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TECHNICAL REPORT

California Ambulatory Surgery Centers

A Comparative Statistical and Regulatory Description

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Sponsored by the California HealthCare Foundation

RAND HEALTH

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PREFACE

Ambulatory surgery centers (ASCs) are rapidly growing as a setting for the delivery of health care services, both in California and in the United States. At present, little is known about either the measurement of quality in the ASC setting or about the regulation of ASCs by the various U.S. state governments. The purpose of this report is to describe the California ASC landscape, to compare California ambulatory surgery centers to hospital outpatient surgery departments, and to compare California's regulation of ambulatory surgery centers to the regulations of other states.

This work was sponsored by the California HealthCare Foundation under a grant entitled "Ambulatory Surgery Centers: Relevant Policy Trends," for which Robbin Gaines serves as the project officer. The research was conducted in RAND Health, a division of the RAND Corporation. A profile of RAND Health, abstracts of its publications, and ordering information can be found at www.rand.org/health.

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SUMMARY

Over the last 20 years, there has been enormous growth in the number of ambulatory surgery centers (ASCs), nationally and in California. With this growth has come an increased interest in ASCs in the scholarly, legislative, and policy communities. Most ASCs are for-profit; many ASCs are physician-owned; and ASCs compete directly with hospitals in the provision of profitable outpatient surgery services. Furthermore, little is known about ASC quality measurement, and there has been little work systematically measuring either the ways in which ASCs are currently regulated or the ways such regulations affect costs, quality, and other outcomes of interest.

Regulatory issues are particularly salient for California at present. California has a unique two-track process for regulating ASCs. Physician-owned ASCs are regulated by the Medical Board as "outpatient settings," whereas other ASCs are regulated by the Department of Public Health (DPH) as "surgical clinics." Recently, the California legislature has been considering changes to this regulatory framework.

This report describes the current state of ASCs in California, compares the patients in ASCs and hospital outpatient departments, compares the various categories of ASCs, and compares the regulatory environment in California to that in other states and to the regulatory regime for Medicare-participating ASCs.

The report draws on several data sources. Financial, ownership, location, volume of services, and capital expenditures for all DPH-regulated ASCs are reported to California's Office of Statewide Health Planning and Development (OSHPD), which organizes this information into the Primary Care and Specialty Clinics Annual Utilization Dataset. Patient encounter data for all DPH-regulated ASCs and all hospital outpatient surgery departments are also reported to OSHPD and collected in the Emergency Department and Ambulatory Surgery Dataset. Both datasets were acquired from OSHPD for 2005 and 2006.

For the regulatory comparison, RAND retained Stateside Associates, a regulatory consulting firm, to collate and summarize ASC regulatory

requirements for 15 large U.S. states and for the Medicare program. Stateside abstracted statutes and regulation and interviewed responsible officials. Data on state regulation of ASCs related to licensure, inspection, independent accreditation, quality improvement programs, and data and quality reporting were collected.

The 473 California ASCs that report encounter data account for about 1.1 million outpatient surgery encounters, while the 360 California hospitals reporting ambulatory surgery data account for about 1.7 million encounters. Compared to hospital outpatient surgery departments, ASCs perform a lower overall volume of surgeries and are more focused on a few types of procedures. ASCs generally achieve higher volume on those procedures in which they specialize. In general, ASCs tend to serve a higher-income and more-generously-insured population.

On one recognized quality indicator, transfer to a hospital, ASCs appear to score slightly worse than do hospital outpatient departments, although performance on this measure improved markedly between 2005 and 2006. However, given the immaturity of the ASC quality measurement literature and the lack of controls for patient risk factors in the work reported here, this finding should be treated with great caution. This finding does point to the need for more research to determine whether the higher transfer rate in ASCs represents a difference in quality.

ASCs perform proportionately more cosmetic procedures than do hospitals, and 44 OSHPD-reporting California ASCs specialize in cosmetic procedures. These cosmetic-specializing ASCs serve a younger, more-female, and slightly higher-income patient base than do non-cosmetic-specializing ASCs. Furthermore, patients at cosmetic-specializing ASCs are much more likely to be paying for their procedures out of pocket.

On the regulatory front, all 15 states surveyed require inspection for licensure, but the frequency of that inspection varies. Under the "outpatient settings" track of California's two-track regulation, preannouncement of inspections is required; under the "surgical clinics" track in California and in all other states, there is no such requirement. Licensing/approval is unrelated to accreditation by an agency such as The Joint Commission for the Accreditation of Healthcare

Organizations (JCAHO) under the "surgical clinics" track in California and in five other states. Accreditation satisfies all requirements under the "outpatient settings" track in California and in North Carolina. In the remaining states, accreditation either facilitates licensure, or it is required.

Quality regulation was also compared. Most surveyed states and Medicare require ASCs to implement quality assessment and improvement programs; California does not. Most surveyed states require ASCs to report various quality indicators (deaths, transfers to hospitals, wrong-site surgeries, etc) to regulators, while California does not. Most states do not require the reporting of encounter data to regulatory authorities. For those licensed by the DPH, California does.

There are a number of avenues for further research regarding public policy for ambulatory surgery centers. First, the research revealed differences in patterns of volume and procedure specialization between ASCs and hospital outpatient surgery departments. These differences could have implications for quality if high volume is associated with quality or if more specialization is associated with higher quality. There is little research on these questions for outpatient surgery at present. Given the heterogeneity in states' strategies for regulating ASCs and given that ASC quality measures are currently under development, research into the effects of different regulatory strategies on ASC quality would be promising. Finally, given the differences we document in the income and insurance status of hospital and ASC patients, it would be interesting to analyze how the geographical distribution of ASCs and hospital outpatient departments vary and how this affects their respective patient populations. In addition, it would be valuable to analyze competition among ASCs and hospital outpatient departments and how this competition affects the distribution of patients among facilities.

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CHAPTER 1. BACKGROUND AND INTRODUCTION

Ambulatory surgery centers (ASCs) are outpatient facilities which perform surgeries which do not require a hospital stay. The most common types of surgery performed in ASCs are eye (often cataract surgery), gastrointestinal (often colonoscopy or endoscopy), pain management (spinal injections), and orthopedic (often arthroscopy).

Over the last 20 years, there has been enormous growth in the number of ambulatory surgery centers, reflecting the movement of surgical procedures from an inpatient to outpatient setting. In 1985, there were 336 Medicare-registered ASCs. By 1990 there were 1,197, and by 2006, 4,707 (CMS, 2007). California followed a similar trend: The number of licensed ASCs nearly doubled[1] from 253 in 1996 to 482 in 2006. There has also been a parallel growth in the number of specialty hospitals--small, for-profit hospitals that perform ambulatory surgery and also inpatient surgery. While most general hospitals are not-for-profit, about 95% of ASCs and specialty hospitals are for-profit, and many are physician-owned. (GAO, 2003; Gabel et al., 2008).

General hospitals now see growth in ASCs as quite threatening. According to surveys, 45% of hospital executives perceive ASCs as an important competitive threat, and 70% believe that they will be soon. In addition, 21% of hospital executives view competition with physicians as one of the top three concerns facing their hospital, up from 11% in the past. Anecdotal evidence suggests that some hospitals responded to these new threats through a "medical arms race," pursuing strategies of new investment and higher marketing expenses in an effort to retain threatened business. (Bian and Morrisey, 2007; Casalino, 2008; Casalino et al., 2003; Devers et al., 2003; GAO, 2006; Lynk and Longley, 2002)

Because ASCs are generally for-profit and physician-owned, there is an often expressed concern about inappropriate self-referral by

[1] See Chapter 2.

physician-owners. The Stark Law[2] generally forbids physician self-referral, but has several exceptions, including one for physician-owned ASCs. (Cassalino, 2008) In a recent report, Cassalino (2008) found strong evidence that self-referral increases medical care use and indirect evidence that some of this increase is inappropriate. That report also found that ASCs were less expensive per case and provided quality of care comparable to hospital outpatient departments.

The evaluation, monitoring, and reporting of quality information about ASCs is currently in its infancy. CMS, following a mandate from Congress, is currently considering requiring that ASCs report quality information, but there are no concrete proposed measures as yet and the earliest that such measures would be reported is 2010. (Medicare Program, 2008) In December 2007, the National Quality Forum (NQF),[3] an organization that endorses standards for measuring and publicly reporting performance, released nine quality measures for ASCs. (National Quality Forum, 2007) These comprise four quality measures developed by the Ambulatory Surgical Centers Quality Collaboration (ASC QC) and five developed jointly by the National Committee for Quality Assurance (NCQA) and the American Medical Association's Physician Consortium for Performance Improvement (AMA PCPI). Appendix D contains a summary of the NQF-endorsed measures.

The phenomenal growth of ASCs raises important policy questions. ASCs may provide benefits to patients via convenience, to payers via lower prices, and to physicians via enhanced income and job satisfaction. On the other hand, some concerns have been raised about this growth. The ability of hospitals to cross-subsidize unprofitable services might be adversely affected if ASCs were to specialize in unusually profitable patients or procedures. In the case of physician-owned ASCs, self-referral might lead to inappropriate care. The entry of ASCs may also duplicate extant hospital outpatient capacity.

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[2] See §1877 of the Social Security Act and implementing regulations at 42 C.F.R. §411.350 through §411.389.

[3] NQF's website is at http://www.qualityforum.org

If policymakers wish either to encourage or to discourage ASC growth, there are levers available to them. The most straightforward lever is reimbursement. ASCs and hospital outpatient departments are reimbursed by Medicare at different rates. Medicare is in the midst of an ASC payment reform affecting reimbursement for fee-for-service (FFS) Medicare patients. Raising ASC rates would likely encourage further growth, while lowering them would likely discourage it. Public policymakers additionally have the ability to set and to increase or decrease the stringency of regulation[4] of certificate of need, self-referral, quality, and quality reporting for both ASCs and for hospital outpatient surgery departments.

ASCs are becoming an increasingly important part of the healthcare infrastructure, and policy concerns about them abound. Yet despite the proliferation of ASCs, basic data describing who is using them, how the ASCs compare to hospitals, and what their quality outcomes are, remain thin. Efforts to develop quality measurement technology and infrastructure over the past two decades have largely focused on other parts of the healthcare system (e.g., hospitals). The purpose of this report is to provide basic descriptive information with regard to California ASCs and to offer some preliminary observations for how California data may contribute to the emerging policy debate and landscape in that state.

The general issues of ASCs described above are particularly salient in California because, first, California takes a distinctive approach to the regulation of ASCs, and, second, the California legislature has recently been considering changes to this system. California has a "dual track" system of regulating ASCs, with some ASCs regulated by the Department of Public Health and some ASCs regulated by the Medical Board. Against this backdrop, three bills[5] (described in Chapter 3)

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[4] Several of these are discussed in Chapter 3.

[5] For comprehensive legislative analyses of these proposed measure, see http://info.sen.ca.gov/pub/07-08/bill/asm/ab_1551-1600/ab_1574_cfa_20080814_213459_asm_floor.html, http://info.sen.ca.gov/pub/07-08/bill/asm/ab_2951-3000/ab_2968_cfa_20080813_195016_asm_floor.html, and

recently under consideration by the California legislature pertain to ASCs and would change this regulatory framework.

In this context, RAND proposed, and the California Healthcare Foundation funded, a study intended to inform public decisionmaking relating to ASCs in California. In consultation with the California Healthcare Foundation, the following four objectives were developed for the study, and these objectives are pursued in the remainder of this technical report:

1. Describe the current state of ASCs in California.
2. Compare ASCs to hospital outpatient departments.
3. Compare the various ownership categories of ASCs.
4. Compare the regulatory regime in California to those of other states and to that of the Center for Medicare and Medicaid Services (CMS).

