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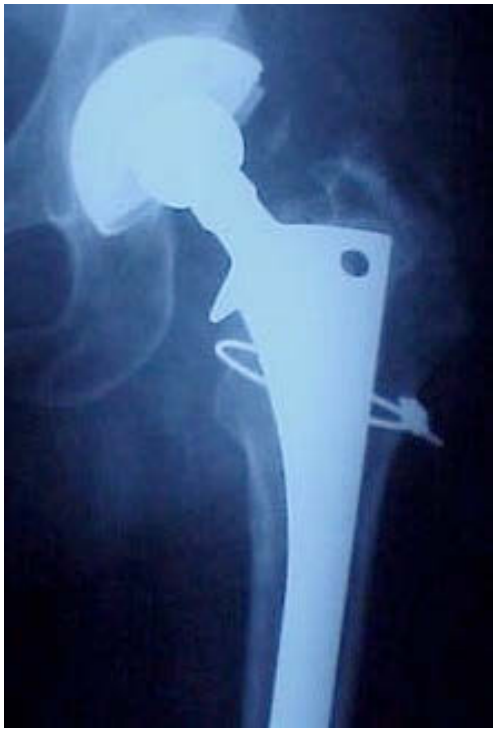
CONFIDENTIALITY AND TRANSPARENCY FOR MEDICAL DEVICE PRICES:

MARKET DYNAMICS AND POLICY ALTERNATIVES



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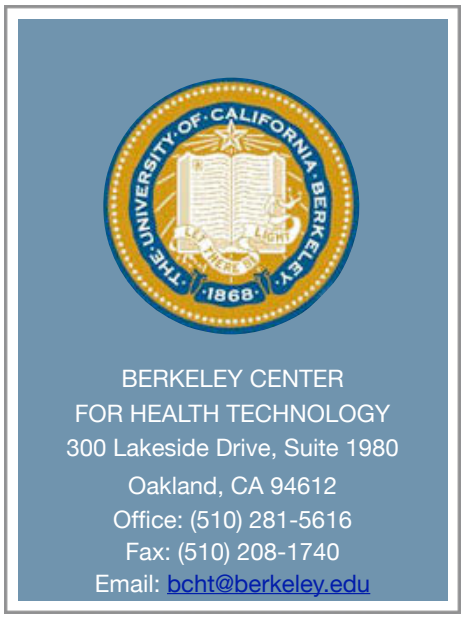

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Executive Summary

Hospitals 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 on 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.

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.

This report 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 requiring 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 non-compete 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.

Hospitals 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, and into Congress, where legislation was proposed in 2007 that would have mandated price disclosure by device firms. The larger context for the debate over price transparency in the device market 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.

This report 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

Implantable medical devices offer great clinical benefits to many patients, and are particularly salient in cardiology and orthopedics. The costs of devices are rising much faster than are hospital reimbursement rates, as new devices come with substantially higher prices than those they replace. Between 1996 and 2007, for example, the cost of orthopedic hip replacement implants rose from 29% to 63% of the Medicare hospital DRG reimbursement.[1] This narrowing gap between revenues and costs is particularly important to hospitals because, traditionally, the device-intensive orthopedic and cardiac

service lines have been profitable and used by hospitals to subsidize care for Medicaid beneficiaries and uninsured patients. As for any business, costs outpacing revenues is unsustainable.

For Medicare patients, hospitals are paid a fixed per-admission rate and must absorb device price increases. For commercially insured patients, most hospitals in California 'carve out' device costs from their per-day and per-admission rates and bill these as a supplemental fee-for-service charge to insurers. These costs are then passed on by the insurers to employers through premium increases and to individual enrollees through coinsurance and deductibles. Uninsured patients are at financial risk for the full price of the device, as well as other components of care, though they often lack the resources to pay and the costs of their care are absorbed by the hospital as bad debt.

The importance of medical devices and their costs extends beyond immediate impacts on hospital, insurer, and consumer finances to interact with the larger drivers of health care cost growth. The complex business relationship between doctors and hospitals -- physicians typically are neither employees nor owners of these institutions but, rather, independent businesspeople who use hospital facilities (and inputs such as implantable devices) without financial responsibility – results in fragmentation rather than coordination of responsibility for cost and quality. The inattention to device costs on the part of the physicians who make the most important financial decisions (e.g., which patient will get which procedure and which implant) limits the ability of the delivery system to enter into a virtuous cycle of process analysis, improvement, and cost reduction.

