GOVERNOR'S UNAUTHORIZED OPT-OUT OF MEDICARE REQUIREMENT REQUIRING PHYSICIAN SUPERVISION OVER CERTIFIED REGISTERED NURSE ANESTHETISTS (CRNAS)

In a flagrant violation of federal and state law, Governor Schwarzenegger opted out of the federal Medicare requirement that certified registered nurse anesthetists (CRNAs) be supervised by physicians, even though such supervision has been a long-standing public safety requirement deemed appropriate by California law, as established by the Legislature and interpreted by the Attorney General's office. See Business & Professions Code §§2725 and 2825 et seq.; see also 67 Ops.Cal.Atty.Gen. 122 (1984) (California law authorizes a CRNA to administer general and regional anesthetics only under direct physician supervision).

Prior to 2001, federal Medicare conditions for participation for hospitals required that CRNAs be supervised by physicians. Since that time, however, federal law was amended to provide an "opt-out" provision allowing hospitals that so choose, to be exempt from the supervision requirement in those states where the governor submits a letter to the Centers for Medicare and Medicaid Services (CMS) containing federally mandated attestations (42 C.F.R. §482.52.) CMS decided to have flexibility in this area in order to, among other things, (1) recognize "a state's traditional domain in establishing professional licensure and scope of practice laws" and (2) allow the governor to decide whether an opt out is consistent with state law where there are differences of opinion in the state concerning the CRNA scope of practice and whether it requires physician supervision. See 66 Fed.Reg. No. 219, Nov. 13, 2001, at pp. 56763, 56764.

Accordingly, federal law now authorizes a hospital to be exempted from the requirements of physician supervision if, in the state in which the hospital is located, the Governor submits a letter to CMS attesting each of the following:

(i) that the Governor has consulted with both the State Boards of Medicine and Nursing about issues related to both:

   • Access to anesthesia services in the state, and
   • Quality of anesthesia in the state;

(ii) that it is in the best interests of the state's citizens to opt out of the physician supervision requirement; and

(iii) that the opt-out is consistent with state law, including state scope of practice laws.

See 42 C.F.R. §482.52.

Based on the information we have received to date, it appears the Governor has violated every aspect of this regulation.
A. An Opt-Out Violates Long-Established California Scope of Practice Laws Requiring Physician Supervision over CRNAs

Perhaps the most flagrant example demonstrating the illegality of the Governor's action is the fact that the opt-out is not consistent with existing California law. California law unequivocally requires physician supervision and thus this state is not one of those states where a debate exists over the state requirement that CRNAs must be supervised by a physician.

Business & Professions Code §2725 sets forth the scope of practice of a registered nurse. This provision authorizes nurses to assist in certain patient care activities so long as those activities are performed under the supervision of physicians. (Id.) As the Attorney General stated:

"At the point when the Nursing Practice Act was amended in 1974, then the concept of supervision by a physician who would bear responsibility for treating a patient was considered to be the sine qua non for permitting a registered nurse to assist a physician in a case by performing many acts which would constitute the practice of medicine... (citations omitted).... The new Act must be viewed in light of this decisional background (citations omitted).... Since the Legislature did not significantly redefine the scope of nursing practice to compromise that background we must presume that the Legislature intended that it be carried over in interpreting the statute as amended."


The authority for nurses, including CRNAs, to administer anesthesia is Business & Professions Code §2725(b)(2). That section allows for "the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention or rehabilitative regime ordered by ... or physician ...." (Emphasis added.) Thus, nurses have no independent authority to provide anesthesia services.

Nurse anesthetists are governed by the Nurse Anesthetist Act. (Business & Professions Code §2825) A "nurse anesthetist" is a "person who is a registered nurse, licensed by the board (of Registered Nursing) and who has met standards for certification from the board." (Business & Professions Code §2826.)