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http://info.sen.ca.gov/pub/07-08/bill/sen/sb_1451-1500/sb_1454_cfa_20080708_153239_asm_comm.html (accessed on August 23, 2008).

CHAPTER 2. CALIFORNIA'S AMBULATORY SURGERY CENTERS

This section provides an overview of the market for outpatient surgery in California. It features a statistical overview of the differences among the patients treated in ASCs and hospital outpatient surgery departments and among the patients treated in various categories of ASCs. ASC patient populations are compared among ASCs with different ownership arrangements, among ASCs according to certification status, and among ASCs specializing in cosmetic surgery and in other surgeries.

As previously discussed, quality measurement and reporting for ASCs is in its infancy. In this report, we present three potential quality indicators: mortality, transfer to a hospital, and procedure volume. ASCs in several large states are required to report mortality as a quality monitoring device (see Chapter 3). Transfer to a hospital is one of the ASC quality measures proposed by the NQF and the ASCQC. Finally, for many inpatient hospital procedures, there is evidence that higher procedure volume correlated positively with better outcomes,[6] although the evidence for this link in the case of outpatient surgery is weaker. (Casalino, 2003)

DATA SOURCES AND METHODS

The statistical description of California ASCs draws upon two primary data sources, each collected by OSHPD: the Annual Utilization Report Data and the Emergency Department and Ambulatory Surgery Data. All surgical clinics licensed by the Department of Public Health are required to file with OSHPD an "Annual Utilization Report." Data based on these reports are available on OSHPD's web site,[7] and these data have

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[6] This correlation, often called "the volume-outcome effect," is generally thought to be the result of the hospital improving at performing particular procedures, either via accumulation of experience by physicians and hospital personnel or via improvements in hospital routines through organizational learning.

[7] See http://www.oshpd.ca.gov/hid/Products/Hospitals/Utilization/PC_SC_Utilization.html

been obtained from 1996 through 2006. Furthermore, since 2005, these clinics also have been required to report encounter data (data on each treatment encounter with a patient). In addition, essentially all California hospitals performing outpatient surgery are required to report these encounter data. These encounter data are collected in the Emergency Department and Ambulatory Surgery Dataset. Both datasets were acquired from OSHPD for 2005 and 2006.

The Annual Utilization Report contains information on each clinic in five sections.

- The first section contains clinic name, address, and other basic information.
- In the second section, there is information on the clinic's ownership (e.g., government, non-profit, and for-profit).
- Information on the number of patient encounters, the number of surgeries, and the number of operating rooms is in the third section of the report.
- The fourth section contains financial information (revenues, expenses, and income).
- Finally, the fifth section reports major capital expenditures by the facility.

The utilization data characterize the growth in ASCs from 1996 through 2006 and identify the different categories of ownership for comparative purposes. Unfortunately, the utilization report does not specifically identify physician ownership; furthermore, there does not appear to be any readily available source for this information. Another limitation of the utilization data is that some facilities do not comply with the reporting requirement and, therefore, are omitted from the analysis. In 2005, there were 37 nonreporters among the 476 licensed ASCs, and in 2006 nonreporters numbered 67 of the 482 total ASCs. Six facilities reported invalid data. Another potential limitation is California's unusual dual licensing system for ASCs (see the discussion in Chapter 3). The ASCs accredited as outpatient settings by the

Medical Board would not be covered by OSHPD reporting requirements.[8] The Medical Board does not make available a similar set of data for the ASCs which it regulates.

Since 2005, all hospitals and ASCs licensed by the Department of Public Health have been required to report data for each ambulatory surgery patient encounter. This information consists of a facility identifier, demographic information on the patient (age, sex, race, ethnicity, zip code of residence), information on the patient's diagnoses (ICD9-CM codes[9] for the principal diagnosis and up to 24 other diagnoses), information on the patient's treatments (CPT codes[10] for the primary and up to 20 other procedures), the patient's disposition at the end of the encounter (discharged to home, transferred to a hospital, etc.), the expected source of payment (Medicare, Medicaid, private insurance, etc.), and various other information. As in the case of the utilization data, patient encounter data are not reported (or not reported completely) by some facilities, either because they have obtained "data exceptions" from OSHPD or because they are noncompliant with the data reporting requirement. Of the 476 licensed ASCs in 2005, data are available from 466; of the 482 licensed ASCs in 2006, data are available for 473.

A limitation of these data arises from the need to protect the privacy of patients. To protect the identity of individual patients, OSHPD masks some data elements for some encounters. Masking affects age, sex, race, ethnicity, and zip code to varying degrees. For

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[8] It is a matter of controversy whether physician-owned ASCs have the choice of which type of accreditation to seek. The Department of Public Health's position is that physician-owned ASCs must be accredited by the Medical Board rather than by DPH, and the California Medical Association's position is that it is a matter of choice by a physician-owned ASC.

[9] ICD9-CM codes are five-digit codes that identify the disease or condition for which the patient was treated. ICD9-CM stands for International Classification of Diseases, 9th Revision, Clinical Modification. (see Medicode, 2008.)

[10] CPT codes are five-digit codes that identify which procedures are performed on a patient. CPT stands for Current Procedural Terminology. (see AMA, 2008.)

example, although the five-digit zip code is available for the vast majority of patients, about 3% of encounters have this variable masked--patients who reside in zip codes that supply only a few encounters have their zip codes masked to prevent identification. Therefore, sample sizes will vary from analysis to analysis, based on masked elements.

In addition, some supplemental data sources are used. Data from the 2000 census link each patient's zip code of residence to median family income in that zip code in 1999. Information on accreditation of California ASCs was obtained from the Web sites of three accreditation agencies: The American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), The Accreditation Association for Ambulatory Health Care (AAAHC), and JCAHO.

To perform the analysis presented below, we linked these datasets together. Patient encounter data were linked to facilities in the utilization data using the facility identifier assigned by OSHPD. Zip code income data were linked to patient encounter data via the zip code field in the encounter data. Accreditation information was linked to the facilities in the utilization data using the name and address information in those data. All the statistical findings were derived from this linked database. Demographic, medical, and payer information ultimately was derived from the encounter data; income was derived from the zip code data; ownership type information was derived from the utilization data; and accreditation was derived from the Web-collected accreditation data.

To determine statistical significance for differences in the distribution of categorical variables among different facility types, Pearson chi-squared tests are employed. To determine differences in the distributions of continuous variables among different facility types, t-tests (in the case of two facility types) or one-way analysis of variance (in the case of more than two facility types) are used. Detailed test results are not presented in the text below because, owing to very large samples sizes, every such test performed resulted in statistically significant differences at the $p<0.01$ level or better. Therefore, the discussion focuses only on the substantive significance of the findings.

FINDINGS

Over the last 20 years, there has been enormous growth in the number of ambulatory surgery centers, reflecting the movement of surgical procedures from an inpatient to outpatient setting. In 1985, there were 336 Medicare-registered ASCs. By 1990 there were 1,197 ASCs; by 2006, 4,707 ASCs. (CMS, 2007) California utilization data show a similar trend. The number of licensed ASCs nearly doubled--from 253 in 1996 to 482 in 2006. There was similarly rapid growth in the number of surgeries, from about 419,000 in 1996 to about 998,000 in 2006, and in net revenue, from $535 million in 1996 to $1.34 billion in 2006. Total encounters (not all of which were necessarily surgical encounters) showed a similarly rapid increase, rising from about 539,000 in 1996 to 1.1 million in 2006.

Describing Ambulatory Surgery Centers

Of the 409 ASCs with usable utilization data in 2006 (482 licensees less 67 nonreporters less 6 with invalid data), 400 (97.8%) were for-profit, seven (1.7%) were non-profit , and two (or 0.5%) were government-owned. The for-profit ASCs were further subdivided according to whether they were owned by corporations (42.5%), partnerships (36.7%), limited liability companies (11.2%), or individuals (7.3%). Unfortunately, according to discussions with the Department of Public Health, these categories do not map in any natural way onto whether or not the ASC is physician-owned.

Ambulatory surgery centers tend to specialize, to a considerable extent, in certain types of procedures. Of the 5,331 different principal procedures in the outpatient surgery encounter data in 2006, the top 10 ASC principal procedures accounted for 58%, the top 50 principal procedures accounted for 77%, and the top 100 principal procedures accounted for 84% of total ASC encounters. The analysis below focuses on the categories of eye surgery, gastrointestinal procedures, pain management, arthroscopy, and cosmetic surgery. The first four of these categories are generally recognized as areas in which ASCs specialize, and the fifth area was added because of its potential relevance in California (see the discussion in Chapter 3).

In order to categorize ASCs according to the procedures in which they specialize, each procedure that was among the top-100 outpatient surgery procedures for either ASCs or hospitals (105 procedures in all) was placed into one of the above five categories or into a catch-all "Other" category. The categorization was based on the CPT code of the principal procedure and is described in detail in Appendix C. Using the encounter data, each ASC was defined as specializing in one of the categories if at least 50% of its procedures (again, measured by principal procedure code) fell into one of these categories. Over 60% of the 473 ASCs with usable encounter data in 2006 specialized in one of the five categories: 121 (26%) specialized in gastrointestinal procedures, 68 (14%) specialized in eye surgery, 65 (14%) specialized in pain management, 44 (9%) specialized in cosmetic surgery, and 11 (2%) specialized in arthroscopy. Of the remaining ASCs, 161 (34%) did not perform a majority of their procedures in any of the categories, and 3 (1%) could not be classified because none of their procedures were in the top 100 procedures.

Comparing ASCs and Hospital Outpatient Surgery Departments

Of the 2.9 million outpatient surgery encounters in 2006 in California, about 1.1 million took place in ASCs and 1.7 million took place in hospital outpatient surgery departments. The encounter data contained 473 ASCs and 360 hospitals. Hospital outpatient departments perform a more diverse mix of procedures. Recall that the top 10, 50, and 100 ASC principal procedures accounted for 58%, 77%, and 84% of all ASC encounters. The corresponding figures for hospital outpatient departments are 30%, 52%, and 63%. Thus, only 30% of hospital outpatient surgeries come from among the top 10 hospital principal procedures, while 58% of ASC encounters come from among the top 10 ASC principal procedures.

Table 1 presents the top 10 principal procedures for ASCs and the top 10 principal procedures for hospital outpatient departments. Because there is considerable overlap in these two top-10 lists, the joint list has 13 procedures. The first column contains the CPT code for the procedure and the second a very brief description of the

Table 1: Top Surgical Procedures in ASCs and Hospitals

		Rank		Volume			
				Total (000s)		Average	
CPT	Procedure[a]	ASC	Hosp	ASC	Hosp	ASC	Hosp
45378	Colonoscopy	1	1	166	115	893	412
66984	Cataract	2	2	116	94	732	412
43239	Endoscopy	3	3	92	83	496	307
45380	Colonoscopy	4	4	77	59	433	233
45385	Colonoscopy	5	5	56	36	327	157
62311	Spinal injection	6	6	53	29	292	174
64483	Spinal injection	7	18	38	13	246	145
29881	Arthroscopy, knee	8	9	23	26	128	94
66821	Laser lens surgery	9	37	21	7	198	88
45384	Colonoscopy	10	19	15	12	161	90
93510	Left Heart Cath	N/A	7	N/A	29	0	242
49505	Hernia repair	19	8	7	26	63	86
47562	Cholecystectomy	66	10	2	25	53	104

[a] For brevity, the details of the types of colonoscopy, endoscopy, and spinal injections are omitted.

procedure. The third and fourth columns give the rank of the procedure, in terms of total volume in the state, among ASCs and hospital outpatient surgery departments. For example, Table 1 shows that a diagnostic colonoscopy procedure (CPT code 45378) was the most common surgical procedure in both ASCs and hospital outpatient surgery departments and that Cholecystectomy (CPT code 47562) was the 66th most common procedure overall in ASCs and the 10th most common procedure overall in hospital outpatient surgery departments. The fifth and sixth columns contain the overall number of procedures in each type of facility in the state. The final two columns show the average volume,[11] for ASCs and hospitals, of the procedure among facilities which do at least ten per year.

