

## COSMETIC SURGERY IN THE DOCTOR'S OFFICE: IS STATE REGULATION IMPROVING PATIENT SAFETY?

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In fact, hot dog vendors on the street are more regulated than office surgeons. At least their carts have to be inspected to see if they are meeting public safety codes.<sup>1</sup>

Surgery in an outpatient setting has grown enormously over the last several decades.<sup>2</sup> Convenience, improved technology, and advanced techniques have made surgery outside the hospital a feasible and less costly alternative.<sup>3</sup> Over eight million outpatient surgeries were performed in 2000,<sup>4</sup> and by 2005 it is estimated that eighty percent of all surgeries will be performed in an outpatient facility.<sup>5</sup> One quarter of those outpatient surgeries will be performed in the private physician's office.<sup>6</sup>

While surgery has migrated to the doctor's office, oversight and regulation have not followed.<sup>7</sup> Private physician offices are not subject to the same state and federal regulatory oversight as hospitals and freestanding surgical centers (an outpatient setting).<sup>8</sup> A doctor's medical license establishes the authority to perform a procedure of any scope and complexity in a private office, regardless of the level of training, certification, and experience of the physician.<sup>9</sup> The only

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1. NEW YORK STATE SENATE COMMITTEE ON INVESTIGATIONS, TAXATION, AND GOVERNMENT OPERATIONS, PROBLEMS OF OFFICE SURGERY (1999), available at <http://www.senate.state.ny.us/Docs/surgery.htm> [hereinafter NEW YORK STATE SENATE COMMITTEE].

2. Elizabeth M. Lapetina & Elizabeth M. Armstrong, *Preventing Errors in the Outpatient Setting: A Tale of Three States*, HEALTH AFF., July/Aug. 2002, at 27.

3. *Id.* at 27 (Noting that the cost of a surgical procedure outside the hospital is sixty to seventy-five percent less than in the hospital). A freestanding surgical center has two or more operating rooms, several physicians, surgeons, anesthesiologists, and nursing staff, and many states require accreditation of these facilities. *Id.* at 27-28. Types of procedures performed in an office setting include cancer screening, biopsies, colonoscopy, arthroscopy, cataract removal, microlaparoscopy, pregnancy termination, liposuction, and cosmetic augmentation/reduction. Adrian Hochstadt, *How States Regulate Office Surgery - A Primer*, 22 PLASTIC SURGICAL NURSING 133, 133-134 (2002).

4. Lapetina & Armstrong, *supra* note 2, at 27.

5. Rod J. Rohrich & Paul F. White, *Safety of Outpatient Surgery: Is Mandatory Accreditation of Outpatient Surgery Centers Enough?* 107 PLASTIC & RECONSTRUCTIVE SURGERY 189, 189 (2001).

6. *Id.*

7. Robert del Junco et. al., *Report of the Special Committee on Outpatient (Office-based) Surgery*, 88 J. MED. LICENSURE & DISCIPLINE 160, 162 (2002).

8. *Id.*

9. COMMITTEE ON QUALITY ASSURANCE IN OFFICE-BASED SURGERY, A REPORT TO: NEW YORK STATE PUBLIC HEALTH COUNCIL & NEW YORK STATE DEPARTMENT OF HEALTH, ix (2000)

oversight of physicians who practice outside a hospital occurs through the licensing and disciplinary functions performed by either a state's Board of Medicine or Department of Health.

The current standard for private physicians is that "[t]he care delivered in such offices is expected to meet prevailing standards of care for the licensed profession."<sup>10</sup> Without the benefit of uniform guidelines that specify the standard of care, for the patient seeking surgery in a private physician's office, the rule of *caveat emptor* prevails.<sup>11</sup> The federal government held hearings in the 1990s to discuss regulation of outpatient settings, but no legislation resulted.<sup>12</sup> States have been left to respond to public pressure concerning safety in the office setting. While some states have created legislation, regulations, or guidelines for office surgery, not all have done so, and patient safety remains a concern.<sup>13</sup>

In addition, while there is a consensus in the medical field that there should be minimum standards in *any* setting where surgery is performed to ensure patient safety, medical societies and specialty organizations disagree on what those standards should be.<sup>14</sup> These organizations spend time and effort trying to prove their commitment to patient safety by arguing that their members are perfect and therefore the problem must lie with other healthcare providers. The dialogue about patient safety in some specialties has degraded to such an extent that there have even been accusations made that certain specialties are using this issue to monopolize services performed in an office setting for personal greed.<sup>15</sup> The end result of this controversy is that the patient's safety and concerns are ignored.

This note will address the issue of patient safety in three sections. Section I will outline the scope of the problem with a specific focus on liposuction. Section II will discuss the necessity of regulation and describe the current regulatory schemes of three states: New York, New Jersey, and Florida. Section III will analyze whether existing regulation is working and what might be done in the future.

## I. OFFICE SURGERY IS NOT SAFE, ESPECIALLY LIPOSUCTION

### A. *Are Patients Really Dying in the Doctor's Office?*

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[hereinafter COMMITTEE ON QUALITY ASSURANCE IN OFFICE-BASED SURGERY].

10. COMMITTEE ON QUALITY ASSURANCE IN OFFICE-BASED SURGERY, *supra* note 9, at ix.

11. Madelyn Schwartz Quattrone, *Is the Physician Office the Wild, Wild West of Health Care?*, 23 J. AMBULATORY CARE MGMT. 64, 66 (2000).

12. Hochstadt, *supra* note 3, at 134.

13. Lapetina & Armstrong, *supra* note 2, at 28.

14. Hochstadt, *supra* note 3, at 134.

15. Larry G. Hornsby, *Anesthesia's New Frontier: Ensuring Patient Safety in the Office Setting*, 22 PLASTIC SURGICAL NURSING 112, 113 (2002).

The fact that private physicians who perform surgery in their offices are largely unregulated by any state or federal agency may indicate that errors can happen and are happening. We do not need to speculate on this, however. Cases speak for themselves.

A nine-year-old girl went to a doctor's office in Texas to have tubes inserted into her ears. She was given an overdose of anesthetic, went into cardiac arrest, and died. The failure of the doctor and certified registered nurse anesthetist ("CRNA") to administer the anesthesia properly, use of thirty-year-old unmaintained anesthesia equipment, and the failure to monitor the child's condition during the surgery, directly resulted in her death.<sup>16</sup> Also in Texas, a fourteen-month-old child underwent laser surgery to remove a birthmark in a doctor's office. The anesthesia lines were mistakenly crossed and she was asphyxiated with nitrous oxide.<sup>17</sup>

In 1997, a forty-seven-year-old woman in California, with an undiagnosed heart problem, died during a ten-and-a-half-hour surgery in her doctor's office. She had plastic surgery on her face, abdomen, thighs, hips, arms, back, calves, knees, and buttocks; all at the same time.<sup>18</sup> A thirty-three-year-old New Jersey man died in 1998 after undergoing liposuction by a non-licensed physician at a New York clinic.<sup>19</sup> During another liposuction procedure, a New York doctor punctured a forty-year-old woman's colon seven times, nearly killing her. The doctor had been censured and reprimanded by the New York State Health Department eight years earlier for practicing his profession fraudulently and negligently.<sup>20</sup>

Two deaths occurred in the same New Jersey dermatologist's office during liposuction surgery where the physician's training in the procedure consisted solely of a thirty-minute videotape.<sup>21</sup> A doctor in Southern California allowed his bookkeeper to administer anesthesia to a patient, who died as a result.<sup>22</sup> A health care provider who administered anesthesia to an older man undergoing eyelid surgery left the room shortly after giving him the anesthetic. During this absence, the patient failed to receive enough oxygen and was permanently brain damaged. This tragedy could have been prevented if the health care provider had been in the room and did not delay resuscitating the patient.<sup>23</sup> An eighteen-year-old

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16. NEW YORK STATE SENATE COMMITTEE, *supra* note 1.

