



Ambulatory Surgery Center Malpractice Risk Overview

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The Joan Rivers 2015 wrongful death lawsuit focused public interest on professional negligence risks presented by ambulatory surgery centers ("ASC") (also referred to as outpatient surgery centers or same day surgery centers). Ms. Rivers underwent a laryngoscopy and endoscopy. Her vocal cords closed and breathing ceased in the course of the procedures. Investigation revealed numerous alleged errors at the clinic, including a failure to notice or take action to correct Rivers's deteriorating vital signs for 15 minutes, a discrepancy in the medical records about the amount of anesthesia she received, an apparent failure to weigh Rivers - a critical factor in calculating an anesthesia dose - and the performance of a procedure to which Rivers had allegedly not given informed consent. In addition, one of the procedures was performed by a physician who was not credentialed by the center. See Sandra G. Boodman, *Joan Rivers's Death Spurs New Look at Outpatient Centers*, Wash. Post, Dec. 15, 2014; Marc Santora, *Settlement Reached in Joan Rivers Malpractice Case*, N.Y. Times, May 12, 2016.

Similar news accounts have added to public interest in the subject. See, e.g., Joe Dahlke, *Paralyzed Castle Rock Woman Receives \$14.9 Million in Lawsuit Against Surgery Center*, Fox 31 Denver, Apr. 6, 2017; Cynthia Lambert, *Jury Awards \$543k in Lawsuit Against Pismo Beach Outpatient Surgery Center*, Telegraph News, Dec. 21, 2013; Monica Mendoza, *Paralyzed Colorado Woman Wins \$14.9 Million Malpractice Verdict*, Denver Bus. J., Apr. 6, 2017 (involving same day surgery center); Amanda Cuda, *Suit Raises Concern About Outpatient Clinics*, The News-Times, Apr. 20, 2015.

We review here ASC malpractice claim risks in terms of the regulatory environment, reported commentary about professional liability threats, and recent case law authorities, after first examining the background of this underreported segment of the professional negligence space.

Ambulatory Surgery Center Background

An ASC is "a public or private facility, not a part of a hospital, which provides surgical or obstetrical treatment performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization." *Georgia Soc'y of Ambulatory Surgery Ctrs. v. Georgia Dep't of Cmty. Health*, 710 S.E.2d 183, 185 (Ga. App. 2011); accord *DeBartolo v. HealthSouth Corp.*, 569 F.3d 736, 738 (7th Cir. 2009) (stating that ASCs are non-hospital facilities equipped with operating and recovery rooms where physicians perform outpatient surgeries and other procedures); 42 C.F.R. § 416.2 (2017) (stating that ambulatory surgical center means any

distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission). ASCs aim to improve the quality of care, provide services in an environment closer to users' normal surroundings, reduce the risk of nosocomial infection and release hospital beds for other uses demanded by the population, thus reducing health costs. M. Cordero Ponce, *et al.*, *Approach to the Patient in the Ambulatory Surgery Unit* (Enferm Clin. May-June 2008) (adding that nursing activity in these units should aim to restore health and aid the rapid recovery of patients in their homes).

A growing number of complicated surgical patients, with significant or multiple comorbidities, are utilizing the outpatient setting. More painful and invasive procedures, such as shoulder and total knee arthroplasty, mastectomy, and advanced laparoscopic surgery, which were previously considered inappropriate for ambulatory surgery, are increasingly performed as day surgeries. In office-based surgical practices, the caseload has more than doubled in volume. Ophthalmic, gastrointestinal, and cosmetic procedures comprise the bulk of office-based practice, which has now extended the coverage to podiatry, gynecology, interventional radiology as well as vascular and cardiology procedures. Susan Dabu-Bondoc, *et al.*, *Management of Comorbidities in Ambulatory Anesthesia: a Review*, *Ambulatory Anesthesia* (June 2015) (surveying the most common comorbidities present among ASC patients including HTN, diabetes, CAD, pulmonary dysfunction (COPD and OSA), and obesity).

Thus the demand for non-hospital based surgical procedures increases each year. In 2013 there were, for example, 17 million plastic surgery procedures performed in an office or ASC setting, a 4% increase since 2012. Alexander R. Facque, *et al.*, *Ambulatory Anesthesia in Plastic Surgery: Opportunities and Challenges* (Dovepress, Oct. 1, 2015). The appeal extends beyond plastic surgery, of course, as patient convenience, doctor/owner profit center (ASCs compete against hospitals for patients), and lower costs are fueling this growth.

