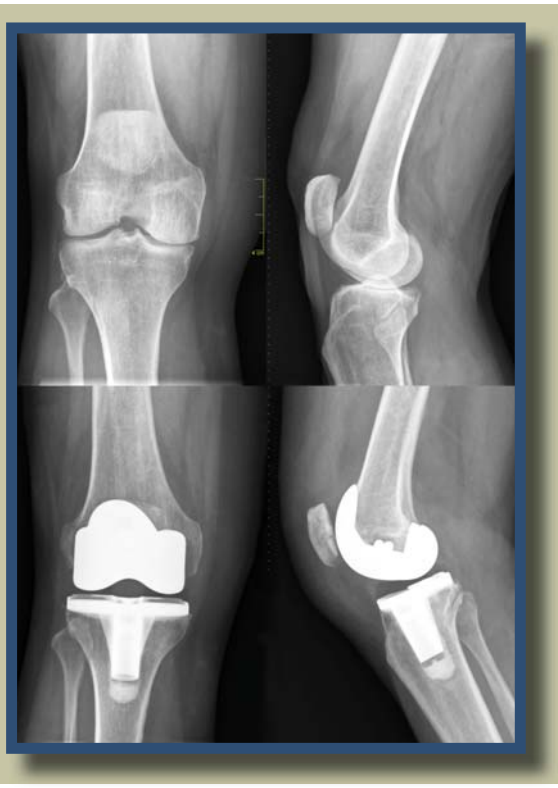

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