Opt-Out
Section Contents

- Medicare Opt-Out Background and Related Activity
- 2013 Dr. Zerwas Letter of Opposition to the Wyoming State Board of Nursing
- 2013 Dr. Fitch Letter of Opposition to the Wyoming State Board of Nursing
- 2013 Wyoming Medical Society Letter of Opposition to the Wyoming State Board of Nursing
- 2013 American College of Surgeons Letter of Opposition to the Wyoming State Board of Nursing
- 2013 ASA Testimony before the Wyoming Board of Medicine
- 2013 Wyoming Medical Society Position Statement – Physician Supervision of Nurse Anesthetists
- 2013 Wyoming State Board of Nursing Letter to Wyoming Department of Health Director re Opt-Out
- ASA Statement on the Anesthesia Care Team
- AMA Policy: H-160.929 Anesthesiology is the Practice of Medicine
- AMA Policy: D-160.993 Limitation of Scope of Practice of Nurse Anesthetists
- AMA Policy: D-35.985 Support for Physician Led, Team Based Care
MEDICARE OPT-OUT BACKGROUND AND RELATED ACTIVITY

On November 13, 2001, the Bush Administration published a final rule regarding the Medicare and Medicaid anesthesia Conditions of Participation (COP) for hospitals, critical access hospitals (CAHs) and ambulatory surgical centers (ASCs). The rule retains the current requirement for physician supervision of nurse anesthetists, but allows state governors to opt-out of this requirement under certain circumstances.

To opt-out, a governor must first consult with the medical and nursing boards regarding access to and the quality of anesthesia services in the state. If opting-out is consistent with state law, and if the governor determines that it is in the best interests of the citizens of the state to opt-out, the governor must advise the Centers for Medicare & Medicaid Services (CMS) in writing. The opt-out becomes effective upon submission of the request. A governor may retract this action at any time.

The American Society of Anesthesiologists strongly opposes gubernatorial opt-outs.

2013 Activity
In 2013, administrative agencies in two states (Vermont and Wyoming) have or are expected to consider opt-out.

- **Vermont**: The Vermont Medical Society received a communication from the Director of the Vermont Board of Medical Practice (VBMP) that the Board expects to see a request for the VBMP’s opinion on opt-out. The topic is likely to be scheduled at the October board meeting (Wednesday October 1, 2013).

- **Wyoming**: At the request of the Wyoming Department of Health, both the Wyoming Board of Medicine (WBM) and the Wyoming State Board of Nursing (WSBN) have held hearings on opt-out. The WSBN supported the concept while WBM has yet to formalize its position. (See attached 2013 letters to WBM and WSBN)

Current Opt-Out States
Seventeen states have opted out of the federal requirement for physician supervision of nurse anesthetists. The list includes:

- Iowa (December 2001)
- Nebraska (February 2002)
- Idaho (March 2002)
- Minnesota (April 2002)
- New Hampshire (June 2002)
- New Mexico (November 2002)
- Kansas (March 2003)
- North Dakota (October 2003)
- Washington (October 2003)
- Alaska (October 2003)
- Oregon (December 2003)
- Montana (January 2004)
- South Dakota (March 2005)
- Wisconsin (June 2005)
- California (July 2009)
- Colorado (September 2010)*
- Kentucky (April 2012)

Patient safety must be the driver behind any modification to our health laws. Comprehensive medical management of the patient is required to ensure best chances of a full recovery.

* Limited to Critical Access Hospitals and specified rural hospitals.
July 5, 2013

Carrie Deselms, MSN, APRN, FNP-BC
President, Wyoming State Board of Nursing
130 Hobbs Ave., Suite B
Cheyenne, WY 82002

Dear Ms. Deselms,

On behalf of the over 50,000 members of the American Society of Anesthesiologists (ASA), I am writing in strong opposition to the Wyoming State Board of Nursing’s consideration of eliminating the federal safety requirement for physician supervision of nurse anesthetists. A decision to remove the supervision requirement would not be in the best interest of the residents and patients of Wyoming. Such a decision will jeopardize patient safety and ignores patients’ overwhelming preference for a physician to be responsible for their anesthesia care (Appendix I).

Providing anesthesia is a serious and complex medical procedure. When problems occur, comprehensive medical management of the patient is required to ensure best chances of a full recovery. To prepare for the split second decision-making required to medically address life and death emergencies, physicians undergo nearly a decade of formal post-graduate medical education and residency training. For example, physician anesthesiologists have 12,000-16,000 hours of clinical training – seven times more training than nurse anesthetists, who generally have about 1,650 hours.

When physician anesthesiologists and nurses work together as a team, patients receive high-quality and safe anesthesia care. Nursing skills are important but cannot replace the training of a physician. An independent study published in the peer-reviewed journal Anesthesiology found that mortality and failure-to-rescue rates were higher for patients who underwent operations without medical direction by a physician anesthesiologist (Appendix II). A physician anesthesiologist’s advanced medical training allows for better management of complications, thereby decreasing the severity of such complications, and leading to fewer negative outcomes.

Patient safety must be the driver behind any modification to our health laws. Nearly all states require nurse anesthetists to practice within some kind of collaborative or supervisory agreement as part of a physician-led health care team. A common arrangement for providing anesthesia care is through the Anesthesia Care Team (Appendix III) where selected tasks of overall anesthesia care may be delegated to qualified team members with overall responsibility resting with the physician anesthesiologist.

Patients requiring anesthesia deserve to know a physician is responsible for their care. When asked, four out of five patients prefer a physician to have primary responsibility for leading and coordinating their health care (Appendix I). As perioperative physicians providing medical care to patients throughout the surgical experience, physician anesthesiologists are intimately aware of the challenges associated with providing surgical care in rural areas. For nearly 50 years in rural hospitals, patients have had access to appropriate anesthesiology care. Arguments that a physician is not available to supervise are inaccurate. Federal law requires supervision by the operating practitioner or anesthesiologist. An operating practitioner is present during the procedure to supervise the nurse anesthetist and provide medical input into the care of the patient before, during, and after surgery. Simply put, there is no aspect of opting-out that improves patient access to anesthesia care.
American Society of Anesthesiologists Comments
July 5, 2013

On behalf of the ASA, I strongly encourage your support in maintaining the federal physician supervision requirements that have served the citizens of Wyoming since 1966. Thank you for your consideration of this very important issue. Should you have any questions, please feel free to contact Jason Hansen, M.S., J.D., Director of State Affairs, at j.hansen@asahq.org or by phone at (202) 591-3705.

Sincerely,

[Signature]

John M. Zerwas, M.D.
President
July 5, 2013

Carrie Deselms, MSN, APRN, FNP-BC
President, Wyoming State Board of Nursing
130 Hobbs Ave., Suite B
Cheyenne, WY 82002

Dear Ms. Deselms,

As a Board-Certified physician anesthesiologist and Professor and Chair of the Department of Anesthesiology at the University of Oklahoma, I am writing to express my deep concern over the Wyoming State Board of Nursing’s consideration of opting-out of the federal safety requirement for physician supervision of nurse anesthetists. Removal of this important requirement would directly impact patient safety for Wyoming’s most vulnerable patients.

Prior to becoming a physician anesthesiologist, I was a nurse anesthetist. As one who has completed education and training in both medicine and nursing, I can tell you differences exist between a nurse anesthetist and a physician. Those differences warrant continued physician supervision because they directly impact one’s ability to comprehensively manage the medical care and emergent needs of patients.

In my experience, there are two main differences in the education and training of a physician and nurse anesthetist:

1. **Length of Training**: Nurse anesthetist education and training ranges from 4-6 years after high school. Nurse anesthetists trained in the past two decades have obtained a baccalaureate degree in nursing (four years), worked a minimum of one year in an intensive care setting, and then participated in an approximately 30-month anesthesia training program. Nurse anesthetists average about 1,650 hours of patient care training in their curriculum (Appendix I).

   Conversely, a physician’s education and training ranges from 12 or more years after high school. For example, to become an anesthesiologist, one must complete a bachelor’s degree with a pre-medicine curriculum (four years), medical school (four more years), and an additional year of hospital-based training in general medicine, pediatrics, surgery, or combination (internship year). Only then does a physician begin their specialty residency training in anesthesiology. The residency training is a three-year program. After residency, many physician anesthesiologists also complete subspecialty training (one – two additional years after residency) in areas including: pain management, cardiac anesthesia, pediatric anesthesia, neuroanesthesia, obstetric anesthesia, or critical care medicine. Altogether, physician anesthesiologists have anywhere from 12,000 – 16,000 hours of patient care training in their curriculum.

2. **Depth of Medical and Surgical Knowledge**: Equally important as the difference in education and training is the difference in depth of knowledge. Physicians complete all courses relevant to the practice of medicine, including associated laboratory courses. The breadth of courses plus the duration and hours of course work allow for detailed, comprehensive medical knowledge. Nurse anesthetists take selected courses related to anesthesia. The limited number of courses plus the shorter duration and fewer hours do not allow for detailed, comprehensive knowledge.
Physician anesthesiologists are keenly aware of the challenges to delivering surgical care in rural areas. As a profession, however, our first priority is to patient care and safety. Based on the differences in education and training between physicians and nurse anesthetists, we feel strongly that, for the sake of patient safety, in the absence of a physician anesthesiologist, a physician should retain responsibility for the patient when a non-physician anesthesia provider administers anesthesia. Nurse anesthetists are not educated or trained in medical decision-making, differential diagnoses, medical diagnostic interpretations, or medical interventions. Physician supervision, whether by a physician anesthesiologist or surgeon, is key to patient safety, as most of the patient-related problems encountered in the perioperative period relate to underlying medical illnesses or to the surgical procedure rather than to a specific anesthesia-related problem.

Because of the aging population and increasingly complex medical and surgical procedures, the need for physician supervision has never been greater. Nurse anesthetists are valuable members of the healthcare team; however, the medical practice of anesthesiology is far too critical to remove physician supervision. I can attest from personal experience, the medical education and training process best serves the interests of our patients.

As one who relies on her training as a physician each day in the operating room, I respectfully request that the Wyoming State Board of Nursing maintain the safety net that our patients deserve and that the public demands for their anesthesia care by continuing physician supervision of nurse anesthetists.

Sincerely,

Jane C.K. Fitch, M.D.
President-Elect
July 8, 2013

Carrie Deselms, MSN, APRN, FNP-BC  
President - Wyoming State Board of Nursing  
130 Hobbs Ave., Suite B  
Cheyenne, WY 82002

Dear President Deselms:

The Wyoming Medical Society (WMS) is a not-for-profit organization dedicated to advocating for physicians and their patients in the state of Wyoming. Established in 1903, we have a long history of promoting sound policies both within state government and the private sector to promote and protect our members’ ability to deliver quality patient care in our state.

WMS appreciates this opportunity to share our position on the question of whether or not it is in our patients’ best interest for Wyoming to opt-out of the Center for Medicare and Medicaid Services’ Conditions of Participation (CoP) for hospitals, critical access hospitals, and ambulatory surgical centers requiring physician supervision of nurse anesthetists (CRNAs).

After full consideration of this issue, the WMS Board of Trustees believes that at this time it is not in Wyoming’s best interest to opt-out of CMS requirements that CRNAs be supervised by a physician. Patient safety is paramount for WMS and we do not believe that removing physician supervision improves patient safety in Wyoming. Additionally, it is likely that pursuing an opt-out would establish barriers to recruitment of anesthesiologists, which would further exacerbate physician shortage and access issues that currently exist for patients.

Patient safety should be optimized with oversight of anesthesia services provided by a residency-trained anesthesiologist. We realize that many of our Critical Access Hospitals have relatively low patient volumes that make it difficult to recruit anesthesiologists. WMS is committed to partnering with the Wyoming Society of Anesthesiologists (WSA) to address these concerns through increased education of non-anesthesia physicians in their supervisory roles of CRNAs, and potentially further exploring telemedicine options for CRNA supervision.

Thank you for the opportunity to share our position on this important issue. If we can be of service to you as you deliberate this topic, please don’t hesitate to contact me.

Sincerely,

Sheila Bush  
Executive Director, Wyoming Medical Society

Cc: Governor Matt Mead, Wyoming State Capitol  
Cynthia LaBonde, Executive Director, WY State Board of Nursing
Dear Ms. LaBonde:

On behalf of the American College of Surgeons (ACS), I am writing to urge the Wyoming Board of Nursing to support the retention of the federal physician supervision requirement that is currently followed in a majority of states. A decision to remove the supervision requirement would not be in the best interest of the residents and patients of Wyoming as it would jeopardize patient safety.