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. Ervin Moss, *Revelations: New Jersey Office Regulations Adopted*, AM. SOC'Y ANESTHESIOLOGISTS NEWSLETTER, Aug. 1998, available at [http://www.asahq.org/Newsletters/1998/08\\_98/Revelations\\_0898.html](http://www.asahq.org/Newsletters/1998/08_98/Revelations_0898.html).

22. NEW YORK STATE SENATE COMMITTEE, *supra* note 1.

23. NEW YORK STATE SENATE COMMITTEE, *supra* note 1.

Pennsylvania man and a fifty-five-year-old Florida woman both died from fat clogs lodged in their lungs after undergoing liposuction in their doctors' offices.<sup>24</sup>

*B. Is Liposuction Unsafe?*

When an individual in good health dies during an elective surgery, it captures attention. There have been over one hundred news reports of deaths during liposuction since 1990.<sup>25</sup> Liposuction is the only cosmetic surgery that has a mortality rate.<sup>26</sup> Exactly what that mortality rate is has been the subject of heated debate in the medical field.

The first thing to consider is the enormous amount of liposuction surgery being performed each year. According to the American Society of Aesthetic Plastic Surgery National Data Bank, almost two million surgical cosmetic procedures were performed in 2003: half of those were in a doctor's office, and liposuction was the most common.<sup>27</sup>

Deaths during liposuction in the doctor's office may be higher than those resulting from car crashes.<sup>28</sup> The fatality rate from car accidents is 15.2 out of every 100,000.<sup>29</sup> A 1997 study by the American Society of Plastic and Reconstructive Surgeons found a death rate of 20.6 per 100,000 for liposuction.<sup>30</sup> In 2000, Grazer and de Jong published a survey of liposuction outcomes from 1994 to 1998 that found a death rate of 19.1 per 100,000.<sup>31</sup> These two surveys taken together give an oft quoted mortality rate of one in five thousand for liposuction in the doctor's office.<sup>32</sup>

The troubling aspect of these studies is that the physicians who responded to these voluntary surveys were certified in plastic surgery by the American Board of Plastic Surgery.<sup>33</sup> The question becomes then, what is the death rate among physicians not certified in plastic surgery or cosmetic surgery who are routinely performing liposuction in their offices? Grazer and de Jong note that the fatality rate for liposuctions has risen significantly since 1988 and believe this rise is due to the increased demand for liposuction, newer techniques, equipment,

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24. Hochstadt, *supra* note 3, at 133.

25. *Id.*

26. Daniel J. Penofsky, *Cosmetic Liposuction Malpractice Litigation*, 80 AM. JUR. TRIALS 32 (2001).

27. AMERICAN SOCIETY FOR AESTHETIC PLASTIC SURGERY, COSMETIC SURGERY NATIONAL DATA BANK 2003 STATISTICS (2003) <http://www.surgery.org/download/2003-stats.pdf> (384,626 liposuction surgeries were performed in 2003).

28. Lapetina & Armstrong, *supra* note 2, at 29.

29. *Id.*

30. *Id.*

31. Frederick M. Grazer & Rudolf H. de Jong, *Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeons*, 105 PLASTIC & RECONSTRUCTIVE SURGERY 436, 436 (2000).

32. *Id.*

33. Grazer & de Jong, *supra* note 31, at 437.

medications, overzealous surgeons, progressive trivialization of the procedures, and the entry of lesser-trained physicians into the surgeon pool.<sup>34</sup>

Other studies have been published that seemingly contradict these numbers and claim zero mortality rates for surgery, including liposuction, in the doctor's office.<sup>35</sup> The problem with these studies, however, is that only board certified physicians (certified in the particular specialty of the surgery performed) in accredited surgical facilities were surveyed.<sup>36</sup> The doctors surveyed were *already* practicing safely and with the appropriate education, experience, resources, and personnel. In fact, these studies are strong evidence in support of regulations. If regulations impose a standard of care that has already been proven to be safe, then all patients in all settings will benefit.

### C. Why Aren't Physician Offices Safe?

While the risks of a specific surgical procedure may be thought to be the same in any setting, unlike hospitals, many office physicians and staff are unprepared and unable to deal with complications if they arise. A large portion of office surgical procedures are cosmetic procedures, specifically liposuction.<sup>37</sup> These cosmetic surgeries very often require the patient to undergo some form of anesthesia. The administration of general anesthesia, specifically during a

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34. Grazer & de Jong, *supra* note 31, at 441.

35. See H. Steve Byrd et al., *Safety and Efficacy in an Accredited Outpatient Plastic Surgery Facility: A Review of 5316 Consecutive Cases*, 112 PLASTIC & RECONSTRUCTIVE SURGERY 636, 636 (2003) (Showing zero deaths in 5,316 surgeries performed by the same six board certified plastic surgeons in a single accredited facility between 1995 and 2000); George Bitar et al., *Safety and Efficacy of Office-Based Surgery with Monitored Anesthesia Care/Sedation in 4778 Consecutive Plastic Surgery Procedures*, 111 PLASTIC & RECONSTRUCTIVE SURGERY 150, 150-51 (2003) (Showing zero deaths in 4778 procedures performed in a plastic surgery center with surgeons certified in multiple board specialties and CRNAs in a single American Association for Accreditation of Ambulatory Surgical Facilities ("AAAASF") accredited facility between 1995-2000. The center contained the most technologically advanced equipment, all surgeons had privileges to perform the same surgeries at a hospital, all staff were trained in Advanced Cardiac Life Support, and there were emergency transfer agreements with two nearby hospitals); Tamara Salam Housman et al., *The Safety of Liposuction: Results of a National Survey*, 28 DERMATOLOGIC SURGERY 971, 973 (2002) (Showing zero deaths out of 66,570 liposuctions from polled members of the American Society of Dermatologic Surgery. Yet, ninety-one percent of surgeons reported only performing tumescent liposuction surgery which does not require general anesthesia and has a much higher safety record than liposuction under general anesthesia); Steven M. Hoefflin et al., *General Anesthesia in an Office-Based Plastic Surgical Facility: A Report on More Than 23,000 Consecutive Office-Based Procedures Under General Anesthesia With No Significant Anesthetic Complications*, 107 PLASTIC & RECONSTRUCTIVE SURGERY 243, 250 (2001) (Showing no deaths in over 23,000 surgeries under general anesthesia in an accredited facility with board certified surgeons and anesthesiologists. However, this facility probably is better classified as a freestanding surgical facility than an office-based practice).

