Should Ambulatory Surgery Centers in California Require State Licensing?

By

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A Thesis Submitted to the Department of Public Policy and Administration
School of Business and Public Administration
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In Partial Fulfillment for the Degree of
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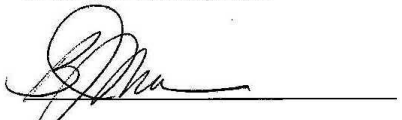

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We accomplish nothing without education. Future generations and the success of our country depend on our knowledge of history, government, economics, and ethics.

Each professor at California State University, Bakersfield instills this knowledge and challenges students to see all possibilities, as it relates to rational thinking and allows one to move forward without reinventing the wheel. The professors encourage all students to explore and exceed their potential. And, it is through their wisdom that the student is guided to the path of success.

Similarly, the physicians and staff at Millennium Surgery Center strive for health care excellence when caring for every patient, family member, and each other. The team demonstrates a commitment to compassion and quality every day. Their professional respect and personal support for all members is inspiring.

Most importantly, in this journey through life and the quest for truth, come family and friends. I embrace the positive criticism from parents and the poignant lessons gleaned from children compel me to embrace passionately of all that I have learned. Not to be forgotten is the person who stood by, and at times, carried this student through the process as editor in chief.

"Don't ask what the world needs. Ask what makes you come alive, and go do it. Because what the world needs is people who have come alive." ~ Howard Thurman. Each person who has touched my life throughout the past two years is credited for making me the person I am today. I am eternally grateful for all of you.

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Executive Summary

For the past four years, the State of California has been divided. The California Medical Board has maintained jurisdiction over physicians for decades. Since 2007, the role of the California Medical Board has expanded to oversee physician-owned ambulatory surgery centers as well. The California Department of Public Health regulates ambulatory surgery centers with no physician ownership. Thus, California has a split in the authority pertaining to the ambulatory surgery center industry.

The California Department of Public Health will license facilities under its jurisdiction. No other facilities can become state licensed. This is a disparity in the system. The California Medical Board, on the other hand, allows accreditation of physician-owned ambulatory surgery centers. The Medical Board authorizes four different agencies with as many sets of standards to credential the physician-owned facilities. This represents another contradiction in the California system. Finally, the Centers for Medicare and Medicaid Services require certification of all ambulatory surgery centers that treat Medicare beneficiaries, with no distinction of ownership, representing yet another set of standards. Further complicating the situation, the Centers for Medicare and Medicaid Services granted specific accreditation agencies the power to deem ambulatory surgery centers meet the federal regulations for treating Medicare recipients.

All agencies and stakeholders have one goal, to protect the health and safety of individuals seeking treatment in ambulatory surgery centers. The need for simplification and conformity appears obvious, as the efficiencies would add much needed value and transparency to the complex and confusing healthcare system.

Chapter One

The Significance of Ambulatory Surgery Centers

The Beginning

In 1970, Wallace Reed, M.D. and his partner, John Ford, M.D., built the nation's first ambulatory surgery center (ASC) in Phoenix, Arizona. As an extension of their physician practice, the ASC offered high quality, efficient, state-of-the-art healthcare that was also affordable and accessible. Their surgery center set the standard and established the foundation for the ASC industry (Celebrating 40 years, 2010).

An ambulatory surgery center is a facility that performs outpatient surgery, or same day surgery. This became the alternative to the hospital outpatient department (HOPD) or operating room suites in general hospitals. As physician entrepreneurs identified the benefits and efficiencies of the ASC, many facilities began opening and operating in a similar manner. Thus, federal and state standards, very similar to the standards required for hospitals, became a requirement to build and operate an ASC in order to protect the health and safety of the patient.

The ambulatory surgery center industry has many facets. Single specialty facilities specialize in one type of treatment. Pain Management, Gastroenterology, cosmetic surgery, and Ophthalmology are common examples of such specialization. In addition, some ambulatory surgery centers are multi-specialty, performing procedures from various specialties. Figure 1 illustrates the nation's average of specialty services provided by ASCs.

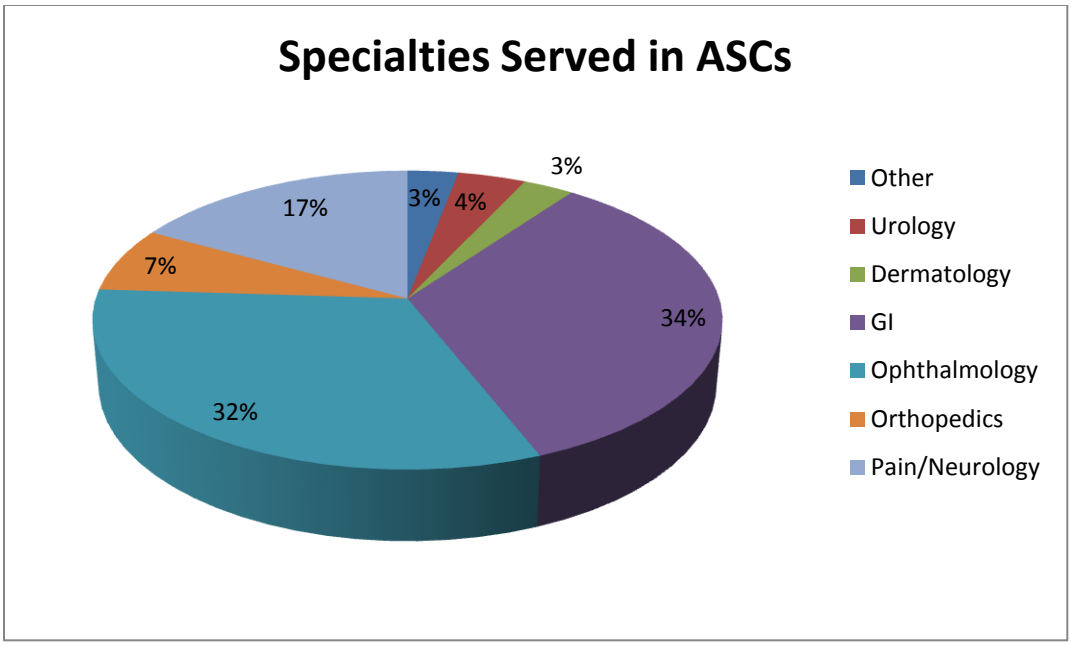

Figure 1. Specialties Served in ASCs. Retrieved from ASCAssociation.org. Based on Medicare 2006 Data.

Despite the differences in service lines, all ambulatory surgery centers mimic the systems model of healthcare in the hospital environment and scale the concept down to a "focus factory" or niche. Economists recognize the advantages of focus factories or specialty facilities (Casalino, Devers, & Brewster, 2003). Strategic advantages to focus factories are as follows: efficiency, cost control, less bureaucracy, and quality improvement. The advantage of ASC specialization is that it can successfully compete with traditional hospitals because the management of an ASC can focus on providing one health care service with dedicated staff, focus on equipment expenses, control costs, and remain more consumer friendly to patients and physicians (Shactman, 2005). An ASC has only one service line and as a business with only one service line has some disadvantages. There is no room for cost shifting between departments. One department cannot cover any excessive expenses of another. And, all services performed at an ASC require a physician on site to perform the procedure.