The ACS has a strong history of addressing matters relating to patient care and safety, and we are concerned that an opt out would allow Certified Registered Nurse Anesthetists (CRNAs) to practice medicine without the oversight and education requirements imposed on medical doctors. Practicing outside of their scope of practice and without proper supervision by a medical doctor may open up Wyoming citizens to unsafe environments and procedures.

Since 1966, Medicare/Medicaid law has required supervision of nurse anesthetists by a physician (anesthesiologist or operating surgeon). While we respect the role nurse anesthetists fulfill in the delivery of health care, their level of education, training and experience does not justify independent practice. A decision to opt out, thereby removing physicians from providing medical expertise and supervision during the administration of anesthesia would place patients at a great risk. Wyoming patients do not deserve a lower standard of care that has effectively worked for more than 40 years. Opting out would deprive the patients of Wyoming from receiving the high quality of care that is offered to millions of citizens nationally.
Physicians are uniquely qualified, by extensive education and training to provide medical diagnosis, care, and treatment of the patient. Because of their medical knowledge, they are best able to recognize, intervene and manage the medical complications that exist before, during and after surgery. While anesthesia has become safer, plenty of risks remain. Those risks necessitate retaining physician supervision of nurse anesthetists.

In the interest of patient safety, the American College of Surgeons believes that opting out of physician supervision in Wyoming places patients in jeopardy. As such, the ACS urges the nursing board to protect patient safety for Wyoming citizens and support the maintenance of the current supervision requirement for nurse anesthetists.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director
Testimony

of

Randall M. Clark, M.D.
Director, American Society of Anesthesiologists

before the

Wyoming Board of Medicine

Regarding Possible

Medicare Opt-Out

April 13, 2013

130 Hobbs Avenue
Cheyenne, Wyoming
ASA Testimony Concerning Medicare Opt-Out
April 13, 2013

Good morning President Storey and members of the Wyoming Board of Medicine. I am Dr. Randy Clark who, like Dr. Schmidt from Cody, is a member of the American Society of Anesthesiologists’ (ASA) Board of Directors. On behalf of ASA President John Zerwas, I thank you for the opportunity to discuss the Wyoming Board of Medicine’s consideration of eliminating the requirement for physician supervision of nurse anesthetists. Today I will discuss patient safety and what we believe should be the proper structure of the nurse anesthetist/physician relationship.

The ASA is a 50,000 member educational, research, and advocacy organization dedicated to raising the standards in the science and art of anesthesiology and to improving the medical care of our patients. Since its founding in 1905, the Society’s achievements have made it the leading voice and the foremost expert in American Medicine on matters of patient safety in the perioperative environment. You need not take our word for it, The Institute of Medicine, in its 2000 report To Err is Human, identified anesthesiology and its professional organizations as the leading example of systematic improvements in patient safety and quality of care.¹

As both a practicing anesthesiologist and chair of an anesthesiology department at the largest children’s hospital in Colorado, I work daily (and like many of you nightly) to ensure patients’ medical needs are being met safely and effectively. In my hospital as well as in much of the United States, we practice in the model known the Anesthesia Care Team² which includes the delegation of appropriate medical tasks to non-physicians. In each of those circumstances, the authority and responsibility for those takes remains with the supervising physician. Since the advent of modern anesthesia in the 19th century, the Anesthesia Care Team has safely and effectively delivered anesthesia care with either an anesthesiologist assistant or nurse anesthetist as the non-physician anesthetist member of the team.

Medicare regulations, which provide a common nationwide standard of care, have mirrored the team approach to anesthesia care since the inception of the program in 1966. As it is today, anesthesia was understood then to be a complex and potentially dangerous medical procedure performed most safely by a physician or a physician-supervised provider. In 2001 the Bush Administration, after reviewing and revising previous Clinton administration changes to the Medicare rules, published a final rule regarding the anesthesia section of the Medicare Conditions of Participation (COP) for hospitals, critical access hospitals (CAHs) and ambulatory surgical centers (ASCs). The rule retained the long-standing requirement for physician supervision

¹ To Err is Human: Building a Safer Health System. Institute of Medicine. 2000.
² See ASA Standards, Guidelines and Statements: Statement on the Anesthesia Care Team available at http://www.asahq.org/For-Members/~/media/For%20Members/documents/Standards%20Guidelines%20Stmts/Anesthesia%20Care%20Team.ashx
ASA Testimony Concerning Medicare Opt-Out
April 13, 2013

of nurse anesthetists, but allows state governors to opt-out of this requirement under certain circumstances. Included in the criteria required to opt-out, the governor must determine that removing the supervision rule is in the best interests of the citizens of the state. ASA opposes gubernatorial opt-outs as matter of patient safety. Despite the language of the rule, under no circumstances would it be in a citizen’s best interests to have physician oversight of anesthesia care removed or reduced. In its simplest description, anesthesia removes all of the patient’s protective reflexes and places him or her in a state which resembles a medically-induced coma. Physician supervision of this type of care is essential.

How should supervision work in those circumstances where an anesthesiologist may not be available? In the absence of an anesthesiologist, the operating surgeon must medically evaluate the patient before surgery, assess the patient’s fitness for surgery and anesthesia, determine the likely risk to the patient and if those risks can be mitigated, direct or manage the patient’s medical conditions during surgery, manage any perioperative medical complications, and supervise the post-operative care. In the absence of an anesthesiologist, there is only one other medical professional in the operating room with the education and training to perform these services; the surgeon. Nurse anesthetists are a valued member of the anesthesia and perioperative team, but their education and training does not warrant their making these kinds of decision without physician oversight. This is, at its core, the practice of medicine. To say that nurse anesthetists can perform all of these services without physician supervision is to say, in essence, that nurse anesthetists are physicians.

Some may argue that removing the federal requirement would improve the overall availability of care in the state, especially in rural areas. We believe it is more likely to increase the opportunities for near misses and adverse events. For example, in Iowa, which is a current opt-out state, a malpractice lawsuit is pending which alleges that independently practicing nurse anesthetists have harmed patients, provided excessive and unnecessary treatment, and fraudulently billed for services. In addition, a military case recently came to light (Witt v. United States) that raised the question regarding the safety of reduced supervision of nurse anesthetists in the military’s somewhat unique environment. The case resulted in the death of a U.S. Air Force Airman during a routine appendectomy. Collecting these types of complications is extremely difficult as the legal system is not set up to have this information pooled in any meaningful way. Yet, despite this difficulty, we have evidence of a growing number of these tragic events in Colorado as the degree of supervision is reduced. You and the others here today likely have better information on what is happening in Wyoming.
ASA Testimony Concerning Medicare Opt-Out
April 13, 2013

Beyond what we learn from the legal system, the scientific literature also shows the impact to patient safety when supervision is lessened. A 2000 study on anesthesia outcomes\(^3\) found that for every 10,000 Medicare patients who had general or orthopedic surgery, there were 25 more deaths when an anesthesiologist did not direct the anesthesia care. For every 10,000 patients suffering a complication, the absence of a supervising anesthesiologist resulted in 69 additional patients not surviving the 30-day period after hospital admission. It is reasonable to conclude that the mortality rate would have been even higher had there been no physician supervision of nurse anesthetists at all.

You may be aware of a study paid for by the nurses and published a few years ago in *Health Affairs*; the notorious Cromwell article.\(^4\) The underlying methodology of the study is seriously flawed, using billing data rather than medical records to describe the various roles of all of the participants. Beyond these fundamental flaws, the conclusion that was used as the title of the article is incorrect. The authors’ own data showed that the patients receiving care from unsupervised nurses did worse than they should have. The authors would have you believe that patients in the two groups had the same overall outcomes. The title would have been correct if the two patient populations were the same, yet they were not. The patients in the supervised group were sicker and had bigger and longer procedures. If the outcome was the same in the two groups, it means that the unsupervised nurses did a poorer job of caring for the patients in their cohort.

Patient safety must be the driver behind any modification to our health regulations, not specious claims like improved access to care. As you are aware, in 2010 then Governor Ritter exempted Colorado’s rural and critical access hospitals from the federal supervision requirement. To date, there is no evidence of any kind to suggest that the removal of the physician supervision requirement has increased the availability of surgical and anesthesia services in rural hospitals in Colorado. As I mentioned, we have anecdotal evidence of an increase in adverse events with un- or under-supervised nurses.

Surgeons significantly add to patient safety and quality of care by assuming medical responsibility and directing all perioperative care when an anesthesiologist is not present. When asked, four out of five patients want a physician to have primary responsibility for leading and coordinating their health care.\(^5\) As a physician and an anesthesiologist who has practiced for 25 years, I strongly encourage you not to trade significant and


\(^{5}\) Baselice & Associates conducted a telephone survey on behalf of the AMA Scope of Practice Partnership between March 8–12, 2012. Baselice & Associates surveyed 801 adults nationwide. The overall margin of error is +/- 3.5 percent at the 95 percent level.
ASA Testimony Concerning Medicare Opt-Out  
April 13, 2013  
demonstrable advancements in patient safety for the illusion of increased availability or the unsupported claims of some kind of equivalence between the contributions nurses and physicians make to the care of their patients.

The physicians and nurses of Wyoming have every reason to be proud of the health care system you have in place and the care you provide to Wyoming’s citizens. In anesthesia and perioperative care, that system was built on physician supervision. Taking the physician out of anesthesia care will not make that system better. Lowering the standard of care is not what Wyoming’s citizens deserve.

Thank you for your consideration. I am happy to answer any questions you may have.

###
Wyoming Medical Society  

The Wyoming Medical Society (WMS), representing the full scope of primary and specialty care physicians, affirms that anesthesiology is the practice of medicine including, but not limited to, preoperative patient evaluation, anesthetic planning, intraoperative and postoperative care and the management of systems and personnel that support these activities. WMS further affirms that, whenever possible, this specialized practice of medicine should be personally provided or directly supervised by a physician anesthesiologist. When certain settings necessitate the administration of anesthesia by a Certified Registered Nurse Anesthetist (CRNA) without direct supervision by an anesthesiologist, WMS believes that a physician (MD or DO) should supervise the care, as currently required by Wyomng’s acute care hospital licensing regulations. This is consistent with existing WMS policy stating that patient care is safest when delivered by a physician led medical care team.

WMS affirms that Wyoming should avoid jeopardizing patient safety in anesthesia care, and reject proposals to opt-out of the Centers for Medicare and Medicaid Services (CMS) Anesthesia Services Conditions of Participation (CoP) for hospitals, critical access hospitals, and ambulatory surgical centers requiring that the operating practitioner supervise nurse anesthetists. WMS further supports the Wyoming Department of Health’s acute care licensing regulations, requiring that a physician supervise CRNAs. WMS further urges that the critical access hospital and ambulatory surgery center licensing regulations be likewise clarified to require physician supervision, to ensure that Wyoming does not create a two-tier system for patient safety, as some other states seem to be doing.

WMS values CRNAs as critical members of the physician led medical team. However, differences in training between physicians and CRNAs present concerns regarding care and treatment of patients who are ill or severely injured whom may require significant airway management or hemodynamic treatment beyond the routine administration of anesthesia. Removing physician oversight and supervision from the administration of anesthesia care does not improve patient safety.

In reviewing this topic a number of issues surfaced that WMS is committed to addressing in partnership with the Wyoming Society of Anesthesiologists. Due to the rural nature of medical care in Wyoming, the majority of critical access hospitals do not have access to anesthesiologist physicians. Hospitals without resident anesthesiologists provide anesthesia care through CRNA services that are currently supervised by the operating physician rather than an anesthesiologist. WMS and WSA will be working together diligently to better educate non-anesthesiologist physicians about supervising anesthesia care, and explore possibilities for anesthesiologist to assume more responsibility of supervising anesthesia care in Wyoming communities through other methods such as telemedicine.

April 2013  
WMS Board of Trustees
July 15, 2013

Thomas O. Forslund, Director  
Wyoming Department of Health  
401 Hathaway Building  
Cheyenne, WY 82002  

Topic: Certified Registered Nurse Anesthetists

Dear Mr. Forslund,

I am responding to the letter I received from you regarding CRNAs expressing an interest in an opt-out of the current physician (MD/DO) supervision requirement. Three specific questions were posed, of which the Board was asked to provide their position on the issues. On behalf of the Board and as the Executive Director of the WSBN, I will respond to the questions.

