SUMMARY
October 15, 2020

**2020COA145**

**No. 19CA0186, *Smith v. Surgery Center* — Torts — Negligence — Negligence Per Se; Hospitals — Corporate Practice of Medicine Doctrine — Vicarious Liability**

This case involves claims of negligence and negligence per se against an ambulatory surgical center (ASC) after the plaintiff was severely injured during a procedure to treat her back pain. Applying the corporate practice of medicine doctrine, the division holds that the ASC was not liable for failing to protect the plaintiff from the treating physician's negligence. The division also holds that the state and federal regulations that establish the framework for licensing and Medicare reimbursement were not primarily enacted to protect patient safety, and therefore cannot serve as the basis for a negligence per se claim.

COLORADO COURT OF APPEALS **2020COA145**

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Court of Appeals No. 19CA0186
Douglas County District Court No. 15CV30922
Honorable David J. Stevens, Judge

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Robbin Smith and Doyle Edward Smith, Jr.,

Plaintiffs-Appellees and Cross-Appellants,

v.

Surgery Center at Lone Tree, LLC,

Defendant-Appellant and Cross-Appellee.

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JUDGMENT REVERSED AND CASE
REMANDED WITH DIRECTIONS

Division I
Opinion by JUDGE GROVE
Welling and Vogt*, JJ., concur

Announced October 15, 2020

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*Sitting by assignment of the Chief Justice under provisions of Colo. Const. art. VI, § 5(3), and § 24-51-1105, C.R.S. 2019.

¶ 1 In this negligence action, defendant, Surgery Center at Lone Tree, LLC (SCLT), appeals the judgment entered on a jury verdict in favor of plaintiffs, Robbin Smith and Doyle Edward Smith, Jr. The Smiths cross-appeal, contending that the trial court violated their constitutional rights by reducing the amount of the jury award under Colorado's Health Care Availability Act (HCAA). Applying the corporate practice of medicine doctrine, we conclude that SCLT was entitled to judgment as a matter of law. Accordingly, we reverse the trial court's judgment and remand for entry of judgment in SCLT's favor. Because of our disposition, we do not consider the constitutional challenges that the Smiths raise on cross-appeal.

## I. Background

¶ 2 Ms. Smith visited SpineOne Spine & Sport Medical Clinic (SpineOne) for an evaluation of her back pain. She scheduled a series of transforaminal epidural steroid injections to treat it. After her treating physician, Hashim Khan, M.D., performed an epidural injection into her spine, Ms. Smith lost all feeling in her lower extremities. She was eventually diagnosed with bilateral lower extremity paraplegia secondary to spinal infarct/ischemia and remains permanently paralyzed below the waist.

¶ 3 Dr. Khan performed the first procedure, a "bilateral S1, L1-L2 transforaminal steroid injection using the particulate corticosteroid, Kenalog," at SCLT. He did not note any complications during the procedure, but after a short time in the recovery area, the nurse anesthetist, Stacy Cason, determined that Ms. Smith was unable to move her legs. Dr. Khan examined Ms. Smith and decided to transfer her to another medical center, the first of many transfers that would be required. Ms. Smith never regained feeling in her lower extremities.

¶ 4 Ms. Smith and her husband filed suit against three defendants: Dr. Khan, SpineOne (Dr. Khan's employer), and SCLT (the ambulatory surgical center (ASC) where Dr. Khan performed the procedure). The Smiths settled their claims against Dr. Khan before trial and the trial court dismissed their claims against SpineOne. Only the claims against SCLT proceeded to trial, and only those are at issue in this appeal.

¶ 5 The Smiths' claims against SCLT asserted "corporate negligence," "uninformed consent," and "negligence per se." Following an eight-day trial, the jury found in the Smiths' favor and awarded them $14,905,000.00 in damages. Applying the HCAA,

§§ 13-64-101 to -503, C.R.S. 2019, the trial court reduced the amount of the verdict by more than half, to $6,974,692.27. SCLT appeals the judgment entered on the jury verdict. Arguing that the HCAA violates, among other rights, the right to a civil jury trial guaranteed by the Seventh Amendment, the Smiths cross-appeal the trial court's order reducing the amount of damages awarded by the jury.

