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ANIMAL PROGRAMS IN ILLINOIS LONG-TERM CARE FACILITIES TWENTY YEARS LATER (1990-2010)

Robert J. Behling, University of St. Francis
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ABSTRACT

Many researchers have reported that animal programs are beneficial to the institutionalized elderly. This study is a follow-up of a 1990 exploratory and descriptive study of animal programs and animal assisted therapy in Illinois long-term care facilities. Data was collected using a self-administered questionnaire. The vast majority of facilities are favorable about animal programs requested by residents, friends and family of residents, staff, and organizations that provide such programs. Non-scheduled animal visits, scheduled animal visits, resident animals, and animal assisted therapy are occurring in approximately the same percentage of facilities in 2010 as in 1990. There was a significant increase in the number of requests from staff for animal programs. Animal programs continue to be perceived as having significant psychological and physical benefits for residents. There was a significant increase in the number of facilities that have formal policies and procedures for animal programs.

THE IMPACT OF HEALTHCARE REFORM ON THE MEDICAL DEVICE INDUSTRY: THE CASE OF MEDTRONICS INC.

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ABSTRACT

The Patient Protection and Affordable Care Act (PPACA) that was signed into law on March 23, 2010 and the Health Care and Education Affordability Reconciliation Act (HCEARA) that was signed into law on March 30, 2010 will have a significant impact on the healthcare system. In particular, these reforms include several provisions that, upon full implementation, will have positive and negative, direct and indirect, impacts on the medical device industry. Health associations played a significant role in shaping healthcare reform. Such associations will continue to lobby Congress for legislation that is in the best interest of their members. The goal of this paper is to examine the impact this change in health policy will have on the management of medical device organizations, specifically Medtronic Inc., and on the consequent delivery of healthcare services. Additionally, the role of healthcare associations in influencing health policy is examined by reviewing the legislative efforts of AdvaMed, the leading medical device trade association.

INTRODUCTION

The Patient Protection and Affordable Care Act (PPACA) that was signed into law on March 23, 2010 and the Health Care and Education Affordability Reconciliation Act (HCEARA) that was signed into law on March 30, 2010 (henceforth referred to as "healthcare reform" or "reform") will have a significant impact on the healthcare industry. In particular, these reforms include several provisions that, upon full implementation, will have positive and negative, direct and indirect, impacts on the medical device industry. These provisions include, among others: new industry fees, regulations pertaining to comparative effectiveness research, funding for medical device innovation, physician payments, fraud and abuse reforms, and reimbursement reforms. Health associations played a significant role in shaping the recent healthcare reform. AdvaMed, the leading medical device trade association, will continue to affect the future of health reform by lobbying for amendments and other changes that are in the interest of its members. The purpose of this paper is to examine the impact of this change in health policy on the management of medical device organizations, specifically Medtronic, Inc. (hence forth

referred to as "Medtronic") as a case study, and on the consequent delivery of health care services. The paper will begin with an overview of Medtronic as the basis for the case study of the impact of health reform. Next, the role AdvaMed will be reviewed related to influencing the policy-making process. The paper then discusses implications of health reform for the medical device industry and more specifically Medtronic, as a leading medical device manufacturer. Conclusions are then offered.

MEDTRONIC COMPANY OVERVIEW

Medtronic has successfully grown into a company with a $38 billion market cap. This growth has been achieved through internal research and development (R&D) and the acquisition of smaller device companies. With the development of new products and the acquisition of various companies, Medtronic has assembled a diverse product portfolio that should drive increasing revenues into the future. This diverse portfolio will also help shield it from concentrated risks (Datamonitor, 2010). Not only is Medtronic protected from concentrated risks due to its diverse product offerings, it is also extremely diversified geographically. Medtronic's sales are dispersed around the world and this provides a diversification of Medtronic's revenue streams. Issues in one or two geographic regions should not have a material impact on the overall performance of the company (Datamonitor, 2010). Medtronic's sheer size should allow it to aggressively compete with its competitors by taking advantage of economies of scale and bargaining power. Medtronic is also in a position to leverage its brand recognition to make new product offerings more efficient and profitable. Finally, Medtronic's size creates a significant barrier of entry for new competitors (Datamonitor, 2010). Medtronic is well positioned to continue its growth through new product launches and additional company acquisitions. The company has a financially strong position and should be able to capitalize on new treatment methods and the favorable demographic trends that appear to point toward increased healthcare utilization as the number of older American's who utilize the most healthcare resources continues to grow as well as recent reforms that provide for expanded benefits.