Are there issues related to access to and the quality of anesthesia services in Wyoming?

*The WSBN is unaware of any issues related to the access and the quality of anesthesia services currently provided in Wyoming.*

Is it in Wyoming’s citizens’ best interests to opt-out of the current physician (MD/DO) supervision requirement?

*The mission of WSBN is to serve and safeguard the people of Wyoming through the regulation of nursing education and practice. Advanced Practice Registered Nurses (APRNs) in the state of Wyoming can practice to the fullest extent of their licensure which includes practice without physician supervision. With the exception of CRNAs, all other APRNs practice independently. Through authority of the Wyoming Nurse Practice Act, Administrative Rules and Regulations, the WSBN supports APRN independent practice and in order to protect the public, will implement the Board’s authority to conduct investigations, hearings and proceedings concerning violations of the NPA, or the Board’s rules and regulations, and to determine and administer appropriate disciplinary action.*

Is the opt-out option consistent with State Law?

*From the Board of Nursing’s perspective, the CRNA opt-out would be consistent with the Wyoming Nurse Practice Act and Administrative Rules and Regulations which do not require physician supervision of Advanced Practice Registered Nurses, which includes CRNAs.*

Thank you for allowing the WSBN an opportunity to respond to this very important topic. If we may be of additional assistance, please don’t hesitate to contact us.

Respectfully submitted,

Cynthia LaBonde MN, RN  
Executive Director, WSBN
STATEMENT ON THE ANESTHESIA CARE TEAM

Committee of Origin: Anesthesia Care Team

(Approved by the ASA House of Delegates on October 18, 2006, and last amended on October 21, 2009)

Anesthesiology is the practice of medicine including, but not limited to, preoperative patient evaluation, anesthetic planning, intraoperative and postoperative care and the management of systems and personnel that support these activities. In addition, anesthesiology involves perioperative consultation, the prevention and management of untoward perioperative patient conditions, the treatment of acute and chronic pain, and the care of critically ill patients. This care is personally provided by or directed by the anesthesiologist.

In the interest of patient safety and quality of care, the American Society of Anesthesiologists believes that the involvement of an anesthesiologist in the perioperative care of every patient is optimal. Almost all anesthesia care is either provided personally by an anesthesiologist or is provided by a nonphysician anesthesia provider directed by an anesthesiologist. The latter mode of anesthesia delivery is called the Anesthesia Care Team and involves the delegation of monitoring and appropriate tasks by the physician to nonphysicians. Such delegation should be specifically defined by the anesthesiologist and should also be consistent with state law or regulations and medical staff policy. Although selected tasks of overall anesthesia care may be delegated to qualified members of the Anesthesia Care Team, overall responsibility for the Anesthesia Care Team and the patients’ safety rests with the anesthesiologist.

Core Members of the Anesthesia Care Team

The Anesthesia Care Team includes both physicians and nonphysicians. Each member of the team has an obligation to accurately identify themselves and other members of the team to patients and family members. Anesthesiologists should not permit the misrepresentation of nonphysician personnel as resident physicians or practicing physicians. The nomenclature below is appropriate terminology for this purpose.

Physicians:

ANESTHESIOLOGIST – director of the anesthesia care team - a physician licensed to practice medicine who has successfully completed a training program in anesthesiology accredited by the ACGME, the American Osteopathic Association or equivalent organizations.

ANESTHESIOLOGY FELLOW— an anesthesiologist enrolled in a training program to obtain additional education in one of the subdisciplines of anesthesiology.

ANESTHESIOLOGY RESIDENT – a physician enrolled in an accredited anesthesiology residency program.

Nonphysicians:

NURSE ANESTHETIST – a registered nurse who has satisfactorily completed an accredited nurse anesthesia training program.

ANESTHESIOLOGIST ASSISTANT – a health professional who has satisfactorily completed an accredited anesthesiologist assistant training program.

STUDENT NURSE ANESTHETIST – a registered nurse who is enrolled in an accredited nurse anesthesia training program.

ANESTHESIOLOGIST ASSISTANT STUDENT – a health professions graduate student who has satisfied the required coursework for admission to an accredited school of medicine and is enrolled in an accredited anesthesiologist assistant training program.
STATEMENT ON THE ANESTHESIA CARE TEAM

Although not considered core members of the Anesthesia Care Team, other health care professionals make important contributions to the perianesthetic care of the patient (see Addendum A).

Definitions

ANESTHESIA CARE TEAM – Anesthesiologists supervising resident physicians in training and/or directing qualified nonphysician anesthesia providers in the provision of anesthesia care wherein the physician may delegate monitoring and appropriate tasks while retaining overall responsibility for the patient.

QUALIFIED ANESTHESIA PERSONNEL/PRACTITIONER -- Anesthesiologists, anesthesiology fellows, anesthesiology residents, oral surgery residents, anesthesiologist assistants and nurse anesthetists. An exception is made by some clinical training sites for non-physician anesthetist students (see “Non-physician Anesthetist Students” below).

SUPERVISION AND DIRECTION – Terms used to describe the physician work required to oversee, manage and guide both residents and nonphysician anesthesia providers in the Anesthesia Care Team. For the purposes of this statement, supervision and direction are interchangeable and have no relation to the billing, payment or regulatory definitions that provide distinctions between these two terms (see Addendum B).

SEDATION NURSE AND SEDATION PHYSICIAN ASSISTANT -- A licensed registered nurse, advanced practice nurse or physician assistant (PA) who is trained in compliance with all relevant local, institutional, state and/or national standards, policies or guidelines to administer prescribed sedating and analgesic medications and monitor patients during minimal sedation (“anxiolysis”) or moderate sedation (“conscious sedation”), but not deeper levels of sedation or general anesthesia. Sedation nurses and sedation physician assistants may only work under the direct supervision of a properly trained and privileged medical doctor (M.D. or D.O.).

Safe Conduct of the Anesthesia Care Team

In order to achieve optimum patient safety, the anesthesiologist who directs the Anesthesia Care Team is responsible for the following:

1. Management of personnel – Anesthesiologists should assure the assignment of appropriately skilled physician and/or nonphysician personnel for each patient and procedure.

2. Preanesthetic evaluation of the patient – A preanesthetic evaluation allows for the development of an anesthetic plan that considers all conditions and diseases of the patient that may influence the safe outcome of the anesthetic. Although nonphysicians may contribute to the preoperative collection and documentation of patient data, the anesthesiologist is responsible for the overall evaluation of each patient.

3. Prescribing the anesthetic plan – The anesthesiologist is responsible for prescribing an anesthesia plan aimed at the greatest safety and highest quality for each patient. The anesthesiologist discusses with the patient (when appropriate), the anesthetic risks, benefits and alternatives, and obtains informed consent. When a portion of the anesthetic care will be performed by another qualified anesthesia provider, the anesthesiologist should inform the patient that delegation of anesthetic duties is included in care provided by the Anesthesia Care Team.
4. **Management of the anesthetic** – The management of an anesthetic is dependent on many factors including the unique medical conditions of individual patients and the procedures being performed. Anesthesiologists should determine which perioperative tasks, if any, may be delegated. The anesthesiologist may delegate specific tasks to qualified nonanesthesiologist members of the ACT providing that quality of care and patient safety are not compromised, but should participate in critical parts of the anesthetic and remain immediately physically available for management of emergencies regardless of the type of anesthetic (see Addendum B).

5. **Postanesthesia care** – Routine postanesthesia care is delegated to postanesthesia nurses. The evaluation and treatment of postanesthetic complications are the responsibility of the anesthesiologist.

6. **Anesthesia consultation** – Like other forms of medical consultation, this is the practice of medicine and should not be delegated to nonphysicians.

**Safe Conduct of Minimal and Moderate Sedation Utilizing Sedation Nurses and PA’s**

The supervising doctor is responsible for all aspects involved in the continuum of care – pre-, intra-, and post-procedure. While a patient is sedated, the responsible doctor must be physically present and immediately available in the procedure suite. Although the supervising doctor is primarily responsible for pre-procedure patient evaluation, sedation practitioners must be trained adequately in pre-procedure patient evaluation to recognize when risk may be increased, and related policies and procedures must allow sedation practitioners to refuse to participate in specific cases if they feel uncomfortable in terms of any perceived threat to quality of care or patient safety.

The supervising doctor is responsible for leading any acute resuscitation needs, including emergency airway management. Therefore, ACLS (PALS or NALS where appropriate) certification must be a standard requirement for sedation practitioners and for credentialing and privileging the non-anesthesiologist physicians that supervise them. However, because non-anesthesia professionals do not perform controlled mask ventilation or tracheal intubation with enough frequency to remain proficient, their training should emphasize avoidance of over-sedation much more than treatment of the same.

**Supervision of Nurse Anesthetists by Surgeons**

*Note: In this paragraph “surgeon(s)” may refer to any appropriately trained, licensed and credentialed nonanesthesiologist who may supervise nurse anesthetists.*

General, regional and monitored anesthesia care all expose patients to risks. Nonanesthesiologist physicians may not possess the expertise that uniquely qualifies and enables anesthesiologists to manage the most clinically challenging medical situations that arise during the perioperative period. While a few surgical training programs provide some anesthesia specific education (e.g., some oral and maxillofacial residencies), no surgical, dental, podiatric or any other nonanesthesiology training programs provide enough training specific to anesthesia to enable their graduates to provide the level of medical supervision and clinical expertise that anesthesiologists provide. However, surgeons can still significantly add to patient safety and quality of care by assuming medical responsibility for all perioperative care when an anesthesiologist is not present. Anesthetic and surgical complications often arise unexpectedly
STATEMENT ON THE ANESTHESIA CARE TEAM

and require immediate medical diagnosis and treatment. Even if state law or regulation says a surgeon is not “required” to supervise nonphysician anesthesia providers, the surgeon may be the only medical doctor on site. Whether the need is preoperative medical clearance or intraoperative resuscitation from an unexpected complication, the surgeon, both ethically and according to training and ability, should be expected to provide medical oversight or supervision of all perioperative health care provided, including nonphysician nurse anesthesia care. To optimize patient safety, careful consideration is required when surgeons can be expected to be the only medical doctor available to provide oversight of all perioperative care. This is especially true in freestanding surgery centers and surgeons’ offices where, in the event of unexpected emergencies, consultation with other medical specialists frequently is not available. In the event of unexpected emergencies, lack of immediately available and appropriately trained physician support can reduce the likelihood of successful resuscitation. This should always be a consideration when deciding which procedures should be performed in these settings, and on which patients, particularly if the individual supervising the nurse anesthetist is not a medical doctor with training appropriate for providing critical perioperative medical management.

Non-Physician Anesthetist Students

Definition: AA students, SRNAs, dental anesthesia students, or possibly other student types satisfactorily enrolled in nationally accredited training programs. Anesthesiologists should be dedicated to providing optimal patient safety and quality of care to every patient undergoing anesthesia and also to education of anesthesia students that is commensurate with that dedication. The ASA Standards for Basic Anesthetic Monitoring sets forth the minimum conditions necessary for the safe conduct of anesthesia. Standard #1 of that document states that, “Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.” The definitions above are inadequate to address the issue of safe patient care during the training of non-physician anesthetist students. Further clarification of the issues involved is in the best interests of patients, students, and the anesthesia practitioners involved in the training of non-physician anesthetists.

Distinction between situations where students may be alone with patients: During supervision of non-physician anesthetist students it may become necessary to leave them alone in operating rooms or procedure rooms (OR/PR) to accommodate needs of brief duration. This should only occur if judged to cause no significant increased risk to the patient.

This practice must be distinguished from that of scheduling non-physician students to patients as the primary anesthesia provider, meaning no fully trained anesthesia practitioner also assigned to the case and expected to be continuously present monitoring the anesthetized patient. While the brief interruption of 1:1 student supervision may well be necessary for the efficient and safe functioning of a department of anesthesiaology, the use of non-physician students in place of fully trained and credentialed anesthesia personnel is not endorsed as best practice by the American Society of Anesthesiologists. While the education of non-physician anesthetist students is an important goal, patient safety remains paramount. Therefore, the conduct of this latter type of practice must meet certain conditions intended to protect the safety and rights of patients and students, as well as the best interests of all other parties directly or indirectly involved (i.e. involved qualified practitioners, patients’ families, institutions, etc.).