The most striking result in this table is that the top six procedures for hospitals and ASCs are the same. Four of these are

[11] This average is interesting because of its potential implications for quality. Many procedures have been shown to exhibit a "volume-outcome effect" in which facilities or physicians who perform a higher volume of the procedure achieve better outcomes.

gastrointestinal procedures (colonoscopies and endoscopies), one is eye surgery, and one is a pain management procedure. Another interesting result is that, for these top six procedures, ASCs provide a higher volume per facility. This despite the fact that ASCs are, on average, smaller than are hospital outpatient surgery departments in terms of overall procedure volume. Another interesting contrast is the presence of left heart catheterization on the hospital top-10 list and its complete absence on the ASCs' list.[12]

Tables 2 through 4 show differences in patient demographic, economic, and medical characteristics between ASCs and hospitals. On demographics, hospitals treat a younger patient population, while race, sex, and ethnicity distributions look very similar between the two settings. In 2006, 36% of ASC patients were older than 65 years while only 31% of hospital patients fell into this age group.

The economic differences between ASC and hospital patients are significant. ASCs treat significantly more patients from high-income zip codes. Eleven percent of ASC patients in 2006 came from a zip code with median family income of over $100,000 and 22% came from zip codes with median family income of over $80,000. By contrast, only 7% of hospital patients came from zip codes with median family incomes of over $100,000 and 15% of hospital patients came from zip codes with median family incomes of over $80,000.

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[12] Observe that, in Table 1, the rank in terms of overall statewide volume for a procedure does not always correspond to the rank in volume per ASC. This is because some ASCs do not perform some procedures. For example, procedure 29881, an arthroscopic knee surgery procedure, was fourth overall in the state in terms of ASC procedure volume, and procedure 66821, a laser eye surgery procedure, was fifth. However, among the 106 ASCs that perform the eye surgery procedure, average volume was 198, while among the 177 ASCs that perform the knee surgery, average volume was 128. So, overall statewide volume for the knee surgery was higher than was the overall statewide volume for the eye surgery, even though per-ASC volumes showed the reverse ranking.

Table 2: Demographic Differences Between Hospital and ASC Patients

Variables	2005		2006	
	ASC	Hospital	ASC	Hospital
Age (years)				
<1	0.05%	0.30%	0.04%	0.29%
1-17	3.29	7.51	3.26	7.57
18-34	7.14	10.91	6.79	10.56
35-64	52.97	49.58	53.64	50.15
>=65	36.54	31.70	36.27	31.43
Sample Size	939,564	1,595,727	1,022,611	1,587,782
Percent Masked	10.71	8.73	10.41	8.41
Sex				
Female	58.17	57.78	58.03	57.50
Male	41.83	42.22	41.97	42.50
Sample Size	708,142	1,250,948	776,062	1,243,067
Percent Masked	32.70	28.06	32.01	28.29
Race				
Native American	0.24	0.33	0.33	0.13
Asian	5.49	5.07	5.79	5.57
Black	1.84	3.06	2.16	3.25
Hawaiian	0.26	0.55	0.22	0.30
White	80.37	82.66	79.06	82.80
Other	11.80	8.33	12.43	7.95
Sample Size	464,160	1,045,612	518,346	1,037,757
Percent Masked	55.89	39.87	54.59	40.14
Ethnicity				
Non-Hispanic	85.64	83.03	84.60	83.37
Hispanic	14.36	16.97	15.40	16.63
Sample Size	399,176	962,145	448,553	954,043
Percent Masked	62.07	44.67	60.70	44.97

There are also differences in expected source of payment[13] between ASCs and hospitals. In 2005 and 2006, about 5% of patients in ASCs paid for their procedures out of their own pockets, compared to 3.6% and 2.5% for hospital patients in 2005 and 2006, respectively. This may represent a higher proportion of cosmetic procedures, which are usually

[13] The OSHPD encounter data contain a 20-category classification scheme for expected source of payment. This is collapsed into seven categories as described in Appendix Table A7: Self, Medicare, Medicaid, Other Public, Managed Care Organization, Fee-For-Service, and Other.

Table 3: Economic Differences Between Hospital and ASC Patients

Variables	2005		2006	
	ASC	Hospital	ASC	Hospital
Income (1999 Dollars)				
<$20,000	0.14%	0.26%	0.15%	0.27%
$20,000 – $40,000	17.76	21.83	17.56	21.96
$40,000 – $60,000	34.30	36.50	34.58	36.29
$60,000 – $80,000	25.85	25.90	26.09	25.95
$80,000 – $100,000	10.60	8.82	10.70	8.87
>$100,000	11.35	6.69	10.92	6.66
Sample Size	1,052,270	1,738,779	1,141,428	1,733,536
Percent Masked	8.74	5.69	8.42	5.93
Payer				
Self	5.04	3.61	5.05	2.50
Medicare	33.37	29.90	32.67	30.78
Medicaid	3.55	9.45	3.44	9.60
Other Public	1.30	2.19	1.41	2.29
Managed Care	24.70	38.51	25.33	39.33
Fee-For-Service	21.00	11.63	22.07	11.33
Other	11.05	4.72	10.03	4.17
Sample Size	1,051,482	1,738,400	1,141,105	1,733,073
Percent Masked	0.07	0.02	0.03	0.03

not covered by insurance. Patients with traditional fee-for-service coverage represented 22% of ASC encounters in 2006 but accounted for only about 11% of hospital encounters. Hospitals served a higher proportion of Medicaid patients (over 9% of hospital business versus less than 4% of ASC business) and a larger proportion of other public business (payers such as Workers Compensation and the Department of Veteran's Affairs). There were differences in representation of managed care as well; these patients accounted for about 25% of ASC volume and 39% of hospital volume. Medicare represented 33% of ASC business and 31% of hospital business in 2006.

The medical (disposition and types of procedures) differences between patients served by ASCs and hospitals are depicted in Table 4. Disposition describes where patients go at the end of their encounter. The vast majority, more than 95%, of outpatient surgery patients go home at the end of their surgery encounter, presumably reflecting the fact

that relatively low-risk patients and procedures tend to be treated in an outpatient surgical setting.

As previously discussed, two potential quality indicators are mortality and transfer to a hospital.[14] Consistent with previous research on outpatient surgery, mortality is found to be a very rare event. In 2006, there were only 132 deaths among the 2.9 million encounters: this outcome is too rare to support any quality comparisons. Although not common, transfers to hospitals were reported in the data. In 2006, the percentage of ASC patients transferred to hospitals was almost twice as high as that for hospital outpatient surgery departments (0.22% versus 0.12%)), despite the decline in ASC transfer rates from 2005 to 2006 (from 0.79% to 0.22%). This result constitutes no more than a preliminary indicator, however. To make definite conclusions about quality differences among the settings would require a more-detailed study that took into account differences in diagnosis, risk factors, and treatments.

Another difference between ASCs and hospitals lies in how many procedures are done at each encounter. To calculate the number of procedures per visit, the number of procedures (both principal and other) reported for each encounter are summed and then the average is taken across settings. In both 2005 and 2006, ASCs did fewer procedures per visit than hospital outpatient surgery departments. Ambulatory surgery centers averaged 1.4 procedures per visit, while hospitals averaged 2.1 procedures per visit. The differences in number of procedures per visit may reflect differences in behavior between ASCs and hospital outpatient departments, differences in patient mix between ASCs and hospitals, or differences in coding practices between the two types of organizations.

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[14] *Transfer to a hospital* in the encounter data and in common use means transfer to inpatient care at a hospital. In principle, it should mean the same thing for ASCs and hospital outpatient departments.

Table 4: Medical Differences Between Hospital and ASC Patients

Variables	2005		2006	
	ASC	**Hospital**	**ASC**	**Hospital**
Disposition				
Home	95.74%	97.47%	97.18%	98.57%
Hospital	0.79	0.15	0.22	0.12
Post-Acute Facility	0.20	0.31	0.16	0.31
Home Health, Hospice	0.01	0.07	0.00	0.06
Died	0.00	0.01	0.00	0.01
Other	3.26	1.99	2.44	0.93
Sample Size	1,051,644	1,738,564	1,141,324	1,733,330
Percent Masked	0.00	0.00	0.00	0.00
Procedure Type				
Gastrointestinal	43.47	38.54	45.30	38.24
Nerve / Pain	17.62	9.58	17.38	9.41
Eye	16.58	13.44	15.90	12.97
Arthroscopy	7.23	7.56	6.92	7.79
Cosmetic	3.45	1.95	3.17	2.10
Other	11.65	28.93	11.33	29.49
Sample Size	876,438	888,779	962,166	885,884
Percent Masked	0.00	0.00	0.00	0.00
Procedures / Encounter	1.37	2.08	1.38	2.17
Sample Size	1,052,270	1,738,779	1,141,428	1,733,536
Percent Masked	0.00	0.00	0.00	0.00

Comparing Cosmetic and Other ASCs

Table 5 presents a comparison of the distribution of characteristics of patients going to ASCs specializing in cosmetic procedures and the distribution of characteristics of patients going to ASCs not specializing in cosmetic procedures. There were 44 ASCs specializing in cosmetic procedures in California. About 19,000 encounters were reported at these facilities in each of 2005 and 2006. In light of the smaller sample sizes and the lack of any significant differences between the years, 2005 and 2006 data are pooled for this comparison. Thus, all of the results in Table 5 represent calculations on combined 2005 and 2006 data.

Patients in ASCs specializing in cosmetic procedures are very different from patients in other ASCs. There are many fewer patients aged 65 and older (15% in cosmetic versus 37% in other ASCs). Cosmetic-specializing ASCs see a higher proportion of female patients. Patients

Table 5: Patients in Cosmetic-Specializing ASCs

Variables	2005-6 combined	
	Cosmetic	Not
Age (years)		
<1	0.16%	0.04%
1-17	0.47	3.31
18-34	21.17	6.81
35-64	62.89	53.22
>=65	15.32	36.63
Sample Size	21,003	1,941,172
Percent Masked	44.92	9.95
Sex		
Female	84.87	57.90
Male	15.13	42.10
Sample Size	10,795	1,473,409
Percent Masked	71.69	31.65
Income (1999 Dollars)		
<$20,000	0.03	0.12
$20,000 - $40,000	18.37	18.00
$40,000 - $60,000	36.58	34.93
$60,000 - $80,000	23.82	26.93
$80,000 - $100,000	11.08	11.01
>$100,000	10.12	9.00
Sample Size	25,766	1,979,891
Percent Masked	32.43	0.12
Payer		
Self	71.21	3.87
Medicare	9.81	33.41
Medicaid	0.25	3.55
Other Public	2.35	8.58
Managed Care	5.85	25.37
Fee-For-Service	8.36	21.79
Other	2.18	3.42
Sample Size	38,132	2,154,455
Percent Masked	0.01	0.05
Number of ASCs	44	429

in cosmetic-specializing ASCs hail from zip codes that are modestly higher in income compared to ASC patients overall. Finally, consistent with the fact that cosmetic procedures are not generally covered by health insurance, the patients at cosmetic-specializing ASCs are much more likely to be self-paying (71% versus 4%) than are patients at ASCs overall.