¶ 6 We conclude that the trial court should have dismissed the corporate negligence and uninformed consent claims against SCLT as a matter of law because, under the corporate practice of medicine doctrine, SCLT was not vicariously liable for any malpractice by Dr. Khan, nor did it owe a duty to Ms. Smith to assume any medical responsibilities that Dr. Khan failed to fulfill. We likewise conclude that the trial court should have dismissed the Smiths' claim for negligence per se because the state licensing and federal Medicare regulations that they rely on were not enacted primarily for the public's safety. Based on our disposition of these issues, we do not reach either the evidentiary issues that SCLT raises or the Smiths' cross-appeal challenging the constitutionality of the HCAA.

## II. Corporate Practice of Medicine

¶ 7 SCLT contends that the Smiths' negligence claims against it are barred by the corporate practice of medicine doctrine, and thus should not have been submitted to the jury. We agree.

### A. Standard of Review and Governing Law

¶ 8 We review de novo a trial court's denial of a motion for directed verdict or a motion for judgment notwithstanding the verdict. *Parks v. Edward Dale Parrish LLC*, 2019 COA 13, ¶ 10. In doing so, "[w]e view the evidence, and all inferences that may reasonably be drawn therefrom, in the light most favorable to the nonmoving party." *Id.* A court should not grant either motion "unless there is no evidence that could support a verdict against the moving party on the claim." *Id.*

¶ 9 To prevail on a claim of negligence, a plaintiff must show that (1) the defendant owed her a legal duty of care; (2) the defendant breached that duty; (3) the plaintiff suffered injury; and (4) the cause of that injury was the defendant's conduct. *Laughman v. Girtakovskis*, 2015 COA 143, ¶ 9.

## B. Relevant Facts

¶ 10 This case revolves around Kenalog, a particulate corticosteroid that Dr. Khan used in Ms. Smith's procedure. The Smiths argued that Dr. Khan caused Ms. Smith's injuries while using Kenalog off-label — i.e., in a way that had not been approved by the Food and Drug Administration (FDA) — and that he failed to obtain Ms. Smith's informed consent to his off-label use of the drug. As relevant to the issues in this appeal, the Smiths claimed that SCLT had a duty to prevent Dr. Khan's off-label use of Kenalog, or at least to ensure that Ms. Smith had given her informed consent to its off-label use in the event that Dr. Khan failed to obtain such consent.

¶ 11 Kenalog is one of a number of medications that SCLT kept on hand for use in its facility as part of what the trial court found was a "formulary."[1] SCLT did not tell its physicians how they could use Kenalog or any other drug that it stocked, but it was undisputed at trial that Kenalog has a wide variety of uses consistent with its

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[1] A formulary is a list of approved prescription drugs maintained by a healthcare facility or insurance program. *See J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc.*, 485 F.3d 880, 884 (6th Cir. 2007).

labeling. It was likewise undisputed that Dr. Khan did not inform Ms. Smith either that he intended to use Kenalog during her procedure or that he intended to use it in a manner inconsistent with the manufacturer's label.

¶ 12 Ms. Smith signed three separate consent forms before her procedure began. The forms each had different titles and, importantly here, different purposes: Patient Consent and Registration (PCR), Evidence of Informed Consent (EIC), and Consent for Anesthesia Services (CAS). The PCR and CAS forms had the SCLT logo on the front page, but the EIC form did not.

¶ 13 Ms. Smith discussed the procedure with Dr. Khan, her pre-operative nurse Rhodalyn Roff, and the nurse anesthetist, Ms. Cason. Ms. Smith and Ms. Roff both signed the PCR form. Ms. Smith, Ms. Roff (as a witness), and Dr. Kahn all signed the EIC form. The CAS form was signed by Ms. Smith, Mr. Smith, and Ms. Cason.

¶ 14 It was undisputed at trial that no one explained to Ms. Smith that Kenalog would be used off-label. Nor did the forms that Ms. Smith signed disclose that information.

### C. Plaintiffs' Claims and Trial Court's Ruling

¶ 15 As the Smiths' trial brief put it, "[t]his case is about [SLCT's] failure to protect its patients by allowing a drug called Kenalog to be used for transforaminal epidural injections in the lumbar spine after the manufacture[r] warned it should not be used for epidural injections." In essence, the Smiths asserted that SCLT had a duty to Ms. Smith that it breached by failing to prevent Dr. Khan from using Kenalog during the procedure or, in the alternative, by failing to ensure that she was fully informed of — and consented to — its off-label use.