Although Medtronic appears to be well positioned, there are several challenges that it faces. Significant challenges are litigation, FDA warnings, the FDA 501k approval process, and product recalls. Medtronic currently has several open patent disputes. In addition, Medtronic recently suspended worldwide distribution of its Sprint Fidelis family of defibrillation leads, which the FDA subsequently classified as a Class I recall. Due to the issues with these leads, Medtronic is the plaintiff in approximately 3,700 lawsuits including 47 class action suits representing approximate 8,100 individuals who are claiming personal injury (Medtronic, Inc 2010). Obviously these events have the potential to significantly tarnish the Medtronic brand and negatively impact future sales. In addition to events that could tarnish Medtronic's image, there are several other potential challenges that could negatively impact Medtronic's profitability. Macro-economic conditions have a high probability of continued downward pressure on volume, which will most likely have a negative impact on revenue. In addition, the potential of persistent reductions in reimbursement rates will continue to impact Medtronic's profitability. In

addition to macro-economic conditions and reductions in reimbursement, the new excise tax (discussed below) will certainly put significant pressure on Medtronic's bottom line.

OVERVIEW OF ADVAMED

The Advance Medical Technology Association (AdvaMed) represents companies associated with the production of medical devices, diagnostic products, and health information systems. AdvaMed was formed in 1974 as the Health Industry Manufacturers Association (HIMA). In 2000, the association was renamed AdvaMed to reflect the association's goal as a medical device innovation industry. Currently, AdvaMed represents companies which produce 90% of health related technology in the U.S. and more than 50% globally. Its vision is to produce technologies, "that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments" (AdvaMed official website). Key issues which address member companies' interests (as taken from Advamed's official website) are: Product innovation; FDA approval; Medicare and reimbursement; International trade; Health care reform. The mission of AdvaMed is to provide legal and regulatory assistance to its members including the rapid approval of new products. It also provides opportunities for its members to sell their products in international markets.

HEALTHCARE REFORM AND IMPLICATIONS FOR MEDTRONIC

This section includes a discussion of reform provisions and their implications for the medical device industry with a focus on Medtronic. The reforms are grouped into four primary areas, including: financial, quality, fraud and abuse, and reimbursement reforms.

Financial - Industry Fees Section 1405 of the reform provides for a 2.3% tax on medical devices that will be levied on manufacturers, producers, and importers and effective March 2012. The tax applies to the initial lease of medical devices as well as for any lease over 90 days. The definition of a "taxable medical device" includes any device that is defined in Section 201(h) of the Federal Food, Drug and Cosmetic Act and is intended for human use. A limited number of medical devices, including eyeglasses, contact lenses, and hearing aids, as determined by the Centers for Medicare and Medicaid Services (CMS), are exempted from this fee under a "retail exception." Unlike the pharmaceutical fee, the medical device fee will be tax deductible and applies to all manufactures, regardless of size or revenue levels (Werling, 2010).

Financial - Physician Payment Sunshine Act. To enforce transparency, section 1128(g) includes revisions to the Physician Payment Sunshine Act. Beginning March 13, 2013, and on the 90th day of each calendar year thereafter, payments or transfers of value including consulting fees, payments for clinical trial participation, charitable donations, royalties, and a variety of payments that may be made to physicians and teaching hospitals must be reported in electronic form to the Secretary of Health and Human Services (HHS) (Werling, 2010). The start date for recording such payments is January 1, 2012.