Comparing ASCs by Ownership Type

The comparison among ASC ownership categories is treated briefly since the vast bulk of ASCs are for-profit and the information available from California's Department of Public Health has not been sufficient to distinguish physician-owned from non-physician-owned ASCs. Tables A1 through A3 in Appendix A correspond to Tables 2 through 4 and present the demographic, economic, and medical comparisons among government-owned, non-profit, and for-profit ASCs.[15] Furthermore, Tables A4 through A6 present comparisons among ASCs broken out by the more detailed ownership types reported in the utilization data.

The principal differences among ASCs of different ownership types were that the government ASCs were more apt to treat a younger, less-wealthy, more-Medicaid population relative to for-profit ASCs. Non-profit ASCs were more likely to specialize in arthroscopy and pain management, and they served a richer and younger population than did the for-profit ASCs.

Turning to the differences among the various for-profit ownership forms reported in Tables A4 through A6, the differences among these groups of ASCs were modest. The differences in patient demographics were quite small. For-profit ASCs owned by individuals treated a lower-income population and more Medicaid, Medicare, and self-pay patients than did the other forms. Individually-owned ASCs performed more cosmetic surgery, less pain management, and less arthroscopy than did the other forms. Partnerships served fewer patients covered by public insurance and more managed-care patients. Partnerships were also more likely to discharge patients to the hospital and performed slightly more procedures per encounter than did the other forms. Corporate-owned ASCs treated an older population and performed more gastrointestinal procedures. Finally, LLC-owned ASCs treated a higher-income and more

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[15] The OSHPD utilization data contain a nine category ownership categorization scheme. Appendix Table A8 contains a description of the mapping between this scheme and the three category (government, non-profit, for-profit) scheme used in Tables A1 through A3.

FFS-insured population, and they were more likely to provide neurological and pain-management services.

Accreditation

To assess the extent to which California ASCs were accredited or certified by national agencies, a list of California ASCs accredited by The American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), The Accreditation Association for Ambulatory Health Care (AAAHC), and The Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) was compiled. These data were collected online from June through October, 2008.

Many California ASCs have sought accreditation from one of the three organizations examined. The JCAHO had accredited 95 California ASCs. The AAAASF had accredited 197 California ASCs. The AAAHC had accredited 292 ASCs. Many of these ASCs, however, are likely regulated in California as outpatient settings by the Medical Board rather than as specialty clinics by the Department of Public Health. ASCs not regulated by the Department of Public Health are absent from both the utilization and encounter data.

The ASCs from the three accreditation agencies were linked to the ASCs from OSHPD's outpatient clinic utilization database using the name and address of the ASCs. Because there is no common identifier among the OSHPD, AAAASF, AAAHC, and JCAHO databases, the linking was imperfect. Of the 482 California ASCs regulated by the Department of Public Health, 183 matched to records from the certifying agencies. These ASCs were assigned to JCAHO, AAAHC, and then AAAASF in that order. Using these matching rules, 126 were certified by AAAHC, 43 were certified by JCAHO, and 14 ASCs were certified by AAAASF. Six ASCs were certified by two organizations and none had three certifications.

A comparison of patients in ASCs certified by the various certification agencies appears in Tables 6 and 7. The columns in these tables correspond to the type of ASC certification. The column labeled "No Match" corresponds to those California ASCs that did not match to any certifying agency in the database. This failure to match could arise either from the ASC not being certified or from a match failure

Table 6: ASC Certification and Patient Characteristics, 2006

Variables	AAAASF	AAAHC	JCAHO	No Match
Age (years)				
<1	0.04	0.04	0.02	0.04
1-17	1.21	3.63	3.08	3.16
18-34	11.87	7.91	7.97	5.91
35-64	57.38	52.74	58.19	53.18
>=65	29.49	35.69	30.74	37.72
Sample Size	15,166	297,572	107,518	602,355
Percent Masked	22.00	9.43	10.88	10.47
Income (1999 Dollars)				
<$20,000	0.23	0.10	0.04	0.14
$20,000 – $40,000	10.02	14.04	14.70	20.56
$40,000 – $60,000	24.90	34.03	37.11	35.44
$60,000 – $80,000	26.32	28.94	30.41	25.37
$80,000 – $100,000	22.74	12.65	12.46	9.62
>$100,000	15.80	10.25	5.28	8.88
Sample Size	19,406	328,264	120,592	671,903
Percent Masked	0.20	0.09	0.04	0.13
Payer				
Self	26.29	4.68	4.96	4.64
Medicare	22.35	31.81	29.29	33.99
Medicaid	1.09	1.97	1.24	4.62
Other Public	8.04	9.03	6.93	7.93
Managed Care	25.09	27.20	28.33	23.88
Fee-For-Service	15.76	22.51	27.17	21.13
Other	1.39	2.80	2.08	3.82
Sample Size	19,444	328,477	120,580	672,604
Percent Masked	0.00	0.03	0.05	0.02
Number of ASCs	13	115	40	305

arising from the lack of a unique identifier in the data, so it would not be correct to interpret those ASCs in the "No Match" category as being uncertified.

Table 6 reveals that the age profile of patients certified by the various agencies was roughly similar, with the AAAHC-certified and unmatched ASCs serving a slightly older population. The income and payer were not similar however. ASCs certified by AAAASF had a higher proportion of high-income and self-paying patients than did other ASCs. Furthermore, ASCs certified by JCAHO had a lower-income, higher-FFS and a slightly higher managed-care population.

Table 7: Medical Differences and ASC Certification, 2006

Variables	AAAASF	AAAHC	JCAHO	No Match
Disposition				
Home	99.49	97.33	99.78	96.56
Hospital	0.08	0.62	0.06	0.05
Post-Acute Facility	0.10	0.02	0.04	0.24
Home Health, Hospice	0.00	0.00	0.02	0.01
Died	0.00	0.00	0.00	0.00
Other	0.33	2.02	0.10	3.15
Sample Size	19,444	328,570	120,642	672,772
Percent Masked	0.00	0.00	0.00	0.00
Procedure Type				
Gastrointestinal	26.07	31.17	38.18	53.50
Nerve / Pain	19.71	23.04	18.11	14.60
Eye	13.42	18.26	15.77	14.90
Arthroscopy	7.30	8.92	8.70	5.69
Cosmetic	17.75	2.55	4.93	2.78
Other	15.75	16.06	14.31	8.53
Sample Size	15,073	267,254	118,315	581,524
Percent Masked	22.48	18.66	18.51	13.56
Procedures / Encounter	1.34	1.39	1.47	1.36
Sample Size	19,444	328,570	120,642	672,772
Percent Masked	0.00	0.00	0.00	0.00

Related to this difference, Table 7 reveals that AAAASF ASCs treated a greater proportion of cosmetic surgery patients. These patients tend to have higher incomes and are more likely to be self-pay than are other ASC patients. That same table also shows that the JCAHO ASCs and the unmatched ASCs are more likely to specialize in gastrointestinal procedures. The AAAHC-certified facilities are more likely to discharge patients to hospitals than are facilities in the other categories. This could represent differences in case mix or differences in quality between this category of ASCs and the others. The AAAHC-certified facilities are somewhat more likely than the other facilities to perform nerve/pain procedures and arthroscopic procedures; these procedures are, in turn, the two most likely categories to lead to a discharge to a hospital.

CHAPTER 3. A COMPARISON OF ASC REGULATION

Recently, the California legislature was considering three bills that would, in part, regulate the delivery of health care by ASCs. In order to help inform this process, we reviewed a variety of policies relating to licensure and quality of ASCs and compared California's current approach to the approaches adopted by the 14 next-largest U.S. states. This section offers a comparative perspective on the regulation of ambulatory surgery centers, comparing California's approach to the regulatory approaches of a number of other large states.

BACKGROUND

California takes a distinctive approach to the regulation of ASCs. California ASCs must be licensed as surgical clinics by the Department of Public Health (DPH) or accredited as "outpatient settings" by the Medical Board. In *Capen v. Shewry* (2007),[16] the court decided that physician-owned ASCs are to be regulated by the Medical Board, while all other ASCs are to be regulated by the DPH. The DPH has interpreted *Capen* to mean that ASCs with any physician owners cannot opt to be licensed as surgical clinics. (Billingsley, 2008)[17]

Against this backdrop, three bills recently under consideration by the California legislature in its 2007/8 session pertain to ASCs. The substance of each of these bills as of August 23, 2008 is described below.[18]

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[16] *Capen v. Shewry* (155 Cal. App. 4th 378 (2007).

[17] The validity of this interpretation is a matter of some dispute, however. (Meghrigian, 2008)

[18] For comprehensive legislative analyses of these proposed measure, see http://info.sen.ca.gov/pub/07-08/bill/asm/ab_1551-1600/ab_1574_cfa_20080814_213459_asm_floor.html, http://info.sen.ca.gov/pub/07-08/bill/asm/ab_2951-3000/ab_2968_cfa_20080813_195016_asm_floor.html, and http://info.sen.ca.gov/pub/07-08/bill/sen/sb_1451-1500/sb_1454_cfa_20080708_153239_asm_comm.html (accessed on August 23, 2008).

Assembly Bill 1574. This measure, introduced by Assemblymember George A. Plescia, would modify access to drugs by ASCs and specify Board of Pharmacy inspection requirements. Under current law, ASCs that are licensed surgical clinics have wholesale access to drugs and may administer them to patients. This bill would extend the same rights and responsibilities to ASCs that are accredited as outpatient settings or Medicare-certified. Specifically, it would

- allow accredited outpatient settings or Medicare-certified ASCs to obtain drugs at wholesale prices and to administer drugs to patients, upon receipt of a license from the State Board of Pharmacy
- require that the Board of Pharmacy inspect accredited outpatient settings or Medicare-certified ASCs within 120 days of licensure and at least annually thereafter;
- permit the Board of Pharmacy to inspect licensed surgical clinics within 120 days of licensure and at least annually thereafter
- require that all ASCs conduct self-assessments within 30 days of licensure by the Board of Pharmacy and at least 30 days prior to license renewal
- impose various other clinical and administrative requirements.

Assembly Bill 2968. This measure, introduced by Assemblymember Wilma Carter, would regulate elective cosmetic surgery. The bill would require that, prior to such surgery, a patient receive a physical examination by, and written clearance from, a licensed physician or, in certain circumstances, a certified nurse practitioner or licensed physician assistant.

Senate Bill 1454. This measure, introduced by former Senator Mark Ridley-Thomas, would regulate the healing arts in outpatient settings. This bill contains numerous changes to the accreditation of outpatient settings. The bill would also

- eliminate an existing requirement that the Medical Board or an accreditation agency give reasonable notice and present proper identification prior to an inspection

- require an outpatient setting to develop and submit for approval by an accrediting agency comprehensive plans, standardized procedures, and protocols for dealing with serious surgical complications or side effects
- require outpatient settings be inspected at least once every three years and as often as necessary to ensure the quality of care
- require inspection reports (potentially including recommendations for reinspection), as well as any provider comments and plans of correction, be retained by the Medical Board of California or accreditation agencies, and that this information be open to public inspection
- require that an outpatient setting agree with the accreditation agency on a plan of correction and publicly post the plan, in the event of a deficiency
- require that the Medical Board notify the public whether an outpatient facility is accredited, certified, or licensed; whether these have been revoked, suspended, or placed on probation; or whether the setting has been reprimanded by an accreditation agency
- require that an accreditation agency immediately notify the Medical Board when an outpatient setting is denied accreditation
- require that the Medical Board evaluate the performance of accreditation agencies at least once every three years
- require that the Medical Board post information on its web site pertaining to the risks of cosmetic surgery.