1. All delegating anesthesiologists and the department chairperson must deem these non-physician student anesthetists fully capable of performing all duties delegated to them, and all students being delegated to must express agreement with accepting any responsibility delegated to them.
2. **Privileging** – A privileging process must precede this practice to officially and individually label each student as qualified to be supervised 1:2 by a qualified anesthesia practitioner who remains immediately physically available. Students must not be so privileged until they have completed a significant predetermined portion of both their didactic and clinical training that may reasonably be assumed to make this practice consistent with expected levels of safety and quality (if at all, at the earliest the last 3-4 months of student training). Privileging must be done under the authority of the Chief of Anesthesiology and in compliance with all federal, state, professional organization and institutional requirements.

3. **Case Assignment and Supervision** – These students must be supervised on a one-to-one or on a one-to-two ratio. Assignment of cases with regards to students must always be done in a manner that assures the best possible outcome for patients and the best education of students and therefore must be commensurate with the skills, training, experience, knowledge and willingness of each individual non-physician anesthesia student. Care should be taken to avoid placing students in situations that they are not fully prepared for. It is expected that most students will get their experience caring for high risk patients under the continuous supervision of fully trained anesthesia personnel. This is in the best interest of both education and patient safety. As students are incompletely trained, the degree of continuous supervision must be at a higher level than that required for fully trained and credentialed AAs and NAs. If an anesthesiologist is engaged in the supervision of non-physician students, he/she must remain immediately physically available throughout the conduct of the involved anesthetics, meaning not leaving the OR/PR suite to provide other services or clinical duties that are commonly considered appropriate concurrent activities while directing fully trained and credentialed AAs or NAs.

4. **Backup support** – If an anesthesiologist is concurrently supervising two non-physician anesthetists students assigned as primary anesthesia providers (meaning the only anesthesia personnel continuously present with a patient), the anesthesiologist could be needed simultaneously in both rooms. To mitigate this potential risk, one other qualified anesthesia practitioner must also be assigned and must remain immediately physically available if needed (e.g., alone on call anesthesiologist should not be supervising more than one student without appropriately trained and credentialed back up immediately available).

5. **Informed Consent** – The Chief of Anesthesia is responsible for assuring that every patient (or their guardian) understands through a standardized departmental informed consent process that they may be in the OR/PR with only a non-physician student physically present, although still directed by the responsible anesthesiologist. As it is in the best interest of all involved parties, documentation of this aspect of informed consent must be included in the informed consent statement.

6. **Disclosure to Professional Liability Carrier** – To be assured of reliable professional liability insurance coverage for all involved (qualified anesthesia practitioners, their employers and the institution), the Chief of Anesthesia must notify the responsible professional liability carrier(s) of the practice of allowing non-physician anesthesia students to provide care without continuous direct supervision by a fully trained, credentialed and qualified anesthesia practitioner.
STATEMENT ON THE ANESTHESIA CARE TEAM

ADDENDUM A:

Other personnel involved in perianesthetic care:

POSTANESTHESIA NURSE – a registered nurse who cares for patients recovering from anesthesia.

PERIOPERATIVE NURSE – a registered nurse who cares for the patient in the operating room.

CRITICAL CARE NURSE – a registered nurse who cares for patients in a special care area such the intensive care unit.

OBSTETRIC NURSE – a registered nurse who provides care to laboring patients.

NEONATAL NURSE – a registered nurse who provides cares to neonates in special care units.

RESPIRATORY THERAPIST – an allied health professional who provides respiratory care to patients.

CARDIOVASCULAR PERFUSIONISTS – an allied health professional who operates cardiopulmonary bypass machines.

Support personnel whose efforts deal with technical expertise, supply and maintenance:

ANESTHESIA TECHNOLOGISTS AND TECHNICIANS

ANESTHESIA AIDES

BLOOD GAS TECHNICIANS

RESPIRATORY TECHNICIANS

MONITORING TECHNICIANS

ADDENDUM B:

Commonly Used Billing Rules and Definitions

ASA recognizes the existence of commercial and governmental payer rules applying to billing for anesthesia services and encourages its members to comply with them whenever possible. Some commonly prescribed duties include:

- Performing a preanesthetic history and physical examination of the patient;
- Prescribing the anesthetic plan;
- Personal participation in the most demanding portions of the anesthetic, including induction and emergence, where applicable;
- Delegation of anesthesia care only to qualified anesthesia providers;
- Monitoring the course of anesthesia at frequent intervals;
- Remaining physically available for immediate diagnosis and treatment while medically responsible;
- Providing indicated postanesthesia care, and;
- Performing and documenting a post-anesthesia evaluation.
STATEMENT ON THE ANESTHESIA CARE TEAM

ASA also recognizes the lack of total predictability in anesthesia care and the variability in patient needs that can, in particular and infrequent circumstances, make it less appropriate from the viewpoint of overall patient safety and quality to comply with all payment rules in each patient at every moment in time. Reporting of services for payment must accurately reflect the services provided. The ability to prioritize duties and patient care needs, moment to moment, is a crucial skill of the anesthesiologist functioning safely within the anesthesia care team. Anesthesiologists must strive to provide the highest quality of care and greatest degree of patient safety to ALL patients in the perioperative environment at ALL times.

MEDICAL “DIRECTION” by anesthesiologists – A billing term describing the specific anesthesiologist work required in and restrictions involved in billing payers for the management and oversight of nonphysician anesthesia providers. This pertains to situations where anesthesiologists are involved in not more than four concurrent anesthetics. See individual payer manuals for specifics.

MEDICAL “SUPERVISION” by anesthesiologists – Medicare payment policy contains a special payment formula for “medical supervision” which applies “when the anesthesiologist is involved in furnishing more than four procedures concurrently or is performing other services while directing the concurrent procedures.” [Note: The word “supervision” may also be used outside of the Anesthesia Care Team to describe the perioperative medical oversight of nonphysician anesthesia providers by the operating practitioner/surgeon. Surgeon provided supervision pertains to general medical perioperative patient management and the components of anesthesia care that are medical and not nursing functions (e.g., determining medical readiness of patients for anesthesia and surgery, and providing critical medical management of unexpected emergencies).]
H-160.929 Anesthesiology is the Practice of Medicine

It is the policy of the AMA that anesthesiology is the practice of medicine. Our AMA seeks legislation to establish the principle in federal and state law and regulation that anesthesia care requires the personal performance or supervision by an appropriately licensed and credentialed doctor of medicine, osteopathy, or dentistry. (Sub. Res. 216, I-98; Reaffirmed: BOT Rep. 23, A-09; Reaffirmed: BOT Rep. 9, I-11)
D-160.993 Limitation of Scope of Practice of Certified Registered Nurse Anesthetists

Our AMA, in conjunction with the state medical societies, will vigorously inform all state Governors and appropriate state regulatory agencies of AMA’s policy position which requires physician supervision for certified registered nurse anesthetists for anesthesia services in Medicare participating hospitals, ambulatory surgery centers, and critical access hospitals. (Res. 220, I-01; Reaffirmed: CMS Rep. 7, A-11)
D-35.985 Support for Physician Led, Team Based Care

Our AMA:


2. Will identify and review available data to analyze the effects on patients' access to care in the opt-out states (states whose governor has opted out of the federal Medicare physician supervision requirements for anesthesia services) to determine whether there has been any increased access to care in those states.

3. Will identify and review available data to analyze the type and complexity of care provided by all non-physician providers, including CRNAs in the opt-out states (states whose governor has opted out of the federal Medicare physician supervision requirements for anesthesia services), compared to the type and complexity of care provided by physicians and/or the anesthesia care team.

4. Will advocate to policymakers, insurers and other groups, as appropriate, that they should consider the available data to best determine how non-physicians can serve as a complement to address the nation's primary care workforce needs.

5. Will continue to recognize non-physician providers as valuable components of the physician-led health care team.

6. Will continue to advocate that physicians are best qualified by their education and training to lead the health care team. Will call upon the Robert Wood Johnson Foundation to publicly announce that the report entitled, "Common Ground: An Agreement between Nurse and Physician Leaders on Interprofessional Collaboration for the Future of Patient Care" was premature; was not released officially; was not signed; and was not adopted by the participants. (BOT Rep. 9, I-11; Reaffirmed: CMS Rep. 1, A-12)
Nearly a decade ago, Dr. Barry Gleimer, an orthopedic surgeon in New Jersey, performed arthroscopic knee surgery on a twenty-eight year old man.\(^1\) Arthroscopy is a common surgical procedure where incisions are made, and a pencil-sized camera is inserted through those incisions after utilizing local, regional, or general anesthesia.\(^2\) Shortly after Dr. Gleimer performed the knee arthroscopy, the presiding nurse anesthetist-who at first failed to notice the patient turning blue from lack of oxygen-struggled to insert a breathing tube and quickly sought help from a nearby anesthesiologist.\(^3\) Due to the nurse anesthetist’s inability to treat the patient during his desperate time, Dr. Gleimer’s patient currently suffers from short-term memory loss.\(^4\) The resulting harm in the described procedure is conspicuous; however, the medical knowledge disparity between certified registered nurse anesthetists (CRNAs) and anesthesiologists, in cases such as Dr. Gleimer’s, is far more noteworthy than the memory loss itself.

### A. The Issue

Anesthesiologists and nurse anesthetists commonly work together in operating rooms to sedate patients and ease pain, but cooperation between the two groups ends once outside the hospital doors.\(^5\) For years, these two interconnected medical
NURSES PROVIDING ANESTHESIA NOT A “LAUGHING”... 9 Ind. Health L. Rev. 281

professions have fought a bitter political battle over who should be sedating patients, under whose supervision, and for what compensation. The battle intensified when, just before his term ended in 2001, President Bill Clinton, whose mother coincidentally served as a nurse anaesthetist for thirty-five years, wanted to remove supervision requirements. As a result, President Clinton approved a government rule giving more autonomy to nurse anaesthetists. President Clinton’s approval was in response to a 1997 proposal by the Health Care Financing Administration requesting that nurses be able to work by themselves, without doctor supervision, if allowed by state-specific law.

Upon Clinton’s departure from office, the Bush administration delayed the Clinton-approved nurse autonomy rule and planned to write a new rule reverting back to the requirement that nurse anaesthetists could only administer anesthesia when supervised by a doctor. The possible reversion sparked lobbying before Congress from former Senate majority leader, Robert J. Dole, and former Democratic representative, Tom Downey, on behalf of the anesthesiologists, while former House Speaker-designate, Bob Livingston, lobbied for the nurse-anesthetists. Ultimately, the anesthesiologists’ representatives convinced President Bush of the possible safety hazards and risks involved with nurses independently administering anesthesia. However, both Tommy G. Thompson, who was the Secretary of Health and Human Services, and President George W. Bush were strong advocates for state autonomy; therefore, the Bush administration crafted a supervision rule giving governors the option to avoid the supervision requirement.

The Centers for Medicare and Medicaid Services’ (CMS) final rule that was published in the Federal Register in November 2001 now allows state governors to opt out of reimbursement for CRNA activity, permitting CRNAs to practice without supervision if the opt-out is consistent with state law. Thus, under the CMS amended opt-out rule, patients, like Dr. Gleimer’s arthroscopic knee patient, may not have physician supervised CRNAs in hospitals, ambulatory surgical centers, or critical access hospitals, which could lead to more severe injuries than just short-term memory loss due to the nurse and doctor knowledge disparity.

Interestingly, recent studies have challenged the knowledge gap between anesthesiologists and nurse anaesthetists by concluding that there is not a significant difference in the quality of care administered by CRNAs as compared to anesthesiologists. After evaluating six years of Medicare data, two analysts at the Research Triangle Institute, an independent, non-profit research institute, recently recommended that nurse anaesthetists should be able to administer anesthesia without any surgeon or anesthesiologist supervision. Jerry Cromwell, the study’s co-author and health economics fellow at the Research Triangle Institute, said, “This study shows that patient safety is not compromised by the opt-out policy. Using nurse anaesthetists more broadly could save on health care costs because they typically earn less than anesthesiologists.” The study’s recommendation is based on a lack of evidence to confirm that opting out of CRNA supervision has increased inpatient deaths or complications.