When enacting the laws governing nurse anesthetists, the Legislature took great pains to ensure that it was not expanding or restricting the existing scope of practice of a nurse anesthetist, nor authorizing a nurse anesthetist to practice medicine. See Business & Professions Code §§2833.3, 2833.5, 2833.6. For that reason, the law "simply provides for the certification of qualified registered nurses as 'nurse anesthetists' and does not add to or subtract from the authority the nurse anesthetist has as a registered nurse." (67 Ops.Cal.Atty.Gen. 122 (1984).) Therefore, the scope of practice of a CRNA is essentially the same as a registered nurse. Under those circumstances, the Attorney General had no trouble concluding that a CRNA could only administer general and regional anesthetics under direct physician supervision. (Id.).

In his opinion, the Attorney General was asked to consider whether CRNAs could lawfully administer regional anesthetics pursuant to "standardized procedures," as authorized pursuant to
Business & Professions Code §2725. When concluding a CRNA could not administer anesthetics pursuant to a "standardized procedure," but rather required direct supervision, the Attorney General reasoned as follows:

It would appear anomalous for the nurse anesthetist to administer an anesthetic in accordance with a "standardized procedure" as defined, rather than in accordance with the orders of the physician who is performing the surgery. This would mean that the manner in which the anesthetic is administered by the nurse anesthetist would be governed by the "policies and protocols" developed through collaboration among the administrators and health professionals, including physicians and nurses by an organized health care system. We doubt that the Legislature intended to remove the control over an integral part of the surgical procedure from the physician responsible for the surgery and place it in the hands of a nurse acting in accordance with a standardized procedure. Standardized procedures were meant to govern the nurse's actions in situations when the physician responsible for the patient's care is absent and they do not apply when the responsible physician is present and orders a different procedure. This does not mean that the physician responsible for the patient's surgery may not direct the nurse anesthetist by means of some written instructions. It does mean that the physician responsible for the surgery retains control over the actions of the nurses involved in the surgery, including the nurse anesthetist, in spite of any standardized procedures which may have been developed. This is necessary to permit the physician to react to conditions which develop in the patient's best interest, which conditions may not have been foreseen at the time the standardized procedures for nurses were developed. (Id.)

Supervision of CRNAs was such a critical component of the Nursing Practice Act that the Legislature enacted Business & Professions Code §2762, which makes it unprofessional conduct for CRNAs (as well as other nurses) to obtain, prescribe or administer anesthetic agents except as directed by a licensed physician, dentist or podiatrist.

Given the authorities cited above, California law unequivocally requires physician supervision over CRNAs. In addition to the fact that any opt-out of the physician supervision requirement is plainly not consistent with California law, there are a number of other additional violations with respect to the Governor's "opt-out" of the physician supervision requirement.

1 Business & Professions Code §2725 permits nurses to implement "standardized procedures" or "changes in treatment regimen in accordance with standardized procedures" based on a patient’s observed abnormalities. These procedures "were meant to govern the nurse’s actions in situations where the physician responsible for the patient is absent. . . ." See 67 Ops.Cal.Atty.Gen. 122 (1984). "Standardized procedures" are written policies and protocols that have been developed through collaboration among administrators and health professionals, including physicians and nurses. These written protocols represent an intermediate level of supervision, more than that accorded for traditional nursing functions, but less than direct supervision. (Business & Professions Code §2725(d); 64 Ops.Cal.Atty.Gen. 240 (1981) (supervision is found in the "standardized procedure"); 66 Ops.Cal.Atty.Gen. 427 (1983).)
B. Additional Violations of Federal Law

1. There Was No Consultation with the Medical Board

When CMS was adopting the rule, CMS explained the importance of the consultation requirement as serving:

…as an opportunity for participants on both sides of the issue to have their opinions, issues and concerns heard, firsthand, by the individual or designee responsible for making the decisions regarding whether to opt out of the federal supervision requirement. (66 Fed.Reg. at 56764.)

