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10/23/03
Date

2003 SENATE HUMAN SERVICES

SB 2413

2003 SENATE STANDING COMMITTEE MIN
BILL/RESOLUTION NO. SB 2413

Senate Human Services Committee

☐ Conference Committee

Hearing Date February 17, 2003

Tape Number	Side A	Side B	Meter #
1	X		0 - end
		X	0 - end
2	X		0 - 505
Committee Clerk Signature	Donna Kramer		

Minutes:

SENATOR JUDY LEE, Chairman, called the meeting to order for SB 2413 relating to the powers and duties of the board of nursing.

Roll call was read. Four present and SENATOR ERBELE was absent.

SENATOR TOM FISCHER, sponsor, introduced the SB 2413.

DR. SCOTT KLEIN, Physician and president of the North Dakota Anesthesiologists, testified in support of the bill. He stated he worked at the Heart and Lung Clinic in Bismarck. He explained his work. "Team care" approach has served them well. SB 2413 is here because of the change in the Federal law. (Written testimony and proposed amendments attached) Recommended support of the amendments and a do pass on the bill. (Meter # 158 - 2130)

DR. GAYLORD KAVLIE, testified in behalf of himself. He stated he works in Bismarck with MidDakota Clinic and Primecare Group. Explained his background and work experience.

Explained process prior to surgery. He stated he bears brunt of responsibility. Urged support of the bill. (Meter # 2172 - 2852)

DR. DUANE ANDERSON, general surgeon practicing in Williston, testified in his behalf in support of the bill. Served as chapter president for the College of Surgeons. He stated he needs collaboration between not only the physician side of anesthesia, but my nurse anesthetist. There is ungoing dialogue during surgery. (Meter #2890 - 3117)

SENATOR POLOVITZ: Collaborative agreement - is this a written agreement?

DR. DUANE ANDERSON: We don't have any "written agreement" right now. It's more or less a verbal arrangement. (Meter #3144)

SENATOR POLOVITZ: Written agreement. Two words not used in your amendments.

DR. SCOTT KLEIN: Initially, the interpretation was unclear. Continued discussion with committee members and Dr. Anderson regarding working relationship and collaborative written agreement. (Meter # 3190 - 3478)

SENATOR POLOVITZ: Why do we need the bill? (Meter #3479)

DR. SCOTT KLEIN: Provision in Federal statues that there is supervision for medical direction - removing that provision could remove surgeon from room. (Meter # 3548 - 3732)

SENATOR POLOVITZ: Does supervision mean also that Medicare would then provide both the physician and the anesthesiologist different payments? Would that mean that the surgeon or who ever is in charge of the operation at that time gets a bigger or lesser share of Medicare payments? (Meter # 3727 -3804)

DR. SCOTT KLEIN: Fees are split for those who are providing the service. Continued discussion with SENATOR POLOVITZ. (Meter # 3805 - 4051)

SENATOR BROWN: Does this legislation if passed have anything to do with fees?

DR. SCOTT KLEIN: From what I've seen, has nothing to do with fees. Continued discussion with SENATOR BROWN as to current legislation having nothing to do with fees or if the Governor opts out. Then left with rules initially set up to provide for patient care and the care team model is defined differently. (Meter # 4077 - 4140)

SENATOR FAIRFIELD: How changes?

DR. SCOTT KLEIN: Concern is that operating physician to do the operating or the anesthesiologist is there to lend the direction. Continued discussion with SENATOR FAIRFIELD regarding who would be in the surgery room. (Meter # 4248 - 4459)

SENATOR FISCHER: If the Governor opts out, how would the model be defined then?

DR. SCOTT KLEIN: Removes Federal supervision requirement.

Continued with SENATOR FISCHER regarding critical times, who defines that or decides what times are critical? (Meter # 4487 - 4595)

DR. SCOTT KLEIN: Changes in the patient's vital signs. (Meter # 4596 - 4710)

SENATOR FISCHER: In the states where the governors have not opted out, how many states have initiated legislation such as this?

DR. SCOTT KLEIN: Dr. Ogden may be able to address that. (Meter # 4753)

DR. PHILIP ODGEN, a practicing anesthesiologist at Medcenter One in Bismarck, testified in behalf of himself. He stated in response to the question of how many states have requirements in the state law that would tie the CRNA to the practice of a physician. I believe that it is all of the states that have not opted out have such requirements in place. To the best of my knowledge by information provided by the American Society of Anesthesiologists, there is only one state ...