Currently, sixteen states, including five of interest in this Note (California, Colorado, Iowa, Washington, and Wisconsin), have elected to opt out of reimbursement from CMS for nurse anaesthetist activity as of October 2010. As a result of the two most recent national studies dealing with CRNA safety and cost-effectiveness, state governors now have unequivocal evidence to persuade state medical and nursing boards to support a move to accept unsupervised nurses. Nevertheless, under the 2001 CMS amendment, governors still need to discern and balance the quality of care given to anesthesia patients, cost-effectiveness of not having physician supervision, and patient access in rural settings. Even if these factors are appraised, and opting out decreases state budgets, which is presently necessary in many states, the preemptive steps may not be enough to relieve patients of the risk of death or grave harm when a nurse anaesthetist’s treatment ability is challenged like that of the nurse in the aforementioned anecdote.

B. Roadmap

This Note discusses the CMS final rule allowing for unsupervised nurse anaesthetists to administer anesthesia if their state of practice has opted out of Medicare reimbursement for such service. In order to facilitate a better understanding of the nurse anaesthetist practice, Section II explains the history and development of the certified registered nurse anaesthetist practice, sets out the educational requirements necessary for certification as a CRNA, examines how nurse anaesthetists are dealt with in Indiana, and provides CRNA reimbursement basics. Section III analyzes the major, recent studies proposing eliminating supervision of nurse anaesthetists based on cost effectiveness and quality of care, while also providing the responses given by the American Society of Anesthesiologists to these controversial studies. Section IV introduces the requirements for a state to opt out of nurse anaesthetist supervision and compares opt-out states’ administrative code or statutes dealing with anesthesia...
regulation to Indiana’s corresponding statutes. In particular, this section focuses on opt-out states’ decisions that have been legally challenged for being inconsistent with state law, allowing for a prediction of the consistency of Indiana regulations if they were challenged. Also, in addition to looking at state law consistency issues, Section IV analogizes a CRNA scope of practice challenge to further highlight the disparity in anesthesiologist and nurse anesthetist training. Finally, Sections V and VI lay out problems that would arise if Indiana opted out of reimbursement and concludes Indiana should keep the status quo for nurse anesthetist supervision, or in the alternative should ramp up recognition or certification requirements of certified registered nurse anesthetists.

II. History and Background of Certified Registered Nurse Anesthetists

In order to determine whether Indiana should opt out of nurse anesthetist supervision, an understanding of the development of the profession itself is essential. This section explains the practice of CRNAs in general, how the practice of nurse anesthetists developed, what educational and experience requirements are necessary to become certified as a nurse anesthetist, different methods of recognizing the nurse anesthetist practice, and, finally, offers rudimentary background on CRNA reimbursement.

A. History and Development of the Nurse Anesthetist Practice

Nurses, not anesthesiologists, were the first professional group to administer anesthesia in the United States, which led to the recognition in the late 1800s of the first clinical nurse specialty, nurse anesthesia. For over 150 years, beginning with providing anesthesia to wounded soldiers during the Civil War, nurses have been administering anesthesia in the United States. In addition to caring for soldiers, the development of the nurse anesthetist occupation was also a response to surgeons’ search for a solution to the high death rate during anesthesia in the late 1800s, as medical residents wanted to observe surgery, not give undivided attention to the administration of anesthesia.

By 1908, Cleveland-based surgeon George Crile asked a nurse, Agatha Hodgins, to become his anesthetist. Hodgins became an expert at administering anesthesia and began informally teaching others the anesthesia process, including English and French nurses who provided care to Allied Forces during World War I. Upon Hodgins’s return from the war, she established the Lakeside Hospital School of Anesthesia in Cleveland, Ohio, a center that sent graduates across the country to provide nurse anesthesia care. Soon thereafter, in 1931, Hodgins brought her alumnae to Cleveland and founded the National Association of Nurse Anesthetists, which in 1939 became the American Association of Nurse Anesthetists (AANA) and remains as such today. At present, greater than ninety percent of the nation’s nurse anesthetists, of which over forty-one percent are men, are members of the AANA.

Later, in 1956, the official credential of certified registered nurse anesthetist was born. Being recognized as one of the first specialties within nursing, CRNAs acted with a high level of independence, accountability and responsibility. According to the AANA, over 42,000 CRNAs across the country provide about thirty-two million anesthetics to patients each year.

B. Educational/Certification Requirements and Statutory Recognition

In order to become a CRNA and be able to provide anesthetics, special education and experience requirements must be met. These requirements include:

1) Earning a Bachelor of Science in Nursing or other appropriate baccalaureate degree;

2) Holding a current license as a registered nurse;

3) Serving at least one year of experience as a registered nurse in an acute care setting or facility;

4) Graduating with at least a master’s degree from a Council on Accreditation of Nurse Anesthesia Educational Programs accredited nurse anesthesia educational program;

5) Passing the national certification examination following graduation; and
6) Recertifying on a biennial basis, which requires a current nursing license, forty hours of continuing education, certification that the nurse has been engaged in anesthesia practice for the previous two years, and verification of no other problems that could adversely affect their practice of anesthesia. 37

Although these requirements are virtually standard nationwide, states may have different regulations or certifications that alter or eliminate such obligations. 38 For example, Indiana and Michigan are the only two states that claim nurse anesthetists do not require additional certification in order to practice. 39 In Indiana, a CRNA “is properly certified by successfully completing the certification examination administered by the Council on Certification of Nurse Anesthetists or its predecessor.” 40 The Indiana Association of Nurse Anesthetists interprets this certification provision as simply a definition, not a requirement to be additionally certified after passing the national examination by the Council on Certification of Nurse Anesthetists or other nationally recognized certifying body, as is required in all other states if a nurse wants to practice as a CRNA. 41

Indiana nurse anesthetists are also distinct because “Indiana does not specify a specific method or process by which it authorizes nurse anesthetists to practice,” 42 whereas CRNAs are a type of “advanced practice nurse” or “advanced registered nurse practitioner” in the majority of states in this country. 43 Under Indiana’s Advance Practice Nurse Act, which deals with nurses obtaining additional skills through a specialized program to provide patient care in collaboration with the health care team, only nurse practitioners, nurse midwives, and clinical nurse specialists are mentioned. 44 Because of their exclusion, nurse anesthetists believed the stricter collaboration requirements required of advance practice nurses would not apply to them, which would give them more autonomy to practice without supervision. 45 However, under the Indiana Code, a CRNA may only administer anesthesia “[i]f the certified registered nurse anesthetist acts under the direction of and in the immediate presence of a physician.” 46 Therefore, even though Indiana has not statutorily established an advanced practice nurse label akin to most states, the scope of the nurse anesthetist practice in Indiana is still collaborative due to the supervision requirement.

Although any type of physician may collaborate with nurse anesthetists while the nurse sedates patients, much of the time CRNAs and anesthesiologists work closely together in operating rooms to administer anesthesia. 47 The American Society of Anesthesiologists (ASA) “believes that nurse anesthetists are qualified to perform some, but not all, of these services [that anesthesiologist can perform], and only under the supervision of a physician, preferably an anesthesiologist.” 48 This sentiment is often rooted in the differing educational and training requirements of the two disciplines, with anesthesiologists believing their profession is prepared to make sudden medical judgments that nurse anesthetists never learn in their curriculum. 49 While a nurse anesthetist must gain a master’s degree that usually takes two to three years (in addition to four years of nursing undergraduate work), anesthesiologists must complete twelve years of formal schooling, including: 50 four years of science-intensive pre-medical education; four years of medical school in which the individual gains knowledge of the fundamental science of the human condition (biochemistry, biophysics, anatomy, pharmacology, physiology, and pathology) and receives extensive clinical instruction and experience in medical diagnosis and therapy; and four years of residency training that includes one year of clinical medicine, two years of clinical anesthesiology and one year of concentrated study and experience in connection with the most serious complications. 51

It is clear that educational requirements for anesthesiologists and nurse anesthetists differ, which is one reason why the “ASA opposes the independent practice of nurse anesthetists and views legislation and regulations designed to grant independent practice authority . . . as efforts to confer a medical degree by political means rather than by educational means.” 52 Regardless of the ASA’s contradicting view on nurse anesthetists’ independence, state governors are given the authority to “confer” more power to nurse anesthetists, despite educational differences, based on the November 2001 CMS rule. 53

C. Reimbursement of CRNA Service

Government programs, along with public and private health plans, provide reimbursement to CRNAs for performing anesthesia to patients. 54 Medicare, a health plan for senior citizens and individuals with certain disabilities, is the largest program for reimbursement directly to CRNAs. 55 Medicare uses a formula to determine reimbursement amounts: the sum of base units (which describe the complexity of the anesthesia procedure) and time units (where fifteen minutes equals one unit)
multiplied by a conversion factor (in dollars). In addition to CRNA reimbursement, anesthesiologists can be paid under Medicare for directing administration of anesthesia, but only when certain conditions are met. Under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), an anesthesiologist must carry out the following conditions in each case in order to be reimbursed under a claim for directing anesthesia:

1) Performance of a pre-anesthetic examination and evaluation;

2) Preparation of an anesthesia plan;

3) Personal participation in the most demanding parts in the anesthesia plan, most importantly induction and emergence;

4) Assurance that a qualified anesthetist performed any part of the anesthesia plan not performed by himself or herself;

5) Frequent monitoring of anesthesia administration;

6) Physical presence in case of emergency or need for immediate diagnosis; and

7) Provide post-anesthesia care.

Combining the reimbursement of nurse anesthetists and the conditions for anesthesiologist payment, Medicare Part B reimburses in different ways. For “non-medically directed CRNA services,” when an anesthesiologist is not involved enough in a case to justify payment for medical direction, CRNAs are reimbursed one hundred percent of the Medicare fees according to the formula outlined above. When a physician fulfills the seven conditions under TEFRA, these so-called “medically directed CRNA services” are reimbursed according to the same Medicare formula, with fifty percent of the fee going to the directing anesthesiologist and the remaining fifty percent going to the CRNA. When an anesthesiologist oversees multiple anesthesia cases, or “medically supervised CRNA services,” Medicare reimburses fifty percent of the fee to the CRNA and two or three base units to the anesthesiologist. If medically supervising, an anesthesiologist may be reimbursed for up to five simultaneous CRNA cases, as long as the seven TEFRA conditions are met.

III. Analysis of Recent Nurse Anesthetist Studies

A. Anesthesiologist Direction and Patient Outcome

The first important study of anesthesiology that is relevant to the comparison between anesthesiologists and nurse anesthetists was performed in 2000. The study compared outcomes of Medicare surgery patients whose anesthesia was performed, or medically directed, by an anesthesiologist to outcomes that were not. The study sought to determine if elderly patients’ general and orthopedic surgical outcomes differed based on anesthesiologist involvement in anesthesia delivery. As mentioned above, when discussing reimbursement basics, in order to be directed, physicians or anesthesiologists must fulfill the seven criteria that allow them to bill under Medicare Part B. The study included 194,430 directed and 23,010 undirected cases in 245 Pennsylvania hospitals. The patient data studied was categorized into outcomes, which included death rate within thirty days of hospital admission, in-hospital complication rate (applying forty-one events defined by International Classification of Diseases), and the rate of death after complications (failure-to-rescue rate). In order to account for possible differences in hospital administration tactics and patient individuality, the study was adjusted using a list of eleven hospital and patient characteristics that standardized results.

After analysis, the study found “higher mortality and failure-to-rescue rates for patients who underwent operations without medical direction by an anesthesiologist.” As shown below, percentages of death, complication, and failure-to-rescue were all higher in the study’s undirected cases. The unadjusted results, based just on patient outcomes alone, were as follows.
directed group) for death and failure-to-rescue were greater than 1, at 1.08 and 1.10 respectively. The death and failure-to-rescue odds ratios correspond to 2.5 excess deaths per 1,000 patients and 6.9 excess failure-to-

The results of this study may be easily skewed by hospital differences (for example, the number of beds over 200, the hospital’s nurse-to-bed ratio, or the percentage of anesthesia staff that is board certified) or from basing conclusions on elderly Medicare patients; however, even after adjusting for both of these factors, the effect of an anesthesiologist providing care was still shown to benefit patients. In concluding that mortality rates prior to and after complications were lower when anesthesiologists provided anesthesia, this study acknowledged a limitation of basing the findings on claims data and an inability to rule out the possibility conclusions could be based on differences in quality of direction, the lack of direction itself, or a combination of the two.