¶ 16 Along with several other defenses, SCLT maintained that it could not be held liable for Ms. Smith's injuries as a matter of law. Relying on the corporate practice of medicine doctrine, which prohibits a corporation that employs a physician from interfering with the physician's medical judgment, SCLT argued in its motion for directed verdict, and again in its motion for judgment notwithstanding the verdict, that because it had no control over Dr. Khan's medical decisions, it was not responsible for negligent acts that Dr. Khan committed during Ms. Smith's course of treatment, and that it did not have — and had not assumed — an independent

duty to ensure that Ms. Smith gave her informed consent. *See Daly v. Aspen Ctr. for Women's Health, Inc.*, 134 P.3d 450, 452 (Colo. App. 2005); *see also* § 12-36-117(1)(m), C.R.S. 2019; § 25-3-103.7, C.R.S. 2019; *Hall v. Frankel*, 190 P.3d 852, 861 (Colo. App. 2008). Arguing that the administrative regulations the Smiths relied on did not provide for a private cause of action, SCLT also sought judgment as a matter of law on the Smiths' negligence per se claim.

¶ 17 The trial court rejected SCLT's arguments. While it acknowledged that the corporate practice of medicine doctrine would shield SCLT from vicarious liability for Dr. Khan's negligence, the court ruled that the evidence showed that SCLT *itself* "practiced medicine" notwithstanding its corporate status. In particular, the court concluded that "when [SCLT] overtook the policy of controlling the formulary and providing informed consent to patients, it danced on, and over, the line of practicing medicine." By doing so, the court found, SCLT opened itself up to liability for its own negligence, which was established by its inclusion of Kenalog on the formulary and its failure to advise Ms. Smith that Dr. Khan's use of that drug would be inconsistent with its label. The court also found that the Smiths could recover under a theory of negligence per se,

based on SCLT's alleged failure to adhere to state and federal administrative regulations that govern the licensing of, and Medicare reimbursement to, ASCs.

D. Applicable Law

¶ 18 "A hospital has certain inherent responsibilities regarding the quality of medical care furnished to its patients, and to meet this standard of responsibility, the hospital has a duty to supervise the competence of its staff." *Braden v. Saint Francis Hosp.*, 714 P.2d 505, 507 (Colo. App. 1985); *see also Camacho v. Mennonite Bd. of Missions*, 703 P.2d 598, 600 (Colo. App. 1985). Failure to supervise staff may amount to negligence and result in the hospital being held liable for a patient's injuries. *See, e.g.*, *Garhart ex rel. Tinsman v. Columbia/Healthone, L.L.C.*, 95 P.3d 571, 576-77 (Colo. 2004) (hospital held vicariously liable for a nurse's negligent failure to promptly inform an obstetrician of a fetus's deteriorating condition).

¶ 19 A hospital's supervisory authority over its staff, however, does not extend to physicians, whether or not the hospital employs them. *See* § 25-3-103.7(3) ("Nothing in this section shall be construed to allow any health care facility that employs a physician to limit or otherwise exercise control over the physician's independent

professional judgment concerning the practice of medicine or diagnosis or treatment."). And because a hospital may not dictate to a physician how he or she may practice medicine, it likewise may not be held liable for lapses in a physician's professional judgment. *Daly*, 134 P.3d at 452-53.

¶ 20 The only exception to this general rule appears in the form of a negligent credentialing claim: "In extending staff privileges to a doctor, a hospital does not generally expose itself to liability for the doctor's negligence unless it knows or should know of a propensity on the doctor's part to commit negligent acts." *Settle v. Basinger*, 2013 COA 18, ¶ 57 (quoting *Braden*, 714 P.2d at 507); *see also Krane v. St. Anthony Hosp. Sys.*, 738 P.2d 75, 78 (Colo. App. 1987).

E. Analysis

¶ 21 Having outlined these general rules, we turn next to whether SCLT could be held liable either for permitting Dr. Khan's off-label use of Kenalog or for failing to obtain Ms. Smith's informed consent. As we understand the trial court's ruling, it concluded that by maintaining a formulary that included Kenalog — thereby approving it for use by physicians in its facility — SCLT took on the responsibility of ensuring that those physicians would not use the

drug negligently. SCLT's policy of "controlling the formulary," the trial court found, together with its policy of "providing informed consent to patients," amounted to the practice of medicine.

