

<p>DISTRICT COURT, CITY AND COUNTY OF DENVER, COLORADO</p> <p>Address: 1437 Bannock Street, Room 256 Denver, Colorado 80202</p> <p>Telephone: (303) 640-2491</p>	<p>FILED Document CO Denver County District Court 2nd JD Filing Date: Sep 28 2010 4:53PM MDT Filing ID: 33504523 Review Clerk: Matthew Palmer</p>
<p>Plaintiffs: COLORADO MEDICAL SOCIETY, a Colorado nonprofit corporation, and THE COLORADO SOCIETY OF ANESTHESIOLOGISTS, a Colorado nonprofit corporation</p> <p>Defendant: BILL RITTER, JR., in his official capacity as the Governor of Colorado</p>	<p>▲ COURT USE ONLY ▲</p>
<p>Attorneys for Plaintiff Colorado Medical Society:</p> <p>Kari Hershey, No. 34246 Hershey Skinner, LLC 10463 Park Meadows Drive, Suite 209 Littleton, Colorado 80124 Telephone: (303) 226-1680 E-Mail: kari@hersheyskinner.com</p> <p>Attorneys for Plaintiff Colorado Society of Anesthesiologists:</p> <p>Joseph J. Bronesky, No. 7973 Frederick Y. Yu, No. 4501 Sherman & Howard L.L.C. 633 Seventeenth Street, Suite 3000 Denver, Colorado 80202 Telephone: (303) 297-2900 E-Mail: jbronesky@shermanhoward.com fyu@shermanhoward.com</p>	<p>Case No. 2010 CV _____</p> <p>Courtroom _____</p>
<p align="center">COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF</p>	

Plaintiffs, Colorado Medical Society and The Colorado Society of Anesthesiologists, state the following for their Complaint:

1. The Colorado Medical Society (the "Medical Society") is a Colorado non-profit corporation whose membership includes the majority of physicians practicing in Colorado. As

the largest organization of physicians, residents, and medical students in Colorado, the Society's mission is to promote the science and art of medicine, the betterment of public health, and the welfare of the medical profession and the patients it serves.

2. The Colorado Society of Anesthesiologists (the "Anesthesiologist Society") is a Colorado non-profit physician organization which is committed to patient safety, educational advancement, and providing the best anesthesia care to patients. The Anesthesiologist Society is a resource for patients, physicians, and the public by defining and advancing the standard of anesthesia care and supporting the practice of anesthesiology in Colorado.

3. The Medical Society and the Anesthesiologist Society bring this action to protect interests that are germane to their purposes. Although the members of the Societies would have the right to bring an action in their own right, neither the claim asserted, nor the relief requested, requires the participation of these members.

4. Defendant, Bill Ritter, Jr., acts in his official capacity as Governor of the State of Colorado in complying with certain requirements imposed by the United States Government and its departments and agencies.

5. This action is proper for declaratory judgment pursuant to C.R.S. § 13-51-101 and C.R.C.P. 57, and for injunctive relief pursuant to C.R.C.P. 65, because of the existence of a controversy between the Societies and Defendant about the construction and application of various statutes and precepts of common law pertaining to the practice of medicine and delivery of anesthesia care. This controversy, including the "opt-out" action described in paragraph 13 below, adversely affects the Societies and their members because it creates confusion and misunderstanding as to (a) the legal responsibility of a physician to his or her patient to supervise all persons under his or her control; (b) the legal and practical scope of practice of physicians and nurses known as certified registered nurse anesthetists ("CRNAs"); (c) the levels of education, skill, and training that are required to administer anesthesia safely to patients; and (d) the diminished level of public protection due to the absence of physician supervision of CRNAs. The "opt-out" decision will diminish patient safety in the state of Colorado.

6. Venue is proper in this judicial district because it is the official residence of the Defendant.

The Applicable Facts

7. The Social Security Act provides for the establishment of certain specified requirements, known as Conditions of Participation, for various medical facilities that participate in the Medicare program, including ambulatory surgical centers, hospitals, and critical access hospitals. The Conditions of Participation are set forth in federal regulations and establish standards for each of these types of facilities for the administration of anesthesia. Generally speaking, these standards require that anesthesia be administered only by a qualified

anesthesiologist, a physician qualified to administer anesthesia, a CRNA, or, in some cases, by an anesthesiology assistant.