In addition to these bills before the California legislature, CMS has been considering promulgating regulations on the reporting of quality measures by ASCs. CMS has mandated that hospitals participating in the outpatient prospective payment system[19] publicly report measures of the quality of outpatient care in 2009 or receive reductions in

[19] This constitutes most hospitals. Important exceptions are hospitals in Maryland, Critical Access Hospitals, and Indian Health Service hospitals.

annual updates to Medicare reimbursement rates.[20] In early July 2008, CMS stated its intent to impose similar requirements on ASCs in future rulemaking.

While these proposed policies are quite varied, they appear motivated by a common concern about the quality of outpatient care. Moreover, many of these regulations seek to assure quality through licensure requirements, e.g., periodic on-site inspections. Therefore, the most relevant aspects of ASC regulation in California and the comparison states revolve around issues relating to quality and licensure.

APPROACH AND METHODS

The following questions were chosen for the regulatory comparison:

- Must ASCs be licensed or otherwise approved by regulatory authorities?
- How often are ASCs inspected?
- Must inspections be conducted with prior notice or during certain hours?
- Is accreditation related to licensing or regulatory approval?
- Must ASCs implement quality-assessment or improvement programs?
- Must ASCs report encounter-level data to regulatory authorities?
- Must ASCs report quality indicators to regulatory authorities?

These questions were addressed for the regulatory regimes of the 15 largest states and for the regulatory regime of CMS. The 15 largest states were chosen according to the Census Bureau's estimated population in 2006.[21] Table 8 lists the states studied.

Initially, ASC legal and regulatory issues published for health-law practitioners by the American Health Lawyers Association (Becker et al.,

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[20]See CMS-1404-FC at http://edocket.access.gpo.gov/2008/pdf/E8-26212.pdf (accessed November 22, 2008.)

[21] The Statistical Abstract of the United States reports state population, most recently as of 2006, at http://www.census.gov/compendia/statab/ (accessed on September 16, 2009).

2006) was reviewed. RAND then retained Stateside Associates, a regulatory consulting firm, to collate and summarize the regulatory requirements in the target states and CMS. The consulting firm abstracted statutes and regulation and interviewed responsible officials.

FINDINGS

The findings are reported in Table 8 and in Appendix B in Tables B1 through B7. Table 8 summarizes the findings for each of the regulatory issues identified in the preceding section; Tables B1-B7 detail the sources of information for each of these issues. When reading the descriptions below, it is important to keep in mind that, in the context of California regulation, "surgical clinics" are ASCs regulated by the DPH while "outpatient settings" are ASCs regulated by the Medical Board.

ASC Licensing Requirements

Table B1 reports the findings state-by-state on ASC licensure and approval. ASCs must be licensed/approved within all of the states studied, as well as by CMS for Medicare purposes.

In California, non-physician-owned ASCs must be licensed as surgical clinics by the Department of Public Health (DPH), while physician-owned ASCs must be accredited as outpatient settings by the Medical Board.[22]

Among the states studied, California is distinctive, and apparently unique, in licensing/approving ASCs under a dual regime. Nevertheless, the role of the physician is relevant in other jurisdictions. For example, some authorities distinguish between freestanding facilities operated for the purpose of providing ambulatory surgery (that is, ASCs) and physicians' offices.[23]

[22] See, however, the discussion in footnotes 8 and 17 above.
[23] See, for example, 105 CMR 140.020 in Massachusetts.

Table 8: ASC Regulatory Comparison Summary

Regulatory Issue → \ Authority ↓	Must ASCs be licensed or otherwise approved by regulatory authorities?	How often are ASCs inspected?	Must inspections be conducted with prior notice or during certain hours?	Is accreditation related to licensing or regulatory approval?	Must ASCs implement quality-assessment or improvement programs?	Must ASCs report encounter-level data to regulatory authorities?	Must ASCs report quality indicators to regulatory authorities?
California	Yes	As needed	Depends	Can satisfy	No	Yes	No
Florida	Yes	Annually	No	Facilitates	Yes	Yes	Yes
Georgia	Yes	1-4 years	Yes	Required	No	No	Yes
Illinois	Yes	As needed	Yes	No	No	Yes	Yes
Indiana	Yes	Annually	No	No	Yes	No	Yes
Massachusetts	Yes	As needed	No	No	Yes	No	Yes
Michigan	Yes	By incident	No	Required	Yes	No	No
New Jersey	Yes	As needed	No	Required	Yes	No	No
New York	Yes	By incident	No	Required	Yes	Yes	Yes
North Carolina	Yes	As needed	No	Satisfies	Yes	No	No
Ohio	Yes	As needed	No	Facilitates	Yes	No	Yes
Pennsylvania	Yes	As needed	No	No	No	No	Yes
Texas	Yes	As needed	Yes	Facilitates	Yes	No	Yes
Virginia	Yes	As needed	No	No	No	Yes	No
Washington	Yes	18 months	No	Facilitates	Yes	No	Yes
Medicare	Yes	Initially	No	Satisfies	Yes	Yes	No

ASC Inspection Frequency

ASC inspection frequencies vary among states. Findings on the frequency with which authorities conduct on-site inspections of ASCs are presented in Table B2.

In a majority of jurisdictions, statute or regulatory code explicitly provides that ASCs may be inspected as necessary to ensure compliance with regulatory requirements. Even where there is not an explicit provision, regulation may allow for inspection in the event of a complaint or a serious incident; Michigan and New York are examples. In other jurisdictions, regulation stipulates the frequency of inspection. For example, ASCs must be inspected every 18 months in Washington. Some regulations call for periodic inspections. In Georgia, current practice is to inspect facilities every one to four years, based on the findings of a facility's last survey. At the federal level, CMS ordinarily requires an inspection only upon initial Medicare certification, although regulatory officials report that CMS has ordered special inspections this year.

Under California's dual licensure/accreditation regime, ASCs that are surgical clinics or outpatient settings may be inspected as necessary; ASCs that are licensed as surgical clinics are exempt from periodic inspection. Senate Bill 1454 would explicitly require that outpatient settings be inspected every three years but as often as needed. Assembly Bill 1574 would require that ASCs that are accredited as outpatient settings or Medicare-certified be inspected at least annually by the State Board of Pharmacy; in addition, the Board of Pharmacy would be permitted to annually inspect ASCs that are licensed as surgical clinics.

Prior Notice for Inspections

The effectiveness of inspections presumably has to do with the manner and timing of those on-site inspections. Findings on the variation among states in the manner and timing of on-site inspections are presented in Table B3.

In ten states and under Medicare policy, there are no explicit restrictions on the manner and timing of inspections. In Georgia, Illinois, and Texas, the timing must be reasonable. In none of these cases was prior notice required.

In California, current regulations vary. Surgical clinics may be inspected at any time without notice. Outpatient settings, by contrast, must be given reasonable notice, and inspection must be conducted at a reasonable time. Senate Bill 1454 would eliminate the requirement of notice to outpatient settings.

Accreditation and Licensing/Approval

Accreditation agencies, such as JCAHO, AAAASF, and AAHC, often play a role in the regulation of ASCs. Findings on the variation in this role among state and federal regulatory regimes are presented in Table B4.

In Pennsylvania, Virginia, Illinois, Indiana, and Massachusetts accreditation is unrelated to licensure. By contrast, accreditation plays a central role in some states, in which it is either necessary or sufficient for licensure (Georgia, Michigan, New Jersey, New York, and North Carolina.) In the remaining states, accreditation facilitates licensure. For example, in Ohio ASCs must submit to an on-site inspection by the Ohio Department of Health. However, this requirement may be waived if the ASC provides an approval letter from Medicare (this approval requires accreditation by a Medicare-approved accrediting body) and access to the accreditation report from the Medicare-approved accrediting body. At the federal level, an ASC may be "deemed" Medicare-certified through accreditation.

In California, accreditation currently satisfies the requirements for approval as an outpatient setting but is unrelated to licensing for surgical clinics. Medicare certification and licensure as a surgical clinic also satisfy the requirements for approval as an outpatient setting.[24]

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[24] The narrow issue in *Capen* was whether a physician-owned ASC *had* to be licensed as a surgical clinic by the DPH. The dispute over the

Quality Assessment and Improvement Programs

ASC regulation often features mandates for the development and implementation of programs for quality assessment or improvement. These requirements are distinct from, and often supplementary to, more basic regulations intended to ensure quality and safety (e.g., requirements with respect to medical staff or infection control). Findings of a comparison of these quality assessment and improvement regulations are summarized in Table 8, while Table B5 reports the full findings.

A majority of the states studied require such programs. For example, New Jersey ASCs must establish and implement a written plan for a quality assurance program, to be reviewed once a year and overseen by a multidisciplinary committee; in Texas, ASCs must "develop, implement and maintain an effective, ongoing, organization-wide, data driven Patient Safety Program." At the federal level, Medicare conditions of coverage mandate that an "ASC, with the ongoing participation of medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided . . ."

In California, ASCs are not currently required to implement quality programs. Senate Bill 1454 would impose a requirement that outpatient settings develop comprehensive plans for dealing with serious surgical complications.

Encounter-Level Data Reporting

Patient encounter data must be reported by ASCs to state authorities in some states. These data may be useful to authorities in assessing quality and performance more generally. For example, transfer to a hospital, which can indicate an adverse outcome, might be included in encounter-level data (Woods et al., 2007). Public- or restricted-use data sets may also be available to health researchers for related analyses. The findings are summarized in Table 8, while Table B6 reports the full findings.

DPH's interpretation of *Capen* is whether a physician-owned ASC *may* opt for DPH licensure (Meghrigian, 2008) rather than obtaining approval as an outpatient setting based on Medicare certification or accreditation by an organization such as JCAHO.

ASCs report encounter-level data in Florida, Illinois, New York, and Virginia. In each case, patient diagnosis, medical procedure, and discharge status are included. ASCs currently report claims data to the Medicare program.

In California, outpatient encounters at ASCs regulated as surgical clinics and hospital outpatient departments are currently reported to OSHPD, but ASCs regulated as outpatient settings do not have this reporting requirement. These data include diagnoses, procedures, and discharge status.

Quality Indicator Reporting

The public reporting of quality indicators has been increasing in recent years, and the ASC sector has not been excepted. Some states require ASCs to report quality indicators to state regulators, which are sometimes made publicly available. Data on these indicators may also be used to assess ASCs. The findings are summarized in Table 8, while Table B7 reports the full findings.

In most of the big states studied, ASCs must report quality indicators specified by authorities. Information pertaining to deaths must be reported in five states (Florida, Indiana, Massachusetts, Pennsylvania, and Texas); surgery on the wrong site or patient must be reported in three states; and hospital transfers must be reported in five states. Illinois, Michigan, New Jersey, North Carolina, and Virginia do not require quality reporting, though Illinois and Virginia have access to some quality-related information based on encounter-level data. ASCs are not currently required to report quality indicators for Medicare purposes, though CMS is considering such requirements.

In California, ASCs are not currently required to report any quality indicators that are not present in, or derivable from, encounter-level data. These data include deaths as well as transfers to hospitals.