New Hampshire ... one state opted out. ... Continued testimony - regarding disparities in Medicare service from state to state and from one side of the state to another, economic pressures on small hospitals. ... Concern of anesthesiologist's fee. (Meter # 4770 - 5531)

DR. STEVEN BERNDT, anesthesiologist practicing at Meritcare in Fargo, testified in behalf of himself. In their practice at Meritcare, they utilize the anesthesia team approach. What is place now is mandated by the Federal government. If Governor opts, it would remove the requirement - unsupervised practice. Study was done. (Meter # 5610 - 6060)

ROB SCHMEIG, Certified Registered Nurse Anesthetist, and on behalf of the North Dakota Association of Nurse Anesthetists, testified and encouraged a Do Not Pass recommendation. He stated that is unreasonable to believe that without this bill, CRNAs would be offering anesthesia to anyone at anytime. He also indicated that CRNAs are already regulated by a national certifying board and the North Dakota Board of Nursing, we don't need another level of regulation. (Written testimony provided) (Tape 1, Side A, Meter # 6150 - end and Side B, Meter # 0 - 1217)

SENATOR LEE: No state had laws mandating MD supervision before 1996?

ROB SCHMEIG: The current Medicare physician supervision law for reimbursement or hospital compliance took effect in 1986 for hospitals. (Meter # 1270 - 1303)

SENATOR ERBELE: Do the amendments soften your opposition to the bill? (Meter #1316)

ROB SCHMEIG: No, to us it seems to be more restrictive now. (Meter #1340 - 1355)

SENATOR BROWN: Bottom line, are you suggesting do not pass this law, go back to the Governor for opt out?

ROB SCHMEIG: Yes, that is my intent. Continued discussion on whether the Governor will opt out. (Meter # 1422 - 1470)

PAULA SCHMALZ, CRNA residing in Fargo, testified and recommended a Do Not Pass. (Written testimony) She said she contracts with facilities in North Dakota. (Meter # 1492 - 2786)

ROSS GONITZKE, from Grand Forks, had letter delivered with Paula Schmalz and read. He asked for a Do Not Pass. (Written testimony provided)

CAL ROLFSON, Attorney and representing North Dakota Association of Nurse Anesthetists, spoke in opposition to SB 2413. Stated model already in statute. Nurses must have collaboration ... always been there. (Written testimony provided and map of ND Anesthesia Coverage By City) (Meter # 3023 - 4295)

DR. CONSTANCE KALANEK, Executive Director of the North Dakota Board of Nursing, testified stating the Board of Nursing members voted unanimously to oppose this legislation. (Written testimony) Committee discussion with Dr. Kalanek regarding rules that address who is responsible for what, specific procedures and practices that would address communication, and policies of hospital and clinic. (Meter # 4394 - 5546)

SENATOR LEE: Question to Dan Ulmer as what changes he might see from BCBS perspective if this bill passed.

DAN ULMER, representative of BCBS, stated they did not perceive any change in any reimbursement. ... Fees are indeed split. (Meter # 5676 - 5775)

SENATOR FISCHER: Question to Dr. Klein regarding anesthesiologist stopping by ... would it be a case that there would be several people being cared for by a nurse anesthetist and an anesthesiologist and collaboration with several patients at the same time?

DR. SCOTT KLEIN: That is correct. ... Fees are split. (Meter # 6046 - 6110)

SENATOR FAIRFIELD: If this does not pass, do you see your role as anesthesiologist expanding? Your reaction to the statement that this bill is protecting the established medical profession? (Meter # 6133 - 6200)

DR. SCOTT KLEIN: Enjoying a good relationship. ... System as it is and has been safe. Will not change the way practice is now. (Tape 1, Side B, Meter # 6201 - end and Tape 2, Side A, 0 - 95)

SENATOR LEE: Relationship change if the Governor opts out?

DR. SCOTT KLEIN: I think that relationship can change - the relationship in the rural areas. ... Surgeon in the room does not know tremendous amounts about the anesthetic, but they do understand basics of the anesthesia that is provided. But, they do know medically the patient. (Meter #109 - 199)

ARNOLD THOMAS, of the North Dakota Healthcare Association, was asked by SENATOR LEE what changes he would see if this bill were put into rule. He responded that the conditions of Medicare participation is through rule. If the rules change, statutory rule will need to be changed. (Meter # 247 - 340)

SENATOR FAIRFIELD: Without this bill, there could be a shift - for example decision making? (Meter #356)

ARNOLD THOMAS: Application has worked well has worked well in North Dakota for many years. Economic factor - concern. (Tape 2, Side A, Meter #405 - 505)

Public hearing closed on SB 2413.