Progress

The Centers for Medicare and Medicaid Services (CMS) began paying the ASC industry for surgeries performed in 1982. CMS originally required Conditions for Coverage (CfC) effective September 7, 1982 (CMS, 2011). The Code of Federal Regulations 42 CFR 416.2 and 416.40-49 included 10 conditions and 16 standards at that time. The CfC contains the minimum health and safety standards that all ASC's must meet in order to care for Medicare beneficiaries. CMS revised the Conditions for Coverage for ASC's on May 18, 2009. The new Code of Federal Regulations, 42 CFR 416.2; 416.41-43; and 416.49-52, required an additional three conditions, the revision of four conditions, and no change in six conditions. The revision of the CfC was brought about by concerns of patient safety in the media. The new CfC incorporated 13 conditions and 35 standards, see Table 1.

The interpretive guidelines for the new regulations became available only on the eve of the new policy change. These interpretive guidelines, provided by CMS, were over 186 pages long. These additional conditions and standards later implemented in 2009 should increase the health and safety for Medicare beneficiaries.

Medicare Certification is the process in which CMS surveyors' document that ASCs meet all requirements or standards set forth in the Conditions for Coverage. These conditions include the continued use or addition of numerous healthcare specific standards for managing the ASC. Infection control guidelines can include the official Centers for Disease Control and Prevention (CDC) Guidelines and/or the Association for Professionals in Infection Control and Epidemiology (APIC) Guidelines for ASCs to meet the conditions for Infection Control. The Association of periOperative Registered Nurses (AORN) Standards is also included in the CfC to meet the perioperative health and safety

Centers for Medicare and Medicaid Services – Conditions for Coverage

Conditions	Standards
1. Compliance with State Law	• No Physician-owned ASC License Requirement
2. Governing Body & Management	• Contract Services • Hospitalization • Disaster Preparedness Plan
3. Surgical Services	• Anesthetic Risk & Evaluation • Administration of Anesthesia • State Exemption
4. Quality Assessment & Performance Improvement	• Program Scope • Program Data • Program Activities • Performance Improvement Projects • Governing Body Responsibilities
5. Environment	• Physical Environment • Safety from Fire • Emergency Equipment • Emergency Personnel
6. Medical Staff	• Membership and Clinical Privileges • Reappraisals • Other practitioners
7. Nursing Services	• Organization and Staff
8. Medical Records	• Organization • Form and Content
9. Pharmaceutical Services	• Administration of Drugs
10. Laboratory & Radiologic Services	• Laboratory Services • Radiologic Services
11. Patient Rights	• Notice of Rights • Advance Directives • Submission & Investigation of Grievances • Exercise of Rights & Respect for Property & Person • Privacy & Safety • Confidentiality of Clinical Records
12. Infection Control	• Sanitary Environment • Infection Control Program
13. Patient Admission, Assessment & Discharge	• Admission & Pre-Surgical Assessment • Post-Surgical Assessment • Discharge

Table 1 CMS Conditions for Coverage Retrieved from ASCAssociation.org

requirements. The CMS CfC also requires the ASC to incorporate the National Fire Protection Association (NFPA) Edition 99 Standard for Health Care Facilities and the NFPA Life Safety Code Edition 101, among others.

California was the first state to require accreditation for all ambulatory surgery centers and medical offices administering sedation or general anesthesia. Governor Pete Wilson signed Assembly Bill 595 on September 30, 1994. The bill prohibits any physician from performing surgery in any outpatient environment that administers anesthetics in doses that might put a patient at risk (Franco, 2001). The physicians and outpatient entities cannot perform surgery without accreditation from an agency approved by the Division of Licensing of the Medical Board of California. Accreditation is a voluntary survey that establishes that an ASC meets or exceeds national criteria from an approved accrediting agency.

In 1977, The Plastic Surgery Center in Sacramento, California, as stated on its web page, was the first ASC to be licensed in the state of California (The Plastic Surgery Center, n.d.). The California Department of Public Health, (formerly known as the Department of Health Services), surveyed the ASC, and ensured the center met the stringent life safety codes.

California Health and Safety Code 1204 (b) (1) defines a "surgical clinic" as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. The code continues to exclude any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the

establishment. However, the same code states "physicians or dentists may, at their option, apply for licensure from the state."

Throughout California and the United States, the number of ASCs continued to increase. The Ambulatory Surgery Center Association's web page, "The History of ASCs," states surgeons perform over eight million procedures in over 4,000 ASCs across the country each year (ASCA, n.d.). In addition, according to the Department of Health and Human Services (HHS), ASCs are the fastest growing provider type participating in the Medicare program. HHS estimates this growth rate between 2002 and 2007 to be over 38 percent (Department of Health and Human Services, 2009).