One study calculated typical surgical specialties involved in ASC encounters and reported these findings: plastic (40%), ENT (24%), ophthalmology (18%), urology (12%), podiatry (3%), vascular (2%), other (1%). See Viviane Jesequel & Robert D. Henry, *Top Allegations and Risk Concerns for ASC* (MedPro Grp. Mar. 31, 2015).

Regulatory Regime

The government sets the conditions an ASC must meet to participate in the Medicare program, per Section 1832 of the Social Security Act (42 U.S.C. § 1395k). ASCs are regulated by the Centers for Medicare and Medicaid Services (“CMS”), the Joint Commission on Accreditation of Healthcare Organizations, individual states, and by professional associations including the Accreditation Association for Ambulatory Health Care (AAAHC), and the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) (from which CMS seeks guidance). CMS will determine that an ASC meets regulatory requirements if it is accredited by a national accrediting body (see 75 Fed. Reg. 51464), or licensed by a state agency. 42 C.F.R. § 416.26(a)(1) (2017). CMS measures ASC healthcare quality and efficiency through its Ambulatory Surgical Center Quality Reporting (ASCQR) Program. In addition, the Centers for

Disease Control and Prevention surveys the need for objective, reliable information about ASC services through its National Ambulatory Medical Care Survey (NAMCS).

The portal to federal regulations relating to ASCs are published at 42 C.F.R. § 416 (2017).

Surgical Care Risk Environment Generally

Professional liability risk exposures in the ASC setting mimic those found in the inpatient setting. They include as categories, for example, wrong surgical site, foreign body retention, nerve trauma, infection, failure to diagnosis complications, insufficient follow-up, negligent credentialing, negligent performance of surgical procedure, negligent performance of anesthesiology procedure, and failure to perform adequate pre-surgical assessment. Viviane Jesequel & Robert D. Henry, *Top Allegations and Risk Concerns for ASC* (MedPro Grp. Mar. 31, 2015). But ASC procedures present additional risks as outlined below.

ASC/Inpatient Comparative Claim Frequency

Some data suggests that malpractice claims for major adverse events are less common in outpatient settings than in inpatient settings. One study showed that more than twice as many inpatient surgical patients have high severity outcomes compared with patients treated in ambulatory surgery centers. MedPro Group, *Otolaryngology, Malpractice Claims Data & Risk Analysis* (2016). But the changing nature of ambulatory care in which sicker patients needing complex surgeries may alter that inertia. See Julia Metzner, *Ambulatory Surgery: Is the Liability Risk Lower?*, *Ambulatory Anesthesia* (Dec. 2012) (adding that areas of future concern focus on postoperative discharge criteria, care of obstructive sleep apnea, and choice of anesthetic techniques such as neuraxial blocks and monitored anesthesia care).

Another study analyzing 2005 to 2009 data found that there are almost 30 times more outpatient visits than hospital discharges annually. The number of paid malpractice claims in each setting was similar, and higher in the inpatient setting, but still the average paid claim was approximately \$300,000 in the outpatient setting. Almost \$1.3 billion in malpractice claims was paid for outpatient events in 2009. Among the concerns is that many outpatient sites may be too small to have well-trained staff who devote significant attention to improving patient safety. See Tara F. Bishop, *et al.*, *Paid Malpractice Claims for Adverse Events in Inpatient and Outpatient Settings*, *JAMA* (June 2011) (noting that diagnosis-related events were the most common reason for paid claims). The Bishop study triggered an editorial in the *Journal of the American Medical Association* whose authors called the study “a wake-up call” regarding “an increasing risk of malpractice in the ambulatory care setting.” Gianna Zuccotti, *et al.*, *Malpractice Risk in Ambulatory Settings: An Increasing and Underrecognized Problem*, *JAMA* (June 15, 2011) (adding that “there are likely many near-misses or events with less severe outcomes that can be related to process errors similar to those that [result in claims]”).