36. See *id.* and accompanying text.

37. Hochstadt, *supra* note 3, at 133.

cosmetic procedure, can impair lung and heart functioning for which the patient needs assistance during the surgery.<sup>38</sup> Due to this dramatic impact on the body, anesthesia can be very dangerous without proper procedures and monitoring, especially in an office setting.<sup>39</sup> Other complications a patient might face are lidocaine toxicity, skin perforation, vital organ injury, hypothermia, adverse anesthesia reaction, pulmonary embolus, and fat embolus.<sup>40</sup>

In a study of adverse events (errors) during sedation (anesthesia) in a pediatric population between 1969 and 1996, research found that a child died from an error that occurred in a hospital thirty-seven percent (37%) of the time.<sup>41</sup> When those errors occurred in an outpatient setting, a child died ninety-three percent (93%) of the time, usually due to inadequate resuscitation.<sup>42</sup> In a report of the American Society of Anesthesiologists Closed Claim Project, office-based claims were more severe than hospital-based claims.<sup>43</sup> Patients died three times more often in an office than in a hospital.<sup>44</sup> The patient care in the office-based claims was more often judged to be substandard and the injuries preventable with better monitoring.<sup>45</sup> Office-based claims were also more likely to be paid, and the amount was higher on average.<sup>46</sup>

In contrast to the celebration of reduced risk for anesthesia in the hospital-based practice, there has been an outcry to address unreasonable risk in the office-based setting. The problem is that inattention to proper standards in many (but certainly not all) office-based surgery practices has returned death rates for healthy office-based patients today to the death rates for sick hospitalized patients decades ago.<sup>47</sup>

The typical checks and balances present in a hospital are absent in an office setting.<sup>48</sup> In many states, “there are no requirements for board certification, continuing medical education, or peer review to monitor the performance of

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38. del Junco et al., *supra* note 7, at 169.

39. *Id.*

40. Ronald E. Iverson et al., *Practice Advisory on Liposuction*, 113 PLASTIC & RECONSTRUCTIVE SURGERY 1478, 1487 (2004).

41. Lapetina & Armstrong, *supra* note 2, at 28.

42. *Id.*

43. Karen B. Domino, *Office-Based Anesthesia: Lessons Learned From the Closed Claims Project*, AM. SOCIETY OF ANESTHESIOLOGISTS NEWSLETTER, June 2001, at 9, available at [http://depts.washington.edu/asaccp.ASA/Newsletters/asa65\\_9\\_11.pdf](http://depts.washington.edu/asaccp.ASA/Newsletters/asa65_9_11.pdf)

44. *Id.* (sixty-four percent of the claims from an office setting were due to death of the insured, while only twenty-one percent of the claims from a hospital were due to death of the insured).

45. *Id.* at 10.

46. *Id.*

47. James F. Arens, *Anesthesia for Office-Based Surgery: Are We Paying Too High a Price for Access and Convenience?*, 75 MAYO CLINIC PROC. 225, 225 (2000).

48. *Id.*

surgery or the administration of anesthesia and postoperative care in the private physician office.”<sup>49</sup>

Many states do not require physician offices to be accredited by one of the three nationally recognized accreditation organizations: the Joint Commission for Accreditation of Healthcare Organizations (“JCAHO”), the American Association for Ambulatory Health Care (“AAAHC”), or the American Association for Accreditation of Ambulatory Surgical Facilities (“AAAASF”).<sup>50</sup> Since accreditation can be expensive and time consuming, many small practices do not go through this process. In order to save money, physicians may purchase outdated and poorly maintained anesthesia equipment, inadequately evaluate the patient for appropriateness of surgery, and monitor the patient poorly or not at all during anesthesia.<sup>51</sup>

Additionally, there may be no assurance that the surgeon or anesthesia administrator is well-versed in resuscitation techniques because cardiac arrest is uncommon in an office setting.<sup>52</sup> Also, the office may not have appropriate pharmacological stocks to treat serious complications which can contribute to adverse outcomes.<sup>53</sup> The absence of an agreement with an emergency medical service to transport patients to the hospital, and the lack of staffing privileges of the physician at a nearby hospital, can further affect the outcome of an adverse event.<sup>54</sup>

The most important contributors to adverse patient outcomes are the education, training, and certification of the physician and staff.<sup>55</sup> Physicians who operate outside of their board certified specialty, including non-surgeons performing cosmetic surgery, may not be adequately trained to perform a procedure correctly and safely.<sup>56</sup>

#### *D. How are Physicians' Offices Regulated?*

Physicians' offices are set apart from hospitals and ambulatory surgical centers in that each state's Department of Health regulates hospitals and surgery centers, while the state's Board of Medicine regulates individual physicians.<sup>57</sup> A Board of Medicine is usually responsible for regulating the practice of medicine, including issuing medical licenses and disciplining individual physicians.<sup>58</sup> In order to bring

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49. Quattrone, *supra* note 11, at 66.

50. Arens, *supra* note 47, at 226.

51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.*

55. Lapetina & Armstrong, *supra* note 2, at 29.

56. *Id.*

57. *Id.* at 32.

58. *See, e.g.*, N.J. STAT. ANN. § 45:9-2 (West 2004) (authorizing the New Jersey Board of

equivalent regulations from hospitals to physicians' offices, each state must adopt rules by its own Board of Medicine or create rules through the state legislature.<sup>59</sup> This process is fraught with roadblocks.

First, the promulgation of regulations and the legislative process can take a lengthy amount of time. Second, various medical and nursing specialties have lobbying influence (and competing interests) over the legislature and state agencies. Third, even if states are successful in adopting regulations or guidelines, they will almost certainly be challenged in state court. A lengthy and costly court battle may ensue, and if the regulations are held invalid, the state will have to start the process over again. Currently twenty-two states have adopted some form of regulations or non-binding guidelines for office-based surgery.<sup>60</sup>

## II. CURRENT STATE REGULATION OF OFFICE-BASED SURGERY

### A. Is Regulation Even Needed?

If people were not dying in their doctors' offices from preventable causes, rules defining the minimum standard of care would not be needed. Rules, and not guidelines, are important because office surgery guidelines already exist, yet patients are still dying. The only time noncompliance with the guidelines comes to light is when an individual complains or sues the doctor because of an injury or death. Dr. Arens of the Anderson Cancer Center in Houston, Texas writes, "[i]t is a sad commentary that legislation is required to improve patient safety. It is abundantly clear that self-regulation by the medical profession, nursing profession, and hospital administration has not worked."<sup>61</sup> The onus should not be on the patient to ferret out poor and unsafe physicians after they have been injured. Regulations can prevent many injuries and can clarify the standard of care for litigants in malpractice cases.