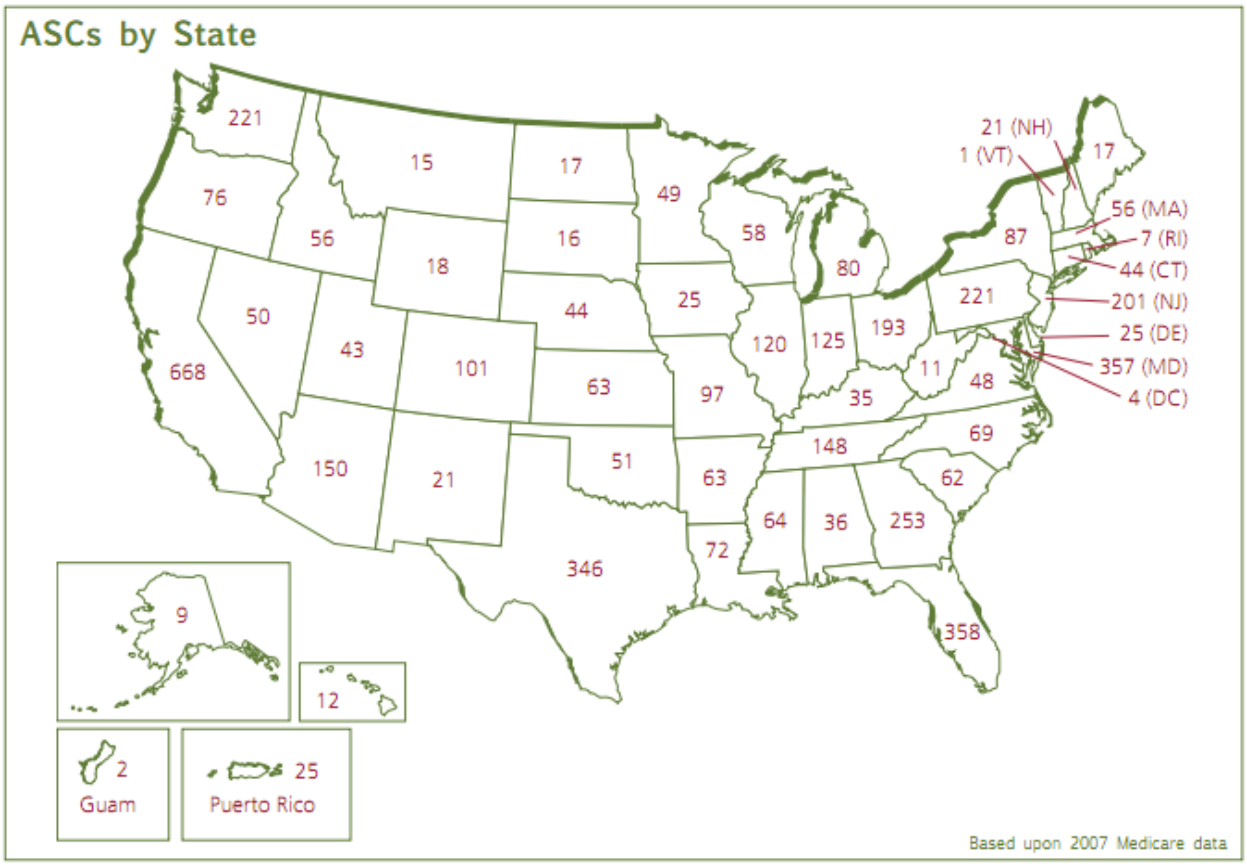

Figure 2 Number of ASCs by State. Retrieved from ASCAssociation.org

From the birth of ASCs in 1970, ambulatory surgery centers became one of the most regulated healthcare facilities in the United States. Since that time, the federal government implemented CMS Certification, 43 states passed laws to require state licensing of ASCs, and the State of California mandated accreditation for facilities providing general anesthesia. Government and private insurance agencies acknowledge significant cost savings utilizing ASCs and patient satisfaction surveys demonstrate public approval of ASCs as an alternative site for treatment. Lawmakers and healthcare leaders legitimized the ASC industry across the United States, at the federal level and many state levels. Uniformity and collaboration began to develop in state and federal agencies. Transparency in standards and outcomes in the ASC and the healthcare industry were improving across the country.

The Turning Point

Private industry and government benefit from historical events; in this case, it would be the precedent setting decision by the state court involving licensing. The ASC industry has been a significant player, redefining healthcare options for Californians throughout the last 41 years. As the number of ASCs in California grew, the credentialing process and the state licensing process became overtaxed. Centers were on a waiting list for inspection, and the amount of wait time continued to increase. There were not enough inspectors at the California Department of Public Health (CDPH) to lessen this period of time that rendered the ASC unable to operate. In 1996, the Health Care Financing Administration (HCFA), now known as the CMS, granted authority to two accreditation agencies to provide surveys or inspections to ASCs for "deemed status" as meeting the Conditions for Coverage requirements as specified in the regulations required by Title XVII

of the Social Security Act (Federal Register, 1996). The "deemed status" accreditation was optional, but sometimes it would prove a quicker process than waiting for the Department of Health Services, or CDPH, to facilitate the inspection. The deemed status survey was only performed if the ASC requested to provide care for Medicare patients. The deemed status accreditation is voluntary and the California state license is optional. Yet, CMS certification is required only if Medicare patients will receive treatment at the facility. Therefore, the rigorous requirements and long waiting period had owners researching their options. Many owners would consider what steps were best for their business. One orthopedic surgeon decided he would not apply for a state license for his ASC that he considered an extension of his practice. The Department of Health Services disagreed with the physician and believed his ASC required a state license. This led to a lawsuit between Dr. Capen and the Department.

In 2007, the appeals process ended when the State Supreme Court determined that Dr. Capen was not required to obtain a state license for his wholly owned surgery center. Subsequently, the opinion of the CDPH, Licensing and Certification Division, was formalized as written policy. The CDPH decided not to renew the state license of any facility with physician owners or partners. A letter from the CDPH states that the California Medical Board (CMB) shall oversee ASCs because the CMB oversees physicians. This is not the interpretation of the CMB. Yet, the CMB does recognize four accrediting bodies for ambulatory surgery centers: The Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities and the Institute for Medical Quality. Some states allow accreditation in lieu of state licensure.

Problem with Interpretation

Can the state of California find clarity in the state licensing process for physician-owned ambulatory surgery centers? Licensure is the state's authorization for ASCs and hospitals to operate. Today, 43 states require the state licensure of ambulatory surgery centers. Since their inception, original law in California did not require ambulatory surgery centers to be state licensed. The Court's decision in Capen v. Shewry (2007) 155 Cal. App. 4th. 378 allowed Dr. Capen the liberty of not obtaining a state license from the California Department of Health Services. The original law stated that state licensure is an option for centers wholly owned by a physician or group of physicians. Over 480 ASCs opted to obtain a state license in the state prior to this ruling. These standards were important enough to the physician-owned centers to undergo the arduous task of becoming state licensed. The health and safety of patients is and shall remain the highest priority, and the number of physician-owned centers that have acquired a state license keenly reflects the importance and value of this credential.

Methodology

The purpose for this policy analysis is to understand how and why practices have developed and to determine whether a state license should be required of ASCs in the state of California. Clearly, state licensure, accreditation, and CMS certification all contribute to the health and safety of patients. The quality of healthcare is paramount as the need to provide healthcare to the citizens of this country that is affordable and accessible, continues to increase. The analysis will focus on ASCs state licensure and the comparison to its alternatives.

Current law defines an ASC as a specialty clinic, specifically a surgical clinic. Surgical clinics provide outpatient surgery to Americans in a facility that is not part of a hospital.

ASCs meet or exceed similar building codes, life safety codes, and Medicare requirements as hospitals. This practice ensures the safety of all patients treated at the facility. Surgical clinics reflect the economic value of concentrating on a detail oriented organization, thus maximizing the quality and economic success of the business. The continued success of surgical clinics will encourage all health care entities to strive for that competitive edge.

In order to reach meaningful conclusions that identify the value of surgical clinics in controlling the health and safety of healthcare, the analysis of statistical data is imperative. Statistical data from secondary sources combined with empirical data from personal experience and observation is essential. Review of legislature, law, policies and regulations, and historical information will provide insight. Data gathered from governmental agencies, specialty groups, healthcare organizations and federal and state law will be considered. This extensive process will produce relevant information for analysis. The political and economic positions of the stakeholders, physicians in single practice, hospitals, insurance providers, government payors and the ASC industry will be included in the research. Procedures of the study will attempt to incorporate all key research variables and the relationships between these variables.