Procedure or Specialty-Specific Regulation

Since ASCs typically specialize in one or a few areas (see the discussion in Chapter 2), a question naturally arises as to whether any

states have ASC regulation specifically targeted at various types of ASCs. For example, do any states have regulations specifically targeted at cosmetic surgery ASCs or at gastroenterological ASC? No regulation that distinguished among ASCs in this way was found.[25] Were it to become law, California's AB 2968 would specifically regulate cosmetic surgery procedures.

[25] Ophthalmology, orthopedics, gastroenterology, and urology were considered specifically in the review.

CHAPTER 4. SUMMARY AND CONCLUSIONS

Over the last 20 years, there has been enormous growth in the number of ambulatory surgery centers, nationally and in California. Because of this growth, because ASCs compete with hospital outpatient surgery departments, because they are generally for-profit, and because they are often physician-owned, a number of policy and regulatory questions have arisen. This report describes the current state of ASCs in California, compares the patients in ASCs and hospital outpatient departments, compares the various categories of ASCs, and compares the regulatory environment in California to that in other states and to the regulatory regime at CMS.

The 473 California ASCs that report encounter data account for about 1.1 million outpatient surgery encounters, while the 360 California hospitals reporting ambulatory surgery data account for about 1.7 million encounters. Compared to hospital outpatient surgery departments, ASCs perform a lower volume of surgeries and are more focused on a few types of procedures. ASCs generally achieve higher volume on those procedures in which they specialize. In general, ASCs tend to serve a higher-income and more-generously-insured population. ASCs tend to do fewer procedures per visit than do hospitals.

On one recognized quality indicator, transfer to a hospital, ASCs appear to score slightly worse than do hospital outpatient departments, although performance on this measure improved markedly between 2005 and 2006. However, given the immaturity of the ASC quality measurement literature and the lack of controls for patient risk factors in the work reported here, this finding should be treated with great caution. It is not possible to conclude from it that ASCs provide lower-quality care than do hospitals. This finding does point to the need for more research to determine whether the higher transfer rate in ASCs represents a difference in quality.

ASCs perform proportionately more cosmetic procedures than do hospitals, and 44 California ASCs specialize in cosmetic procedures. These cosmetic-specializing ASCs serve a younger, more-female, and

slightly higher-income patient base than do non-cosmetic-specializing ASCs. Furthermore, patients at cosmetic-specializing ASCs are much more likely to be paying for their procedures out of pocket.

Because of the lack of a consistent identifier among data sources, only 183 California ASCs could be matched to records of accreditation agencies. Among those facilities for which matches were found, AAAASF-certified ASCs tended to serve a higher-income population and to perform more cosmetic procedures. Facilities certified by AAAHC tended to transfer more patients to hospitals.

Given the recent interest in the California legislature concerning ASC regulation, California's regulatory regime was compared to that in the 14 next-most populous U.S. states. Like all the states examined, California requires ASCs to be licensed; however, California is distinctive in using a "two-track" process whereby ASCs are licensed/approved by the Department of Public Health ("surgical clinics") or the Medical Board ("outpatient settings"). Physician-owned ASCs are eligible to be regulated by the Medical Board[26] while non-physician-owned ASCs are regulated by the Department of Public Health. Although it is a matter of some controversy, the Department of Public Health interprets a recent court decision as forbidding it from issuing licenses to ASCs with any physician ownership, so that ASCs with any physician ownership are now regulated by the Medical Board.

All the states surveyed require inspection for licensure, but the frequency of that inspection varies. Under the "outpatient settings" track of California's two-track method, preannouncement of inspections is required; under the "surgical clinics" track in California and in all other states, there is no such requirement. Licensing/approval is unrelated to accreditation by an agency such as JCAHO under the "surgical clinics" track in California and in five other states. Accreditation satisfies all requirements under the "outpatient settings"

[26] There is disagreement on whether these facilities must be so regulated. See the discussion in footnotes 8, 17, and 18.

track in California and in North Carolina. In the remaining states, accreditation either facilitates licensure or is required.

Quality regulation was also compared. Most big states and Medicare require ASCs to implement quality assessment and improvement programs; California does not. Most big states require ASCs to report various quality indicators (deaths, transfers to hospitals, wrong-site surgeries, etc.) to regulators, while California does not. Some quality indicators can be derived from California's encounter data, however. Most states do not require the reporting of encounter data to regulatory authorities. For ASCs licensed as surgical clinics, California does.

One key issue in the regulation of ASCs is physician self-referral. Because of an exception in the federal anti-referral law, the so-called Stark Law, it is legal for physicians to refer patients to physician-owned ASCs in which they have an interest. Unfortunately, because California does not collect and report information on physician ownership, it was not possible to study this important issue.

There are a number of avenues for further research regarding public policy for ASCs. First, the lack of validated, routinely reported quality measures for ASCs points to the need for research directed at creating and validating such measures. In particular, it would be valuable to investigate the causes and consequences of rare events, such as transfer to hospital, which are most easily measured in patient encounter data and which have been identified by National Quality Forum and the Ambulatory Surgical Centers Quality Collaboration as potential quality indicators.

The research revealed differences in patterns of volume and procedure specialization between ASCs and hospital outpatient surgery departments. These differences could have implications for quality if high volume is associated with quality or if more specialization is associated with higher quality. There is little research on these questions for outpatient surgery at present. Given the heterogeneity in states' strategies for regulating ASCs and given that ASC quality measures are currently under development, research into the effects of different regulatory strategies on ASC quality would be promising. Finally, given the differences we document in the income and insurance

status of hospital and ASC patients, it would be interesting to analyze how the geographical distribution of ASCs and hospital outpatient departments vary and how this distribution affects their respective patient populations. In addition, it would be valuable to analyze competition among ASCs and hospital outpatient departments and how this competition affects the distribution of patients among facilities.

APPENDIX A. ASC OWNERSHIP COMPARISON

This appendix contains a number of tables supplemental to Chapter 2 of the report. Tables A1-A3 describe the differences among the patient populations receiving care in government, non-profit, and for-profit ASCs. These tables parallel the similar tables in Chapter 2 that compare patients of ASCs to those of hospital outpatient departments. They provide comparisons of demographic, economic, and medical differences among the three patient populations.

Tables A4-A7 concern the patient populations of for-profit ASCs. Those tables compare the patient populations receiving care in ASCs having various ownership forms: individual, partnership, limited liability corporation, and corporation.

Finally, Table A8 describes the re-classification from OSHPD's more detailed ownership schema to the simple government, for-profit, non-profit schema used in Tables A1-A3.

Table A1: Demographic Differences Among ASC Ownership Types, 2006

Variables	Government	Non-Profit	For-Profit
Age (years)			
<1	0.09%	0.00%	0.04%
1-17	7.83	7.21	3.13
18-34	12.26	8.89	6.71
35-64	61.56	54.46	53.57
>=65	18.26	29.44	36.55
Sample Size	5,569	25,867	990,506
Percent Masked	10.53	7.59	10.41
Sex			
Female	57.42	57.94	58.03
Male	42.58	42.06	41.97
Sample Size	4,143	18,667	752,677
Percent Masked	34.15	33.48	32.04
Race			
Native American	0.16	0.03	0.34
Asian	0.28	4.89	5.86
Black	3.25	1.70	2.17
Hawaiian	0.06	0.00	0.23
White	90.51	91.92	78.66
Other	5.75	1.45	12.75
Sample Size	3,202	13,547	501,057
Percent Masked	47.90	51.96	54.70
Ethnicity			
Non-Hispanic	80.19	89.26	84.50
Hispanic	19.81	10.74	15.50
Sample Size	6,191	27,982	1,106,442
Percent Masked	54.97	57.69	61.03

Table A2: Economic Differences Among ASC Ownership Types, 2006

Variables	Government	Non-Profit	For-Profit
Income (1999 Dollars)			
<$20,000	0.00%	0.05%	0.15%
$20,000 – $40,000	17.40	19.52	17.51
$40,000 – $60,000	43.27	27.91	34.70
$60,000 – $80,000	27.62	22.30	26.17
$80,000 – $100,000	10.48	10.40	10.71
>$100,000	1.23	19.82	10.75
Sample Size	6,191	27,982	1,106,442
Percent Masked	12.10	4.69	8.08
Payer			
Self	10.50	2.09	5.10
Medicare	17.17	33.59	32.72
Medicaid	10.27	1.86	3.44
Other Public	9.29	0.17	1.40
Managed Care	36.59	50.71	24.62
Fee-For-Service	8.11	9.90	22.47
Other	8.08	1.69	10.25
Sample Size	6,191	27,982	1,106,119
Percent Masked	0.00	0.00	0.03

Table A3: Medical Differences Among ASC Ownership Types, 2006

Variables	Government	Non-Profit	For-Profit
Disposition			
Home	99.63%	99.61%	97.11%
Hospital	0.03	0.10	0.22
Post-Acute Facility	0.00	0.03	0.16
Home Health, Hospice	0.00	0.00	0.00
Died	0.00	0.00	0.00
Other	0.34	0.25	2.51
Sample Size	6,191	27,982	1,106,338
Percent Masked	0.00	0.00	0.00
Procedure Type			
Gastrointestinal	44.58	12.10	40.80
Nerve	17.83	31.13	4.53
Eye	16.15	0.00	22.58
Arthroscopy	7.06	20.66	6.26
Cosmetic	2.95	4.44	3.80
Other	11.43	31.66	22.03
Sample Size	2,454	21,112	843,775
Percent Masked	0.00	0.00	0.00
Procedures / Encounter	1.72	1.29	1.38
Sample Size	3,933	27,054	998,256
Percent Masked	0.00	0.00	0.00

Table A4: Demographic Differences Among For-Profit ASCs, 2006

Variables	Individual	Partnership	LLC	Corporation
Age (years)				
<1	0.01%	0.03%	0.05%	0.05%
1-17	2.54	3.45	2.65	2.91
18-34	7.15	7.25	6.99	5.84
35-64	51.42	55.81	54.97	50.19
>=65	38.88	33.47	35.33	41.00
Sample Size	29,182	484,127	123,187	354,010
Percent Masked	17.31	10.15	11.00	10.09
Sex				
Female	56.34	57.86	57.92	58.40
Male	43.66	42.14	42.08	41.60
Sample Size	19,061	363,604	94,112	275,900
Percent Masked	51.02	32.84	32.47	29.42
Race				
Native American	0.13	0.31	0.88	0.20
Asian	4.04	4.05	4.89	9.12
Black	1.30	1.80	2.05	2.83
Hawaiian	0.11	0.12	0.08	0.47
White	79.41	83.33	85.58	68.88
Other	15.00	10.38	6.53	18.49
Sample Size	12,804	258,756	61,358	168,139
Percent Masked	58.59	52.55	57.27	56.62
Ethnicity				
Non-Hispanic	78.08	87.55	84.62	80.61
Hispanic	21.92	12.45	15.38	19.39
Sample Size	11,596	215,143	55,010	151,472
Percent Masked	62.71	60.92	62.17	60.66