Risks for a patient undergoing office surgery still exist even in states that have comprehensive regulations. A Florida study that compared the risks of surgery in an office to an ambulatory surgery center found that a patient was ten times more likely to die in his or her doctor's office than in an ambulatory surgery

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Medical Examiners to regulate the practice of medicine and issue regulations, rules, and by laws in order to do so). *See also* N.J. STAT. ANN. § 45:9-6 (West 2004) (authorizing the Board of Medical Examiners to issue medical licenses).

59. Lapetina & Armstrong, *supra* note 2, at 32.

60. Michelle Tackla, *Are Permanent Restrictions to Come? Physicians Ponder the Impact of Florida 90-Day Ban on Combined Liposuction/Abdominoplasty Procedures in an Office Setting*, COSMETIC SURGERY TIMES, Apr. 1, 2004.

61. Arens, *supra* note 47, at 227.

center.<sup>62</sup> The study analyzed adverse incident reports to the Florida Board of Medicine from April 2000 to April 2002.<sup>63</sup> These reports were available due to recent regulations promulgated by the Florida Board of Medicine imposing standards for office surgery that included a mandatory reporting of adverse outcomes.<sup>64</sup> The authors found that the mortality rate in offices was 9.2 in 100,000 whereas it was 0.78 in 100,000 in ambulatory surgery centers.<sup>65</sup> Only half of the office facilities were accredited, but the majority had surgeons that were board certified and had hospital privileges.<sup>66</sup>

In the offices where deaths occurred, an anesthesiologist was present only fifteen percent (15%) of the time.<sup>67</sup> The sections of the Florida Board of Medicine regulations requiring an anesthesiologist to supervise all Level III anesthesia (general anesthesia or conscious sedation) were implemented after the end of the study.<sup>68</sup> Since anesthesiologists were present in all of the ambulatory surgical centers, the authors postulate that this, in combination with accreditation or lack thereof, may be a contributing factor to poorer outcomes and to the higher mortality rate in offices.<sup>69</sup>

Evidence that regulations can improve safety has been shown. The authors of the Florida study performed a follow-up study during 2002 and 2003.<sup>70</sup> The mandate of anesthesiologist supervision of all general anesthesia in the office setting was in effect during this time, and the number of deaths dropped.<sup>71</sup> There were three deaths in offices during 2002 and 2003 compared to thirteen during 2000 through 2002.<sup>72</sup> The number of offices meeting the accreditation/inspection requirement of the regulations also increased, from fifty-six percent (56%) in 2002 to eighty-six percent (86%) in 2003.<sup>73</sup>

#### *B. What Are States Doing About Patient Safety?*

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62. Hector Vila, Jr. et al., *Comparative Outcomes Analysis of Procedures Performed in Physician Offices and Ambulatory Surgery Centers*, 138 ARCHIVES OF SURGERY 991, 993 (2003).

63. *Id.* at 991.

64. *Id.* at 992.

65. *Id.* at 993.

66. *Id.* at 994 (indicating that board certification and hospital privileges alone cannot ensure patient safety).

67. Vila et al., *supra* note 62, at 994.

68. *Id.*

69. *Id.* at 995.

70. Hector Vila, Jr., *Office Surgery Can Be a Risky Operation*, MOFFIT MONOGRAPHS, Winter 2003/2004, at 10-11.

71. *Id.* at 11.

72. Vila, *supra* note 70.

73. Hector Vila, Jr. et al., Poster Presentation at the American Society of Anesthesiologists Meeting: 2003 Update: Outcomes Analysis of Procedures Performed in Florida Physician Offices and Ambulatory Surgery Centers (2003).

Standard practice guidelines for office-based surgery, office-based anesthesia, and office-based cosmetic surgery have been created by various medical societies and organizations.<sup>74</sup> The AAAHC has even established a special Office-Based Surgery Accreditation Program.<sup>75</sup> In spite of this activity, guidelines have not completely ensured patient safety because there is “no incentive for physicians to comply with them and no way for patients or state officials to know whether or not physicians are following them.”<sup>76</sup>

Starting in 1994 with California, states have slowly moved towards improving patient safety by regulating surgery in the doctor’s office.<sup>77</sup> Currently thirteen states have enacted laws or enforceable regulations.<sup>78</sup> The laws or regulations vary widely in scope and specificity of requirements. Also, six states have issued guidelines for office-based surgery through the state Board of Medicine or Department of Health.<sup>79</sup> Perhaps the only common element of these regulations and guidelines is that offices that perform surgery should or must obtain and maintain accreditation by one of the three nationally recognized accrediting agencies.

### C. New York, New Jersey, and Florida

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74. The National Patient Safety Foundation, JCAHO, AAAHC, AAAASF, the Federation of State Medical Boards, American College of Surgeons, American Medical Association, American Society of Anesthesiologists, American Society of Dermatologic Surgery, American Society of Plastic Surgeons, American Society for Aesthetic Plastic Surgery, and the American Association of Nurse Anesthetists have all been concerned with and addressed the issue of office surgery safety through guidelines or requirements. See Hochstadt, *supra* note 3, at 134. See also, Hornsby, *supra* note 15, at 112.

75. Hochstadt, *supra* note 3, at 134.

76. Lapetina & Armstrong, *supra* note 2, at 33.

77. Frederick P. Franko, *State Laws and Regulations for Office-Based Surgery*, AORN J., Apr. 2001.

78. See RULES ALA. BD. MED. EXAMINERS ch. 540-X-10 (2003); CAL. BUS. & PROF. CODE § 2215 (West 2003); CONN. GEN. STAT. ANN. § 19a-690 (2003); FLA. ADMIN. CODE ANN. r. 64B8-9.009 (2003); ILL. ADMIN. CODE tit. 68, §§ 1305.10 - 1305.100 (regulating the qualifications of a nurse) (2005); LA. ADMIN. CODE tit. 46, § 7301-7315 (2004); MISS. BD. MED. LIC. R. & REGULATIONS § XXIV (2005); N.J. ADMIN. CODE §§ 13:35-4A.1 to 4A.18 (2005); OHIO ADMIN. CODE §§ 4731-25-01 to -07 (2004); 28 PA. CODE § 551 (2004); R.I. CODE R. 23-17-PASC §§ 1.0-37.0 (Weil 2000); 22 TEX. ADMIN. CODE §§ 192 (2004); 18 VA. ADMIN. CODE §§ 85-20-310 to -390 (West 2003).

79. See American Society of Anesthesiologists, State Legislative and Regulatory Activities: Office Based Anesthesia: State Statutes, Regulations and Guidelines, <http://www.asahq.org/Washington/rulesregs.htm> (last visited Nov. 25, 2005). These states are Colorado, Massachusetts, Oklahoma, New York, North Carolina, and South Carolina.

The New York Department of Health has adopted a comprehensive set of guidelines, but these standards do not have the force of law.<sup>80</sup> Florida and New Jersey have enacted the most extensive regulations for office surgery to date. These states merit discussion because of the huge effort they have made to improve patient safety and the enormous opposition they have encountered. Specifically, these states have been hampered in their attempts to regulate office surgery by turf wars between specialties and between physicians and nurses.