B. Cost Effectiveness Analysis of Anesthesia Providers

Conversely, in a more recent 2010 study, the Lewin Group analyzed anesthesia administration models in order to determine if different anesthesia delivery models affect quality and cost-effectiveness of anesthesia services. The study used “independent” CRNAs to refer to nurses who provide anesthesia but are not medically directed or supervised. As in other studies and costing models, the terms “medically directed” or “supervised” were used to define CRNAs who provide anesthesia under anesthesiologist oversight. The first issue considered in this study was quality of care, which is an important aspect of using alternative anesthesia delivery models.

The authors of this study cite multiple reports that “have found no significant differences in rates of anesthesia complications or mortality between CRNAs and anesthesiologists or among delivery models for anesthesia that involve CRNAs, anesthesiologists, or both after controlling for other pertinent factors.” However, impreciseness, the inability to distinguish between whether CRNAs or medical residents were being directed, and utilizing typical hospital practices instead of providers’ specific practice are all mentioned as limitations of the past-cited studies. Then, the authors conclude that it is “not surprising there are no studies that show a significant difference between CRNAs and anesthesiologists in patient outcomes.” Although the authors identified multiple flaws in such studies, and the aforementioned Silber study found differences in outcomes based on supervision, the authors quickly concluded that there is no difference in quality of care between anesthesiologists and nurse anesthetists and thus sweepingly generalized a point of utmost concern to the ongoing battle between these two relevant professions.

In addition to literary data, the Ingenix national database that contained integrated medical and financial claims data from commercial payers in 2008 was studied by the Lewin Group. Out of 52,636 anesthesia claims that were reviewed, no complications arising from anesthesia were found. On top of Ingenix, the Healthcare Cost and Utilization Project Nationwide Inpatient Sample, which compiled information from about eight million U.S. community hospital stays, was also observed. Even though anesthesia provider information was not included in the hospital stay data, this study based its quality of care conclusion on the fact that the complication percentage for the representative sample was 0.12%.

If quality of care is assumed to be equal regardless of who administers anesthesia, as the authors of this study portray to their readers, then the best anesthesia delivery method for patients and facilities alike is the one that minimizes costs. In order to estimate costs and revenues under the different delivery models, a model was developed to simulate costs for each type of delivery. The user of the model must specify a number of key factors, such as: demand (number of patients seeking an operation in a day), characteristics of the anesthesia procedure (a base unit complexity number and the time required to do the procedure), and a payer distribution (noting the type of payment for each patient). Further, the cost estimation model used the salary or annual earnings of anesthesiologists and CRNAs to determine the final values. Results of the simulation when patient flow was sufficient to have four anesthesia procedures per day were as follows.

**TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE**

Results of the simulation when patient flow was only two anesthesia procedures per day, when four were possible, were as follows.
This data showed the most cost-effective delivery model was CRNAs practicing alone, regardless of what level of demand is present. When demand was below average, which would include many rural areas of the United States, all delivery modes except CRNAs alone would require subsidies to be a viable option. Overall, this study hypothesized that CRNAs are less costly to train, provide higher revenues, and are interchangeable with anesthesiologists, as they can perform the same anesthesia services as medical doctors for less pay.

After this bold conclusion regarding the cost effectiveness of nurse anesthetists was released, the American Society of Anesthesiologists was quick to respond. Dr. Alexander Hannenberg, President of the American Society of Anesthesiologist (ASA), offered seven reasons to question the cost-effectiveness study, including:

1) The scope of service given by an anesthesiologist and a CRNA is not the same because an anesthesiologist provides critical care medicine, pain management, and on-call coverage.

2) The comparison of outcomes is invalid because the types of procedures done “solo” by CRNAs are of lower complexity, since patients, surgeons, and facilities prefer physician care for the more serious procedures.

3) Only a few states are exempt from federal standards that make it necessary for a surgeon performing a procedure to supervise CRNAs; thus, defining CRNA services as “solo” is a misnomer.

4) Medicare fees for using CRNAs and anesthesiologists are equal, so overall costs may increase if the CRNA calls for medical assistance or consultations.

5) The wage estimations for CRNAs and anesthesiologists that are used assume equal work hours. Not only do the two professions not work the same hours, but also if CRNAs surpass the forty-hour week, employment costs are considerably increased, which is not the case with anesthesiologists.

6) The Center for Disease Control concluded in 1980 that a comparative outcomes study could not be done based on the infrequency of major adverse anesthesia events. As thirty years have passed with fewer adverse events, the study is substantially less accurate. Also, the Ingenix database that was used is “fraudulent, discredited and outlawed.”

7) In 2001, a study showed that seventy percent of all respondents would oppose a CRNA without supervision if a medical doctor could supervise the procedure at no additional cost; thus, patients tend to prefer anesthesiologists administering anesthesia.

Dr. Hannenberg closed by saying, We [anesthesiologists] stand for access to safe and leading care for patients. We’ve gone through years and years of rigorous training in medical school, internships, residencies and fellowships. Anesthesiologists provide critical knowledge and expertise needed to keep total watch over the human body, to keep people stable and intervene when they are not. We are the leaders of anesthesia care teams which include CRNAs. The role of the anesthesiologist is to keep watch over a patient’s vital health when he/she is at his/her most vulnerable. We take pride in this role each and every day.

C. No Harm Found when Nurse Anesthetists Work Without Supervision by Physicians

In a 2010 article, researchers at the Research Triangle Institute, an independent, non-profit research institute, explored the change in the CMS supervision requirement by analyzing Medicare data for 1999-2005 in order to determine if the 2001 CMS policy had a negative impact on patient outcomes. To show an effect on outcomes, the opt-out policy must actually change the way anesthesia is being provided and there has to be a difference in the outcomes linked to the new arrangement. The study identified three arrangements for anesthesia being administered: anesthesiologists practicing solo, certified registered nurse anesthetists practicing solo, and team anesthesia where nurses were directed or supervised.

Studied data resulted in 741,518 surgical discharges, but only two-thirds possessed anesthesia claims. The 481,440 hospitalizations that remained for analysis included 412,696 in non-opt-out states and 68,744 in opt-out states. Similar to
the first study discussed in this Note, inpatient mortality, measured by checking discharge abstracts, and complications, detected by identifying seven possible problem indicators, were the two measured outcomes. To adjust for hospitals referring more difficult procedures to anesthesiologists, the statistics were controlled to deal with patient characteristics and procedure complexity.

Resulting data showed that solo practicing nurse anesthetists did increase in opt-out states, which is exactly what the CMS rule allows after 2001; thus, the first conclusion of the study is not shocking. Next, the study presented results as follows of surgical inpatient mortality.

### Tabular or Graphic Material Set Forth at This Point Is Not Displayable

*297 “In non-opt-out states, mortality rates for the [two] anesthesia arrangements followed a general downward trend throughout the seven-year period.” However, of interest is the “general downward trend” in opt-out states. After increasing from 1999 to 2001, the rate decreased from 2001 to 2005. Nevertheless, the rate did not significantly decrease between 2001 and 2005; rather, it increased almost a quarter from 2002 to 2003 (one year after CMS opt-out inception) and increased again from 2004 to 2005. Further, the study failed to note that the mortality rate was lower for solo MDA administration in three of five years after the supervision requirement was implemented; thus, allowing physicians to practice alone without CRNAs seems to be a safer alternative, regardless of the “decreasing trend” of CRNA solo practitioners.

As stated earlier, linking the amended CMS rule to patient outcome changes “requires both that the proportion of surgical procedures for which certified registered nurse anesthetists alone provided anesthesia changed as a consequence of the policy change, and that the type of anesthesia provider affects the likelihood of in-hospital mortality or other adverse event.” The data demonstrated neither of the two necessities. Instead, the data found that the proportion of anesthesia without anesthesiologist supervision increased five percentage points in all states, not just opt-out states. Nonetheless, declining mortality (or at least a downward trend according to the study) was normal despite the increasing number of solo nurse anesthetists in opt-out states. This mortality rate was even lower than solo anesthesiologists’ mortality rate. These results led researchers to recommend that “CMS return to its original intention of allowing nurse anesthetists to work independently of surgeon or anesthesia supervision without requiring state governments to formally petition for an exemption.” Thus, the researchers here advocate adopting the aforementioned Clinton nurse autonomy rule that was a response to the 1997 “original” intention of the Health Care Financing Administration.

Like the cost-effectiveness study, the ASA did not allow this article to be published without comment. The ASA believes the AANA-sponsored paper “is an advocacy manifesto masquerading as science and does a disservice to the public. It makes dangerous public policy recommendations on the basis of inadequate data, flawed analysis and distorted facts.” The inadequate data stems from the fact that billing data was used to make forthright conclusions about doing away with supervision of nurse anesthetists. Such data does not distinguish between complications that happen during surgical procedures or due to anesthesia. Further, conditions are not noted as existing prior to surgery or as a result of anesthesia or surgery; thus, utilizing such data for a momentous hypothesis is flawed.

In addition, if using the Institute of Medicine’s current death per anesthesia mortality estimate based on 481,000 cases, the study would have discovered two anesthesia-related deaths, which is an unrealistic number on which to base mortality hypotheses. Lastly, ASA member and former nurse anesthetist, Ann C. Still, M.D., averred, “Having cared for patients as a CRNA and now as an anesthesiologist, I see daily how safe patient care requires a physician’s training.”

### IV. Opt-Out State Requirements, Statutes, and Regulations Versus Current Similar Indiana Law

As of October 2010, sixteen states have opted out of the federal supervision requirement since the enactment of the November 13, 2001, CMS Rule. Of particular importance in this Note are New Jersey, California, and Colorado because these states’ nurse anesthetist regulations or opt-out decisions have been legally challenged. Scrutinizing the claims against each state in these cases will allow for a better prediction regarding the consistency or inconsistency of a possible opt out in Indiana as compared to nurse anesthetist regulations currently in place in opt-out states. Further, a more unproven analytic comparison of Indiana and the opt-out states of Iowa, Washington and Wisconsin based on geographic and demographic data bolsters the argument that Indiana is not similarly situated to necessitate opting out.
A. Opt-Out Requirements

In order to opt out of the federal supervision requirement, the state’s governor must send a confirmation letter to CMS stating that he or she has consulted with the state’s boards of medicine and nursing regarding issues related to patient access and quality of care of anesthesia, opting out is in the best interest of the state citizens, and the opt-out is consistent with state law. Upon the governor’s submission of the attestation letter, the opt-out becomes immediately effective.

In response to comments about the opt-out rule, CMS made clear that consultation between governors and state boards of medicine and nursing is required in order to include both sides in the opt-out discussion; however, “consultation” was purposefully not explicitly defined so that governors have maximum flexibility when making the opt-out decision. The fact that decisive authority remained in the hands of governors, who may not be scientifically endowed to review literature and make decisions, worried many commentators. CMS countered by pointing out that most scope-of-practice regulations for practitioners are made by states, thus enacting the opt-out rule to eliminate such regulations is no different.

Another gray area is the interpretation of the “consistency with state laws” requirement, which produced the most comments when the opt-out rule was proposed. This requirement dealt with requests to outline steps in determining “consistency.” CMS recognized the differing opinions between anesthesiologists and nurse anesthetists on the state law issue (anesthesiologists say that only New Hampshire allows CRNAs to practice without supervision, while nurse anesthetists, based solely on nursing regulations, argue that thirty-nine states do not have supervision requirements for CRNAs) but believed governors were the best suited to determine if opting out was consistent with state law. The bottom line is that “the governor’s letter to the Administrator of CMS will be accepted on face value, with no independent CMS scrutiny or analysis of the governors’ underlying rationale.”

B. Challenged State Regulations or Opt-Out Decisions

1. State Law Challenges

a. New Jersey office-setting nurse anesthetist supervision

Although New Jersey is not an opt-out state, nurse anesthetist supervision requirements have been challenged both in the Appellate Division of the Superior Court and the New Jersey Supreme Court. In 1997, ironically, the same year that the Health Care Financing Administration proposed the nurse autonomy rule to President Clinton, the New Jersey State Board of Medical Examiners moved in the opposite direction by proposing, and later codifying, supervision regulations for anesthesia administered in a physician’s office. When either general or regional anesthesia is administered by a CRNA in a New Jersey doctor’s office, the CRNA must be “under the supervision” of a “physician privileged by a hospital or the Board” to give anesthesia. In addition, the monitoring physician must “be physically present and available to immediately diagnose and treat the patient in an emergency, without concurrent responsibilities to administer anesthesia or perform surgery, other than minor surgery.”