Importance of Policy Analysis

Americans cannot ignore the unprecedented, ever-rising price of healthcare. The trend of escalating cost is affecting the government and private business to the extent of possible bankruptcy. Healthcare spending in the United States is currently more than 16 percent of the Gross Domestic Product; the most spending per capita in the world (Hayes & McLaughlin, 2008). With the cost of healthcare rising exponentially, controlling these costs

is crucial. Economists believe that increases in healthcare spending and the federal deficit are stressing to the limit all systems used to finance healthcare programs.

Conversely, the ASC industry in California has provided quality healthcare that is affordable and efficient for more than 40 years. The future of the country is counting on the continued use of ASCs to deliver healthcare with superior quality, access, and price. By controlling individual costs, and responsibly managing uniform policy changes associated with healthcare, our nation will benefit economically, even psychologically, while raising the American standard for health.

Chapter Two

What is in the Literature?

Regulations in General

Government regulation is nothing new to Americans. When situations arise in our lives resulting in negative consequences and compelling evidence exists to demonstrate the need for public action, the government generally responds. State licensing, required in many industries, ensures standards are in place to protect American citizens. Health and Safety Standards are created to protect individuals from harm. General hospitals have been subject to government regulation for decades, largely due to the size and number of services provided to patients by contracted physicians and healthcare providers. Stakeholders from all industries continue the acrimonious debate on "how much government is too much?" When lives are at risk, what stakeholder could argue "no regulation is best"?

As the largest provider and consumer of healthcare in America, the federal government continues to evaluate quality and cost while increasing transparency between healthcare providers. In 2009, the Centers for Medicare and Medicaid Services improved the Conditions for Coverage Standards for ambulatory surgery centers. Yet, to date, little information exists regarding state licensure of ASCs in the State of California or comparing licensure requirements between states. As the federal government comes closer to disclosing quality measures throughout the industry, California is sabotaged by the interpretation of the law, as it pertains to ASCs and regulations. Specifically, prior to 2007, more than 480 physician-owned ASCs acquired state licenses and maintained these licenses for a number of years. As the ASCs reached the license renewal date, the CDPH dropped the facilities from their program. Today, physician-owned ASCs, (facilities with

any fraction of physician ownership), have no license and the State of California has no plan nor has made any effort to resolve this issue thus far.

Oversight

Three types of oversight are standard procedure concerning ambulatory surgery centers: certification, state licensing, and accreditation. The safety and quality of health care are measured by standards developed by each category of oversight. Oversight from a disinterested, third party with expertise and knowledge of the ASC business legitimizes the industry, and informs the public that the facility has the credentials to provide quality care in a safe environment.

The certification of ASCs originated in 1982 from the Centers for Medicare and Medicaid Services. Rules and Regulations, (or Conditions for Coverage), were posted in the Federal Register. This list of conditions and standards were revised to encompass a wider range of health and safety obligations in May 2009. The standards apply to all ASCs requesting to treat Medicare beneficiaries. These standards apply to all patients at the certified center, regardless of insurance type. While this certification is optional, it is required to treat Medicare patients and bill for services rendered.

State licensure of ambulatory surgery centers is required in 43 states in America. California is the only state that splits the regulation of ASCs between the California Medical Board and the California Department of Public Health. If the ASC is owned, wholly or partially by a physician, the authority for the ASC belongs to the CMB. If there is no physician ownership, the ASC has the option of becoming state licensed by the CDPH. Due to the staffing and scheduling restrictions of the CDPH, ASCs opt to become state licensed by requesting, “deemed status” from an accreditation organization. This application

process may be shorter with the private agency than with the public agency, but the standards for both organizations are the same.

The accreditation of an ASC is the final type of oversight. Private accreditation organizations have developed standards of care to ensure the quality and safety of patients being treated at an ASC and other healthcare entities, as well. The accreditation process is a voluntary credentialing process that allows ASCs to demonstrate to all concerned that health and safety standards are met. Much like certification and licensing, an accredited organization symbolizes excellence. Each of these three types of oversight ensures that a facility is meeting or exceeding published and accepted practice standards.

California Legislature

Assembly member, George Plescia, attempted to clarify the state licensure process and definitions of "Surgical Clinic" in 2006 with Assembly Bill 2308. This bill would have required the Department of Health Services to convene a workgroup to develop criteria to protect patients receiving medical treatment in an ASC. After passing unanimously in the House and Assembly, this bill was vetoed by Governor Schwarzenegger for not establishing such criteria. The Governor directed the Department of Health Services, (now the California Department of Public Health) to work with stakeholders to develop standards to promote quality care and licensing standards for surgical clinics (Schwarzenegger, 2006).

The RAND Corporation described three assembly bills related to ASCs in California that were introduced in the 2007-2008 session (Vogt & Romley, 2009). Assembly Bill 2968 would regulate elective cosmetic surgery by requiring written clearance from a medical doctor for surgery. Assembly Bill 1454 would regulate healing arts in outpatient settings, and Assembly Bill 1574 would modify access to ASCs without state licensure and specify

Board of Pharmacy inspections. All three bills were unsuccessful. Assembly Bill 2968 was vetoed by Governor Schwarzenegger for time constraints of the state budget process. Assembly Bill 1454 was withdrawn from the committee and Assembly Bill 1574 was vetoed by the Governor for failing to enact safety standards as stated in the past two vetoed bills (Schwarzenegger, 2008).

In 2011, Assembly member Bonnie Lowenthal introduced Assembly Bill 847. If passed, this bill would allow ASCs, either certified by Medicare or accredited by an approved accreditation organization, to purchase pharmaceuticals from wholesalers that require a state license by the Board of Pharmacy. Several physician-owned ASCs were state licensed, prior to the Capen Decision, and they were in possession of a Clinic Permit to purchase medication to be utilized at the ASC. This procedure was instrumental in maintaining appropriate medication records for the health and safety of all patients at the ASC.

Also in 2011, Senator Curren Price Jr. introduced Senate Bill 100 that may also assist in the closing of loopholes in the accreditation process and the state license problems for physician owners (Hiltzik, 2011b). Originally introduced on January 11, 2011, the Bill stated Section 1. (a.) "It is the intent of the Legislature to clarify Capen v. Shewry (2007) 147 Cal.App.4th 680 to give surgical clinics that are owned in whole or in part by physicians the option to be licensed by the State Department of Public Health" (Senate Bill, January 11, 2011, p. 4). This language was struck from the amended bill on April 25, 2011; however, remaining language may assist in notifying the public and competing accreditation organizations of revocation of accreditation and the related health and safety issues of a "surgical clinic" (Hiltzik, 2011b).

Why Do What We Do?

It is important to recognize the benefits of ASCs in the healthcare market. Competition is healthy for the economy, as it promotes quality. Physicians continue to become involved in the development and existence of ASCs as they desire to have greater involvement in facility management decisions, uninterrupted surgery scheduling, and improvement in efficiencies and quality related to the surgical clinic concept (Mitchell, 2010). Experts in any industry or market strive to improve their station. Improvements in time management increase productivity, generally increasing financial return and personal satisfaction.