This consultation requirement is consistent with the federal government's desire to leave the issue up to the individual states as:

States are in the best position to assess the evidence and consider date relevant to their own situations (for example, physician access, hospital and patient characteristics and needs of rural areas) about the best way to deliver anesthesia care.

(Id. at 56763.)

Based on the information we have received to date, it does not appear that the Governor consulted with the Medical Board on these vital issues as required by federal law. While the Medical Board did respond to a letter for information concerning the legal scope of practice of CRNAs from the Deputy Secretary and General Counsel of the California State and Consumer Services Agency, as far as we can tell, it was not consulted by the Governor or any member of his office directly. (See Attachment 1, Letter from Medical Board dated March 2, 2009, to Leslie Lopez, Deputy Secretary and General Counsel, California State and Consumer Services Agency.)

2. The Medical Board Was Not Consulted on Issues Concerning Access and Quality

As can be seen by Attachment 1, even if the letter from the State Consumer Service Agency is deemed to be that of the Governor, it is clear that the "consultation" concerned the legal scope of practice of nurse anesthetists, and not access and quality issues as required by 42 C.F.R. §482.52. In addition, it is worthy of note that the Medical Board letter itself opines that a nurse anesthetist is required to have physician supervision.

3. The Governor's Letter Did Not Attest that He Consulted with the State Board of Medicine (and Nursing) about Issues Related to Access to and Quality of Anesthesia Services

Most likely because the Governor appears not to have consulted with the Medical Board about quality of and access to anesthesia services in California, the Governor's opt-out letter contains no attestation on that point. (See Attachment 2, June 10, 2009 Letter of Governor Arnold Schwarzenegger to Ms. Charlene Fizzerra, Acting Administrator, Centers for Medicare and Medicaid Services.) This failure again violates federal law.
4. The Letter Does Not Attest that the Exemption is in the "Best" Interest of Californians

Federal law requires that the Governor attest that he or she has concluded that the opt out is in the "best interests of the state's citizens." (42 C.F.R. §482.52(c)(1).) The Governor rather concluded that it was merely in the "interests" of the people of California to opt out of this important requirement.

C. The Medical Literature Does Not Support an Opt-Out of the Physician Supervision Requirement

Even apart from the scope of practice considerations, had the Governor done a meaningful analysis of access and quality, it would have become clear that the evidence does not support the elimination of the supervision requirement. Again, when adopting the opt-out provision, CMS was quite clear that its intent was to broaden flexibility of states to make decisions about the best way to deliver health care services since, among other things, they are in the best position to assess evidence and consider data relevant to their own situations, such as physician access. See 66 Fed.Reg. at 56765.

1. Access Will Not Be Increased

Anesthesiologists and CRNAs practice in the same areas in California. As the attached geomap identifying where both anesthesiologists and CRNAs are distributed throughout California demonstrates, having CRNAs practice without supervision will not solve any access to anesthesia issues that may exist in this state. (See Attachment 3.)

2. Patient Outcomes Are Improved with Physician Directed Anesthesia

Further, the medical literature supports physician-directed anesthesia as a mechanism to improve patient outcomes. For example, the Department of Anesthesiology at the Mayo Clinic researched this issue and concluded that outcome studies suggest improved outcomes when physicians medically direct nurse anesthetists, as opposed to when anesthesia is delivered with non-medically directed nurses. See Abenstein, J.P., et al., "Is Physician Anesthesia Cost-Effective?" Anesth. Analg. 2004, March 98 (3):750-7, Department of Anesthesiology, Mayo Clinic. The economic analysis supported by the study also suggests that outcome gains with physician anesthesia may be obtained at cost savings. (Id.)