In each state, a requirement that CRNAs and other non-physicians administering anesthesia must be supervised by either a physician qualified to administer anesthesia or an anesthesiologist, was challenged.<sup>81</sup> Three contentious issues have played a role in each state. Who exactly is qualified to provide anesthesia? Is supervision of anesthesia by an anesthesiologist safer? Is it beyond the authority of the state Board of Medicine to regulate anesthesia services in a way that has an indirect impact on the practice of nurse anesthetists? Challenges to the regulations have recently failed in New York and New Jersey. Also, the standard of care, put on hold during the litigation, can now be enforced in these states.<sup>82</sup> However, a challenge to certain parts of the Florida regulations recently succeeded.<sup>83</sup> The legal challenges resulted in contradictory holdings at the District Court of Appeals level, and the Florida Supreme Court refused to hear an appeal by the Board of Medicine.<sup>84</sup> The result is that a certain portion of the regulations are invalid and unenforceable.<sup>85</sup>

### 1. New York

In 1999, legislation was drafted that would have given the New York Department of Health the authority to issue regulations for office-based surgery, as it does for hospitals and ambulatory surgical centers.<sup>86</sup> This legislation was recommended by the New York State Senate Committee on Investigations, Taxation and Government Operations in their report, *Problems of Office Surgery*.<sup>87</sup> The Committee found serious problems and safety concerns in surgery

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80. COMMITTEE ON QUALITY ASSURANCE IN OFFICE-BASED SURGERY, *supra* note 9, at ix.

81. *See, e.g., infra* notes 82, 83, and 84 and accompanying text.

82. N.J. State Ass'n of Nurse Anesthetists v. N.J. State Bd. of Med. Exam'rs., 859 A.2d 1239 (N.J. Super. Ct. App. Div. 2004), *aff'd*, 875 A.2d 247 (N.J. 2005); N.Y. State Ass'n of Nurse Anesthetists v. Novello, 810 N.E.2d 405 (N.Y. 2004).

83. *See Ortiz v. Dep't of Health, Bd. of Med.*, 882 So. 2d 402 (Fla. Dist. Ct. App. 2004), *review denied* 892 So. 2d 1011 (Fla. 2004); *Fla. Bd. of Med. v. Fla. Acad. of Cosmetic Surgery*, 808 So. 2d 243 (Fla. Dist. Ct. App. 2002).

84. *Ortiz*, 882 So. 2d at 406 (holding that the regulation was invalid because it contravened another state statute); *Bd. of Med.*, 808 So. 2d at 248 (holding that the regulations did not constitute an invalid exercise of delegated legislative authority by the Board of Medicine).

85. *See Ortiz*, 882 So. 2d at 406.

86. Lapetina & Armstrong, *supra* note 2, at 33.

87. NEW YORK STATE SENATE COMMITTEE, *supra* note 1.

performed in an office setting.<sup>88</sup> This legislation failed because of effective lobbying by the Medical Society of New York and the New York State Association of Nurse Anesthetists.<sup>89</sup> However, a requirement mandating the reporting of complications and deaths in office surgery was passed at that time.<sup>90</sup>

Later in 2000, the New York State Department of Health issued guidelines for office-based surgery. These guidelines are comprehensive in their recommendations concerning the qualification of physicians and staff, administration of anesthesia, equipment, facilities, recommendations for accreditation, and policies for patient selection, admission, discharge, and emergency care.<sup>91</sup> These guidelines specifically recommend that non-physicians (mostly CRNAs) who administer anesthesia in an office setting should be supervised by a physician, dentist, or podiatrist who is physically present, qualified by law, regulation, or hospital appointment, to perform and supervise the administration of the anesthesia, and who has accepted responsibility for the supervision.<sup>92</sup> This requirement is no different than the regulations governing hospital administration of anesthesia, where CRNAs are required to be supervised by an anesthesiologist or a physician qualified to administer anesthesia.<sup>93</sup>

The guidelines were challenged specifically because of this provision by the New York State Association of Nurse Anesthetists. The Nurse Anesthetists argued that the guidelines were de facto regulations and therefore invalid because the Department of Health is not authorized to regulate services provided in the private physician's office.<sup>94</sup> The Supreme Court of New York assumed the Nurse Anesthetists had standing to challenge the guidelines and held the guidelines were null and void.<sup>95</sup> The Appellate Division analyzed the standing issue and determined that the Nurse Anesthetists did have standing to challenge the guidelines and the guidelines were illegal because they exceeded the Department of Health's authority.<sup>96</sup> The Court of Appeals of New York reversed the Appellate Division, and held the Nurse Anesthetists lacked standing to challenge the guidelines, finally allowing the guidelines to take effect.<sup>97</sup>

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88. *Id.*

89. Lapetina & Armstrong, *supra* note 2, at 33.

90. *Id.*

91. COMMITTEE ON QUALITY ASSURANCE IN OFFICE-BASED SURGERY, *supra* note 9.

92. *Id.* at 11-16.

93. *Id.* at 11; 10 N.Y. COMP. CODES R. & REGS. § 405.13(a)(1)(iv) (2005).

94. N.Y. State Ass'n of Nurse Anesthetists v. Novello, 810 N.E.2d 405, 406 (N.Y. 2004).

95. *Id.*

96. N.Y. State Ass'n of Nurse Anesthetists, 810 N.E.2d at 406.

97. *Id.* at 406-07 (In order for an individual to challenge a government action, they must have standing. A determination of standing is a two part test where the plaintiff must show injury in fact and the injury asserted must fall within the zone of interests sought to be protected by the enabling statute of the agency. Injury in fact requires the plaintiff to show that he will actually be harmed by the challenged agency action.).

The Court of Appeals held that the Nurse Anesthetists lacked standing to challenge these guidelines because they could not show injury in fact.<sup>98</sup> The plaintiffs' argument was that the guidelines effectively required CRNAs to be supervised by an anesthesiologist and prohibited CRNAs from performing anesthesia services in an office-based setting, thereby restricting their scope of practice.<sup>99</sup> This assumed injury was too speculative for the Court because it neither proved the guidelines would be enforced as regulations nor that they would effectively harm CRNAs.<sup>100</sup>

The Court points out that the guidelines do not explicitly restrict a CRNAs area of practice nor express any intent to do so.<sup>101</sup> The Court of Appeals found that the guidelines merely require a CRNA, who by law must be supervised by a licensed physician, be supervised by a physician who is qualified by law to administer anesthesia and supervise its administration.<sup>102</sup> Any physician is qualified by law to perform any medical procedure, including administering anesthesia, as long as he holds a valid medical license.<sup>103</sup> There is nothing in the Guidelines that prevent the physician performing the surgery from also supervising the anesthesia.<sup>104</sup> “. . . [I]t is not at all ‘obvious’ that, even if enforced as regulations, the Guidelines would in fact injure any of plaintiff’s members as claimed.”<sup>105</sup>

After four years of litigation, New York’s Guidelines for office-based surgery are now in effect. These Guidelines do not have any statutory authority, and as a result they are not enforceable by law. However, the Department of Health has stated that the Guidelines are intended to define the prevailing standard of care for office-based surgery.<sup>106</sup> It remains to be seen what impact these Guidelines will have on the safety of patients undergoing surgery in a private physician’s office.