One analysis contends that more than 50% of malpractice claims against physicians come from the outpatient setting. *Mitigating Surgical Medical Malpractice Exposure in Ambulatory Surgery Centers*, (Clarity Grp., Inc., (2015)
(cdn2.hubspot.net/hubfs/1747782/documents/mitigating_surgical_med_mal_exp_in_ascs_final.p

df) (adding that resources, infrastructure and expertise related to improving patient safety and quality, which are well ingrained in the hospital setting, are often limited in the outpatient setting) (last visited July 25, 2017).

ASC Risk Environment Specifically

Unique malpractice risks for ASCs may involve: insufficiently-comprehensive policy manuals, liability for independent contractors, interactions with the ASC's management company, and potential conflict with managed care companies. Brian S. Kern, *Unique Malpractice Risks of Ambulatory Surgery Centers* (Medscape Nov. 20, 2009) (contending that inadvertent laxity about policies and procedures, failure to check credentials of independent contractor physicians, and failure to monitor management company actions increase ASC risk). Other risks may include lack of an anesthesiologist or nurse anesthetist on site, emergency response equipment absence or failure (e.g., due to lack of maintenance, or lack of batteries), equipment sterilization failure, too-early patient discharge, inadequate staff oversight, procedure gaps in the less formal environment, errant record keeping, procedure performance beyond the facility's capability, lack of resources to respond to complications, the predominant geriatric patient census, lack of transfer protocols, crash cart absence, insufficient attention to cardiac clearance, and unsanitary conditions. Vicarious liability of the ASC for contracted providers also can present legal issues in the ASC setting.

Other commentators have also opined on ASC-specific professional negligence risks. Christopher Kent and others have noted that an adverse event that may be considered unique to ambulatory surgery involves discharge of a patient into an environment that lacks skilled nursing care. Claim reviews have shown that pneumonia, unplanned intubation, wound disruption, bleeding requiring transfusion, and death within 72 hours post-operatively were the five most common adverse events reported. Procedures found most frequently leading to adverse outcomes include laparoscopic cholecystectomy, abdominal wall hernia repair, and inguinal hernia repair. The most common injury associated with ASC malpractice claims was death, followed by nerve injury, eye injury, airway injury, brain damage, pneumothorax, emotional distress, burns, headache, and back pain. Unplanned hospital admissions from ASCs have resulted from obese patient complications, obstructive sleep apnea patients, and pediatric patients with respiratory issues. Adverse events leading to hospital admission include poorly controlled nausea and vomiting, poorly controlled pain, and procedure-related bleeding. Major cardiopulmonary events leading to admission included dysrhythmias, myocardial infarction, heart failure, and angina. Christopher Kent, *et al.*, *An Analysis of Risk Factors and Adverse Events in Ambulatory Surgery*, Ambulatory Anesthesia (June 18, 2014) (concluding nevertheless that "outpatient surgery is an exceedingly safe area of surgical practice").

Problems presented by discharge of unescorted patients are obvious. One study showed escorts are absent in 2 out of every 1,000 procedures, despite physician office and surgery center instructions that an escort is required for ambulatory surgery. Leslie Flowers, *Tips for Enforcing Patient Escort Policies* (OR Manager Inc. July 2006) (adding that ASCs increase liability and malpractice risks when they discharge patients without an escort, because patients may injure themselves or others while groggy or they may not be able to get help for postsurgical complications). See also Frances Chung, *et al.*, *Car Accidents After Ambulatory Surgery in Patients Without an Escort*, Anesthesia & Analgesia (Int'l Anesthesia Res. Soc'y 2008).

With recent advances in surgical and anesthetic technique, there has been a growing emphasis on the delivery of care to patients undergoing ambulatory procedures of increasing complexity. Tracey Stierer and others have written that appropriate patient selection and meticulous preparation are vital to the provision of a safe, quality perioperative experience. It is not unusual for patients with complex medical histories and substantial systemic disease to be scheduled for discharge on the same day as their surgical procedure. The trend to “push the envelope” by triaging progressively sicker patients to ambulatory surgical facilities has resulted in a number of challenges for the anesthesia provider who will assume their care. Tracey L. Stierer, *et al.*, *Preoperative Testing and Risk Assessment: Perspectives on Patient Selection in Ambulatory Anesthetic Procedures*, Ambulatory Anesthesia (2015) (adding that not only should the patient's comorbidities be stable and optimized, but details regarding the planned procedure and the resources available at the facility also should be ascertained)

Facque and Taub have warned that careful selection of patients amenable to ASC care according to the American Society of Anesthesiologists Physical Status score is important in determining which patients may undergo major surgery and return home the same day. They add that cardiac risk assessment is also a key metric in patient ASC care evaluation. Post-surgical care for the elderly requires assessment of reliability of transportation, and the presence of a caretaker at home. At the other end of life, outpatient surgical care for premature infants is not recommended until after the 60th week of life due to post-operative apnea risk. Alexander R. Facque & Peter J. Taub, *Ambulatory Anesthesia in Plastic Surgery: Opportunities and Challenges* (Dovepress, Oct. 1, 2015).