Price Confidentiality Clauses for Medical Devices

Hospitals have a strong interest in comparing medical device prices and the prices they pay for all other supplies across both manufacturers and hospitals and discussing these prices with their affiliated physicians, but, paradoxically, many have signed agreements with device manufacturers containing price confidentiality clauses. These clauses prohibit a hospital from disclosing to any third party the prices it pays for devices; third parties include independent (e.g., non-employed) physicians, insurers, group purchasing organizations, and patients. However, confidentiality clauses are most directly targeted at hospitals' desires to disclose device prices to consultants and other entities engaged in comparing data across device manufacturers and hospitals. Examples of these intermediary entities include Aspen Healthcare Metrics, ECRI Institute, and Orthopedic Network News. To the extent that hospitals cannot provide price data to these intermediaries, the intermediaries cannot develop price benchmarks to evaluate the performance of particular hospitals relative to their peers.

Price confidentiality clauses are not uncommon in non-health industries and are often an unremarked part of a buyer-seller relationship. In health care they are 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 clauses 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, relying on pricing benchmark data from intermediaries. 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) the clauses, they have focused their attention on data intermediaries. As will be discussed below, this attention has led to two high-profile legal cases and subsequently to proposed federal

legislation, which in turn has generated a debate over the costs and benefits of regulatory solutions to what is best described as a market contracting problem.

The issue of medical device price confidentiality highlights the conflicting interests that impede efficiency within the contemporary health care delivery system. On the one hand, hospitals have clear managerial and strategic interests in being able to compare device prices and to discuss these comparisons with the surgeons who make device choices for each particular patient. On the other hand, many hospitals have signed confidentiality clauses that, if enforced, would prevent them from doing exactly that. 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 financial and personal ties to device firms. At the heart of the hospital's market dilemma is its dependency on physicians for patient volume, as it is usually the surgeon who chooses where to operate and where to admit patients. Relationships between hospitals and surgeons have historically been difficult due to this organizational and financial fissure at the heart of the clinical enterprise. 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 surgery facilities, traditional hospitals are more reluctant than ever to alienate their surgical staffs.

Further complicating this difficult situation is the fact that many surgeons have consulting contracts with medical device manufacturers that provide substantial payments in exchange for an often vaguely characterized set of services. 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 often is the case, the hospital cannot obtain volume discounts by consolidating its purchases from particular vendors.

It should be noted that not all hospitals in California object to confidentiality for medical device prices. Some facilities that have close collaborative relationships with their surgeons believe that they are able to obtain the best prices and performance guarantees from device manufacturers because the physicians and the hospital speak with one voice and are willing to shift volume from one vendor to another in exchange for better terms. Although their claims of savings are difficult to verify in an environment of price secrecy, these facilities believe they have achieved lower device prices as a result of their investment in close physician relationships. They do not favor price disclosure because they assume this could lead to other hospitals demanding similarly low prices from device vendors, who then might be reluctant to offer such a significant discount to the more integrated physician-hospital systems. Needless to say, some delivery systems are better placed than others to have their physicians and hospitals 'speak with one voice' with respect to medical device pricing and other matters.

Litigation over Medical Device Price Confidentiality

In an effort to crack down on the sharing of price information in violation of its contracts with hospitals, device maker Boston Scientific (then the Guidant Corporation) brought legal claims beginning in 2004 against two intermediaries that were offering hospitals access to comparative price data. Guidant initiated the first lawsuit against Aspen Healthcare Metrics in federal district court in Minnesota. Aspen had been advising its hospital clients in supply purchasing decisions by comparing the pricing in each hospital client's contracts with pricing obtained by other Aspen clients. In its complaint against Aspen, Guidant asserted trade secret protection under the Minnesota Uniform Trade Secrets Act for its prices and other contract terms. In addition to the trade secrets claim, Guidant alleged that Aspen engaged in interference with its contractual relationships of confidentiality with hospitals.

The second suit was initiated by ECRI Institute in federal district court in Pennsylvania. ECRI, a non-profit research center that publishes an online benchmarking database for medical supplies, filed the suit in response to cease-and-desist letters in which Guidant claimed that ECRI was misappropriating its trade secrets by publishing prices paid by hospitals for cardiac rhythm management devices. Along with prices paid for Guidant's devices, hospitals subscribing to ECRI's database periodically submitted their prices for hundreds of other supplies, from latex gloves to coronary stents, seeking to compare them with low and average prices paid by similarly situated hospitals. ECRI sought a declaration from the court that its publication of low and average prices paid for Guidant's devices did not constitute a misappropriation of trade secrets. In response, Guidant filed counterclaims against ECRI under Pennsylvania trade secret and tort law that paralleled the claims they had filed against Aspen.

Both Aspen and ECRI urged the courts to hold that the prices hospitals pay for Guidant's devices are not eligible for statutory protection as trade secrets as a matter of law. The courts declined to do so, however, concluding that disputed factual questions remained concerning the actual secrecy of the

information in question. Both suits settled on confidential terms before trial, leaving the merits of Guidant's trade secret claims unsettled. In the Aspen case, the court granted Guidant's motion for summary judgment on the firm's claim of interference with confidentiality agreements.