## 2. New Jersey

New Jersey enacted regulations to promote the safety of office-based surgery in 1998 through the New Jersey Board of Medical Examiners (“Board”).<sup>107</sup> The regulations are, and are intended to be, identical to regulations governing hospitals

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98. *N.Y. State Ass’n of Nurse Anesthetists*, 810 N.E.2d at 407.

99. *Id.* at 407.

100. *Id.* at 408.

101. *Id.* at 408.

102. *Id.*

103. *N.Y. State Ass’n of Nurse Anesthetists*, 810 N.E.2d at 408.

104. *Id.* at 408.

105. *Id.*

106. COMMITTEE ON QUALITY ASSURANCE IN OFFICE-BASED SURGERY, *supra* note 9, at ix.

107. N.J. ADMIN. CODE §§ 13:35-4A.1 to 4.A.18 (2005). *See also* Lapetina & Armstrong, *supra* note 2, at 33.

and ambulatory surgical centers, thus providing a uniform standard of care across settings.<sup>108</sup> The New Jersey regulations are as comprehensive as the New York Guidelines, providing requirements for equipment, infection control, patient monitoring, physician and non-physician training and education standards, written protocols of surgical procedures and anesthesia administration, and a mandatory reporting of adverse incidents to the Board.<sup>109</sup> Specifically, the regulations require that a CRNA who administers general and regional anesthesia be supervised by a physician who meets certain privileging requirements.<sup>110</sup> Every physician supervising anesthesia administration, in addition to the privileging requirement, must also have certain education or certification qualifications and fulfill a continuing education requirement every three years.<sup>111</sup> The most stringent requirement is that the physician supervising general or regional anesthesia administration cannot have concurrent duties, such as performing the surgery.<sup>112</sup>

Several years later, the Board decided to provide an alternate privileging requirement for physicians who do not have hospital privileges. Under the alternate privileging requirement, physicians have to meet certain standards set out by the Board to ensure they are qualified to supervise or administer anesthesia.<sup>113</sup> The Board stayed implementation of the supervision requirement through various proceedings, and in March of 2004, the Superior Court of New Jersey, Appellate Division stayed a significant portion of the regulations pending the outcome of a lawsuit by the New Jersey State Association of Nurse Anesthetists.<sup>114</sup>

The New Jersey Association of Nurse Anesthetists challenged the adoption of these regulations, specifically the requirement that CRNAs must be supervised by a physician who is not the surgeon and who is qualified to administer anesthesia. The Association argued that the Board was regulating the nursing profession in an unauthorized manner.<sup>115</sup> Specifically, they claimed the regulations were without any factual or medical support and therefore arbitrary and capricious.<sup>116</sup> The Court held that the regulations were a valid exercise of the Board's authority, as the promulgation of reasonable licensing standards for physicians was exactly what the Board was authorized to do.<sup>117</sup>

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108. Lapetina & Armstrong, *supra* note 2, at 33.

109. Franko, *supra* note 77.

110. N.J. State Ass'n of Nurse Anesthetists v. N.J. State Bd. of Med. Exam'rs., 859 A.2d 1239, 1241 (N.J. Super. Ct. App. Div. 2004), *aff'd*, 875 A.2d 247 (N.J. 2005).

111. *Id.*

112. *Id.* at 1241-42.

113. *Id.* at 1242.

114. *Id.*

115. N.J. State Ass'n of Nurse Anesthetists, 859 A.2d at 1241.

116. *Id.*

117. *Id.* at 1246.

The Court was very clear at the outset of the discussion that their review of administrative regulations was limited in scope because the regulations enjoy the presumption of validity.<sup>118</sup> The Court has a “strong inclination to defer to agency action provided it is consistent with the legislative grant of power.”<sup>119</sup> The Board was granted the authority by the legislature to regulate the practice of medicine, grant licenses to individuals practicing medicine, adopt regulations to protect the health, safety, and welfare of the patients of its licensees, and make standards for the practice of medicine in New Jersey.<sup>120</sup> The Court specifically stated that anesthesia is the practice of medicine; therefore, the Board could issue regulations governing physicians who provided anesthesia services in their private offices.<sup>121</sup>

The Association of Nurse Anesthetists argued that the regulations were without factual or medical support because there were studies showing that anesthesia given under supervision by an anesthesiologist was as safe as that given by a CRNA without supervision.<sup>122</sup> This argument was not persuasive because these studies did not isolate and compare mortality rates amongst anesthesiologists and CNRAs working in an office setting.<sup>123</sup> The fact that services performed by CRNAs may be safe in a hospital setting has no bearing in an office because in a hospital, an anesthesiologist is always on hand for supervision or help if needed.<sup>124</sup> That is not the case in a private physician's office. In the absence of scientific studies, the Board should not be prevented from carrying out its mandate and “. . . should not have to wait for bad results to require that its physicians meet higher standards in the administration of patient care.”<sup>125</sup>

The New Jersey Association of Nurse Anesthetists appealed this decision to the New Jersey Supreme Court<sup>126</sup> where it was upheld.<sup>127</sup> The New Jersey Supreme Court recognized that the regulations would have an impact on the “autonomy and economic life of CRNAs” but reiterated the fact that its review of administrative regulations was limited to the legality of the agency's decision.<sup>128</sup> The Court agreed with the Appellate Division that the administration of anesthesia was the practice of medicine, and therefore the Board was within its

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118. *N.Y. State Ass'n of Nurse Anesthetists*, 859 A. 2d at 1242.

119. *Id.* at 1242 (quoting *Lewis v. Catastrophic Illness Fund*, 764 A.2d 1035, 1039 (N.J. Super. Ct. App. Div. 2001)).

120. *Id.* at 1243.

121. *Id.* at 1245.

122. *Id.* at 1244.

123. *N.Y. State Ass'n of Nurse Anesthetists*, 859 A. 2d at 1244.

124. *Id.*

125. *Id.* at 1244.

126. The appeal was certified on February 16, 2005. *N.J. Ass'n of Nurse Anesthetists v. N.J. State Bd. of Med. Exam'rs.*, 868 A.2d 1032 (N.J. 2005).

127. *N.J. Ass'n of Nurse Anesthetists v. N.J. State Bd. of Med. Exam'rs.*, 875 A. 2d 247, 251 (N.J. 2005).