The integration of the private ASC industry into the public arena of healthcare attempts to blend the market model with political community interests (Stone, 2002). The market model truly illustrates the philosophy of free market enterprise, as physician entrepreneurs work diligently to increase their personal wealth and station. But beyond the physician's personal gain, there are mutual benefits to the community, because his success translates to accessing cost efficient, quality health care, additional local revenue through taxation, and employment opportunities at his facility.

The political community is based on what is best for the community. Public policy illustrates communities working together forming collective will and collective effort (Stone, 2002). The model of polis, or public policy, develops goals and defines the group that such goals should affect. Federal and state governments, as well as accreditation organizations, have developed standards related to the health and safety of patients. The polis model is identifying a community of individuals to collaborate results. This is the basic definition of "public interest."

Federal and state governments are the regulators of private and public sector health care entities providing care for Americans. The regulators provide a seal of approval that our health care has met standards of proficiency and the community will be treated adequately. If the regulatory agencies cease to exist, private industry would be left to regulate itself. The most powerful entity, along with its narrower self-interests would prevail. Thus, the delicate balance of competition and regulation would be lost. Although providers of health care and regulatory agencies often perform adversarial roles, the benefits of their relationship are generally accepted by all health care stakeholders.

Literature of Peers

Controversy is the catalyst for revision and enhancement. Errors in medical care often become headlines in the media. Elected officials are interested in this subject due to the notoriety in cases where patients were injured or died because of negligent health care (Liberman, Rotarius, & Kury, 2001). While hospital errors and negative outcomes require reporting and comparison, ambulatory surgery centers and office-based surgery clinics report less data under current regulations. Researchers agree that health care in the outpatient setting can improve by proactive legislation and the development of regulations rather than frantically responding to sensational events published in the news (Lapetina & Armstrong, 2002).

Researchers analyzed policies and compared different state requirements. While all states have access to the CMS CfC and accreditation organization standards from JACHO, AAAHC, and AAAASF, the state requirements differ. The results of many state regulations are fragmented, at best. While standards appear to increase the quality of patient health care, some states find it difficult to establish regulations. The State of New York legislation

empowered the State Department to issue regulations for office-based surgery clinics; unfortunately, lobbying from special interest groups, like the Medical Society and the State Association of Nurse Anesthetists, killed any progress they might have made (Lapetina & Armstrong, 2002). When regulations came to the forefront in Florida, the Florida Society of Plastic Surgeons argued that the issues documented by the Board of Medicine were the responsibility of a few immoral practitioners and did not represent the majority of physicians who were prudent and conscientious (Liberman et al., 2001).

Literature identifies three areas of risk: health and safety at the facility level, peer review and anesthesia. The facility must meet life safety codes to ensure the facility is prepared for emergencies. A physician practicing independently does not enable colleagues to observe competency and skill. Thirdly, general anesthesia requires appropriate training for administration and treatment of possible adverse reactions to this procedure. The general surgeon in Los Angeles violated these three areas of risk, as he attempted to perform a Laparoscopic Cholecystectomy on a patient in the kitchen of his home (Becerra, 2011). This general surgeon also administered anesthesia himself. The patient passed away from complications. The surgeon did not even attempt to call emergency services for the patient.

Finally, the prevention of medical errors and the improvement of quality of health care are goals embraced by all stakeholders in the ambulatory industry. Research shows that more can be done to analyze the data and improve the system as a whole.

Chapter Three

How the Policy Alternatives Measure Up

Options

While ASC stakeholders, including management, physicians, elected officials, competitors and patients, have positively shared opinions regarding the inconsistencies with the state licensure of ambulatory surgery centers, they have also criticized each other's opinions vehemently. After significant review regarding the issues as to whether or not state licensing should be mandatory for physician-owned facilities, four alternatives are plausible that include: (1) mandatory state licensing, (2) clarity of the current law and interpretation, (3) no state licensing requirement, and (4) maintaining the status quo. Each alternative bears future consequences, spillover, and externalities. All four basic options have differing levels of political feasibility and yield some constraints. However, no matter what the political climate, policy makers all agree the health and safety of patients remains the highest priority.

Mandatory State License

When considering California's state license requirements of ASCs, the alternative most evident originates from the governor's desk. Over the past three years, Governor Arnold Schwarzenegger has vetoed three separate assembly bills that successfully passed in the Assembly and Senate. The State of California could require mandatory state licensing of all ambulatory surgery centers. Currently, only 45 ASCs possess a license in the state of California (Fields, 2010). The state licensing requirement would positively distinguish the difference between an ASC willing to meet such requirements from the smaller centers that, for various reasons, do not feel the need to demonstrate that they adhere to health

and safety regulations from a state agency, and thus, work only under the license of the physician.

Governor Schwarzenegger has emphasized that all ambulatory surgery centers must require state licensure. In a letter to the California State Assembly, Governor Schwarzenegger stated the Assembly Bill 1574 was returned unsigned because it failed to include patient safety standards that were the subject of the two previous vetoed bills. He also stated that he would not support a partial solution to the greater problem regarding quality and licensing issues for physician-owned ASCs (Schwarzenegger, 2008).

The Governor himself, from 2007 through 2010, believed that the unlicensed facilities in California place patients at risk. Previously licensed ASCs, multi-specialty facilities, facilities with corporate management groups and facilities with hospital partners also understand the value added to their business by adhering to the strict rules and regulations mandated by the state license process.

Requiring a state license for all healthcare facilities, including hospitals and ASCs, levels the playing field. The mandatory state license weeds out the facilities that cannot or will not meet the minimum requirements for licensure from competing in the market. Consumers of these services would also be aware that all facilities have earned the same credential and have met the health and safety requirements necessary to provide appropriate care to all patients. Unlicensed facilities would no longer place patients at risk.

A mandatory state license for ASCs in California will assure that the quality issues addressed by the Governor are met. Prior to 2007, the Office of Statewide Health Planning and Development (OSHPD) collected data from healthcare facilities on a quarterly basis. This process requires all facilities to contribute to the cost of the program. ASCs were

required to pay fifty cents per patient encounter to cover expenses. Unfortunately, the Capen decision (rendering certain ASCs exempt from licensing), removed the physician-owned facilities from the program. While some continue to provide information, the OSHPD will no longer allow physician-owned ASCs to participate in the data collection process. This is primarily due to the cost associated with data collection and compilation. State licensed ASCs are not only required to participate in the reporting process, they must pay to participate, thus, funding the program. Unfortunately, the data collected is only a fraction of the data that could be analyzed and available to the public. Kern County documentation from the fourth quarter 2010 reported to OSHPD represented seven hospitals and five ambulatory surgery centers. At least eight ASCs from the Bakersfield area were not represented in the data.