Financial - Payment for Expanded Coverage. The primary purpose of the health reform was to expand coverage to a broader range of patients in the U.S. In part, the reform

accomplishes this expansion through section 2001 that provides for a significant broadening of the eligibility criteria for enrollment in Medicaid. Specifically, the Medicaid expansion enables most individuals with incomes below133% of the Federal Poverty Level to enroll in the Medicaid program. Additionally, the mandatory insurance requirement and broader availability of health insurance through Health Benefit Exchanges will help to ensure that there are more patients that have access to health care. Increases in access to care may result in a positive short-term impact on some device manufacturers, as a result of the increased demand for medical services (Werling, Carnell, & McCormick, 2010). However, there will also be increased costs associated with this expansion due to moral hazard. It is unclear as to how Congress will address these increased costs. One possibility includes decreased provider reimbursements in the future, which will ultimately result in a negative impact for medical device manufacturers in the long-run. In response to these decreased reimbursements, hospitals will in turn attempt to minimize their own losses by forcing medical device companies to absorb the brunt of the increased costs, thereby increasing their cost of doing business.

Quality - Comparative Effectiveness Research. Section EC.399H laid the groundwork for future inclusion of comparative effectiveness measures that CMS will use potentially in the future on making payment decisions. A new independent entity, called the Patient Centered Outcomes Research Institute (PCORI) will be established to study the effectiveness of various products, and will issue reports regarding their effectiveness. The reports will be peer-reviewed to assess scientific integrity and will be screened for conflicts of interest and bias. Initially, CMS will not be directly reliant on these reports, but it can be anticipated that in the future, they will have a major impact on the decision-making of third-party payers when it comes to reimbursement and coverage decisions (Werling, Carnell, & McCormick, 2010).

Quality - Funding for Medical Device Innovation. Section 9023A of the reform includes funding for grant monies to encourage medical device innovation. The grant program is called the Cures Acceleration Network, and it enables the Director of the National Institutes of Health (NIH) to award grants in order to promote innovation in technology supporting advanced research, development, and production of so-called 'high need cures', including through the development of medical products (Werling, Carnell, & McCormick, 2010). In order to receive grant monies, an entity must submit an application containing detailed information about the project for which the entity is seeking the grant, contribute nonfederal funds to the project in the amount of $1 for every $3 awarded under the grant, and must also issue a final report at the end of the project describing the project outcomes (Werling, Carnell, & McCormick, 2010). The single award maximum is $244,479.25 with a maximum of $5 million per company (Daghlian, 2010). In addition to the grant program, the PPACA has authorized the Qualifying Therapeutic Discovery Project, which will grant a tax credit for any taxable year in the amount equal to 50% of the investment in any qualifying project. Alternatively, grants may be provided in lieu of tax credits for investment in a qualifying project in the amount of 50% of the investment, as long as the investment is made in a taxable year beginning in 2009 or 2010 (Werling, Carnell, and McCormick, 2010).

Fraud and Abuse - Stark Law Self-Disclosure Protocol. Under Section 6409, the Stark Law is amended to include a self-disclosure protocol. This statute "prohibits physicians from

referring Medicare patients for certain designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship—unless an exception applies. It also prohibits an entity from presenting or causing to be presented a bill or claim to anyone for a designated health service furnished as a result of a prohibited referral" (referred to as "self-referrals") (CMS, 2009). The reform calls for HHS and the Office of the Inspector General to develop a self-disclosure protocol within six months of the passage of the law that will allow suppliers or providers to disclose "actual or potential" violations. Additionally, the reform allows the Secretary of HHS to reduce penalties based on the type and degree of offense. Penalty reductions are also based on the cooperation of potential violators, timeliness of disclosure, and extent of the violation. The Secretary of HHS is required under the law to report on the protocols effectiveness 18 months after its creation. *Regardless of intent*, violations incur significant financial penalties that range from nonpayment to $15,000 in civil penalties and $100,000 in civil monetary penalties for each violation. Under the law, unintended technical mistakes are subject to the financial penalties (Stark Law, n.d.).