128. *Id.* at 250.

purview to promulgate regulations aimed at improving the education and services provided by physicians in an office setting.<sup>129</sup> The Court additionally denied the Association of Nurse Anesthetist's argument that there was no evidence to show that the administration of anesthesia was more dangerous when performed by a CRNA versus a physician.<sup>130</sup> The Court pointed to "the wealth of testimony adduced at the public hearings" that pointed to the need for these regulations, and noted that it makes sense that more education and training will help improve the safety of patients in an office setting.<sup>131</sup>

### 3. Florida

In 2000, the Florida Board of Medicine was given the authority to promulgate regulations for physicians performing surgery in offices, including the reporting of adverse events.<sup>132</sup> The Board proposed regulations that were later codified as the Standards of Practice for Medical Doctors, which described the standard of care and practice for office surgery.<sup>133</sup>

Portions of these regulations were challenged when they were proposed, specifically the requirement of anesthesiologist supervision during all Level III surgeries in an office.<sup>134</sup> Initially, an administrative law judge ("ALJ") held that the requirement of supervision by an anesthesiologist was an invalid exercise of delegated legislative authority.<sup>135</sup> The ALJ determined that the rule was an invalid exercise of delegated authority because, among other reasons, it was not supported by competent substantial evidence as required by Section 120.52(8)(f) of the Florida Statutes.<sup>136</sup> The Board of Medicine appealed the ALJ's holding, arguing that the ALJ used an improper standard of review under the statute.<sup>137</sup>

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129. *N.Y. State Ass'n of Nurse Anesthetists*, 875 A. 2d at 250-251.

130. *Id.* at 251.

131. *Id.* at 251.

132. Lapetina & Armstrong, *supra* note 2, at 34.

133. FLA. ADMIN. CODE ANN. 64B8-9.001 (2003) (The rules require, among other things, that offices that perform surgery gain accreditation by one of the three nationally recognized accrediting agencies (AAAASF, AAAHC, JCAHO). Only a maximum of four liters of fat can be removed during liposuction, and liposuction in combination with other procedures is restricted. Offices are mandated to report adverse incidents, have a transfer agreement with a hospital, have equipment and facilities that are maintained appropriately and ready for an emergency, and the surgeon must have staff privileges to perform the same procedures at a hospital or have board certification in the appropriate specialty. Lastly, the regulations require that during all Level III anesthesia procedures (general anesthesia or equivalent) the person administering the anesthesia (usually a CRNA) must be supervised by an anesthesiologist.)

134. *Fla. Bd. of Med. v. Fla. Acad. of Cosmetic Surgery*, 808 So. 2d at 243 (Fla. Dist. Ct. App. 2002).

135. *Id.* at 250.

136. *Id.* at 253-6.

137. *Id.* at 257.

The District Court of Appeals of Florida, First District ("First District") reversed, holding that the rule, in fact, did not constitute an invalid exercise of delegated authority.<sup>138</sup>

The First District determined that the rule was not invalid because the ALJ used the wrong standard of review.<sup>139</sup> The court noted that competent substantial evidence has two different meanings.<sup>140</sup> It is a standard of proof when applied by an agency at the fact finding level, but it is a standard of review when applied at the appellate level; meaning legally sufficient evidence.<sup>141</sup> The First District cited precedent under this standard and stated, "the reviewing body may not reweigh the evidence, make determinations regarding credibility or substitute its judgment for that of the agency, even if the record contains some evidence supporting a contrary view."<sup>142</sup> The court implied that the ALJ reweighed the evidence pertaining to the need for supervision by an anesthesiologist and substituted its judgment for that of the Board of Medicine.<sup>143</sup> If this were to be allowed, the "rulemaking process would be turned on its head" and decisions made by agencies created with the expertise and special knowledge of a profession would be taken from them and placed in the hands of an ALJ.<sup>144</sup> The First District did not believe this was what the Florida legislature had in mind and reversed the ALJ's decision.<sup>145</sup>

The appropriate standard of review was quite important in this case. Interestingly, this holding is discussed by those prejudiced against the regulations as if the court, in reality, wanted to invalidate the regulations and uphold the ALJ's decision, but could not because the wrong standard of review was used.<sup>146</sup> This could not be further from the truth. The standard of review, legally sufficient evidence, is the only standard appropriate at this stage to review agency decisions because, as stated in the New Jersey case, agency decisions enjoy the presumption of validity.<sup>147</sup> Agency decisions are given great deference precisely because it is not the court's or the ALJ's place to entirely substitute its judgment for that of the specially qualified panel of experts that make up the agency.

This particular provision requiring anesthesiologist supervision was challenged again; this time by a CRNA, and was rejected by the Division of Administrative Hearings.<sup>148</sup> The decision was appealed to the District Court of Appeals of

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138. *Fla. Bd. of Med.*, 808 So. 2d at 261.

139. *Id.* at 257-58.

140. *Id.* at 257.

141. *Id.*

142. *Id.*

143. *Fla. Bd. of Med.*, 808 So. 2d at 257.

144. *Id.* at 257.

145. *Id.* at 257.

146. *Ortiz v. Dep't of Health, Bd. of Med.*, 882 So. 2d 402, 404-05 (Fla. Dist. Ct. App. 2004).

147. *See supra* note 118.

148. *Ortiz*, 882 So. 2d at 402-03.

Florida, Fourth District (“Fourth District”) where it was overturned.<sup>149</sup> The Fourth District viewed the ALJ’s decision, that was reversed in *Florida Acad. of Cosmetic Surgery* as valid, reiterating that the ALJ found “there was no evidence to indicate any significant difference in patient outcomes whether anesthesia was administered by a CRNA or an anesthesiologist.”<sup>150</sup> The Fourth District then directly contradicted this statement by acknowledging the fact that the Board of Medicine had several studies as evidence that demonstrated a difference in patient outcomes between the two providers.<sup>151</sup>

However, the Fourth District went on to hold, in *Ortiz*, that the rule requiring a surgeon in an outpatient facility to have a licensed anesthesiologist present to supervise the administration of anesthesia for Level III surgery was an invalid exercise of delegated authority because the rule contravened another state statute.<sup>152</sup> The court acknowledged that the Board of Medicine had the statutory authority to regulate the practice of medicine in the state of Florida under Chapter 458, but further mentioned that the legislature had limited that authority in Section 458.303(2).<sup>153</sup> Section 458.303(2) provides that nothing in the rules shall be “construed to prohibit any service rendered by a registered nurse . . . if such service is rendered under the direct supervision and control of a licensed physician who provides specific direction for any service to be performed and gives final approval to all services performed.”<sup>154</sup> Since a physician can be disciplined for not following the regulations, the Fourth District held that the Board of Medicine was trying to do indirectly, what it could not do directly; control the actions of CRNAs.<sup>155</sup>

The Board of Medicine appealed the decision in *Ortiz* to the Florida Supreme Court, hoping the court would resolve the contradictory holdings. The Florida Supreme Court declined to do so without issuing an opinion.<sup>156</sup> Since the Florida Supreme Court did not step in, the holding of the Fourth District invalidates the entire regulation across the state.<sup>157</sup> Now, the only recourse for the Board of Medicine is to either promulgate another rule, or work through the Florida legislature to change the particular statute that the regulation contravened.

This decision by the Florida Supreme Court is unfortunate because the Board of Medicine has the more persuasive argument: the regulations do not contravene another statute. The regulations specifically describe the qualifications of

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149. *Ortiz*, 882 So. 2d at 402-403.