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2413

Senate Human Services Committee

☐ Conference Committee

Hearing Date February 18, 2003

Tape Number	Side A	Side B	Meter #
1	X		0 - 142
Committee Clerk Signature	Donna Kramer		

Minutes:

SENATOR LEE called the committee to order.

Roll call was read. All members present.

SENATOR JUDY LEE opened the committee discussion on SB 2413 relating to the powers and duties of the board of nursing.

SENATOR FISCHER made a motion to DO NOT PASS.

SENATOR ERBELE seconded the motion.

Roll call was read. 6 yeas 0 nays.

SENATOR FISCHER to be the carrier. (Meter # 142)

Date: 02-18-03
Roll Call Vote #: ~~2413~~ 1

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2413

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken DO NOT PASS

Motion Made By Sen. Fischer Seconded By Sen. Erbele

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee - Chairman	✓				
Senator Richard Brown - V. Chair.	✓				
Senator Robert S. Erbele	✓				
Senator Tom Fischer	✓				
Senator April Fairfield	✓				
Senator Michael Polovitz	✓				

Total (Yes) 6 No 0

Absent _____

Floor Assignment Carrier: Sen. Fischer

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE (410)
February 18, 2003 12:49 p.m.

Module No: SR-31-3082
Carrier: Flecher
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

SB 2413: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO NOT PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2413 was placed on the Eleventh order on the calendar.

2003 TESTIMONY

SB 2413

Grand Forks
Anesthesia
Services, P.C.

Lori Bazey, President
820 Oakfield Ave
Grand Forks, ND 58201

Chairman Lee and members of the Senate Human Services Committee

My name is Lori Bazey. I am the owner of Grand Forks Anesthesia Services, PC (GAS) and a Certified Registered Nurse Anesthetist (CRNA) from Grand Forks. I am here today to communicate to you compelling reasons to give SB 2413 a **Do NOT Pass recommendation**.

SB 2413 will restrict the ability of CRNAs to compete in the marketplace of anesthesia services. I currently contract with 2 facilities in ND (North Dakota Surgery Center and the Stadter Center) and 1 rural facility in Minnesota for providing anesthesia care, as well as provide occasional CRNA relief services to various rural hospitals in northeastern North Dakota (ND). Over the last 1 ½ years, myself and the 6 CRNAs that I hire have provided anesthesia to 2,850 ND citizens in a safe and efficient manner. The "collaborative agreement with a licensed physician" which the legislation of SB 2413 requires, will place unnecessary liability concerns on the physicians I provide anesthesia service for. This may force them to contract instead with a physician anesthesia provider i.e. Anesthesiologist. Legislation is intended to protect the citizens of North Dakota, not the status, economic interests, or job security of Anesthesiologists through limitations and restrictions placed on other anesthesia providers such as CRNAs. The analogy of an equivalent bill would be the requirement of each healthcare facility or anesthesia business in ND to hire a CRNA. That is equally unreasonable!

SB 2413 changes healthcare practice that has safely and efficiently served our state for years. Continuity and safety is assured within our current practice. The reality of how anesthesia care is provided is as follows:

- CRNA is requested to provide anesthesia care.
- CRNA develops an anesthesia care plan with consideration to the patients' medical information, surgical requirements, and patient preference. Consultation may be with any number of resources. Explication as to surgical needs from the surgeon, clarification from the Family Practice physician who dictated the patients history and physical preoperatively, elaboration on testing from a Cardiologist, suggestions from other peer practicing CRNAs or Anesthesiologists.
- CRNA provides anesthesia care utilizing their resources as needed.

As you see, the type and source for consultation differs for each patient. To place this responsibility solely on the surgeon is not only inappropriate, but burdens them with the anesthesia liability.

Limiting the CRNA resources to a collaborative agreement and physician would degrade the teamwork and synergy of patient care, not improve it!!

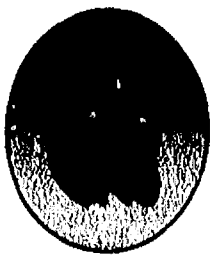
Grand Forks
Anesthesia
Services, P.C.