Once this regulation was adopted, the New Jersey Association of Nurse Anesthetists (NJANA) brought an appeal challenging the adoption, stating that it was without medical support, an arbitrary promulgation, and an overextension of authority to regulate the nursing practice. However, the Medical Board “specifically may adopt rules to protect the health, safety and welfare of its licensees’ patients and provide standards for the practice of medicine in New Jersey.” Regardless, the NJANA argued that studies, similar to those mentioned previously, demonstrate that death rates are the same among patients obtaining care from anesthesiologists as they are among those receiving care from nurse anesthetists working alone, making the supervision arbitrary. The Appellate Division of the Superior Court found persuasive the Medical Board’s position that these studies deal with hospitals, where an anesthesiologist is usually present, instead of the relevant office setting where no such studies have been conducted.

Moreover, the NJANA claimed that no factual basis existed for implementing this regulation; however, the court discarded this argument based on a belief that the Board “should not have to wait for bad results to require that its physicians meet higher standards in the administration of patient care.” Lastly, the NJANA argued that the Board was regulating the
nursing profession, which the court concluded was incorrect, as only physicians who offered anesthesia in their offices were being regulated to ensure certain credential requirements were being met. \textsuperscript{159} Thus, the adoption of regulations by the New Jersey State Board of Medical Examiners was ultimately found to be lawful, and the CRNAs were required to adhere to supervision. \textsuperscript{160}

When the NJANA appealed the decision of the Appellate Division, the Supreme Court of New Jersey affirmed, concluding that the education and training of anesthesiologists better prepares them to “protect patients and to respond when complications occur.” \textsuperscript{161} The court also found that there was insufficient evidence relative to available research to find that safety levels between doctors and CRNAs sedating patients are equal. \textsuperscript{162}

\textbf{b. Louisiana scope of practice ruling}

Another non-opt-out state where CRNA activity has produced litigation is Louisiana. In 2005, the Louisiana State Board of Nursing (LSBN) implemented a policy permitting CRNAs to perform pain management, \textsuperscript{163} stating:

[I]t is within the scope of practice for the CRNA to perform procedures under the direction and supervision of the physician involving the injection of local anesthetics, steroids and analgesics for pain management purposes, peripheral nerve blocks, epidural injections, and spinal facet joint injections when the CRNA can document education, training and experience in performing such procedures and has the knowledge, skills, and abilities to safely perform the procedures based on an order from the physician. \textsuperscript{164}

Consequently, an anesthesiologist pain management group, Spine Diagnostics Center of Baton Rouge, filed suit seeking an injunction against the LSBN to enjoin the adoption of such a provision and prevent CRNAs from practicing pain management. \textsuperscript{165}

Statutorily, CRNAs in Louisiana cannot perform anesthesia unless the anesthetics and ancillary services are administered “under the direction and supervision of a physician or dentist.” \textsuperscript{166} Based on this statute alone, CRNAs may argue that pain management is an allowable anesthetic “ancillary service” they can perform under supervision. In the alternative, the CRNAs could contend that if prohibition of CRNAs performing pain management was intended by the legislature, it would have been included in the Louisiana anesthesia administration statute. \textsuperscript{167}

The Louisiana Court of Appeal did not accept either of these possible CRNA arguments and affirmed the district court’s judgment in favor of Spine Diagnostics Center based on scope of practice reasoning. \textsuperscript{168} The appellate decision concluded that “the statement issued by the LSBN expanded the scope of practice for CRNAs into an area where they have not traditionally practiced” and that “pain management is not within the scope of practice of a CRNA, but rather is solely the practice of medicine.” \textsuperscript{169} Multiple witnesses backed the finding. \textsuperscript{170} In particular, Dr. Frank Falco believed that practicing pain management without proper training could bring about to adverse consequences due to the varying complexity of each patient’s pain management program. \textsuperscript{171}

\textbf{c. California opt-out challenge}

Similar to the challenge by the nurse anesthetists in New Jersey, the California Society of Anesthesiologists brought suit against California Governor Arnold Schwarzenegger in February 2010 to dispute that his 2009 opt-out was inconsistent with state law in California. \textsuperscript{172} In California, CRNAs’ scope of practice is broadly defined under the practice of nursing as: “those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems.” \textsuperscript{173} Nurses can also administer medications and therapeutic agents, which have been universally understood to include anesthesia that are “ordered by and within the scope of licensure of a physician.” \textsuperscript{174} Nevertheless, the practice is somewhat limited because nothing defining the scope of nurse anesthetist practice in California confers the power of a nurse to practice medicine or surgery. \textsuperscript{175}

With only a trial court order available thus far, and appellate review beginning on January 31, 2011, the arguments by the parties to the California opt-out challenge have to be deduced solely from the trial court’s findings. \textsuperscript{176} The California Society of Anesthesiologists, like other anesthesiologists outlined in this Note, claimed that to be “ordered by” a physician is
synonymous with being supervised. As a matter of fact, the ASA notes that “supervision or direction” can come in the “form of a physician’s patient-specific order, request or prescription of treatment for anesthesia services.” Thus, to order a nurse anesthetist to administer medication most assuredly would be supervision. However, the trial court did not accept this argument, simply dismissing it by stating “the plain meaning of the word ‘ordered’ is not ‘supervised.’” In addition, “Cali. *304 form law does not contain any explicit supervision requirement. Rather, at best, it is ambiguous on the supervision issue.” An alternative argument of the Society was that administering anesthesia fits into the practice of medicine; therefore, giving CRNAs the ability to administer anesthesia without supervision contradicts California state law prohibiting nurses from practicing medicine. Like the anesthesiologists’ supervision argument, the trial court did not find their alternative argument persuasive either.

On the contrary, CRNAs in California quickly pointed out that in other provisions defining the practices of different nurse types the word “supervision” appears. For example, when dealing with a midwife, “the furnishing or ordering of drugs or devices by a certified nurse-midwife occurs under physician and surgeon supervision. For purposes of this section, no physician and surgeon shall supervise more than four certified nurse-midwives at one time.” If the legislature intended to include “supervision” for the nurse-midwives, then lawmakers would have included such wording for CRNAs if it were required.

Based on the aforementioned arguments given by both sides, and accepting those offered by Governor Schwarzenegger and the California Association of Nurse Anesthetists as interveners, summary judgment upholding the state opt-out was granted. Therefore, the Superior Court of the State of California, County of San Francisco found that Governor Schwarzenegger’s June 10, 2009 letter to CMS opting out of federal CRNA supervision requirements was not an abuse of his discretion.

d. Colorado opt-out challenge

On September 28, 2010, the Colorado Society of Anesthesiologists brought suit to challenge Governor Bill Ritter’s October 2010 opt-out decision. In their complaint the Colorado Society of Anesthesiologists prayed for a declaratory judgment and injunctive relief based on controversy about statutes dealing with the administration of anesthesia, making the opt-out inconsistent with state law. “On July 29, 2010, Governor Ritter *305 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.’” According to an eight to five vote of the Colorado Medical Board, it was later determined that an opt-out was consistent with state law, sparking firm disagreement from the Colorado Society of Anesthesiologists.

In Colorado, nurse anesthetists are classified as advanced practice nurses, meaning that the nurse has specialized training and has applied to the board to be included in the advanced practice registry. The scope of practice comes under the definition of a delegated medical function, which means “an aspect of care that implements and is consistent with the medical plan as prescribed by a licensed or otherwise legally authorized physician . . . and is delegated to a registered professional nurse by a physician.” For the purpose of defining delegated medical function, “medical plan” includes any written plan, verbal order, or standing order that authorizes specific action.

Using these statutory provisions, the Colorado Society of Anesthesiologists brought many of the same arguments as those in the California Society. For one, the Colorado anesthesiologists believe that delegated medical functions by nurse anesthetists must follow accepted practices; therefore, since administration of anesthesia is practicing medicine, supervision is required under accepted practices in Colorado. On the contrary, Governor Ritter and the nurse anesthetist association would likely make the same argument that was accepted in California: that supervision and an “order” are not synonymous terms. Thus, if a medical plan includes the nurse who administers the anesthesia, Colorado law would not explicitly require supervision of anesthetists. As with California, the language of the Colorado statute does not seem strong enough to overturn the deference given to the governor in opt-out decisions, but continuing to monitor this case as it moves through the Colorado court system is necessary.

e. The Indiana Code language and precedent cases
As mentioned earlier, a CRNA in Indiana can only perform anesthesia “if the certified registered nurse anesthetist acts under the direction of and in the immediate presence of a physician.” Based on the foregoing challenges and the language of the Indiana Code, the Indiana Society of Anesthesiologists would have a much better argument that an opt-out is inconsistent with Indiana state law. Both California and Colorado use the word “order” when defining how a physician monitors a nurse anesthetist. Indiana’s language is much stronger, as its Code requires nurses to be both under the direction and in the presence of a physician. It would be hard for the governor to claim, as in California and Colorado, that direct supervision of CRNAs is not explicitly defined by statute in Indiana. In addition, Indiana could use the New Jersey persuasive authority, even though it deals with office procedures, to bolster the argument that lawmakers have a factual basis to regulate CRNA scope of practice. By pointing to the weaknesses of the cost-effectiveness and Medicare data studies discussed earlier in this Note, Indiana anesthesiologists would also be able to show that, effectively, nurse anesthetists have not come up with an empirical study proving their practice is as safe or safer than anesthesiologists administering anesthesia because input data is flawed.

In addition, Indiana has the ability to draw from the ruling by the Louisiana Appellate Division decision regarding scope of practice. Although the CMS opt-out provision does not expand CRNAs scope of practice responsibilities, the perspective given by Dr. Falco (finding CRNAs under qualified to perform chronic, complex pain management) bolsters the argument that Indiana should not opt out of supervision. Since CRNAs are not able to provide the pain management that anesthesiologists regularly administer, it is logically concluded that the aforementioned knowledge disparity between anesthesiologists and CRNAs is wide. Extending the gap to current CRNAs’ scope of practice abilities shows that complications stemming from CRNAs’ inability to assess “medical” situations are a compelling reason to not eliminate supervision requirements.

C. Similarly Situated Opt-Out States Contrasted to Indiana

1. Rural Setting and Hospital Analysis

Based on similar population and agriculture data in each state, Iowa, Washington, and Wisconsin will adequately demonstrate the differences between three similarly situated, opt-out states as compared to Indiana. The population and farm acreage by state are as follows.

Aside from population and farmland, total land area of each of the four states is also of interest. Indiana is the smallest state in square miles of any of the four at 36,417 (compared to 56,273, 71,298, and 65,496 for Iowa, Washington, and Wisconsin respectively). Lastly, and likely most importantly, Indiana has the most non-federal, short term, acute care hospitals of any of the four mentioned states with 100 (compared to 40, 61, and 75 for Iowa, Washington, and Wisconsin respectively).

This data shows Indiana as the second most agricultural, the second most populated, the smallest in terms of square mileage, and the densest in terms of hospitals when compared to similarly situated states of Iowa, Washington, and Wisconsin. A logical conclusion from these findings is that rural patient access is not as limited in Indiana as the other states because patients travel shorter distances to get to hospitals based on the presumption that there is a link between low square mileage and high number of hospitals in Indiana. Stemming from this analysis, an argument rejecting an Indiana opt-out is reasonable, as doctors are more readily available and in closer proximity to possible facilities that would need a physician to supervise CRNAs upon short notice. Overall, looking solely at rural area and hospital data, arguments against Indiana’s patient access to anesthesia would crumble when compared to similarly situated opt-out states like Iowa, Washington, and Wisconsin, making an Indiana opt-out decision one the governor of Indiana need not contemplate due to anesthesia availability and patient access.

2. Statutory or Code Regulation Comparison of Similarly Situated States

In addition to a geographic and demographic analysis among the four states mentioned, a further look into statutory comparison will also be valuable in assessing why Indiana should not opt out of nurse anesthetist supervision. In Indiana, “a
certified registered nurse anesthetist may administer anesthesia if the certified registered nurse anesthetist acts under the direction of and in the immediate presence of a physician. On the contrary, Iowa hospital regulation only requires at a minimum that, “anesthesia services [are] provided under the direction of a qualified doctor of medicine or osteopathy.” Like Iowa, Washington orders hospitals to adopt policies that “[d]efine the staff qualifications and oversight for administering each type of anesthesia in the hospital.” So, it is clear that some oversight is necessary in Iowa and Washington. However, to reiterate, Indiana is the only state that requires the “immediate presence” of a physician.