150. *Id.* at 404.

151. *Id.* at 404.

152. *Id.* at 403.

153. *Id.* at 406.

154. *Ortiz*, 882 So. 2d at 406.

155. *Id.*

156. Fla. Dep’t of Health, Bd. of Med. v. *Ortiz*, 892 So. 2d 1011 (Fla. 2004).

157. Brief of Petitioner on Jurisdiction at 9, Dep’t of Health, Bd. of Med. v. *Ortiz*, (No. SC04-2042), 2004 WL 2555500 (Fla. Dec. 21, 2004).

physicians who can administer anesthesia. So, it is clear they are regulating physicians. The regulations do not limit the practice of CRNAs by requiring anesthesiologist supervision for all Level III surgeries because the requirement and burden is placed on the *physician*. The physician must have certain qualifications before surgery utilizing general or regional anesthesia can be performed. The rules do not “prohibit any service rendered by a registered nurse . . .,”<sup>158</sup> because they place all additional requirements on the physicians who utilize them.

It is interesting to note that Ohio has adopted regulations extremely similar to those of New Jersey.<sup>159</sup> CRNAs are required to be supervised by a physician, and physicians are required to have certain anesthesia qualifications regardless of who administers the anesthesia.<sup>160</sup> As these rules have not been challenged, it remains to be seen if they will be and what the outcome would be. Litigation is pending in North Carolina and Illinois over office-based surgery regulations.<sup>161</sup> The North Carolina Medical Board adopted a position statement for office surgery, requiring CRNAs to be supervised by a physician, among other things.<sup>162</sup> The Board of Nursing has filed suit against the Medical Board claiming that North Carolina law only requires collaboration of CRNAs with a physician.<sup>163</sup> In Illinois, a lawsuit by nurse anesthetists, challenging the requirement of physicians who supervise CRNAs to have certain anesthesia continuing education requirements, was initially dismissed and then reinstated.<sup>164</sup> Both of these cases are at such an early stage that it is impossible to predict a likely outcome.

### III. EXISTING REGULATIONS ARE WORKING BUT NEED IMPROVEMENT

As studies have shown, the regulations governing office-based surgery in Florida are improving patient safety. The Florida regulations are extensive and detailed. The most important components are the requirements of mandatory reporting, accreditation, and anesthesiologist supervision in all Level III surgeries. Even though the anesthesiologist requirement of the Florida regulations is now invalid, during the several years it was in place, it improved the outcomes of patients undergoing surgery in the doctor's office.<sup>165</sup>

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158. *Ortiz*, 882 So. 2d at 403 (quoting FLA. STAT. § 458.303(2) (2002)).

159. See AMERICAN SOCIETY OF ANESTHESIOLOGISTS, SUMMARY OF 2003 STATE ACTIVITIES: OFFICE-BASED ANESTHESIA (2002), <http://www.asahq.org/Washington/officebased.htm>.

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.*

164. AMERICAN SOCIETY OF ANESTHESIOLOGISTS, *supra* note 159.

165. See Vila, *supra*, note 73 (source on file with the author) (showing a sixty-five percent decrease in the number of injuries/incidents in an office setting from the period 2000-2002 to

Studies evaluating the effectiveness of regulation only exist because the data can be collected. This is an essential ingredient to any statutory standard for the practice of medicine in a state. Mandatory reporting allows the agency to become more efficient by identifying those redundant or unnecessary rules. It also allows the agency to identify what adverse events can be attributed to non-compliance with the regulations or to the inherent risks involved in any surgery, no matter how careful or skilled the doctor.

The accreditation requirement has been shown to be a factor in improved safety for office-based surgery. Accreditation requires the physician to comply with a set of standards governing all aspects of care given to a patient.<sup>166</sup> These range from facility cleanliness to physician qualifications.<sup>167</sup> In addition, accrediting agencies inspect the facility to be accredited to ensure the standards are being met.<sup>168</sup> If a state requires accreditation, it is relying on the accrediting body to define the standard of care and handle inspection and enforcement.

Herein lies a problem with accreditation. The accrediting agencies can only deny or revoke accredited status from a physician if the facility is out of compliance. There are no other penalties for the physician. It is then up to the state to demand that the physician become accredited or lose licensure. This method of enforcement does not seem to have enough strength behind it to provide an incentive for physicians to comply with the standards of the accreditation agency.

Another problem is the standards of the three nationally recognized accrediting agencies vary.<sup>169</sup> The AAAASF standards are more stringent and comprehensive than the AAAHC or JCAHO.<sup>170</sup> The AAAASF requires 100% compliance with the standards to maintain accreditation while the others do not.<sup>171</sup> The AAAHC allows partial or substantial compliance, and JCAHO has five tiers of compliance with five different levels of accreditation.<sup>172</sup> It would make better sense for states to require either AAAASF accreditation along with state inspections or spell out the specific requirements in the regulations.

Anesthesiologist supervision of all Level III surgeries involving general anesthesia is guaranteed to improve the safety of surgery in an office. However, in the only state that adopted this requirement, it has been challenged and defeated. A more feasible rule would be one similar to the New Jersey regulation

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2002-2003 and a fifty-eight percent decrease in the number of deaths from 2000-2002 to 2002-2003).

166. See James A. Yates, *American Society of Plastic Surgeons Office-Based Surgery Accreditation Crosswalk*, 22 PLASTIC SURGICAL NURSING 125 (2002).

167. See *id.*

168. See *id.* at 132.

169. See generally *id.*

170. See *id.* at 125-26.

171. Yates, *supra* note 166, at 126.

172. *Id.*

that requires physicians who want to perform surgery and provide anesthesia in the office to fulfill certain training and education requirements to ensure that anesthesia can be given in a safe manner. Ultimately, states need to decide that anesthesiology is the practice of medicine, and as such, they have the authority to regulate it in a physician's office through various agencies.

Even though some states have specifically discussed cosmetic surgery in their regulations, all need to do so. Cosmetic surgery is the most common type of surgery performed in a private physician's office and since many procedures, like liposuction, can involve general anesthesia, it carries great risks. Standards should be elucidated like those in the Florida regulations that limit the amount of fat suctioned off or the combination of certain procedures that have been shown to be unsafe.

"Regulation is meant to provide the standard for the least competent providers, not the most competent providers, to ensure public safety."<sup>173</sup> Regulating office surgery can have the same effect on patient safety that it has had on the airline industry. It is safer to ride in an airplane than it is to undergo surgery in a private physician's office. Regulation that is intended to provide a uniform standard of care for all individuals, regardless of setting, is developed from the experience of those physicians who are practicing excellent medicine. Regulations transform those practices into law for the benefit of the physician and the safety of the patient.

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173. Telephone interview with Dr. Hector Vila, Jr., Depts. of Anesthesiology and Interdisciplinary Oncology, H. Lee Moffitt Cancer Center and Research Institute in Tampa, Fla. and Dept. of Anesthesiology, Univ. of S. Fla. College of Med. in Tampa, Fla. (Dec. 27, 2004).