Guidant's partial victory in its suit against Aspen and its demonstrated willingness to make demands of ECRI that were backed by an implicit threat of further litigation have produced a chilling effect on the collection and publication of comparative price information. As a result of the out-of-court settlements in both cases, intermediary providers of device price information now operate in a state of legal uncertainty. Also as a consequence of the litigation, hospitals have come to understand that their contractual promises of price confidentiality to device vendors are a potential source of liability not only for themselves, but also for the information providers on whom they have come to rely in their efforts to contain costs. The Guidant litigation has demonstrated that, through the operation of trade secret and tort law, hospitals' promises of confidentiality may become binding on third parties that have no contractual relationships with device manufacturers. Although no device vendor has ever sought to enforce a confidentiality clause directly against a hospital, the clauses are necessary elements of the legal claims that device vendors have pursued against information intermediaries.

Federal Legislative Initiatives to Mandate Device Price Disclosure

S. 2221, The Transparency in Medical Device Pricing Act

In 2007, Senators Charles Grassley and Arlen Specter proposed an amendment to the Social Security Act called the Transparency in Medical Device Pricing Act (TMDPA). The Senators presented the TMDPA as a policy intervention on behalf of hospitals and patients and as a legislative solution to the

growing problem of price secrecy in the device market. Senator Grassley described the device market as one in which hospitals are at the mercy of device vendors, who use their bargaining leverage to condition the sale of devices on anticompetitive promises of price confidentiality. He asserted that passage of the bill "would go a long way toward ensuring that free market forces actually work" in negotiations between hospitals and device makers.

The draft legislation, which did not make it out of committee in the 110th Congress, requires device makers to report average and median sales prices, net of discounts, for all covered devices on a quarterly basis to the Secretary of Health and Human Services. Covered devices are defined as those for which payment is available through health insurance programs funded by the federal government. The bill further requires the Centers for Medicare and Medicaid Services (CMS) to maintain and publish the disclosed price data on their website. Under the proposed legislation, vendors failing to report or misrepresenting any of the required information to CMS are subject to fines of between $10,000 and $100,000 for each omission or misrepresentation.

The Debate over Mandated Disclosure

The introduction of the TMDPA has generated a vigorous debate among policy analysts on the administrative costs, limited usefulness, and potential unintended consequences of a disclosure mandate. While interesting and important for purposes of evaluating the merits of mandatory price disclosure, this discussion does not dispute the pernicious effects of confidentiality clauses on hospitals' abilities to reduce their supply costs, better coordinate with their surgeons, and thereby improve the efficiency of the care they provide. Rather, the policy literature can be interpreted as suggesting that mandated disclosure may be the wrong solution for a real problem.

The first and most obvious problem with mandates to disclose and periodically publish medical device prices is that this process will incur substantial administrative costs while offering only modest social benefits. The TMDPA would mandate disclosure of average and median prices, whereas particular hospitals are interested not only in price averages but also in the lowest prices available to similarly situated facilities. To be most useful, prices would need to be categorized according to the geographic location and size (in terms of number of procedures performed and devices purchased) of the purchasing hospitals. Moreover, devices are subject to frequent incremental design changes, which inevitably bring price increases, making price information difficult to compare over time. Data intermediaries such as those hired by hospitals to aid in price comparisons recognize these challenges and devote substantial effort to keeping their price data current, to categorizing them by hospital characteristics such as geography and size, and to making apples-to-apples rather than apples-to-oranges comparisons. The price data that would be published by CMS in response to a legislative mandate would have no organizational support to ensure timeliness and comparability. Device firms would have no incentive to make the manner in which prices are disclosed easy to interpret and compare. By way of analogy, the mandated disclosure of the amounts that orthopedic device manufacturers pay annually to individual surgeons, published on manufacturers' websites in response to a Department of Justice settlement agreement, provides raw dollar amounts that shed no light on the services performed by surgeons in exchange for the funds.

A more subtle criticism of mandated price disclosure is the potential for actually increasing rather than decreasing device prices. If the TMDPA were to become law, device manufacturers could see the average prices charged by their competitors and would know that competitors could see their average prices, as well. This might facilitate implicit collusion as manufacturers decline to quote prices to hospitals below those quoted by competitors.[2] [3] [4] The more detailed the price data that are disclosed (e.g., lowest as