Lori Bazey, President
820 Oakfield Ave
Grand Forks, ND 58201

Patient safety and satisfaction have always been a concern of CRNAs, surgeons, physicians and health care providers alike. I have personally administered anesthesia as an independent practitioner to the wife of an anesthesiologist, the brother of an anesthesiologist, physicians, and physicians' children. They have entrusted me with their lives and the lives of those they love under my care, just as many citizens of North Dakota have. 64% of anesthetics in ND are delivered solely by independently practicing CRNAs. SB 2413 does nothing to improve the vigilance and watchful care necessary to deliver a safe anesthetic.

The anesthesiologists may try to present the illusion that SB 2413 has to do with patient safety. I could bore you with tedious statistics or scientific studies that have proven the quality and safety of anesthesia care given by CRNAs for over a century. I choose instead to look at this issue from a practical aspect. Do you really believe that hospitals, surgery centers and rural facilities for the past 100 years would continue to hire CRNAs for their anesthesia expertise if the care has not been safe? I think not! The Urologist, Psychiatrists, Orthopedic surgeons and Ophthalmologists I currently provide anesthesia service for all have independent practices of their own. They are not under the safety net of a large clinic group to obtain patient referrals. They have built their individual practices from the ground up. Anybody in business for themselves must realize that if you do not provide a safe quality service, your business will not survive or grow. The patients will go elsewhere. Do you believe that the physicians I provide service for would put at risk their own practice if they did not believe what I provide is of utmost quality and safety for their patients? The current working relationship we have practicing within our current scope of practice provides the quality and safe anesthesia care they so desire for their patients.

<u>SB 2413 and the collaboration agreement it requires, would not improve patient care over the present system in ND, but only greatly increases the liability concerns of physicians whom CRNAs work with.</u> The entire national healthcare system is feeling the reverberations of the current malpractice crisis. Skyrocketing premiums and the closure of agencies willing to provide medical malpractice places liability concerns at the forefront of every practicing physician and health care provider. There is no doubt that affixing physicians with responsibilities of a formalized collaborative agreement with CRNAs, will contribute to their perception and fear of added liability. I read just yesterday that the average malpractice premium rate in Connecticut rose 232% in 2002, and is expected to increase 30% this year. In the early 1990's, there were 9 medical malpractice carriers, but only 5 remain active now. This is just an example of why there is such concern over liability present today. This potential legislation would be asking a physician not trained in anesthesia to assume the liability *for* the anesthesia.



Grand Forks Anesthesia Services, P.C.

Lori Bazey, President
820 Oakfield Ave
Grand Forks, ND 58201

The concept of SB 2413:

- **Is regressive and *does not* fit the healthcare needs of North Dakota.**
- **It *does nothing* to promote patient safety.**
- **It *does* restrict CRNAs from practicing to the extent of their Scope of Practice**
- **It *does* indeed contribute to liability concerns of licensed physicians with whom CRNAs provide anesthesia service.**
- **It *does*, in fact, potentially put at risk the access to 64% of all anesthetics delivered in ND.**

And these are your compelling reasons to give SB 2413 a Do NOT Pass recommendation!

Thank you for the opportunity to speak with you today. I would be happy to answer any questions you may have.

"Tom Bruce" <tbruce@osicable.net>
02/09/2003 06:42 PM

To: <jlee@state.nd.us>
cc:
Subject: SB2413

My understanding of the nurse practice act is a MD collaborator must be of the same specialty (anesthesiologist) and practice in the same facility. So if this bill passes unless these rural hospitals can afford to hire anesthesiologists, which they cannot, CRNA's would be unable to practice in these settings, effectively closing rural anesthesia departments. To my knowledge there has never been or is there now any type of collaboration or supervision requirement for CRNA practice. You have my permission to share this e-mail with others. Tom Bruce BS CRNA Jamestown.

February 10, 2003

Judy Lee
Chairman Human Services Committee
North Dakota Senate

RE: Senate Bill 2413

Dear Ms. Lee:

As per our conversation I am writing this note to you regarding my views pertaining to Senate Bill 2413, introduced by Senator Fischer, which is coming up for the legislative assembly to consider. Under Section 1, paragraph 6B, the sentence stating "the practice of a certified registered nurse anesthetist must include evidence of a collaborative agreement with a licensed physician" is most troublesome. I sincerely believe this is a dangerous statement as this could, in the long run, seriously limit not just the way the CRNA's have the ability to practice in the state, but also directly affect patient care.