8. The federal Medicare Regulations require that anesthesia administered by a CRNA must be under a physician's supervision. A CRNA in a Medicare-certified ambulatory surgery center must be under the supervision of the operating physician (42 CFR § 416.42); a CRNA in a Medicare-certified hospital must be under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (42 CFR § 482.52); and a CRNA in a Medicare-certified critical access hospital must be under the supervision of the operating practitioner (42 CFR § 485.639).

9. The Medicare Regulations give individual states the option to terminate the physician supervision requirement for CRNAs who administer anesthesia in these facilities if "the State in which the facility is located submits a letter to the Centers for Medicare and Medicaid Services, signed by the Governor of the State, following consultation with the State's Board of Nursing and Medicine, that requests exemption from physician supervision of CRNAs." The letter must attest that "the opt-out is consistent with State law."

10. On July 29, 2010, Governor Ritter issued a letter to the Colorado Medical Board and the Colorado Board of Nursing which declared his "understanding" that "the Colorado Nurse Practice Act allows CRNAs to practice without direct supervision from a physician." He requested each Board to inform him whether it understood that the termination of physician supervision of CRNAs was "consistent with State law," and whether it was in the best interests of Colorado residents. He stated his intent to notify the Centers for Medicare and Medicaid Services ("CMS") of his intent to invoke the opt-out unless the Boards provided "compelling arguments against such action."

11. The Colorado Medical Board considered the Governor's request at its meeting on August 19, 2010. It voted 7-6 in favor of a motion to determine that the opt-out was in the best interests of Colorado residents, and 8-5 in favor of a motion to opine that the opt-out was consistent with state law. The Board considered only the Colorado Medical Practice Act, and it did not attempt to determine the general application of Colorado law to the supervision of CRNAs by physicians. Moreover, the Board noted that it had not obtained a legal assessment about the issue.

12. The Colorado Board of Nursing considered the Governor's request at its meeting on August 25, 2010. It also voted to support the opt-out. It also did not attempt to determine the general application of Colorado law to the supervision of CRNAs by physicians.

13. By letter dated September 27, 2010, Governor Ritter notified CMS that he had exercised the option to exempt all critical access hospitals in Colorado, as well as thirteen specifically-identified "rural general hospitals," from the requirement that CRNAs be supervised by a physician. He issued a second, very similar letter dated September 28, 2010, that added

another “rural general hospital” that he decided to exempt. His second letter stated his conclusion that the opt-out was in the best interests of Colorado citizens..

14. The Governor’s determination to opt out is inconsistent with Colorado law and is contrary to the will of the Colorado Legislature as expressed in Colorado statutes.

Colorado Statutory Law

15. Colorado statutes classify a CRNA as an “advanced practice nurse” who possesses specialized education or training. C.R.S. § 12-38-111.5(3).

16. The Colorado Nurse Practice Act, C.R.S. §§ 12-38-101, *et seq.*, defines the practice of advanced practice nursing to include the “practice of professional nursing,” which includes “performance of both independent nursing functions and delegated medical functions in accordance with accepted practice standards.” C.R.S. § 12-38-103(8.5)(a) and (10)(a).

17. Nothing in any definition of nursing contained within the Nurse Practice Act encompasses delivery of anesthesia as an independent nursing function.

18. A “delegated medical function;” however, is “an aspect of care which implements and is consistent with the medical plan as prescribed by a licensed or otherwise legally authorized physician, podiatrist, or dentist and is delegated to a registered professional nurse or a practical nurse by a physician, podiatrist, dentist, or physician assistant.” C.R.S. § 12-38-103(4).

19. A “medical plan” is a written plan, verbal order, standing order, or protocol that authorizes a specific or discretionary medical action, which may include but is not limited to the selection of medication.” *Id.*

20. Anesthesia is a medication.

21. Administration of anesthesia is a component of a medical plan of treatment for an individual. For example, anesthesia is typically administered as a component of surgery performed by a physician. In such a case, the medical plan is the performance of surgery on the patient.