well as average prices) under a mandatory disclosure regime, the more helpful the data to hospitals in their purchasing decisions, but also the more helpful to manufacturers in colluding implicitly with competitors. In some other industries, mandated price disclosure has been found to facilitate this form of implicit collusion. This might play out in the hospital sector to the extent that widely disclosed prices could lead medical device firms to become less willing to grant price discounts to hospitals with strong physician collaboration. The actual extent of the risk of increased collusion for medical device firms under the TMDPA's model of limited disclosure is unclear, however, for the reasons discussed above (average rather than minimum prices, no adjustment for geography and hospital size). Moreover, device manufacturers already collect information on prices charged by competitors by hiring consulting firms to survey hospital purchasing managers; it is unclear whether the additional information obtained consequent to mandated disclosure would further their ability to coordinate prices with competitors. It is telling that the most vociferous proponent of the argument that mandated disclosure would have an unintended price-increasing effect is the Advanced Medical Technology Association (Advamed), the lobbying association for medical device firms that devotes much of its activities to opposing Medicare and other policy initiatives that would limit increases in device prices and payments.[5]

On balance, it appears that the costs of mandated price disclosure, as outlined in the TMDPA, outweigh its benefits. The administrative costs would be meaningful while the value of the average price data would be limited, and ongoing disclosure might exert a dampening effect on price discounting in selected instances. More aggressive disclosure requirements that would lead to publication of the full range of prices rather than mere averages would be more informative and therefore more useful to hospitals, but they would also increase the costs of administration and may increase the risk of parallel pricing among competitors.

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 the 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. 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 such as the California Hospital Association (CHA), the Integrated Healthcare Association (IHA), the California Association of Health Plans (CAHP), the California Association of Physician Groups (CAPG), the American Association of Orthopedic Surgeons (AAOS), and the Healthcare Association of Southern California (HASC). While hospitals cannot cooperate directly with one another in changing contracts due to antitrust concerns, 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 the 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 negotiations and indirectly encourage surgeons to demand that the hospital purchasing department not risk a contractual termination that would require the surgeons to switch device vendors (and, potentially, consulting arrangements). Nevertheless, it

is a reasonable solution to the problem, one that permits hospitals to retain confidentiality of their prices if they wish (i.e., it does not mandate disclosure, but permits it), while allowing others to 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 because it avoids the need to monitor and enforce such mandates. More generally, rejection of confidentiality clauses symbolizes the hospital's assertion of its right to use its data as it sees fit and, in particular, to share price data with its affiliated surgeons.

Legislative Initiatives: Non-Enforceability of Price Confidentiality Contracts

Rather than requiring device makers to disclose price information (and CMS to keep track of it), 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, employees and affiliated physicians, or third-party legal or business advisors. Statutory limits on private bargaining are a common policy lever for preventing the formation or 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 non-compete agreements in most employment contracts void 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 were drafted to limit the information providers could share with patients concerning treatment options and reimbursement. By declaring such provisions void, policy makers in most states have exercised their power to permit speech in the public's interest, even where parties to a contract might otherwise agree between themselves to remain silent.

A statutory nullification of contractual promises by hospitals to keep device prices secret would lift the legal cloud that now hangs over intermediaries like Aspen and ECRI. Moreover, 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 deriving from a breach of secrecy. A shift in regulatory focus from mandatory to permissive disclosure would eliminate the TMDPA's ongoing costs of compliance and administration, and could neutralize the harmful effects of price confidentiality provisions in device contracts if the "just say no" strategy proves ineffective.

Conclusion: Enhancing Efficiency through Transparency

In most sectors of the economy, technological innovation reduces expenditures by improving productivity and efficiency. The health care system generally, and the orthopedic and cardiac surgery services specifically, are characterized by continual innovation in implantable devices (as well as in drugs, diagnostics, and other inputs) but suffer from rising expenditures and widespread evidence of inefficiency. The root problem is that the process of clinical care, at the level of the physician and hospital, is not structured to promote economic self-analysis and self-improvement. Health care features incomplete and non-integrated data, misaligned incentives, and a cultural war of all against all. Physicians, hospitals, and device manufacturers should be working together to develop ever more effective treatments and to diffuse these improvements across the system. Rather, we observe islands of excellence in an otherwise murky sea of mediocrity, inefficiency, hostility, and litigation.

The debate over confidentiality and transparency of pricing for implantable medical devices ultimately needs to be understood within this larger framework where performance comparisons, mutual

learning, and continual process improvement represent the way off the path of rising cost and decreasing access. Hospitals need to benchmark their performance against that of their peers, not only in terms of clinical quality but also in terms of supply prices and financial sustainability. They need to share these performance data with the physicians who are responsible for the important decisions of where to admit their patients, which procedures to perform, and which devices to use. Medical device firms need to work closely with 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 the light of changing technological opportunities.

The acrimonious debate and litigation over device price disclosures have served to fragment rather than coordinate surgical service lines. The obvious first step on the road back is for hospitals to renounce confidentiality clauses and assert their control over their own data, to be shared with intermediaries, physicians, and, as needed, with insurers and patients. 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 illuminate only one dimension of performance, 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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