Fraud and Abuse - Medicare and Medicaid Anti-kickback Statue. Section 6402 of the health reform bill relaxes the element of "intent" in the Anti-Kickback Statue (AKS) and allows for an anti-kickback violation to serve as the basis for a False Claim (False Claim will be discussed in detail in the following section). The AKS "makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program" (e.g. Medicare and Medicaid) (CMS, 2009) . In regards to intent, the reform states that a person does not have to be familiar with the law or intend to commit fraudulent activity to be prosecuted. Formerly, the statue centered on an individual's intent to commit fraudulent activity. The second reform allows anti-kickback violations to serve as a basis for false claims. Under the reformed AKS, a referral violation constitutes a false claim, which is subject to financial penalties above the AKS penalties (Gilchrist, 2010). Individuals can be fined up to $25,000 or charged with a felony and serve up to five years for violating the statue. If convicted or suspect, providers can be prohibited from participating in federal healthcare programs. Civil damages of up to $50,000 per violation can also result (American Health Lawyers Association, n.d.). The statue provides for exceptions referred to as "safe harbors" that and are free from civil or criminal prosecution. Safe harbors are business and financial arrangements that operate within explicitly define and very strict parameters in an effort to reduce corruption that would otherwise violate the statue and include but are not limited to: "investment interests; space rental; equipment rental; personal services and management contracts; sale of practice; referral services; warranties; discounts; employees; and group purchasing organizations" (American Health Lawyers Association, n.d.).

Fraud and Abuse - False Claims Act: Public Disclosure Bar. Section 10104(j)(2) of the reform amends the Public Disclosure Bar False Claims Act (FCA) by allowing individuals typically within the organization (referred to as "relators" or also known as "whistle blowers") to use public information to make a claim and participate in the prosecution of an entity suspect of violating FCA. The reform changes what information is considered publically disclosed. Relators can bring allegations forward based on state and private proceedings and do not have to have direct knowledge; instead they are only required to bring information forward that helps

federal prosecution. Typically, relators receive a percentage of what is recovered for bringing the allegations forward under the qui tam provision (Davidson, 2010).

Reimbursement - Disproportionate Share Hospital (DSH) Payments. As a result of healthcare reform, hospitals will see Medicare and Medicaid DSH reimbursement drastically reduced by an estimated $35.7 billion dollars (see chart 4 below) (Horne LLP, n.d.). DSH payments were instituted as a means of compensating hospitals that had a disproportionate share of uninsured patients or low income patients. These payments often allowed hospitals to remain operational financially by offsetting the cost associated with providing care to uninsured or low income patients (U.S Department of HHS, n.d.). The rationale for reducing DSH payments is that hospitals will see an increase in the number of insured patients and decrease in uncompensated care. Overall, hospital budgets will be calibrating to reduced federal payments to states for uncompensated care for uninsured or low-income populations.

Reimbursement - Gain-sharing Demonstration Projects. Section 3027 extends the Medicare Physician- Hospital Gain-sharing Demonstration Projects. These projects seek to evaluate various physician-hospital arrangements with the goal of reducing costs and improving the efficiency and quality of care with the use of financial incentives (i.e., gain-sharing). Under antifraud and abuse laws, hospitals are prevented from sharing cost savings with physicians; however, the Act allows such arrangements under the supervision of the Secretary of HHS via the demonstration projects. The projects provide for physician- hospital gain-sharing as the result of reduced Medicare costs that result from collaboration and system improvements. Gain-sharing serves as a method to align physician and hospital incentives and induces each party to make operational, financial and/or procedural changes that result in improved quality and efficiency. Additionally, the Act monitors quality and efficiency and requires participating hospitals to report quality performance data based on performance standards established by CMS. The Act prevents excessive physician reimbursement and discriminating referral practices by physicians (e.g. referring healthy patients to the participating hospital and sicker patients to a neighboring hospital) (CMS, n.d.). Such demonstration projects have lead to support for the creation of Medicare Shared Saving Programs.