Presently there are many rural hospitals and surgical centers that use exclusively certified registered nurse anesthetists (CRNA's) without supervision by a physician anesthesiologist (MDA). Even in urban centers like Fargo there are various sites, including my own surgical center, where CRNA's provide anesthesia services.

Some of these include Oakes Hospital in Oakes, Valley City, Mayville, Grafton, Rolla, Tioga, Wishek, Linton, Hettinger, Elgin Devils Lake, Jamestown and in Fargo, Lamb Plastic Surgery, Plastic Surgery Institute, and the oral surgery practices of Dr. Lindemoen and Dr. May. Even larger clinics such as Dakota Clinic in Fargo, the CRNA's provide anesthesia services for Dr. Iverson in the oral surgery clinic. The VA Hospital in Fargo has not had a MDA for many years and CRNA's provide sole coverage for some of the most complex patients treated.

On November 13, 2001, the Center for Medicare and Medicaid Services; formerly known as HCFA, published the final rule concerning the federal conditions of participation provision regarding physician supervision of CRNA's in hospitals, ambulatory surgery centers and critical access hospitals. This rule allows the states to opt out of the federal supervision requirement of Medicare cases. To this date six states including New Mexico, Minnesota, Iowa, Nebraska, Idaho and New Hampshire have opted out. For most rural states to do this is prudent as there are not enough physician anesthesiologists who can go around to some of the outlying and faraway surgical centers to provide the necessary services. This may simply be because of numbers or the physician anesthesiologists desire not to do so.

I sincerely believe CRNA's practice to deliver anesthesia in a safe, efficient and effective manner and their education has been optimized to do this. Supervision has proven not to be necessary. There are numerous amounts of data available to show this. There is no difference in the mortality or morbidity whether the CRNA are supervised or not, if the literature is reviewed. CRNA's do not provide anesthesia services unless ordered by the physician and therefore, they do no prescribe medication directly. Having personally worked with a CRNA for the past seven years providing exclusive anesthesia to my patients, I believe that these individuals are highly capable and certainly do not need the kind of supervision that the

physician anesthesiologists may deem to be necessary. In fact, I can assure you from personal experience, that there have been many incidences when working in larger hospitals where there have been CRNA's supervised by MDA's, most of the anesthetic administered are by CRNA's exclusively and there have been times I have not seen an MDA enter the room through the whole procedure from induction to waking up the patient. Therefore, I firmly believe that confining the CRNA's to rigid rules where they have to be supervised or have restrictive collaborative agreement will limit their access and ability to practice. I think this will impact patient care certainly in rural areas where if a physician anesthesiologist is not available surgeries will not be able to be performed and these patients would have to be shipped centers where such services are available. This of course has its obvious hardships to patients and certainly to the cost of health care to the population of this state and to insurance companies.

The argument that this statement simply would mean a collaborative agreement could be between a CRNA and a licensed physician but does not have to be a MDA. Looking at the wording of some of the century code relating to the powers and duties of nursing, it seems that the logical next move would be to define 'licensed physician'. This has already been defined as licensed physician in that specific specialty. As you can see, this would in turn limit agreement powers to physician anesthesiologists and not any licensed physician such as a surgeon. I think this would also affect the ability of North Dakota to opt out of federal Medicare ruling, as this would override that. I believe Governor Hoeven should review the opt out clause and exercise this option so we can continue anesthesia services as is in ND. I think, in the long run, this is best alternative for all concerned including patients, insurance companies, etc.

I hope this summarizes what we talked about in our phone conversation and is helpful in providing information pertinent to your ruling on this matter.

Sincerely,
Ahmed Abdullah, MD, FACS
Plastic Surgery Institute, Fargo ND

Cc: Senator

ND Society of Anesthesiologists
February 17, 2003

PROPOSED AMENDMENTS TO SB 2413

Page 1, line 8, overstrike "; and" and insert immediately thereafter an underscored period

Page 1, line 13, remove "The practice of a certified registered nurse"

Page 1, replace lines 14 and 15 with:

"c. Require that a certified registered nurse anesthetist who administers anesthesia must be under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed."