In 1977, the first plastic ambulatory surgery center in California received its state license (The Plastic Surgery Center, n.d.). The cost of the state license, again, was dependent on the number of annual patient encounters. This assisted the CDPH in recovering the cost of the survey and administration. The CDPH interpreted the Capen decision in a letter generated in May 2008 stating that the Court of Appeal found that the CDPH does not have authority to license surgical clinics with fractional physician ownership. Thus, the enactment of mandatory state licensing for ASCs would require a state funded program as the CDPH feels that it has been too long since the department was stripped of that authority. However, the ASCs could fund that program by assigning a required fee for licensure as practiced before the Capen decision.

Clarity in the Current Law

A second alternative to the state license dilemma for ASCs would require clarity in the California Health and Safety Code §1204, subdivision (b) (1). As defined in 1978, "a 'surgical clinic' means a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians or dentists may, at their option, apply for licensure." Any clinic or office providing ambulatory care, by definition is a 'surgical clinic'. This code explicitly states that an ASC has the option to obtain a California state license. Yet, at the same time allows physicians the ability to refrain from state licensure under certain conditions, if so desired.

Dr. Capen, and the California Medical Association that supported him, argued that there was statutory ambiguity in the code as written; stating the language quoted above could be interpreted two different ways. Resolving the confusion in the statue requires an interpretive regulation. Combining medical knowledge with legal knowledge, the issue could be clarified and the divided authority between the CMB and CDPH could be understood.

Individual stakeholders, such as plastic surgeons and dermatologists find the state licensure process expensive and cumbersome. Some stakeholders in this group would prefer to have their facility accredited by an agency sanctioned by the California Medical Board. It is typical for several accreditation processes to include Health and Safety Requirements as partial fulfillment of their accreditation award. This group of

stakeholders argues that accreditation is, to some degree, equal to the state license requirements. When one physician is practicing in a solely owned and operated facility, it is a true extension of the physician's practice. In addition, when local anesthetics are utilized instead of general anesthesia, the patient remains in control and has the ability to make his own decisions and the patient's cognitive abilities remain intact.

The California Department of Public Health and several stakeholders value the stamp of approval that a state license offers. These stakeholders believe that the survey process, with its scrutiny and regulations in granting state licenses, should not be optional for physician-owned facilities. This license demonstrates that ASCs have policies and procedures in place for adequately caring for patients that are incapacitated from general anesthesia or similar anesthetics requiring healthcare professionals to make decisions on their behalf.

With clarification of the law and its clearly defined intent, physician-owned ASCs could choose the option of state licensure by the CDPH and continue to provide quality health care as per the original CMS 1982 statute.

No License Requirement

As state license issues evolved because of the Capen v. Shewry decision of 2007, unintended consequences began to develop. The California Department of Public Health's interpretation stripped away the license of all ASCs with any fraction of physician ownership. Prior to 2007, over 480 ASCs had obtained a state license. As of December 2010, only 45 facilities remain licensed by the state. The Health and Safety Code has not changed; yet, the lawsuit involving the CDPH did change the Departments interpretation of the law. According to Centers for Medicare and Medicare Services in 2007, California had

688 Medicare Certified ASCs. To insist that physician-owned ASCs are under the jurisdiction of the California Medical Board divides authority, creating contradictory rules and regulations and adding confusion as to why regulations are mandatory for one entity and not for another when dealing with patients' lives.

The Status Quo

Finally, maintaining the status quo is always an alternative for state licensing of ASCs. Since the Capen Decision of 2007, and the California Department of Public Health's internal opinion, no facility with physician owners in whole or part has held a state license. All facilities previously licensed have lost their state license. All new facilities or facilities with change in ownership have been unable to obtain a state license. Yet, 45 ASCs are licensed by the state of California because these facilities have no physician owners. Physician-owned facilities continue to care for Medi-Cal beneficiaries in the state, a process that required state licensure for participation in the past. The CDPH interprets the Courts decision as not affecting eligibility to enroll in the Medi-Cal program. All ASCs, physician-owned or not, can continue to participate in the CMS Medicare program, by becoming certified by the CMS and meeting the Conditions for Coverage. This certification continues to be performed by the CDPH in the state of California, as it was when the CDPH issued state licenses. CMS contracts with the CDPH to inspect and certify ASCs in California. Accreditation agencies continue to utilize Life Safety Codes and Environmental controls in the accreditation process in a manner similar to the state license process. Thus, in this scenario of numerous processes and programs, health and safety issues are addressed to various degrees.

The status quo becomes complicated when other state agencies and healthcare insurance companies require ASCs to have a state license. An example of this is the Board of Pharmacy. An ASC must retain a state license as a requirement for obtaining a Clinic Permit. The Clinic Permit enables the ASC to purchase medication from a wholesaler in order to treat patients at the facility. The Clinic Permit also allows the facility to obtain a DEA registration number for the purchase and use of narcotics. It is impossible to treat a number of patients or perform hundreds of procedures without the use of medication. The status quo requires a medical director to utilize his individual unique medical license and DEA number for all patients at an ASC. The records continue to be maintained with appropriate policy and procedures for the CMS Conditions for Coverage and all accreditation agencies. Yet, discrepancies in requirements are still present among state agencies.

As the status quo continues, healthcare facility standards continue to become more complicated. While federal and state insurance providers understand the issues of state licensing in California, many private insurance providers do not comprehend their incongruent policies. Many private providers require proof of current state license and their internal forms are utilized across the United States. It becomes difficult, at times, to explain to the credentialing departments in large insurance companies why the facility does not have a state license when contracting its service.

There are also negative externalities related to the status quo. Although some physicians are quite content with not having a state license, stakeholders that maintain large facilities with multiple physicians are extremely dissatisfied with the current environment. Patients are not advised as to the requirements and regulations regarding

treatment facilities, and unfortunately, patients continue to have negative outcomes from facilities that are not licensed, certified, or accredited. While these regulatory options are available, none is required. This is a difficult position for the industry as well as the patient. Without uniform standards, the future of healthcare access, quality, and affordability is questionable at best. The status quo is lacking in these standards.

Constraints and Politics

It is a difficult situation when the majority of stakeholders disagree on the issues that affect everyone. Lobbyists for the California Association of Plastic Surgeons argue that the state license is not required. Others lobbyists, working with multi-specialty ASCs and ASCs with larger numbers of physicians on staff, argue that state licensure is the only way to regulate the industry. Still, creative individuals attempt to correct the issues related to the state license issue without creating controversial strongholds. Nevertheless, the polarization of these groups only intensifies their position, where compromise appears not to be an option. Yet, one would hope that all participants, at least, appreciate the critical need for patient health and safety.

Physicians, nurses and healthcare providers all should maintain virtues and ethics that are consistent with caring for individuals. All providers of ambulatory care are obligated to meet the standards of CMS, state licensing and accreditation, regardless of what treatment the patient receives. No industry is perfect and no environment is without flaws. The system of healthcare has standards and regulations woven together like a strong fabric. Checks and balances are in place to make the system as free from errors as possible. The government, at the federal and state levels, is evaluating the quality of the care provided and the equitable cost factors. Working cooperatively, healthcare providers,

and lawmakers can reach logical solutions and address the current problems related to the licensing of ASCs in the state of California.

