Mandate for Accreditation in Plastic Surgery Ambulatory/ Outpatient Clinics

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KEYWORDS

• History of accreditation • Plastic surgery ambulatory clinics • JCAH • AAAHC • AAAASF • Medicare

KEY POINTS

- Efforts at patient safety are integrated with Medicare requirements.
- Plastic surgeons have taken a lead in patient safety.
- The future of patient safety will depend on data-driven analysis.

BACKGROUND

Patient safety in ambulatory surgery settings has evolved through a combination of state/federal regulation, private accreditation, and increased patient awareness.

A function of state government is the protection of the public. The control of the practice of medicine is a primary exercise of this function. This control is exhibited both in the licensing of those who may practice medicine and in the settings in which it can be practiced. Legal precedent for the privatization of public protection functions exists in a variety of decisions by both state and federal courts.

Technological advances have allowed health care services to migrate across settings increasingly outside of the hospital, and regulatory jurisdictions have the unenviable obligation to protect a public receiving care in more numerous and diverse facilities. From the regulatory perspective, ambulatory surgery encompasses outpatient health care facilities ranging from large multi-suite ambulatory surgery centers to single-physician procedure rooms. Although cosmetic and plastic surgery receive a disproportionate amount of media and legislator attention, concerns related to outpatient care and oversight are not unique to any specialty. Government agencies have the ultimate responsibility to ensure the safety of their constituents and have increasingly turned to private accrediting bodies to establish a comprehensive regulatory program partnering state enforcement authority and private survey capabilities. Twenty-seven states now accept or mandate accreditation in at least one of the ambulatory settings.

PRIVATE ACCREDITATION EVOLUTION

Historically, "Professional societies began regulating medical practice by examining and licensing practitioners as early as 1760. By the early 1800s, the medical societies were in charge of establishing regulations, standards of practice, and certification of doctors."[1] As medical education and regulation began to mature, care began to migrate from the home to the hospital. Emanuel Codman, MD, first proposed for the standardization of hospitals in 1910. The first set of requirements was developed by the American College of Surgeons

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in 1917: a 1-page document.[2] Accreditation mandates in ambulatory surgery are legacies inherited from hospital oversight. The manner in which regulatory oversight is delegated by government to third-party agencies approximates hospital oversight regimen that began with the Hospital Standardization Program in the early part of the twentieth century and formalized with mandated Joint Commission accreditation for Medicare-participating hospitals in 1965. Delegation of authority has followed the decentralization of health care services because it is quite effective for government to identify private regulatory partners whereby public agencies may have a particular weakness or limitation. "The American College of Physicians, the American Hospital Association, the American Medical Association and the Canadian Medical Association joined with the American College of Surgeons as corporate members to create the joint commission on accreditation of Hospitals in 1951."[2] In 1965 The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) was recognized in the Social Security Amendments to provide accreditation of hospitals.

Federal regulatory efforts lagged behind the changes in the provisions of health care. In the early 1970s there was a significant migration of health care and surgical services from the hospital to neighborhood regional ambulatory centers. JCAH at the time did not provide a program of accreditation for these centers. To meet this need, the Accreditation for Ambulatory Health Care was incorporated in Illinois.[3]

In 1980 the American Society of Plastic and Reconstructive Surgeons recognized that surgeons operating in freestanding facilities were unable to access accreditation through JCAH or Accreditation for Ambulatory Health Care and established the American Association for Ambulatory Plastic Surgery Facilities to design and operate a single-specialty accreditation program for outpatient plastic surgery centers. Based on inquiries by other surgical specialties, the American Association for Ambulatory Plastic Surgery Facilities formed the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) in 1992 to accredit other single-specialty and multispecialty surgery facilities, owned and operated by physicians certified by the American Board of Medical Specialties. AAAASF currently accredits facilities that include all the American Board of Medical Specialties surgical disciplines.