A 2000 study suggests troublesome results where anesthesia is allowed to be provided non-medically. See Silber, et al., "Anesthesiologist Direction and Patient Outcomes," Anesthesiology, 2000 (July) 93:152-63. That study examined surgical outcomes in Medicare patients who had different anesthesia providers. Cases were defined as "directed" if an anesthesiologist billed Medicare Part B for personally performing a case or medically directing a CRNA or physician resident. According to the study, compared to the directed group, the undirected group had a higher mortality rate, accounting for 2.5 excess deaths per 1,000 cases, and an even higher failure-to-rescue rate, accounting for 6.9 excess deaths per 1,000 cases with complications. (Id.)
3. **An Expanded Use of CRNAs Will Not Result in Cost Savings**

Further, it does not appear that cost savings will be achieved with an opt-out. In addition to the studies cited above, another study concluded that the costs for that services billed to Texas Medicaid were 19%-26% less per patient when provided by anesthesiologists than CRNAs, despite the lower per unit reimbursement of CRNAs. See Abouleish, A. E., et al., *Anesthesiology*, 2004 Oct. 101 (4) 991-8. The reason the physicians' bills were smaller appears largely due to the fact that the average time per case was significantly higher in the CRNA group (146 minutes) than in the anesthesiologists' group (105 minutes).

In sum, the Governor's action defy both law and public policy and we urge that the opt out letter be withdrawn pursuant to 42 C.F.R. § 482.52(c)(2), which allows the Governor to withdraw the request at any time.

July 27, 2009
Astrid Meghrigian, JD
For CSA/CMA
March 2, 2009

Leslie Lopez
Deputy Secretary and General Counsel
California State and Consumer Services Agency
915 Capitol Mall, Suite 200
Sacramento, CA 95814-2719

RE: Inquiry regarding Nurse Anesthetists dated February 26, 2009

Dear Ms. Lopez:

The Medical Board of California (Board) is in receipt of your request for information regarding nurse anesthetists. The specific question was “Whether a certified registered nurse anesthetist is required to have physician supervision to administer anesthesia?”

This particular question would be more appropriately posed to the Board of Registered Nursing, as this falls within the jurisdiction of their laws relating to scope of practice and requirements for practice with advanced nursing certificates. However, we have researched their laws and regulations and found Business and Professions Code section 2827 states, “The utilization of a nurse anesthetist to provide anesthesia services in an acute care facility shall be approved by the acute care facility administration and the appropriate committee, and at the discretion of the physician, dentist or podiatrist. If a general anesthetic agent is administered in a dental office, the dentist shall hold a permit authorized by Section 1646.” In addition, the Board of Registered Nursing’s Web site states “The nurse anesthetist is a registered nurse who provides anesthesia services under the direction of a physician, dentist, or podiatrist, and is certified by the BRN in this specialty.” Therefore, from a review of their Web site, it appears that a nurse anesthetist is required to have physician (dentist, podiatrist) supervision.

If more specific information is needed, the Board suggests that you contact the Board of Registered Nursing for assistance.

Sincerely,

Barb Johnston
Executive Director
June 10, 2009

Ms. Charlene Fizzerra
Acting Administrator
Centers for Medicare and Medicaid Services
314G Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Fizzerra,

Pursuant to the final rule published in the November 13, 2001, Federal Register, Volume 66, Number 219, I am exercising the option to exempt the State of California from the requirement that certified registered nurse anesthetists be supervised by a physician.

Having consulted with the California Board of Medicine and California Board of Registered Nursing and having determined that this exemption is consistent with state law, I have concluded that it is in the interests of the people of California to opt out of this requirement.

Sincerely,

Arnold Schwarzenegger

/la
California Anesthesiologist and Pain Management Physician to Certified Registered Nurse Anesthetist Distribution Comparison

= the location of one or more actively practicing Anesthesiologists and Pain Management Physicians (n = 4,783)

= the location of one or more actively practicing Certified Registered Nurse Anesthetists (n = 1,296)

Data Source: American Medical Association, American Osteopathic Association (2008) and the Dept. of Consumer Affairs, California State Board of Nursing (July 2008)