1. Formulary

¶ 22 The decision to administer a certain medication to a patient in a certain situation is, without question, a medical decision made by a physician alone. Because SCLT could not dictate to Dr. Khan how he could use Kenalog, SCLT cannot be held vicariously liable for Dr. Khan's negligent administration of that drug.

¶ 23 But that is not what the Smiths argue here. Rather, they contend that once SCLT placed Kenalog on its formulary, it assumed the responsibility of ensuring that the drug would be used safely. We reject this position because it is flatly inconsistent with the corporate practice of medicine doctrine. SCLT did not, by making certain drugs available for use in its facility, dictate to its credentialed physicians how those drugs could be used. Nor could it, because section 25-3-103.7(3) prohibits health care facilities from "limit[ing] or otherwise exercis[ing] control over the physician's independent professional judgment concerning the practice of medicine or diagnosis or treatment."

¶ 24 This is not to say that a facility like SCLT lacks any control over the use of its facilities. As divisions of this court have repeatedly recognized, "a hospital has certain inherent standards to maintain regarding the quality of medical care furnished to its patients." *Krane*, 738 P.2d at 78. But, as we discuss in more detail *infra* Part II.E.2.a, when it comes to the conduct of physicians using its facilities, a health care facility can only maintain those standards by responsibly managing who it credentials to practice medicine there. *See Settle*, ¶ 57. Although the Smiths asserted that Dr. Khan had regularly used Kenalog off-label in the past — and that at least some employees of SCLT were aware of this practice — they did not plead, argue, or prove that SCLT was negligent for allowing Dr. Khan to continue to perform procedures at the facility. Rather, they argued that SCLT was negligent for failing to direct Dr. Khan's treatment of his patients. Because interference with the physician-patient relationship is precisely what the corporate practice of medicine doctrine is intended to prevent, SCLT cannot, as a matter of law, be held directly liable for failing to prevent Dr. Khan's off-label use of Kenalog.

### 2. Failure to Obtain Informed Consent

¶ 25 Next, we consider whether the trial court erroneously ruled that SCLT had an independent duty to ensure that Ms. Smith was adequately advised of, and consented to, Dr. Khan's off-label use of Kenalog. SCLT contends that imposing such a duty runs afoul of the corporate practice of medicine doctrine and the holding in *Krane*, which states that a health care facility generally has no obligation to obtain a patient's informed consent. 738 P.2d at 78. Again, we agree.

¶ 26 "[B]efore performing any medical procedure, a doctor must inform the patient of the procedure's substantial risks and obtain the patient's consent." *Holley v. Huang*, 284 P.3d 81, 83 (Colo. App. 2011). Imposing this duty on the physician both "protect[s] a patient's right to be informed of the risks of surgery," *Krane*, 738 P.2d at 77, and protects the physician from "liability for battery resulting from the performance of a medical or surgical procedure on a patient," *Bloskas v. Murray*, 646 P.2d 907, 914 (Colo. 1982). However, consistent with every state court that has considered the question, this court has held that "a hospital does not generally have a duty to advise the patient prior to surgery as to the surgical

procedure to be employed and the risks involved and, therefore, has no duty to obtain an informed consent similar to that which the surgeon is obligated to obtain." *Krane*, 738 P.2d at 77. *See also Wells v. Storey*, 792 So. 2d 1034, 1038 (Ala. 1999) (observing that "approximately one-half of the states have addressed this issue," and that "[i]n those states, the courts have uniformly held that the duty to obtain a patient's informed consent rests solely with the patient's physician, rather than with a hospital or its nurses (unless, because of special circumstances, the physician is an agent for the hospital)"); *Obermeier v. Nw. Mem'l Hosp.*, 134 N.E.3d 316, 332 (Ill. App. Ct. 2019) (noting that, "unlike a physician, a hospital generally has no duty to obtain informed consent from a patient").