This evolution is consistent with other business sectors requiring specialized knowledge, because agencies often rely on regulation by private arm's length organizations with expertise in the subject matter. Health care facilities, prisons, and institutions of higher learning are commonly associated with private accreditation, not surprising given that the concepts related to administering such institutions are likely to be foreign to most people outside of those fields. Accreditation organizations are representative of the industries they regulate; thus, the people setting and revising standards work in the field and are at the forefront of research, driving the latest developments in quality and safety.

Deferring to private accreditation is, at least in part, an acknowledgment of the institutional inertia that can delay regulatory changes. Although it is certainly possible for a public agency to create its own set of standards, it is less probable for that agency to keep up with the rapid developments of the industry. Revision attempts slow considerably due to political negotiations, bureaucratic review processes, and public comment periods. Competing interests each have the opportunity to voice their opinions during the public revision process, sometimes yielding few rewards. The original Medicare hospital conditions for participation were published in 1966; attempted updates to the conditions began in 1977 but were not finalized until 1986. The Centers for Medicare and Medicaid Services published its first major revisions to the ambulatory surgery center conditions for coverage in mid-2008, 26 years after the initial adoption. By contrast, accreditation organizations typically revisit their standards annually to at least study minor adjustments, if not to undertake wholesale revisions.

Federal and state agencies' biggest impetus for delegating to accreditation agencies may be cost. Administering an inspection and certification regime is a costly enterprise in financial and personnel terms. Private organizations can often realize cost efficiencies that are impossible for government agencies and can therefore perform inspections with lower operating costs. Many states have statutory limits or prohibitions on fees that a facility may be charged. Higher costs and budgetary limits exert extraordinary pressure on government programs. In 1991 Medicare estimated that internally administering the hospital certification program would require 722 additional full-time personnel, an increase of nearly one-third, and $59 million in operating costs that would have to be absorbed into the budget.[4] The state of Washington administers a portion of its Ambulatory Surgery Facility licensing and inspection program, performing at least 1 of the 2 surveys that each facility must complete in each 36-month period. The state department of health identified that its initial cost and personnel estimates for

operating the licensing program were shorter than the actual needs and was able to secure statutory authority to raise licensing fees and add staff. The result is a new tiered licensing fee structure with a maximum 3-year fee of $10,068, or $5410 if the facility is accredited. Private accreditation agencies charge fees directly to facilities; thus, they are not in such a precarious financial position and are able to adjust staff accordingly.

Simple efficiency certainly plays a role in government's willingness to accept or mandate accreditation in lieu of a state process. In the mid-1990s the 2 major US plastic surgery societies (American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons and The American Society of Plastic and Reconstructive Surgeons) mandated that all members operate only in licensed or accredited facilities. This mandate was a critical turning point for plastic surgery as well as for accreditation. The mandate was a demonstration to medical boards and public advocates of the specialty's commitment to quality and safety. Continuing to operate in the office, terrifyingly called unlicensed facilities, as many plastic surgeons did, only put their reputations and professional licenses at risk. As more jurisdictions considered regulating all outpatient settings, the existing foundation of specialty mandated accreditation must have presented an attractive option for regulatory oversight without adding a redundant inspection process.

LEGISLATIVE EVOLUTION

California led the way in officially mandating accreditation. In 1995 the California legislature passed Assembly Bill 595, requiring oversight over all outpatient settings using anesthesia at higher levels than local anesthesia. The primary mechanism for office surgery, those facilities not licensed through the state and not participating in Medicare, to achieve requisite oversight became accreditation. Contemporary articles explain the state's patient safety concerns and the legislature emphasized that the intent of Bill 595 was to "assure that the least costly and effective method of achieving patient safety is required." The bill was initially drafted in response to increased commercial advertisement for office-based cosmetic surgery but gained traction after the death of a pediatric patient under anesthesia. California had a duty to ensure that those physicians advertising for cosmetic surgery were properly trained and qualified to provide those services; without the personnel and financial resources to survey every one of the offices in question, the state favored mandatory accreditation. Passing the law became a moral imperative with the young patient's unfortunate passing.