Reimbursement - Shared Savings Programs and Accountable Care Organizations. Section 3022 provides for the creation of a CMS Shared Savings Programs (SSP) by January 2012 in which CMS will share savings related to a specific Medicare population with providers. Accountable Care Organizations (ACOs) will also serve as the avenue for the implementation of the SSP and the basis for provider coordination. ACOs are intended to knit health care providers together to coordinate the care continuum, control costs (related to Medicare Parts A and B), and provide quality care for a specific Medicare population. Such organizations must meet eligibility criteria established by CMS that are drawn in part from the Physician Group Practice (PDP) Demonstration Project (established by the Medicare, Medicaid, SCHIP Benefits Improvement Act of 2000). ACO eligibility requirements include, but are not limited to; participation for a minimum of three years, the inclusion of primary care physicians, consist of a Medicare patient population of at least 5, 000 (this would require at least 10 primary care physicians), be patient centered, engage in evidence-based medicine, and report on quality and cost measures. ACOs will receive oversight from the Secretary of HHS. Through greater coordination and

accountability and attention to patient needs, ACOs are expected to see their efforts translate into cost savings through enhanced processes and integrated infrastructure (Ronning, 2010).

CONCLUSION

This paper has discussed the impact health policy has on the management of medical device organizations, specifically Medtronic, and the delivery of health care services. Throughout the discussion, AdvaMed's influence on the policy-making process was reviewed and discussed. The paper reveals that health associations, such as AdvaMed, play a major role in shaping health reform. While only a sample of health reform sections were reviewed, the direct and indirect impact of reform on Medtronic and its stakeholders appears to be unfavorable. In order to mitigate the impact of reform, Medtronic and AdvaMed will need to continue aggressive Congressional lobbying efforts to shape future legislation and reforms to ensure favorable benefits accrue to Medtronic and the industry.

References available on request

A METHODOLOGY FOR BENCHMARKING HOSPITAL MALPRACTICE PERFORMANCE

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ABSTRACT

Malpractice is a serious concern in the provision of healthcare. This study examines an aspect of healthcare outcomes represented by the malpractice claims experience of hospitals. Malpractice claims are thought to be associated with reduced access, diminished quality, and increased costs in healthcare.

No widespread measure or benchmark of comparative hospital medical malpractice claims performance has heretofore been developed in the healthcare administration literature. Providing a quantitative risk-adjusted measure, and a quantitative peer based data-driven comparative benchmark for this aspect of hospital quality are important and innovative tools in the study of healthcare services.

This study: (a) develops a theoretical model that explores the structure, process and outcomes relationship between hospital boards of directors, hospital management, and hospital malpractice claims performance; (b) develops a methodology for measuring hospital medical malpractice claims performance; (c) determines the existing risk adjusted malpractice claims performance levels of the subject hospitals; (d) determines an achievable benchmark standard of risk adjusted malpractice claims performance-based on the performance of peer hospitals; (e) and examines selected hospital characteristics that were believed to be significant in predicting hospital performance for correlation with the RAMPS measure developed in this study to determine if they provide convergent validity to the measure and benchmark developed herein.

Given the current and historical importance of patient safety, the development of quantifiable outcome indicators of health care quality are not only welcome additions to existing knowledge, but necessary implements in the pursuit of improved health care quality (Van der Bij and Vissers, 1999). To date, no widespread measure of hospital medical malpractice claims performance, or benchmark of comparative hospital medical malpractice claims performance, has been developed in the health care administration literature. Providing a quantitative risk-adjusted measure, and a quantitative peer based data-driven comparative benchmark for this aspect of hospital quality, is an important and innovative tool in the study of health care outcomes and performance. Such a measure and benchmark can provide valuable information to hospital managers in their efforts to attain organizational goals.

RESEARCH QUESTIONS & METHODOLOGY

Because not-for-profit hospital boards are more responsive to their external environment, they are less likely to exploit consumers for profit due to both incentives and constraints, and are

more likely to be concerned with reputation and perceptions of quality (Schlesinger, Quon, Wynia, Cummins and Gray, 2005).

Do hospitals that report not-for-profit ownership status experience lower RAMPS?