ASC staff communication process procedures have also been mentioned as a key to good risk management. The success of ASCs according to one analysis is largely dependent on how efficiently the staff communicates necessary information to other staff members, patients, and visitors. In the absence of efficient communication significant problems, including wrong-site surgeries and insufficient patient handoffs, are seemingly inevitable. See Bry Bonavita, *et al.*, *Ambulatory Surgery Report* (Cornell U. 2013).

Webster and others have commented that adverse events seen in ambulatory care claims include missed or delayed diagnoses, delay in care, adverse drug events, and as noted above information flow process error. John S. Webster, *et al.*, *Understanding Quality and Safety Problems in the Ambulatory Environment: Seeking Improvement with Promising Teamwork Tools and Strategies* (Agency for Healthcare Res. and Qual. Aug. 2008). Another study showed that over half of the missed diagnoses involved cancer, primarily breast and colorectal cancer. The main breakdowns in the diagnostic process were failure to order appropriate diagnostic tests, inadequate follow-up, failure to obtain an adequate history or perform an adequate physical examination, and incorrect interpretation of diagnostic tests. See Tejal K. Gandhi, *et al.*, *Missed and Delayed Diagnoses in the Ambulatory Setting: A Study of Closed Malpractice Claims*, *Annals of Internal Med.* (2006).

One study found that surgery-related ASC claims included improper performance of surgery, improper management of the patient, retained foreign body, and unnecessary surgery. Other frequently-encountered risk issues included failure to perform adequate pre-surgical assessment, failure to provide timely intervention during a procedure, performing surgery on the wrong body

part, poor infection control management, and negligent use of surgical equipment. See Viviane Jesequel & Robert D. Henry, *Top Allegations & Risk Concerns for ASC* (MedPro Grp. Mar. 2015).

Anesthesia Risk

Anesthesia risks receive heightened commentary in the medical literature. For example, the need to provide rapid-emergence and short-acting anesthetic and analgesic agents safely in the outpatient context is vital. Alexander R. Facque & Peter J. Taub, *Ambulatory Anesthesia in Plastic Surgery: Opportunities and Challenges* (Dovepress, Oct. 1, 2015). Difficult intubation, inadequate oxygenation or ventilation, and airway obstruction are the most common adverse events relating to anesthesia management. Such events according to one study related to regional block placement, and moving or coughing by the patient during anesthesia (usually during eye surgery resulting in injury). See K.L. Posner, *Liability Profile of Ambulatory Anesthesia* (Newsletter 2000). Anesthesia-related incidents in ASCs have also been reported to include improper performance of anesthesia procedure, improper management of the patient while anesthetized, tooth damage, improper choice of anesthetic, and positioning-related harm. See Viviane Jesequel & Robert D. Henry, *Top Allegations & Risk Concerns for ASC* (MedPro Grp. Mar. 2015).

Other Heightened Risk Contexts

Other risks also receive heightened commentary in the medical literature. Surgical site infections in the ambulatory care setting present appreciable risks. See, e.g., M.L. Rinke, *et al.*, *Surgical Site Infections Following Pediatric Ambulatory Surgery: An Epidemiologic Analysis*, *Infection Control Hosp. Epidemiol.* (Aug. 2016) (finding 35 patients with SSI out of 15,448 pediatric ambulatory surgeries). Syringe reuse, single dose vial reuse, failure to prepare medications under aseptic conditions, poor hand hygiene, finger stick use sharing, and inadequate instrument sterilization reportedly are the top infection control risks in ASCs. See Viviane Jesequel & Robert D. Henry, *Top Allegations and Risk Concerns for ASC* (MedPro Grp. Mar. 31, 2015).