Table A5: Economic Differences Among For-Profit ASCs, 2006

Variables	Individual	Partnership	LLC	Corporation
Income (1999 Dollars)				
<$20,000	0.10%	0.13%	0.06%	0.21%
$20,000 – $40,000	32.35	14.69	12.25	21.90
$40,000 – $60,000	43.09	32.73	31.42	37.80
$60,000 – $80,000	11.74	28.80	31.31	22.05
$80,000 – $100,000	3.43	12.83	12.27	7.91
>$100,000	9.29	10.81	12.69	10.13
Sample Size	33,733	538,515	137,735	396,459
Percent Masked	14.98	7.01	7.99	9.19
Payer				
Self	9.21	3.63	5.72	6.52
Medicare	40.36	28.91	36.83	35.83
Medicaid	10.94	2.48	1.21	4.86
Other Public	0.12	1.22	0.53	2.06
Managed Care	21.98	27.32	20.68	22.53
Fee-For-Service	8.45	23.68	27.91	20.14
Other	8.94	12.76	7.11	8.06
Sample Size	33,733	538,351	137,680	396,355
Percent Masked	0.00	0.03	0.04	0.03

Table A6: Medical Differences Among For-Profit ASCs, 2006

Variables	Individual	Partnership	LLC	Corporation
Disposition				
Home	95.89%	96.57%	99.93%	96.96%
Hospital	0.04	0.40	0.03	0.07
Post-Acute Facility	3.62	0.04	0.01	0.07
Home Health, Hospice	0.01	0.01	0.00	0.00
Died	0.00	0.00	0.00	0.00
Other	0.44	2.98	0.03	2.90
Sample Size	33,730	538,445	137,732	396,431
Percent Masked	0.00	0.00	0.00	0.00
Procedure Type				
Gastrointestinal	43.53	41.34	41.64	50.20
Nerve	2.56	20.34	19.64	14.68
Eye	28.32	13.10	16.66	19.45
Arthroscopy	1.00	9.81	6.24	3.90
Cosmetic	7.03	2.66	4.09	2.69
Other	17.56	12.76	11.72	9.08
Sample Size	19,095	418,431	105,571	300,678
Percent Masked	0.00	0.00	0.00	0.00
Procedures / Encounter	1.39	1.44	1.21	1.37
Sample Size	23,801	502,490	125,778	346,187
Percent Masked	0.00	0.00	0.00	0.00

Table A7: Payer Reclassification

Terse Classification	OHSPD Classification
Self	Self-Pay
Medicare	Medicare HMO
Medicare	Medicare Part A
Medicare	Medicare Part B
Medicaid	Medi-Cal
Other Public	Other Non-federal
Other Public	Disability
Other Public	Other Federal
Other Public	Title V
Other Public	Veterans' Affairs
Other Public	Workers' Comp
Managed Care Org	Preferred Provider Organization
Managed Care Org	Point of Service Organization
Managed Care Org	Exclusive Provider Organization
Managed Care Org	Health Maintenance Organization
Managed Care Org	Champus / TRICARE
Fee-For-Service	Blue Cross
Fee-For-Service	Commercial Insurance
Other	Other
Other	Automobile Medical

Table A8: ASC Ownership Reclassification

Terse Classification	OHSPD Classification
Government	City and/or County
Government	District
Government	State
Government	University of California
Non-Profit	Non-Profit Corporation
For-Profit	Investor – Corporation
For-Profit	Investor – Individual
For-Profit	Investor – Limited Liability Company
For-Profit	Investor - Partnership

APPENDIX B. TABULAR STATE REGULATION DATA

This appendix contains more-detailed summaries of the state regulation data discussed in Chapter 3. The tables are organized according to the bulleted list of review questions on page 26 of that chapter. Table B1 summarizes the requirements ASCs must meet in order to be licensed in each state. Table B2 describes whether each surveyed state requires ASCs to be inspected in order to maintain their licensure and the frequency of any such required inspections. Table B3 categorizes surveyed states according to whether or not they provide prior notice to the ASCs that are to be inspected. Table B4 describes the relationship between voluntary accreditation and mandatory state licensure in each state--for example, whether accreditation satisfies some or all of the requirements for licensure. Table B5 describes the required quality assessment and quality improvement programs for each state, if any. Table B6 describes whether or not each state requires the reporting of patient encounter data to the state. Table B7 categorizes states according to whether or not ASCs are required to report quality indicators to the state.

Table B1: ASC Licensing Requirements

Authority	Answer	Comments	Source(s)
California	Yes	Prior to *Capen vs.* Shewry, an ASC had to be licensed by the Department of Public Health or (if anesthesia is used) Medicare-certified or accredited as an outpatient setting by an organization approved by the Medical Board. Based on *Capen*, the Department of Public Health will no longer license ASCs with any physician owners. The Medical Board will regulate physician-owned ASCs, which must be Medicare-certified or accredited.	California Health and Safety Code §1200-1201, 1204-1206, §1248; *Capen vs. Shewry* (65 Cal.Rptr.3rd 890); California Medical Association, March 28, 2008; Department of Public Health, April 4, 2008
Florida	Yes		Florida Statute 395.003
Georgia	Yes		Georgia Adm. Code Ch. 290-5-33-.05
Illinois	Yes		77 Ill. Adm. Code 205.120, 205.125
Indiana	Yes		Indiana Code 21-2-2
Massachusetts	Yes		105 CMR 140.101
Michigan	Yes		Mich. Adm. Code R 325.3811
New Jersey	Yes		New Jersey Adm. Code 8:43A-2.2(a)
New York	Yes	Except for part-time clinic sites, an operating certificate shall be issued to each certified site of health care delivery.	NY CRR Title 10, Section 401.1
North Carolina	Yes		10A North Carolina Adm. Code 13C .0201
Ohio	Yes		Ohio Adm. Code

Authority	Answer	Comments	Source(s)
			3701-83-03
Pennsylvania	Yes		28 Penn. Code §551.31
Texas	Yes		Texas Health and Safety Code, Title 2, Section 243.003
Virginia	Yes		12 Virginia Adm. Code 5-410-50
Washington	Yes		RCW 70.230.030; regulatory official(s)
Medicare	Yes	To participate in the Medicare program, ASCs must be certified as having satisfied conditions of coverage. In addition, an ASC must have a valid license in its state of operation, if so required.	42 CFR §416

Table B2: ASC Inspection Frequency

Authority	Answer	Comments	Source(s)
California	As needed	A representative of the Department of Public Health may enter and inspect an ASC, though these facilities are exempt from periodic inspections. The Division of Medical Quality (or an approved accreditation organization) may also enter and inspect an outpatient setting.	California Health and Safety Code §1227-1228, §1248
Florida	Annually, or upon complaint	Annual inspection is required for ASCs that are not accredited.	Florida Adm. Code 59A-5.004
Georgia	Prior to opening, then periodically	Regulators currently conduct on-site inspections every one to four years, based on facility's survey history.	Georgia Adm. Code 290-5-33-.08(2); regulatory official(s)
Illinois	As needed	The Department shall make investigations it deems necessary. Facilities are inspected upon licensure. Thereafter, facilities are inspected every three years by the state or an accrediting agency. A complaint can prompt an inspection.	210 ILCS 5; 77 Ill. Adm. Code 205.118; regulatory official(s)
Indiana	Annually, or upon complaint		40 Indiana Adm. Code 15-1.3-4(1); regulatory official(s)
Massachusetts	As needed	An inspection or other investigation shall be made prior to the issuance of every license, which is ordinarily valid for two years. Additional inspections may be made whenever necessary for the enforcement of 105 CMR 140.000.	130 CMR 140.111
Michigan	Upon initial licensing, then	Subsequent licensing inspections typically occur when the state inspects facilities	Regulatory official(s)

Authority	Answer	Comments	Source(s)
	periodically or upon complaint	for Medicare purposes	
New Jersey	Upon initial licensing, then as needed, at least biennially	On-site inspections may be prompted by complaint or deficiency finding.	New Jersey Adm. Code 8:43A-3.9(2) , 8:43E-2.1, 8:43E-2.2; regulatory official(s)
New York	Prior to opening, then upon complaint or reporting of an incident		Regulatory official(s)
North Carolina	On initial licensure application, and As needed	The Branch schedules an on-site, pre-opening licensure survey on a date that will coordinate with the Construction Section's projected approval for site occupancy.	NC Statutes Section 131E-150; http://www.ncdhhs.gov/dhsr/floamsu.htm
Ohio	As needed		Ohio Adm. Code 3701-83-06(A)
Pennsylvania	As needed, at least annually	Whenever the Department has received a complaint or has other reasonable grounds to believe that a deficiency exists, the Department may inspect or survey the facility.	28 Pa. Code §551.33, §551.51, §551.71
Texas	As needed	During the initial licensing period, the department shall conduct a survey of the ASC; the ASC shall request that an on-site survey be conducted after the ASC has provided services. An on-site licensing inspection may be conducted once every three years. The department may make any survey or investigation that it considers necessary.	Texas Adm. Code §135.20(e), §135.21
Virginia	As needed, and		Virginia Code

Authority	Answer	Comments	Source(s)
	periodically and at least biennially		§32.1-125.1, §32.1-126
Washington	Every 18 mos.		RCW 70.230.100
Medicare	Ordinarily, only upon initial certification	Inspections ("surveys") are conducted on behalf of Medicare by state agencies.	State Operations Manual, Chapter 1; regulatory official(s)

Table B3: Inspection Notice

Authority	Answer	Comments	Source(s)
California	Depends	The Department of Public Health can inspect a licensed ASC at any time without any notice. The Division of Medical Quality must give an outpatient setting reasonable notice and inspect at a reasonable time.	California Health and Safety Code §1248.35
Florida	No	Complaint inspections must be unannounced.	Florida Adm. Code 59A-5.004
Georgia	During reasonable and/or scheduled hours	In addition, inspectors must present proper identification.	Georgia Adm. Code 290-5-33-.08(1)
Illinois	During reasonable and/or regular hours	Written authorization is required; notice is not.	210 ILCS 5; 77 Ill. Adm. Code 205.118
Indiana	No		
Massachusetts	No		
Michigan	No		
New Jersey	No		
New York	No		
North Carolina	No		
Ohio	No	Notice is voluntary, but at least two weeks must be given for licensing inspection.	Ohio Adm. Code 3701-83-06(A)
Pennsylvania	No	Whenever the Department has received a complaint or has other reasonable grounds to believe that a deficiency exists, the Department may without notice to the ASC investigate, inspect or survey the facility.	28 Pa. Code § 551.71

Authority	Answer	Comments	Source(s)
Texas	Time must be reasonable.	In addition, in the event of an investigation arising from a complaint, an ASC may be entered during normal business hours; notice is not required.	Texas Adm. Code §135.21, §135.25
Virginia	No		
Washington	No		
Medicare	No		

Table B4: Contribution of Accreditation to Licensing

Authority	Answer	Comments	Source(s)
California	Can satisfy in some cases	Accreditation by JCAHO, AAAHC, or AAAASF can satisfy an ASC's regulatory requirements as an outpatient setting. Licensing, if necessary, is independent of accreditation.	California Health and Safety Code §1248.1- 2; California Medical Board website (http://www.medbd.ca.gov/outpatient_surgery.html)
Florida	Satisfies annual inspection requirement	Accreditation by JCAHO or AAAHC is accepted.	Florida Adm. Code 59A-5.004
Georgia	Required for licensing	An applicant for a new ambulatory surgery service shall provide a statement for the intent to meet, within 12 months., the appropriate accreditation requirements of the JCAHO, AAAHC, or AAAASF and/or other appropriate accrediting agency. An applicant for expanded service shall provide documentation that it fully meets the appropriate accreditation requirements.	Georgia Adm. Code 111-2-2-.40
Illinois	No		
Indiana	No		
Massachusetts	No	Required for reimbursement from the Medical Assistance Program.	130 CMR 423.404
Michigan	Required	Accreditation by JCAHO, AAAHC, the American Osteopathic Association (AOA), or Blue Cross/Blue Shield-approved agency is acceptable.	Regulatory official(s)
New Jersey	Required	Each newly licensed ambulatory surgery facility shall submit the report of a survey of the facility performed by an independent	New Jersey Adm. Code 8:43A-3.12(b)