¶ 27 The trial court acknowledged that "Dr. Khan's duty to have informed his patient about the procedure is unassailable," but it also concluded that, for three reasons, SCLT had an independent duty to obtain Ms. Smith's informed consent. First, it found that the evidence supported a conclusion that SCLT "knew or should have known of Dr. [Khan's] propensity to fail to obtain a patient's informed consent prior to surgery." Second, because SCLT "kept the drug available for Dr. Khan to use in an off-label fashion" and in

fact "endorsed" Kenalog's off-label use, the court concluded that SCLT and Dr. Kahn had a "shared" responsibility with respect to informed consent. Finally, the court found that because it provided Ms. Smith with a SCLT-specific consent form, SCLT "undertook a duty to obtain informed consent from the patient in this case." We address each of these rationales in turn.

a. Physician's Failure to Obtain Informed Consent

¶ 28 *Krane* recognizes a narrow exception to the corporate practice of medicine doctrine, holding that "unless a hospital knows or should know of a doctor's propensity to commit negligent acts, such as failing to obtain a patient's informed consent prior to surgery, a hospital generally is not liable for the negligent acts of its physicians." 738 P.2d at 78. In denying SCLT's motion for a directed verdict, the trial court found that it "kn[ew] or should have known of Dr. Khan and perhaps his failure to provide complete informed consent to patients."

¶ 29 Consistent with this finding, the Smiths contend that Dr. Khan's disclosure was inadequate — and that therefore Ms. Smith's consent was not informed — because Dr. Khan did not explain to her that his injection of Kenalog would be an off-label use of the

drug. And, the Smiths contend, SCLT knew or should have known that Dr. Khan was regularly using Kenalog off-label without disclosing that use to patients, and therefore had a duty to step in and give Ms. Smith the information that Dr. Khan did not.

¶ 30 We reject this argument because we do not read *Krane*, or any case in the series of decisions that used similar "propensity" language, as imposing a duty on a health care facility to ensure that a patient has given informed consent in the event that a physician has failed to properly advise her. To the contrary, tracing this language back to its origins clarifies that it does nothing more than recognize one narrow exception to the corporate practice of medicine doctrine: a hospital may be liable for a physician's negligence if it issues credentials to a physician despite the fact that it knows or should know that the physician has a tendency to act negligently. For instance, in *Western Insurance Co. v. Brochner*, the division held that, "*[i]n extending staff privileges to a doctor*, a hospital does not generally expose itself to liability for the doctor's negligence unless it knows or should know of a propensity on the doctor's part to commit negligent acts." 682 P.2d 1213, 1215 (Colo. App. 1983) (emphasis added), *rev'd on other grounds*, 724 P.2d

1293 (Colo. 1986); *see also Braden*, 714 P.2d at 507 (same). Similarly, in *Rosane v. Senger*, 112 Colo. 363, 366, 149 P.2d 372, 374 (1944), the supreme court held that unless a hospital "employs [physicians] whose want of skill is known, or should be known, to it, or by some special conduct or neglect makes itself responsible for their malpractice . . . it cannot be held liable therefor."

¶ 31 Holding that SCLT shares the responsibility of obtaining informed consent from patients like Ms. Smith would not only interfere with the physician-patient relationship but would also run headlong into Colorado's prohibition on the corporate practice of medicine. Indeed, because failing to advise a patient of the substantial risks of a medical procedure is "a variant of medical malpractice," *Bloskas*, 646 P.2d at 914, it follows that providing a patient with the information necessary to obtain informed consent *is* the practice of medicine. But because SCLT cannot practice medicine, the trial court's ruling in this case would put SCLT, and entities like it, in an impossible position — either step in and advise the patient, and thereby improperly engage in the practice of medicine, or refrain from doing so, and thereby violate the duty of care. And, of course, a health care facility's assumption of the

responsibility to advise the patient would create its own set of problems. The quality of patient care could suffer because it is "the surgeon, and not the hospital, who has the technical knowledge and training necessary to advise each patient of the risks of the surgery prior to the patient giving his consent," *Krane*, 738 P.2d at 77, and this gap in knowledge could lead to conflicting advice as to the risks and benefits of any given procedure. Moreover, because an entity like SCLT does not "know the patient's medical history" and "the details of the particular surgery to be performed," *id.*, it would make little sense for it to advise patients — and expose itself to liability — without fully interposing itself into the physician-patient relationship.

b. Placing Kenalog on the Formulary

¶ 32 For many of the same reasons, we conclude that SCLT did not, by approving Kenalog for use in its facility and keeping the drug on hand, assume a shared responsibility with Dr. Khan of obtaining Ms. Smith's informed consent. We recognize that the trial court found that because it "kept the drug available for Dr. Khan to use in an off-label fashion, such off-label use was endorsed by [SCLT]." But even viewing the evidence in the light most favorable to the

Smiths, we cannot agree that SCLT's decision to stock Kenalog is tantamount to an "endorsement" of its off-label use. Nor have the Smiths pointed to any evidence in the record suggesting that SCLT — as an entity — actually knew of or supported Dr. Khan's off-label use of Kenalog in this or any other case.