Adverse drug events are common and often preventable particularly among older patients in the ambulatory clinical setting. Jerry H. Gurwitz, *Incidence and Preventability of Adverse Drug Events Among Older Persons in the Ambulatory Setting*, *JAMA* (Mar. 2003). Adherence to anticoagulation guidelines in the ambulatory surgical setting was found inadequate in one study. See D.H. Eisenstein, *Anticoagulation Management in the Ambulatory Surgical Setting*, *AORN J.* (Apr. 2012) (recommending management by nurse practitioner).

Plastic surgical procedures in particular present many ambulatory care risks, especially with patients who request elective procedures and are then dissatisfied with the outcome. See Am. Soc’y of Plastic Surgeons & The Doctors Co., *Pathways to Preventing Adverse Events in Ambulatory Surgery* (2011).

Whether a surgeon’s investor status in an ASC prompts performance of complicated spine surgeries leading to increased risks due to lack of ready access to hospital emergent care is open to question. See Evan O. Baird, *et al.*, *Ambulatory Spine Surgery: a Survey Study*, *Global Spine J.* (June 2014).

Appellate Authorities

Recent appellate decisions have focused on malpractice risk outcomes in the ASC setting. They include:

- *Burk v. Fairfield Ambulatory Surgery Ctr., Ltd.*, 2014 Ohio 4062 (Ohio App. 2014) (involving premature release of a tourniquet causing excessive Lidocaine release, failure of equipment to sound alarms, and failure to monitor carbon dioxide or respiratory rate).
- *Weeks v. St. Peter's Hosp.*, 128 App. Div. 3d 1159, 1160, 8 N.Y.S.3d 731 (2015) (involving an ASC nurse who had not inserted an IV catheter “in 20 years”)
- *King v. Bryant*, 795 S.E.2d 340 (N.C. 2017) (refusing to enforce arbitration requirement in ASC agreement on grounds physicians breached fiduciary duty to patient; patient’s aorta was injured during repair of inguinal hernia); *Prewitt v. 1-800-Get Thin*, 2014 WL 2591308 (Cal. App. June 20, 2014) (finding that arbitration was waived through suit conduct in case involving esophagus tear during ASC endoscopic procedure)
- *Mooney v. Surgicare Ambulatory Ctr. Inc.*, 2016 N.Y. Slip Op. 30448 (2016) (involving alleged negligent performance of femoral nerve block during outpatient arthroscopic knee surgery)
- *Doherty v. Brown*, 794 S.E.2d 217 (Ga. App. 2016), *cert. granted* (Ga. May 30, 2017) (affirming \$21,981,093.29 verdict on ordinary negligence grounds against ASC and anesthesiologist when patient suffered severe oxygen deprivation during epidural steroid injection procedure because the hypoxic event facts were determinable by lay persons).
- *Maryland Cas. Co. v. Florida Atlantic Orthopedics, P.L.*, 771 F. Supp. 2d 1328 (S.D. Fla. 2011), *aff’d* 469 Fed. Appx. 722 (11th Cir. 2012) (involving a ruling that the clinic’s general liability policy’s professional services exclusion precluded coverage for the heirs of a patient when cardiac arrest occurred following lumbar surgery. Among the liability allegations was that the outpatient surgery center’s elevator was too small to accommodate the rescue team’s stretcher as they attempted to get her to a hospital).
- *Kristensen-Kepler v. Cooney*, 39 So. 3d 518 (Fla. App. 2010) (involving heirs who sued the ASC and orthopedist where decedent patient sustained a spinal infection during a procedure. The suit claimed that the ASC was at fault for the surgeon’s care. But the court held to the contrary on grounds the decedent selected the surgeon for the elective surgery, and the surgeon selected the ASC. The surgeon was not employed by the ASC. Since it had no right to control or direct the surgeon’s treatment of the patient, it could not be held liable for the doctor's negligence under Florida law).

Conclusion

In general, professional liability risks facing health care providers in ASC settings imitate those found in hospital settings. But they also present additional exposures unique to their less formal

realities. The growth in patient acceptance and expansion in procedure suitability does affect ASC risk management exposure. We can expect to see increasing injury lawyer attentiveness to the differences between inpatient and outpatient care when adverse events occur at ASCs. Whether case law addressing standard of care and causation arguments will take into account those differences requires further development and vigilance by providers, risk managers, insurers and defense counsel.