Chapter Four

The Solution

Current Standards Convoluted

Currently California is one of seven states not requiring a state license for physician-owned ambulatory surgery centers. The other six states have no licensing requirement, whether physician-owned or not, for various reasons. The state of Vermont has one ASC; reflecting a lesser demand for regulations than California, with the number of ASCs over 700. The federal government does not require federal licensing; however, the rigorous regulations adopted by the Centers for Medicare and Medicaid Services apply to all patients treated at facilities that are Medicare certified or held "Deemed Status" for CMS by a qualified accrediting organization. Federal regulations impose knowledge, performance, and record keeping in a number of areas, see Table 1. The Conditions for Coverage for CMS beneficiaries and all patient encounters in certified facilities ensure proper governance, surgical services, quality assessment and performance improvement, environment, medical staff, nursing services, medical records, pharmaceutical services, laboratory and radiologic services, patient rights, infection control, and patient admission, assessment and discharge. The thirteen mentioned conditions are accompanied by thirty-five standards. The depth of regulations is all inclusive and well thought out. The coverage of health and safety are exceptional. CMS certification does prove worthy in that all requirements must be met. This is not an option when caring for Medicare recipients as well as all patients at a Medicare certified center as this is a significant part of their regulation.

Accreditation agencies have a multitude of standards. The California Medical Board has approved four non-profit accreditation agencies. All approved agencies firmly believe in the quality, safety, and health of all patients. As healthcare issues occur, standards are

written to provide better protection for patients. Each organization has similar values. Unfortunately, accreditation agencies have no authority to fine or close facilities for unsafe or poor performance. Moreover, the agencies have no reporting mechanism and are not required to share information. If one agency finds a facility unsafe and revokes the facilities accreditation, the facility can move on to another agency. More devastating than "shopping for accreditation", is the case the *Los Angeles Times*, where a plastic surgeon performed surgeries on three patients at an unaccredited surgical facility (Pfeifer, 2011).

Agencies standards are not uniform and do not always include the Medicare Conditions for Coverage. However, accreditation agencies are often a beneficial alternative for ASCs that do not care for Medicare patients, as the agencies are better staffed with more resources for expedient inspections. The CDPH has been known to have an outrageous workload and inspections often require a waiting period. Some agencies work in conjunction with CMS for "deemed status." The agencies' staff is knowledgeable and can act in lieu of the CMS surveyor. Therefore, some accrediting agencies incorporate the CMS conditions and standards, simplifying the regulatory field. However, deemed status surveys must be requested and are lengthier than standard accreditation surveys.

Expeditious Action for the Rights of Americans

Healthcare reform was created in part to improve the access, cost, and quality of healthcare. Consumers have the right not only to understand the law, but also to be able to make informative decisions regarding healthcare providers. All ASCs have the opportunity to become accredited or certified and post or market these accomplishments for consumer awareness. Most insurance contracts require a credentialing process that documents this type of accomplishment.

Consumers may have chosen to do business with a licensed facility due to the quality provided. Most Americans understand the concept of licensure. One cannot drive without a license, practice law, or build a house without a license. The license demonstrates that the licensed person or entity is capable of performing at least the minimum level of proficiency required by that license. The license process requires testing and scoring appropriately to prove competence. The state license for health care is not different. In addition, the law states that facilities have the option to license. Four years, four assembly bills, and one senate bill have not solved the current problem regarding state licensing of physician-owned ASCs. Healthcare providers and legislators must collectively solve this puzzle. While competition is good for the economy, stakeholders must collaborate to address private and public interests as healthcare is a more public industry than a private one. The authority and control of certain aspects of healthcare is better left in the hands of the government (a neutral party considering private and public interests). If the government did not regulate healthcare, it is quite possible that a private company would become the regulator, and unfortunately, the public interest might be exploited by those individuals pursuing their own interests (Stone, 2002).

Ambulatory surgery centers provide patient care. The majority of care requires the administration of general anesthesia. Anesthesia renders a patient incapacitated leaving the patient at the mercy of the healthcare providers. Trained professionals are more than capable of providing such care and understanding what is required to provide it. Patients believe that the healthcare individuals are administering the care utilizing the proper equipment, and that equipment is properly maintained. Patients believe the risks are minimal and that the healthcare professional and organization are responsible, educated,

and competent. Patients tend to believe their care is appropriate and accepted standards are employed to ensure positive outcomes.

Allow for the Option

Large facilities with more than one physician desperately need the option for state licensing. The consequences of the CDPH interpretation of the Capen ruling have made a mess of things. As originally stated in the regulations, licensing is optional. The CDPH's interpretation has not been addressed. Until it is, there will be no clarity. The Capen decision shifted oversight of 700 plus ASCs to the CMB. This agency has no experience and training to perform such inspections, (Hiltzik, 2011a).

Physicians with simpler operations, (one-man shows or less invasive procedures) can opt to become accredited by an agency only. The cost, size, complexity of such entities may not warrant state licensing, but accreditation continues to be required by law if general anesthesia is utilized. The stakeholder stronghold should not hinder progress in resolving this issue.

No New Program

The CDPH discontinued the state licensing of over 650 centers and is currently licensing only 45 centers. The CDPH feels that licensing the physician-owned ASCs would require a new program. As Title 22 has not specific guidelines for ASCs, the CDPH follows the CMS Conditions for Coverage simplifying the standards required to own and operate a physician-owned ASC. The benefit is that the CDPH staff is already knowledgeable and experienced in the CMS CfC, as they are the sole contracted provider for CMS inspections in the State of California. In addition, the increase in surveying or inspecting in the past two years has resulted in the hiring of experts by the CDPH inspecting ASCs. The Los Angeles

Times has discussed the shortfalls within the CMB including lack of knowledge, lack of staff, and lack of funds to regulate ASCs. The public deserves better.

The Simple Truth

The State of California is responsible for the oversight of the majority of health care providers through agencies who possess specific expertise of their respective profession. The California Board of Registered Nursing ensures that registered nurses in California have the credentials to care for patients in a competent manner. The same holds true for the California Medical Board. These Boards are also charged with protecting society from incompetent professionals. Just as health care professionals are licensed by the state to ensure the health and safety of consumers, health care organizations and agencies providing care require state licensure, as well.

State licensure is a social contract between the government and the public. A license is granted to those professionals or organizations demonstrating that basic credentials and standards have been met to ensure the health and safety of the public. Meeting or exceeding these standards decrease the cost of malpractice or negligence and, thus, increase quality. Standards and systems increase positive outcomes (Gawande, 2011).