Hypothesis 1a: Hospitals that that report not-for-profit ownership status will experience lower RAMPS.

Do hospitals that report for-profit ownership status experience higher RAMPS?

Hypothesis 1b: Hospitals that that report for-profit ownership status will experience higher RAMPS.

Resource-based theory maintains that professional employee assets are a source of competitive advantage because their professional knowledge and inter-personal working relationships are difficult to imitate. Resources are valuable when they enable an organization to employ strategies that improve its efficiency or effectiveness (Mukamel, Zwanziger and Bamezai, 2002).

Do hospitals that report greater adjusted full-time equivalent (FTE) registered nurse staffing experience lower RAMPS?

Hypothesis 2a: Hospitals that that report greater registered nurse FTEs, adjusted for average daily census, will experience lower RAMPS.

Do teaching hospitals experience lower RAMPS?

Hypothesis 2b: Teaching hospitals will experience lower RAMPS.

Do larger hospitals, as measured by hospital bed size, experience lower RAMPS?

Hypothesis 2c: Larger hospitals will experience lower RAMPS.

The primary outcome indicator for this study is the frequency of malpractice claims, postulated herein as the number of closed medical malpractice claims filed against a sample of Florida hospitals in the year 2000.

The sample was 119 hospitals (48.57% of the population of general medical and surgical hospitals in 2000), and within the sample hospitals, 756 closed medical professional liability claims (57.62% of the reported 2000 Florida closed claims).

DISCUSSION

This study developed a quantitative (in contrast to qualitative) method of measuring hospital medical malpractice claims performance, the Risk Adjusted Malpractice Performance

Score (RAMPS), which may be used by hospitals to benchmark internal performance, and also enables benchmark comparisons with other hospitals.

After controlling for case mix, bed size, teaching status, and control type, the basic model suggests that larger hospitals, as indicated by bed size, were associated with a lower RAMPS, with lower scores indicating better performance than higher scores. The greatest variation in the RAMPS was found in smaller hospitals as represented by bed size codes for 25 to 49 and 50 to 99 total beds respectively. The smallest bed size category had the largest variation within its group, the highest mean RAMPS, and also the largest individual hospital RAMPS. Once hospital beds exceeded one hundred, the variation of the RAMPS between hospitals decreased notably, as did the overall mean RAMPS for these hospitals.

For-profit ownership status was associated with a higher RAMPS, indicating poorer performance than the other ownership types (government and nonprofit control). Eldenburg and Krishnan concluded "in for-profit hospitals, expenditures on administration are associated with greater revenues. However, there is a negative association between excess income margins and expenditures on administration and accounting. This suggests that these expenditures increase costs to a greater extent than they increase revenues. Thus, for-profit hospitals appear to be ineffective in their use of accounting and administration resources to improve profitability." (2003). It seems plausible that excess spending on administration at the cost of quality of care could be reflected in a poorer outcomes performance for a hospital, and consequently these outcomes may inspire an increase in malpractice claims against the hospital. Other hospital characteristics (e.g., full-time equivalent registered nurse staffing levels, nonprofit control, and teaching status) were not found to be statistically significant.

CONCLUSION

This study makes several contributions to the literature and to the knowledge base of health care administration and management scholars. The study's results corroborated the idea that there was heterogeneity between the malpractice claims performance of the subject hospitals. The study established a scientifically-based methodology for the measurement and benchmarking of hospital malpractice claims performance, and utilized a multivariate regression analysis to provide cross-validation of the RAMPS with predictors of hospital performance from previous studies. Further research is needed to better explain the characteristics of these variations. The study results do give a plausible explanation for the underlying resource-based view assumption that hospitals possess distinct characteristics and capabilities and that further studies of the relationship between hospital characteristics and outcomes is warranted.

The overall implication for theory and practice is that the resource-based view theory of competitive advantage and firm performance was found to have application to the study of hospital performance and outcomes. While not empirically confirmed by the results of this study, stewardship theory is an underpinning of managerial accountability concepts and remains a principal legal basis in judging the performance of hospital boards and management.