Iowa’s and Washington’s “direction” and “oversight” regulations are more lenient and could be construed as only requiring a physician to know a nurse anesthetist is independently administering anesthesia, so that in case of emergency they would be privy to the case. As a result, it is likely that anesthesiologists in both Iowa and Washington, like California, would not be able to prove that state law requires supervision. So, based on a geographic and demographic analysis, along with further statutory code comparisons, Indiana has two key differences from the opt-out states of Iowa, Washington, and Wisconsin before scrutinizing problems that may arise from an Indiana opt-out.

V. Problems Arising If Indiana Were to Opt Out of Physician Supervision

If Indiana were to opt out of physician supervision, problems would arise stemming from certification, legislatures current opinion on CRNAs, and the inability to challenge the opt-out. Regarding certification, CMS stated that the Final Rule is flexible, and “regarding patient safety, this final rule is consistent with our efforts to improve the quality of care furnished through Federal programs, while at the same time recognizing States’ traditional domain in establishing professional licensure and scope-of-practice laws.” However, as stated above, Indiana does not recognize certification or require any further process to practice as a CRNA after the nurse passes the national board certification test. Such leniency in Indiana may lead to less qualified CRNAs attempting to practice in the state, which in turn could lead to less favorable anesthesia outcomes than opt-out states that define CRNAs as advanced registered practice nurses and require licensing. With forty-eight states and the District of Columbia requiring certification beyond the national exam, Michigan and Indiana, two states that have not opted out of federal reimbursement for CRNA activity, remain in the clear minority with regard to officially recognizing nurse anesthetists to practice.

In addition to lagging behind in the certification department, Indiana also does not offer an accredited nurse anesthetist educational program. According to AANA, there are thirty-eight states, including the District of Columbia, that offer a total of one hundred twelve programs. Since Indiana lacks a nurse anesthesia program, quality control of in-state nurse anesthetists could potentially be an issue. If hospitals, critical access hospitals, and ambulatory surgery centers in Indiana are counting on educators from different states to train its nurse anesthetists, there is no way to educate CRNAs as to certain experiences, nuances, preferences, or regulations that are unique to Indiana. Thus, without upholding the supervision requirement in Indiana, physicians would, for all practical purposes, be allowing nurses trained by educators with differing scope of practice regulations in mind to administer anesthesia, which is not a patient friendly idea.

Lastly, Indiana Senator Patricia Miller carried a 2009 bill that attempted to include Indiana CRNAs as advanced registered practice nurses; however, the bill died. The death of this bill, which would have expanded the function of Indiana CRNAs, illustrates that Indiana lawmakers are not ready to hand the control of anesthesia in the state over to nurses. Such a feeling is consistent with a study conducted by The Terrance Group in 2001 which found that seventy percent of Medicare beneficiaries opposed the decision to drop the old requirement of supervision and allow nurse anesthetists to administer anesthesia without supervision.

VI. Solutions and Conclusion: Keep the Status Quo Regarding Supervision in Indiana

After analyzing the available studies, data, and law, Indiana should come to the conclusion that the status quo of requiring physician supervision of certified registered nurse anesthetists should be upheld. For one, physician supervision of CRNAs allows for a more risk-averse, patient preferred anesthesia care. Even though administration of anesthesia is about fifty times safer than it was thirty years ago due to better technology and practice standards, death is still possible. Measures taken to increase the likelihood of saving a human life is undeniably a reason to uphold supervision requirements. Secondly, potential financial costs increase more if physician consultation is needed when a nurse anesthetist is allowed to administer unsupervised care, and something goes wrong. In the current, poor economic times, changing requirements may
also increase costs. When one of the opt-out provision’s cornerstone arguments is cost-effectiveness, is not a sound decision if the state government is to be looking out for the best interests of Indiana citizens.

Nonetheless, if the decision to opt out of physician supervision is made in Indiana, the state should take action to further certify CRNAs apart from the national accreditation test that one must take to practice as a nurse anesthetist. However, in order to effectively certify and educate Indiana nurse anesthetists, the state must invest in a nurse anesthetist education program. Only by requiring state recognition to practice and investing in an education program can Indiana ensure nurse anesthetist procedures are as safe as possible when nurses are unsupervised.

As presented in the Introduction to this Note, Dr. Gleimer’s twenty-eight year old arthroscopy patient is a prime example of why a medical doctor needs to be present when a nurse anesthetist administers anesthesia. Dr. Carol Bannister, a former CRNA and current anesthesiologist, said that many times “[she] felt very much on thin ice,” as a nurse anesthetist and that it frightens her to think about being unsupervised during her time as a nurse.221 Overall, Dr. Gleimer said it best himself: “We’ve all been in the OR, when a nurse anesthetist reaches the end of her ability to treat the patient . . . . At that point, she hollers for an anesthesiologist to get her out of deep water.”222 Indiana can avoid this “thin ice” and “deep water” if they keep the physician supervision requirement required to gain Medicare reimbursement for CRNA activity, or in the alternative take preemptive measures to certify and educate future nurse anesthetists.

Footnotes


3 Sataline, supra note 1.

4 Sataline, supra note 1.


8 Purdum, supra note 7; Goldstein, supra note 7.

9 Goldstein, supra note 7.

10 Goldstein, supra note 7; Rowland, supra note 6.
NURSES PROVIDING ANESTHESIA NOT A “LAUGHING”..., 9 Ind. Health L. Rev. 281

11 Goldstein, supra note 7.

12 Interview with Barry Glazer, Anesthesiologist, St. Francis Hospital & Health Centers, in Indianapolis, Ind. (Jan. 28, 2011).

13 Goldstein, supra note 7.


18 RTI International, supra note 17.

19 Dulisse & Cromwell, supra note 17.

20 Am. Ass’n Nurse Anesthetists, supra note 15.


25 Am. Ass’n Nurse Anesthetists, supra note 23 (citing the History of Nurse Anesthesia Practice section of the compilation).

26 Id. (citing the History of Nurse Anesthesia Practice section of the compilation).

NURSES PROVIDING ANESTHESIA NOT A “LAUGHING”..., 9 Ind. Health L. Rev. 281

28 Am. Ass’n Nurse Anesthetists, supra note 23 (citing the History of Nurse Anesthesia Practice section of the compilation).

29 Id. (citing the History of Nurse Anesthesia Practice section of the compilation).

30 Am. Ass’n Nurse Anesthetists, supra note 24.

31 Id.


33 Id.

34 Id.

35 Am. Ass’n Nurse Anesthetists, supra note 24.

36 Am. Ass’n Nurse Anesthetists, supra note 32.

37 Id.


39 Id.


41 Am. Ass’n Nurse Anesthetists, supra note 38.


43 See id.


45 Interview with Barry Glazer, Anesthesiologist, St. Francis Hospital & Health Centers, in Indianapolis, Ind. (Jan. 28, 2011).


47 Personal Business, supra note 5; see RTI International, supra note 17.

See id.

See Am. Ass’n Nurse Anesthetists, supra note 32; Am. Soc’y Anesthesiologists, supra note 48, at 2.

Am. Soc’y Anesthesiologists, supra note 48, at 2.

Id. at 7.

See American Association of Nurse Anesthetists, supra note 21; Hospital Conditions of Participation: Anesthesia Services, 66 Fed. Reg. 56,762, 56,763 (Nov. 13, 2001) (to be codified at 42 C.F.R. pts. 416, 482, 485) (citing the governor’s ability to exercise the exemption so physician supervision is not required).

Am. Ass’n Nurse Anesthetists, supra note 23 (citing Reimbursement of CRNA Services section of the compilation).

Id. (citing Reimbursement of CRNA Services section of the compilation).

Id. (citing Reimbursement of CRNA Services section of the compilation).

Id. (citing Reimbursement of CRNA Services section of the compilation).

Am. Soc’y Anesthesiologists, supra note 48, at 9-10.

Id. at 9.

Id.

Id. at 10.

Id.

Id.

Id.

Id. at 9-10.

Am. Ass’n Nurse Anesthetists, supra note 23 (citing Reimbursement of CRNA Services section of the compilation).

Id. (citing Reimbursement of CRNA Services section of the compilation).

Id. (citing Reimbursement of CRNA Services section of the compilation).

Id. (citing Reimbursement of CRNA Services section of the compilation).


Id.

Id. at 153.

Id.

Id.

Id. at 154.

Id. at 155; see also Am. Soc’y Anesthesiologists, supra note 48, at 32-33.

Silber et al., supra note 71, at 160.

Id. at 157.

Id.

Id. at 160.

Id. at 158; see also Am. Soc’y Anesthesiologists, supra note 48, at 32-33.

Silber et al., supra note 71, at 158.

Id. at 152.

Id.


Paul F. Hogan et al., Cost Effectiveness Analysis of Anesthesia Providers, 28 Nursing Econ. 159, 160 (2010).
NURSES PROVIDING ANESTHESIA NOT A “LAUGHING”..., 9 Ind. Health L. Rev. 281

88 Id.
89 Id.
90 Id.
91 Id.
92 Id. at 161.
93 Id.
94 Id.
95 Id.
96 Id.
97 Id.
98 Id. at 162.
99 Id.
100 Id.
101 Id. at 163.
102 Id. at 164.
103 Id. at 165.
104 Id.
105 Id. at 168.
107 Id.
Dulisse & Cromwell, supra note 17, at 1470.

Id. at 1471; see also RTI International, supra note 17.

Dulisse & Cromwell, supra note 17, at 1471.

Id. at 1471.

Id. at 1472.

Id. at 1473.

Id.
NURSES PROVIDING ANESTHESIA NOT A “LAUGHING”..., 9 Ind. Health L. Rev. 281

129  Id.

130  Id.

131  Id. at 1475.

132  See generally id.


134  Id.

135  Id.

136  Id.

137  Id.

138  Id.

139  Id.

140  Am. Ass’n Nurse Anesthetists, supra note 15.


142  Am. Ass’n Nurse Anesthetists, supra note 15.


146  Id.

NURSES PROVIDING ANESTHESIA NOT A “LAUGHING”..., 9 Ind. Health L. Rev. 281


Goldstein, supra note 7.


154 N.J. State Ass’n of Nurse Anesthetists, 859 A.2d at 1241-42; Dychkowski, supra note 149.


156 N.J. State Ass’n of Nurse Anesthetists, 859 A.2d at 1244.

157 Id.

158 Id.

159 Id. at 1245-46.

160 See id. at 1246.


162 Id. at 250.


164 Spine Diagnostics Ctr. of Baton Rouge, Inc., 4 So. 3d at 857.

165 Id.

NURSES PROVIDING ANESTHESIA NOT A “LAUGHING”..., 9 Ind. Health L. Rev. 281

167 Spine Diagnostics Ctr. of Baton Rouge, Inc., 4 So. 3d at 863.

168 Ga. Ass’n of Nurse Anesthetists, supra note 163.

169 Spine Diagnostics Ctr. of Baton Rouge, Inc., 4 So. 3d at 867.

170 See id. at 865.

171 Id.


178 Am. Soc’y Anesthesiologists, supra note 48, at 34.

179 See id.


181 Id. at 2.

182 See id. at 6; see also Cal. Bus. & Prof. Code § 2833.5 (2011).


184 See id. at 3.

NURSES PROVIDING ANESTHESIA NOT A “LAUGHING”..., 9 Ind. Health L. Rev. 281


Id. at 7.

Id. at 1.


Id. at 3.

Id.


Id.


Id. at 805 tbl.801.

Id. at 221 tbl.355.


Am. Ass’n Nurse Anesthetists, supra note 23 (citing the Legal Issues in Nurse Anesthesia Practice section of the compilation).

Am. Ass’n Nurse Anesthetists, supra note 38.

Am. Ass’n Nurse Anesthetists, supra note 42.

Am. Ass’n Nurse Anesthetists, supra note 38.


See id.


Id.

Am. Ass’n Nurse Anesthetists, supra note 23 (citing Quality of Nurse Anesthesia Practice section of the compilation).

Rowland, supra note 6.

Sataline, supra note 1 (internal quotation marks omitted).