¶ 33 Even if we were to assume that (1) SCLT, as an entity, knew of Dr. Khan's off-label use of Kenalog; (2) the off-label use of Kenalog (or any other drug) is inherently problematic;[2] and (3) Ms. Smith needed to know about the off-label use in order to give her informed consent,[3] the fact remains that Kenalog has many uses that are

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[2] "Once FDA-approved, prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses; the FDA generally does not regulate how physicians use approved drugs." *United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012). The FDA has recognized that "'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature." Dep't of Health & Human Servs., *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bull. 4, 5 (Apr. 1982), https://perma.cc/D2SR-7MFB; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (noting that off-label use "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine"). Kenalog's label states that it is "NOT FOR IV, ID, INTRAOCULAR, EPIDURAL, OR INTRATHECAL USE."

[3] We need not reach this question, but we note that some courts have rejected the proposition that a physician's decision to use a

consistent with its label. Nothing in the record suggests that SCLT stocked the medication for off-label use alone, nor is it clear that SCLT could have done so without taking the prohibited step of dictating to its physicians how to use that particular drug.

¶ 34 In any event, the Smiths' argument proves too much. If maintaining a formulary constitutes the practice of medicine, then any health care facility that creates an approved list of medications would, by approving certain medications for use, both violate the corporate practice of medicine doctrine and expose itself to liability if a physician were to negligently administer one of those medications. The result would likely be that health care facilities

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drug off-label is material to the question of informed consent. *See, e.g.*, *Shannon v. Fusco*, 89 A.3d 1156, 1182 (Md. 2014) ("Information pertaining to an 'off-label' use provides the patient with no information about the treatment itself."); *Southard v. Temple Univ. Hosp.*, 781 A.2d 101, 107 (Pa. 2001) (holding, with respect to off-label use of a medical device, "that a physician need not disclose a device's FDA classification to the patient in order to ensure that the patient has been fully informed regarding the procedure"). These and other similar cases instead acknowledge that it is the actual risks and benefits associated with the treatment, rather than the scope of FDA approval, that bear on the scope of the informed consent discussion. *See, e.g.*, *Blazoski v. Cook*, 787 A.2d 910, 919 (N.J. Super. Ct. App. Div. 2002).

would no longer maintain formularies at all, which would work to the detriment of patient care.

c. SCLT-Specific Form

¶ 35 Because it is directly contrary to *Krane*, which we find persuasive, we also disagree with the trial court's ruling that, by providing its own consent form, SCLT "undertook a duty to obtain informed consent from the patient in this case."

¶ 36 Ms. Smith signed two informed consent forms authorizing the procedure, one of which was on SCLT's letterhead, and one of which had no letterhead, but was specific to Dr. Khan. (A third form, for anesthesia services, is not at issue.) Among other things, both forms identified the pending procedure and confirmed that Dr. Khan had advised Ms. Smith of its risks and possible complications.

¶ 37 In *Krane*, the patient signed only one consent form, which "included the printed name and address of the [h]ospital." 738 P.2d at 78. But the *Krane* division foresaw the situation in this case, noting that "even if a hospital does undertake to obtain a patient's informed consent to surgery, that fact does not, itself, create any liability on its part concerning the surgical procedures and risks