22. Colorado law also incorporates “accepted practice standards” in the determination of whether an activity is a “delegated medical function.” C.R.S. § 12-38-103(10)(a). Under current practice standards, particularly in institutions participating in the Medicare and Medicaid programs, such standards require physician supervision of the administration of anesthesia by a CRNA.

23. The administration of anesthesia is the “practice of medicine” as defined by the Colorado Medical Practice Act, C.R.S. § 12-36-106(1)(a).

24. The administration of anesthesia by a nurse falls squarely within the definition of a “delegated medical function” under Colorado law.

25. Although the Medical Practice Act exempts the services of licensed certified nurse midwives (one type of advanced practice nurse) from the definition of “practice of medicine” (*see* C.R.S. § 12-36-106(1)(f)(I)), there is no similar exemption for the services of CRNAs.

26. Moreover, although the “rendering of nursing services and delegated medical functions by registered or other nurses in the lawful discharge of their duties as such” is exempt from the definition of the “practice of medicine,” (*see* C.R.S. § 12-36-106(3)(j)), the administration of anesthesia by a nurse anesthetist is a “delegated medical function,” not an independent nursing function, and therefore may only be carried out under physician supervision. Consequently, the administration of anesthesia by a CRNA without physician supervision would constitute the unlawful, unauthorized practice of medicine under Colorado law.

27. The Governor’s conclusion that Colorado law permits a CRNA to administer anesthesia without the supervision of a physician is contrary to the Nurse Practice Act and the Medical Practice Act. His attempt to recognize different scopes of practice for CRNAs in different parts of the State of Colorado—through the issuance of his September 27, 2010, letter—is also contrary to these Acts.

Colorado Common Law

28. The Colorado Supreme Court and Colorado Court of Appeals, as well as the trial courts of the state, have consistently recognized that an operating surgeon has the duty to direct and supervise all personnel who are in an operating room upon his or her request and authorization. These courts have imposed liability upon the operating surgeon for the negligence of such personnel under the vicarious liability principle known as the “captain of the ship” doctrine. *Ochoa v. Vered*, 212 P.3d 963 (Colo. App. 2009), *cert. granted on other grounds* (March 16, 2009). *O’Connell v. Biomet, Inc.*, Case No. 09CA0224 (2010).

29. The Governor’s certification to the federal government that Colorado law permits a CRNA to administer anesthesia without the supervision of a physician is inconsistent with the captain of the ship doctrine enforced in Colorado.

First Claim for Relief Request for Declaratory Relief

30. The Societies incorporate the allegations of paragraphs 1-29.

31. The Societies and the Governor have a dispute regarding the interpretation and application of Colorado law — as established by statute and case law. The positions taken by the

Governor have caused the adverse effects described in paragraph 5 above. The declaratory judgment requested by the Societies is appropriate.

**Second Claim for Relief
Request for Injunctive Relief**

32. The Societies incorporate the allegations of paragraphs 1-31.

33. The opt-out decision described in paragraph 13 has created a danger of real, immediate, and irreparable injury, including the harms described in paragraph 5, which may be prevented by injunctive relief .

34. The Colorado Statutory and Common Law described above demonstrate that the Societies have a reasonable probability of success on the merits.

35. The Societies have no plain, speedy, and adequate remedy at law.

36. The granting of a preliminary injunction to compel a withdrawal of the opt-out letter would not disserve the public interest.

37. The balance of equities favors the issuance of an injunction.

38. An injunction will preserve the status quo pending a trial on the merits.

Prayer for Relief

The Societies request the following relief:

- a. The entry of declaratory judgment that delivery of anesthesia by a nurse is a delegated medical function;
- b. The entry of declaratory judgment that Colorado law requires CRNAs to deliver anesthesia under the supervision of a physician;
- c. The entry of declaratory judgment that any letter issued by the Governor that purportedly exercises the opt-out, and any attestation contained therein, is inconsistent with, and contrary to, Colorado law, void, and ineffective;
- d. The entry of a preliminary injunction compelling the Governor to rescind any letter that is issued to exempt Colorado CRNAs from the supervision of a physician, and the issuance of a permanent injunction against any future attempts at an opt-out; and
- e. An award of costs, expert witness fees, and whatever other relief is appropriate.

DATED this 28th day of September, 2010.

HERSHEY SKINNER, LLC

*Original signature on file at the offices of
Hershey Skinner, LLC*

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