According to Atul Gawande, M.D., in his commencement address on May 26, 2011, at Harvard Medical School, the health care providers that get the best results do not cost the most. The ASCs that implement the basic tools (standards) produce the safest care for society. The knowledge base in medicine, like that in aviation, construction, and engineering, for example, has grown exponentially. An ASC cannot be managed by a solo practitioner. The existence of quality ASCs requires experts in the field, supported by a

team of professionals. The healthcare industry, specifically an ASC, is too large and can no longer be adequately run as a one-physician practice (Gawande, 2011).

The federal or CMS Conditions for Coverage begins with its' first mandate, "compliance with state law." CMS Certification and Accreditation are other vehicles designed to meet quality standards, adding value to the state licensure. Until there is resolution in the division of authority between physician-owned and non-owned ASCs, ASCs desiring the license as affirmation of meeting standards should be allowed to do so. Governor Brown should instruct the CDPH to license all ASCs opting for such license.

Chapter Five

Summation

Lessons Learned

The most important aspect in healthcare is quality of life. All Americans have the right to seek medical treatment and be confident that the practitioners and facilities performing what might be life-threatening procedures are qualified to care for them appropriately. Medical care costs money. No one can expect to be treated free of charge. The time and money spent for all practitioners to learn their trade is huge. The dollars spent for professional liability are equally expensive. State-of-the-art equipment and preventative maintenance is costly, as well. Everything involved in providing healthcare to American citizens and those living illegally in the United States cost providers money and the highest quality care costs even more. Shopping for healthcare is more complex than shopping for a mechanic for your automobile or a lawn service for your lawn.

All Americans must be responsible for their own health. Every American must have access to health care that will maintain and improve their health. Someone must be responsible for payment. The Patient Protection and Affordable Care Act enacted in 2010 represents the need to increase access to healthcare, ensure that healthcare is more affordable, and assist small business with this burden. ASCs assist with the access of healthcare, are more affordable than its competitors are, and are small businesses themselves. The State of California benefits from the services provided by ASCs and California's economy benefits from the health care workers employed by ASCs.

Standards are important to ensure health and safety, as the code implies. Standards are also essential for consumers of healthcare. Consumers include patients, federal and

state governments, and private or third party payers (insurance companies). Standards allow one to evaluate the options. The saying "you get what you pay for" is a tired cliché but a very accurate one. Consumers can choose healthcare providers by cost or quality. It is the consumer's choice. Californians can go to Tijuana, Mexico for Laparoscopic Gastric Banding and get a cheap price, but almost certainly at the expense of quality and safety. A patient with loss of vision knows the value of an ASC after cataract extraction and the placement of an intraocular lens. The patient with a hernia understands the quality after surgery repairs the defect. It is difficult to argue the significance of consumer knowledge. Moreover, if quality or safety standards are measured, the quality and cost of healthcare can be quantified.

Take Action

In the spirit of John F. Kennedy, as he campaigned for presidency, we need to get this country moving again, in spirit and ambitions (Starr, 1982). President Kennedy was astutely aware of the settled complacency and resistance to change in the government in 1961 (Starr, 1982). Today's legislature is not complacent. The senators and Assembly of California want to improve the status quo. The convoluted situation surrounding the state licensing issue of ambulatory surgery centers must be resolved. Time is of the essence. Four years have passed since the split of regulatory jurisdiction over ambulatory surgery centers. As cost is eminently a factor, the simplest solutions would produce the greatest cost savings. There are currently three types of rules and regulations: CMS certification, state licensing and accreditation. The two fundamental concerns in healthcare are health and safety, translated by the Patient Protection and Affordability Act to quality and cost. The federal CFC designed by CMS is all-inclusive and the agency has authority to fine or

close facilities in violation. Deemed status accreditation organizations possess the knowledge and expertise to perform CfC inspections, as well.

The state licensing of ASCs in California as written in the Health and Safety Code § 1204(b) (1) states physicians may, at their option, apply for licensure from the state. The CDPH is currently contracted with CMS to inspect all ASCs in the Medicare Program. The Department has 45 currently licensed facilities under their jurisdiction. The majority of the physician-owned ASCs that desire a state license are multi-specialty and CMS certified. The licensing process for these centers was solidly in place for at least 30 years. State agencies and insurance companies utilized the state license as part of the credentialing process for internal policies and procedures. The law has not changed, only the interpretation of the law has changed.

As the debate continues between different groups of healthcare providers and legislatures as to who should obtain a license and what quality measures should be reported, the legitimate physician-owned ASCs should be granted the right to obtain state licensure. This does not require a change in law or the production of a new program. It requires an interpretation of the current law that authorized the CDPH to license those physician-owned ASCs as stated in the current code. The size and structure of these ASCs are better equipped to operate with the state license option, and that should not be taken away.

The state licensing of ASCs in California requires one set of standards respected by all providers and enforced by public control. The private sector has no authority to fine or close businesses that are noncompliant. Over the past four years, the CDPH significantly ramped up ASC inspections for CMS. The Department is very knowledgeable regarding

rules and regulations as written in the CfC. The federal government estimates 30 percent of CMS certified ASCs have been inspected in the past two years. Therefore, the CDPH is equipped to license physician-owned ASCs that opt to participate. The CfC from CMS is elaborate enough to ensure the health, safety, and quality of all patients treated at an ASC. The credentialing system can be simplified by adopting the CMS CfC, which is the same for accreditation organizations deemed status, and utilizing a uniform set of standards for all credentials: CMS certification, state licensing, and accreditation. To minimize inspection time and supersede fragmented credentials, the CMS certification and deemed status accreditation should be utilized in lieu of additional inspections to reinstate the licensing of physician-owned ASCs. This action will significantly improve the healthcare practices of all facilities opting to do so. Providing quality healthcare is a right for all healthcare providers, regardless of ownership.

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Appendix A

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Date: 15 March 2011

To: Kathleen Allman, PPA Student

cc: Paul Newberry, IRB Chair
R. Steven Daniels, Public Policy & Administration Department

From: Steve Suter, Research Ethics Review Coordinator

Subject: Protocol 11-45: Not Human Subjects Research

Thank you for bringing your protocol. **"Policy Analysis: State Licensure of Physician-Owned Ambulatory Surgery Centers"** to the attention of the IRB/HSR. On the form "*Is My Project Human Subjects Research?*" you indicated the following:

> I want to interview, survey, systematically observe, or collect other data from human subjects, for example, students in the educational setting. **NO**
>
> I want to access data about specific persons that have already been collected by others [such as test scores or demographic information]. Those data can be linked to specific persons [regardless of whether I will link data and persons in my research or reveal anyone's identities]. **NO**

Given this, your proposed project will not constitute human subjects research. Therefore, it does not fall within the purview of the CSUB IRB/HSR. Good luck with your project.

If you have any questions, or there are any changes that might bring these activities within the purview of the IRB/HSR, please notify me immediately at 654-2373. Thank you.

Steve Suter, University Research Ethics Review Coordinator

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