involved." *Id.* This view, which we follow, is consistent with cases throughout the country that have rejected the argument that a health care facility assumes the responsibility of obtaining a patient's informed consent by using its own form. *See Mele v. Sherman Hosp.*, 838 F.2d 923, 925 (7th Cir. 1988) (holding that "the preprinted consent form prepared by the Hospital — in which a patient must affirm that she has 'been informed that there are risks' — . . . does not force the Hospital to guarantee that a doctor has fully informed his patient"); *Porter v. Sisters of St. Mary*, 756 F.2d 669, 673 (8th Cir. 1985) ("[I]f a hospital furnishes consent forms to a patient for his signature, it does not thereby assume duties that are the business of the physician."); *Petriello v. Kalman*, 576 A.2d 474, 479 (Conn. 1990) ("It is quite unlikely that the defendant hospital, in adopting its rule requiring a written consent form to be signed, intended to assume a responsibility greater than the law imposed upon it already."); *Long v. Jaszczak*, 688 N.W.2d 173, 181 (N.D. 2004) (agreeing with the majority of courts that "have held a hospital's written informed consent policies do not create a legal duty to obtain patients' informed consent").

## III. Negligence Per Se

¶ 38 SCLT contends that the Smiths' claim for negligence per se should not have been submitted to the jury. We agree.

### A. Governing Law and Standard of Review

¶ 39 "[N]egligence per se provides that certain legislative enactments such as statutes and ordinances can prescribe the standard of conduct of a reasonable person such that a violation of the legislative enactment constitutes negligence." *Lombard v. Colo. Outdoor Educ. Ctr., Inc.*, 187 P.3d 565, 573 (Colo. 2008). It occurs "when the defendant violates a statute adopted for the public's safety and the violation proximately causes the plaintiff's injury." *Scott v. Matlack, Inc.*, 39 P.3d 1160, 1166 (Colo. 2002). "To recover, the plaintiff must also demonstrate that the statute was intended to protect against the type of injury she suffered and that she is a member of the group of persons the statute was intended to protect." *Id.*

¶ 40 The scope and intent of the statute (or here, administrative regulation) are questions of law that we review de novo. *See Kaltman v. All Am. Pest Control, Inc.*, 706 S.E.2d 864, 872 (Va.

2011). Causation is "generally a factual issue to be decided by the trier of fact." *Id.*

B. Relevant Facts

¶ 41 The Smiths assert that "[t]wo sets of regulations supported Plaintiffs' negligence per se claims: 6 CCR 1011-1 Chap 20 (Colorado ASC Regulations); and 42 CFR 416.40, 41, 42 (Federal ASC Regulations)." Portions of these regulations appear in the record as exhibits, and were referenced by Instruction 32, which stated in full:

> At the time of the occurrence in question in this case, the following Colorado and Federal Regulations were in effect:
>
> 1. 6 CCR 1011-1 Chap 20, and
>
> 2. 42 CFR 416.40, 41, 42
>
> A violation of these Colorado Regulations or Federal Regulations constitutes negligence.

¶ 42 The relevant part of the special verdict form included the following questions:

> 4. Was the defendant negligent *per se* in failing to comply with State and Federal regulations? (Yes or No)
>
> . . .

> 5. Was the negligence *per se*, if any, of the defendant a cause of any of the injuries, damages, or losses, claimed by the plaintiffs? (Yes or No)

¶ 43 The jury answered "Yes" to each of these questions.

C. Analysis

¶ 44 To determine whether these state and federal regulations listed in Instruction 32 may form the basis for a claim of negligence per se, we must consider whether they were (1) "enacted for the public's safety," (2) "intended to protect the class of persons of which the plaintiff is a member," and (3) "enacted to prevent the type of harm suffered by the plaintiff." *Gerrity Oil & Gas Corp. v. Magness*, 946 P.2d 913, 930 (Colo. 1997). Because we conclude it is dispositive, we address only the first of these elements below.

¶ 45 In its order denying SCLT's motion for a judgment notwithstanding the verdict, the trial court concluded that the regulations were enacted for the public's safety because the Colorado regulations "provide[] [that] they are for the welfare and safety of patients," and the federal regulations also "contemplate patient safety, providing care in a safe environment and in a safe manner." On appeal, the Smiths maintain that the state and

federal regulations were enacted for the public's safety because "they protect public safety of ASC patients like [Ms. Smith]."

¶ 46 SCLT responds that, as contemplated by section 25-1.3-103(1)(a)(I)(A), C.R.S. 2019, and section 25-3-101(1), C.R.S. 2019, the state regulations were enacted for the purpose of "set[ting] forth licensure requirements for [ASCs]," and that the federal regulations establish "[t]he conditions that an ASC must meet in order to participate in the Medicare program," "[t]he scope of covered services," and "[t]he conditions for Medicare payment for facility services." *See* 42 C.F.R. § 415.1(b) (2019).