When one considers the impetus for regulation as noted above with the administrative challenges extant for most state and federal agencies, detailed in the previous section, it is only logical that states would prefer a delegated form of regulatory oversight. In this model the government can devote its valuable resources to investigating complaints or adverse incidents and assuring the quality of accrediting organizations that it approves to perform the oversight function. Thus the state only has to perform a handful of routine reviews of accrediting organizations rather than surveying hundreds or potentially thousands of facilities. The result is a more efficient use of public resources and an effective method to assure quality and safety.

Scenarios similar to California's have occurred across the country with largely the same results. A tragic event or the aggregation of several lower impact events cause increased media coverage and foment legislative resolve to protect the public. Traditionally the resulting regulatory regimes subject facilities to oversight with sedation or higher levels of anesthesia use. Adverse events pertaining to plastic surgery are particularly attractive as media stories and receive tremendous public attention because the patients affected are typically healthy when they elect to undergo a procedure. Any resulting long-term damage is particularly compelling. Complications are only exacerbated if the operating physician performs a procedure outside of their specialty training. An attractive feature of accreditation is that every approved accreditation agency has methods by which physicians prove appropriate training and competency in the specialties performed in the facility.

Despite the high-profile nature of complications related to plastic surgery and specialty drift, there are myriad patient safety issues related to the routine provision of care in every medical specialty. The 2008 hepatitis exposure of patients in 2 Nevada gastroenterology facilities is a prime example. The cases were related to improper injection practices and insufficient infection control oversight, not physicians operating outside of their scopes of practice. The resulting regulatory regime requires both state inspection and accreditation of all outpatient facilities.

The emerging trend in mandatory accreditation is to combine oversight based on the level of anesthesia used with enumerating procedures that require accreditation. Unfortunately some physicians have attempted to skirt regulatory requirements by providing inappropriate care under local anesthesia, which not only complicates

matters for physicians providing appropriate care in the form of procedures that can be safely performed under local anesthesia but it also frustrates the efforts of regulators who want to ensure patient safety without overburdening physicians that are safely performing minor procedures under local anesthetic in the office. Proposed solutions include adding mandated accreditation for certain listed procedures most commonly associated with untoward events, no matter what level of anesthetic is used, to existing anesthesia-based requirements. Regulators hope the hybrid approach will discourage unscrupulous practitioners from bypassing rules by dangerously operating under local anesthesia, without overburdening those safely operating within their specialty.

FUTURE REGULATORY TRENDS IN ACCREDITATION

As early as 1994 Timothy Stotzfus Jost predicted a new role for the private accrediting bodies. "If the Joint Commission can establish itself as a credible source measuring quality, it may in the future find that its primary customers are not the institutions it accredits, the doctors who work in those institutions, or the government, but rather the consumers of health care and their institutional agents or the an agent and adviser of purchasers."[5]

A revolution in information has occurred for patients seeking to have more access to a wide variety of information regarding their health. They are bombarded by information in the form of commercials identifying diseases and treatments that they are encouraged to discuss with their physicians. The Internet search engines provide a library of information on every imaginable disease and surgical intervention. This information is seldom based on scientific fact, but becomes a part of fact by frequency.

At the same time that there is this increase in information, there has been a shortage of actual data that measure outcomes controlled for specific interventions. AAAASF has pioneered this type of data collection and analysis by instituting mandated reporting of adverse incidents in all surgical cases. The future of patient safety and accreditation will depend on the evolution of the ability to mine patient safety data from electronic medical records and surgical notes.

The trend seems to couple outcomes data with performance-based purchasing of health care. This next shift in regulation and accreditation may provide adequate information to the consumer and the payer of health care to make decisions based on location of services, patient safety, quality of the care experience, and cost.

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