Authority	Answer	Comments	Source(s)
		accreditation organization approved by the department. Following submission of the initial report, each licensed facility shall submit a report of the most recent survey as part of the annual licensure renewal process. Such survey shall have been performed within three years of licensure renewal.	
New York	Required	Operator shall ensure that accreditation is obtained from either JCAHO or AAAHC. Internal Department of Health policy is that new facility obtain accreditation within two years of receipt of an opening certificate.	NYCRR Title 10, Section 400.18; regulatory official(s)
North Carolina	Satisfies	Accreditation by JCAHO, AAAHC, or AAAASF is accepted. Accreditation does not prohibit inspections.	10A North Carolina Adm. Code 13C .0201
Ohio	Satisfies inspection requirement for license renewal	Accreditation by JCAHO, AAAHC, or AAAASF is accepted.	Ohio Adm. Code 3701-83-05(A)(2)
Pennsylvania	No		
Texas	May substitute for initial survey	Initial licensing survey may be waived if the ASC provides documented evidence of accreditation by JCAHO, AAAHC, or AAAASF and Medicare-deemed status	Texas Adm. Code §135.20(e)(4)
Virginia	No		
Washington	Can help satisfy on license renewal	An ambulatory surgical facility shall be deemed to have met the standards if it submits proof of accreditation by an organization that the secretary has determined to have substantially equivalent standards to those of the department, and successfully completes the survey	RCW 70.230.020, 70.230.100

Authority	Answer	Comments	Source(s)
		requirements, and if the ASC has satisfactorily completed a survey by the department in the previous 18 months.	
Medicare	Satisfies	An ASC may be deemed certified through accreditation by JCAHO, AAAHC, AAAASF, or AOA.	42 CFR §416; regulatory official(s)

Table B5: Quality Assessment/Improvement Program Requirements

Authority	Answer	Comments	Source(s)
California	No		
Florida	Yes		Florida Adm. Code 59A-5.019
Georgia	No		
Illinois	No		
Indiana	Yes		40 Indiana Adm. Code 15-2.4-2, 2.5-1
Massachusetts	Yes	In addition, each clinic shall develop a procedure that ensures prompt and complete investigations of all serious complaints.	130 CMR 140.306, 140.370, 140.613
Michigan	Yes	The conduct of the work of a facility shall be regularly and frequently reviewed in a hospital-operated facility to ensure maintenance of high standards and quality of care. In other facilities, comparable arrangements shall be made.	Michigan Adm. Code R 325.3838
New Jersey	Yes		New Jersey Adm. Code 8:43A-18.1
New York	Yes		NYCRR Title 10, Section 751.8
North Carolina	Yes		10A North Carolina Adm. Code 13C .0306
Ohio	Yes		Ohio Adm. Code 3701-83-12(A)
Pennsylvania	No		
Texas	Yes	Known as Patient Safety Program.	Texas Adm. Code §135.27
Virginia	No	Establishment of an infection control committee is required, however.	12 Virginia Adm. Code 5-410-490
Washington	Yes		RCW 70.230.080
Medicare	Yes		42 CFR §416

Table B6: Encounter-Level Data Reporting

Authority	Answer	Comments	Source(s)
California	Yes	Includes diagnoses, procedures, and discharge status.	California Health and Safety Code §128737, 22 CCR §97213(a)(3), 97216-972133
Florida	Yes	Includes diagnoses, procedures, and discharge status.	Florida Adm. Code 59B-9.011
Georgia	No		
Illinois	Yes	Includes diagnoses, procedures, and discharge status.	77 Ill. Adm. Code 1010.40
Indiana	No		
Massachusetts	No		
Michigan	No		
New Jersey	No		
New York	Yes	Includes diagnoses, principal procedure, discharge status, operating time used, and method of anesthesia.	NYCRR Title 10, Section 400.18
North Carolina	No		
Ohio	No		
Pennsylvania	No		
Texas	No		
Virginia	Yes	Includes diagnoses, comorbidities, procedures, and discharge status	12 VAC 5-218-20
Washington	No		
Medicare	Yes	ASCs submit claims for billing Medicare.	

Table B7: Quality Indicator Reporting

Authority	Answer	Comments	Source(s)
California	No		
Florida	Yes	Adverse incidents must be reported. Such incidents include (but are not limited to) death, surgery on wrong patient, performance of wrong procedure or surgery on wrong site, permanent disfigurement, and transfer to a more acute setting.	Florida Statute 395.0197
Georgia	Yes	ASCs must annually summarize complications, emergencies and hospitals transfers.	Georgia Adm. Code 290-5-33-.12
Illinois	No		
Indiana	Yes	Serious adverse incidents must be reported. Such incidents include (but are not limited to) certain deaths or disabilities, surgery on wrong patient, performance of wrong procedure or surgery on wrong site.	40 Indiana Adm. Code 15-2.4-2.2
Massachusetts	Yes	All surgery- and anesthesia-related complications resulting in death or serious disability must be reported.	130 CMR 140.611
Michigan	No		
New Jersey	No		
New York	Yes	Deaths and hospital transfers must be reported.	NYCRR 751.10
North Carolina	No		
Ohio	Yes	ASCs must report the number of deaths resulting from surgery or surgical complications, as well as number of and reasons for hospital transfers.	Ohio Adm. Code 3701-83-22
Pennsylvania	Yes	ASCs must report to the Department of Health any events that seriously compromise quality assurance or patient safety. Such events include (but are not limited to) certain deaths, hospital transfers due to injuries or accidents, and	28 Penn. Code §51.3

Authority	Answer	Comments	Source(s)
		surgery on wrong site or patient. In addition, ASCs must report certain events to the Pennsylvania Patient Safety Reporting System, including (but not limited to) adverse drug reactions and procedural complications.	
Texas	Yes	ASCs must report and explain in writing to the Department of State Health Services the following events: deaths while under the ASC's care, hospital transfers, development of complications within 24 hours of discharge resulting in hospital admission, and stays exceeding 23 hours. Under the Patient Safety Program, ASCs must annually report on certain events, including (but not limited to) the number of medication errors resulting in unanticipated death or major permanent bodily loss of function, as well as surgeries on wrong site or patient.	Texas Adm. Code §135.26, §135.27
Virginia	No		
Washington	Yes	The department shall require ambulatory surgical facilities to submit data related to the quality of patient care for review by the department. The data shall be submitted every 18 months. The department shall consider the reporting standards of other public and private organizations that measure quality in order to maintain consistency in reporting and minimize the burden on the ambulatory surgical facility.	RCW 70.230.110
Medicare	No	A rule proposed by CMS for 2009 would require that hospital outpatient departments report quality measures or receive a reduced payment update. CMS is considering such a policy toward ASCs but has not yet proposed a rule.	CMS's ASC Payment website

APPENDIX C. TOP 100 PROCEDURES FOR EITHER ASCS OR HOSPITALS

This appendix contains a listing of the CPT codes for each of the top-100 most frequently performed procedures in ASCs and the CPT codes for each of the top-100 most frequently performed procedures in hospitals. In addition, Table C1 contains the scheme by which these procedures were classified as arthroscopy, cosmetic, eye, gastrointestinal, nerve, and other.

Table C1: Top-100 Procedures for ASCs or Hospitals

Principal Procedure CPT code	Classification
00170	Other
14060	Cosmetic
15822	Cosmetic
15823	Cosmetic
15831	Cosmetic
15877	Cosmetic
19120	Other
19125	Other
19316	Cosmetic
19318	Other
19325	Cosmetic
19371	Cosmetic
20610	Other
20680	Other
23412	Other
25000	Other
25111	Other
25447	Other
25620	Other
26055	Other
26160	Other
27096	Other
28080	Nerve
28285	Other
28296	Other
29806	Arthroscopy
29807	Arthroscopy
29823	Arthroscopy
29824	Arthroscopy
29826	Arthroscopy
29827	Arthroscopy
29848	Arthroscopy
29875	Arthroscopy
29876	Arthroscopy
29877	Arthroscopy
29880	Arthroscopy
29881	Arthroscopy
29888	Arthroscopy
30520	Cosmetic
31255	Other
41870	Other
41899	Other
42820	Other
42821	Other
42826	Other
42830	Other

Principal Procedure CPT code	Classification
43235	GI
43239	GI
43248	GI
43249	GI
43251	GI
45330	GI
45331	GI
45378	GI
45380	GI
45383	GI
45384	GI
45385	GI
47562	Other
49505	Other
49585	Other
49650	Other
50590	Other
52000	Other
54161	Other
55700	Other
58120	Other
58558	Other
58563	Other
58662	Other
58670	Other
58970	Other
58974	Other
59820	Other
62264	Nerve
62290	Nerve
62310	Nerve
62311	Nerve
62318	Nerve
62319	Nerve
63650	Nerve
64470	Nerve
64475	Nerve
64476	Nerve
64479	Nerve
64483	Nerve
64484	Nerve
64510	Nerve
64520	Nerve
64622	Nerve
64626	Nerve
64718	Nerve
64721	Nerve
64722	Nerve

Principal Procedure CPT code	Classification
65420	Eye
65426	Eye
65855	Eye
66170	Eye
66761	Eye
66821	Eye
66982	Eye
66984	Eye
66999	Eye
67904	Eye
68320	Cosmetic
69436	Other

APPENDIX D. NATIONAL QUALITY FORUM ASC PERFORMANCE MEASURES

This appendix contains a listing of performance measures for ASCs developed by the NQF in order to "facilitate efforts to assess and improve the quality of care delivered in our nation's outpatient surgical facilities." (National Quality Forum, 2009)

Table D1: NQF ASC Performance Measures

Measure	Description	Developer
Patient Burn	Percentage of admissions experiencing burn prior to discharge.	ASC CC
Propylactic IV Antibiotic Timing	Percentage of ASC patients who receive IV antibiotics for surgical site prophylaxis on time.	ASC CC
Hospital Transfer/Admission	Percentage of ASC patients who require hospital transfer or admission prior to ASC discharge.	ASC CC
Patient Fall	Percentage of ASC admissions experiencing a fall prior to discharge.	ASC CC
Wrong Site etc.	Percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant.	ASC CC
Selection of Prophylactic Antibiotic, 1st or 2nd Generation Cephalosporin	Percentage of surgical patients aged > 18 years undergoing procedures with the indications for a 1st or 2nd generation cephalosporin prophylactic antibiotic who had an order for cefazolin OR cefuroxime.	NCQA/AMA PCPI
Timing of Prophylactic Antibiotics, Ordering Physician	Percentage of surgical patients aged > 18 years with indications for prophylactic parenteral antibiotics who have an order for an antibiotic to be given within one hour (if vancomycin, two hours) prior to the surgical incision or start of procedure when no incision is required.	NCQA/AMA PCPI
Timing of Prophylactic Antibiotics, Administering Physician	Percentage of surgical patients aged > 18 years with indications for prophylactic parenteral antibiotics for whom administration of the antibiotic has been initiated within one hour (if vancomycin, two hours) prior to the surgical incision or start of procedure when no incision is required.	NCQA/AMA PCPI
Discontinuation of Prophylactic Antibiotics, Non-Cardiac Procedures	All non-cardiac surgical patients aged > 18 years undergoing procedures with indications for prophylactic antibiotics who have an order for discontinuation of the antibiotic within 48 hours of surgical end.	NCQA/AMA PCPI

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