¶ 47 Section 25-1.5-103(1)(a)(I)(A) requires the Colorado Department of Public Health and Environment (CDPHE) to "annually license and to establish and enforce standards for the operation of," along with a host of other types of health care facilities, "ambulatory surgical centers." Complementing this licensing requirement, section 25-3-101(1) provides that it is "unlawful . . . to open, conduct, or maintain any . . . ambulatory surgical center . . . without having first obtained a license from" CDPHE.

¶ 48 CDPHE has adopted the regulations required by these two statutory provisions, which are codified at Department of Public Health and Environment Ch. 20, 6 Code Colo. Regs. 1011-1.[4] They comprehensively outline various conditions of ASC licensure, ranging from, among other things, administration to recordkeeping to sanitation. Ensuring patient safety is an important benefit of the rules, but it is not their *raison d'être*. *See Lawson v. Stow*, 2014 COA 26, ¶ 44 (holding that Colorado's false reporting statute could not form the basis of a negligence per se claim because, while it "relates to public safety to some extent," its "*primary purpose* . . . is to conserve finite law enforcement resources") (emphasis added); *see also Burgess v. Religious Tech. Ctr., Inc.*, 600 F. App'x 657, 666 (11th Cir. 2015) (rejecting negligence per se claim based on rehabilitation facility's "failure to comply with state licensing regulations" because the "regulations were 'intended for licensing

[4] The version of these rules appearing in the record before us was adopted on December 17, 2014, but the record version includes only section 1 through 15 and omits sections 16 through 25. For the purposes of this opinion, we take judicial notice of the portion of Department of Public Health and Environment Ch. 20, 6 Code Colo. Regs. 1011-1 that is missing from the record.

and inspection purposes and not for the creation of a standard of conduct to protect individuals'") (citation omitted).

¶ 49 Rather, CDPHE adopted the regulations pursuant to its authority to "annually license and to establish and enforce standards for the operation of . . . ambulatory surgery centers," § 25-1.5-103(1)(a)(I)(A). While the rules state that an ASC's "governing body shall provide facilities, personnel, and services necessary for the welfare and safety of patients," Dep't of Pub. Health & Env't Ch. 20, Reg. 4.1, 6 Code Colo. Regs. 1011-1, those requirements represent a condition of licensure rather than the agency's core regulatory focus. The regulations therefore cannot serve as the basis for a negligence per se claim.

¶ 50 For many of the same reasons, we reach the same conclusion with respect to the federal regulations listed in Instruction 32. Title 42, chapter IV, subchapter B of the Code of Federal Regulations is titled "Medicare Programs." Part 416 of that subchapter sets forth regulations pertaining to Ambulatory Surgical Services and

Medicare, and section 416.1[5] sets the "Basis and Scope" of these regulations:

> (b) *Scope*. This part sets forth —
>
> (1) The conditions that an ASC must meet in order to participate in the Medicare program;
>
> (2) The scope of covered services; and
>
> (3) The conditions for Medicare payment for facility services.

42 C.F.R. § 416.1 (2019).

¶ 51 These regulations clearly explain what they are intended to accomplish — the establishment of requirements for an ASC to receive Medicare reimbursement from the federal government. As is true for the rules promulgated by CDPHE, scattered references to factors that may bear on patient safety — like requiring facilities to maintain a "safe environment," 42 C.F.R. § 416.41 (2019), and to operate on patients "in a safe manner," 42 C.F.R. § 416.42 (2019) — do not change the fundamental character and purpose of the regulations as a whole. We therefore conclude that the federal

[5] This subsection is likewise not in the record, but we take judicial notice of it, together with the entirety of 42 C.F.R. part 416 (2019).

regulations in Instruction 32 could not serve as the basis for a negligence per se claim against SCLT.

## IV. Remaining Issues

¶ 52 Because we conclude that the trial court should have ruled in SCLT's favor as a matter of law, we need not address either the evidentiary issues raised by SCLT or the Smiths' cross-appeal challenging the constitutionality of the HCAA.

## V. Conclusion

¶ 53 We reverse the judgment and remand the case for entry of judgment in favor of SCLT.

JUDGE WELLING and JUDGE VOGT concur.