Renumber accordingly

NOTE: *The intent of this proposed amendment is to maintain the status quo by incorporating the current federal language requiring a Certified Registered Nurse Anesthetist to be supervised by the operating practitioner [42 CFR 482.52(a)].*

TESTIMONY IN SUPPORT OF SB 2413, AS AMENDED
NORTH DAKOTA SOCIETY OF ANESTHESIOLOGISTS
SENATE HUMAN SERVICES COMMITTEE
FEBRUARY 17, 2003

Madam Chairman and Members of the Committee. Good morning. My name is Scott Klein. I'm a physician and am President of the North Dakota Society of Anesthesiologists. I have come today to urge you to support SB 2413, with amendments we will be proposing this morning. Several others are also here and will follow me to provide additional testimony. I was born and grew up in Minot, and attended the University of North Dakota for four years as an undergraduate, majoring in chemistry. After an additional four years I graduated from the UND School of Medicine. I then went on to complete five years of medical residency training in Chicago at the University of Illinois. Following this period of formal instruction I returned to North Dakota to practice the specialties of anesthesiology and critical care medicine here in Bismarck at the Heart & Lung Clinic.

In this role I work diligently to ensure that my patients are cared for in a safe manner.

While attending to the surgical patients, I review their medical history and work up and determine whether they are fit to undergo surgery. I then order additional testing as appropriate and proceed only when the pre-operative evaluation is satisfactory and it is safe to conduct the surgical procedure. Some patients may need more advanced monitoring because of their more serious medical conditions. I weigh the benefits provided by the added margin of safety from this monitoring technology versus the risks encountered in utilizing the technology. There are times when it is not advisable to proceed with an operation and at that time I am the voice of advocacy for the patient. My role as a physician is to ensure the patient's safety. It goes back to a tenet taught in the first week of medical school - *first do no harm.*

The federal government developed the Medicare program to establish a uniform standard of care in providing medical services for our nation's elderly. In their design of this program the operating physician or practitioner was generally required to supervise the anesthesia care of these patients. This meant that the operating practitioner – the surgeon, podiatrist or dentist performing the operation, or an anesthesiologist if available -- would provide supervision or

medical direction during the preoperative period. This system allowed those who were the most knowledgeable about the patient's medical history and condition to direct that patient's care. This care team approach, involving anesthesiologists, operating surgeons, and CRNAs has served us well across the nation and in North Dakota and the safety of our citizens has been enriched with this team practice.

The intent of SB 2413 is to maintain the status quo in the provision of anesthesia services, in response to a change in federal law.

SB 2413 is here today because of a change in federal law. It has been a longstanding requirement in federal law as a condition of participation or coverage for Medicare and Medicaid that anesthesia services provided by a certified registered nurse anesthetist must be under the supervision of an anesthesiologist, the operating physician, or other practitioner performing the surgery, which might also be a dentist, oral surgeon, or podiatrist. This situation changed on November 13, 2001, when the federal Centers for Medicare and Medicaid Services (CMS) issued a final rule amending three anesthesia services issues: the conditions of participation for hospitals, the surgical services conditions of participation for critical access hospitals, and the surgical services conditions of coverage for ambulatory surgical centers. The new rules maintain the current physician supervision requirement for certified registered nurse anesthetists, unless the governor of a state, in consultation with the state's boards of medicine and nursing, exercises the option of exemption from this requirement. I've included these specific federal regulations as Appendix A attached to my written testimony. We have always referred to this new authority in the Governor as the Governor's "opt out" authority. The Governor may opt out of the longstanding physician supervision requirements upon a finding that such an opt out is (1) consistent with state law, and (2) in the best interest of the people of the state.

In its comments to this "opt out" rule, the Centers for Medicare and Medicaid Services noted the dilemma many states might have in their earlier reliance on Medicare physician supervision requirements in establishing state scope of practice laws and monitoring practices. In those comments, CMS stated:

> "In some cases, state laws and regulations may have been written with the assumption that Medicare would continue its longstanding policy requiring physician supervision of the anesthesia care provided by CRNAs. Eliminating Medicare requirements now could change supervision practices in some states without allowing states to consider their individual situations. In the absence of federal regulations, we were concerned that states might have promulgated different laws or different monitoring practices."

So, there were concerns that state laws on CRNA practice were put in place in reliance on the federal regulations and that an "opt out" should include a close review of state law.

In my earlier conversations in 2000 with members of our Congressional Delegation who were involved in this issue and the CMS rule, I received correspondence from Representative Earl Pomeroy, expressing his view that patient care would not suffer under the CMS deference to state law on this issue. He said:

> "I have faith that our state licensing board will ensure that only properly trained and licensed individuals will be allowed to administer this critical health care service. I also am confident that doctors and nurse anesthetists in North Dakota will be able to work with the state legislature to determine an appropriate, fair, and comfortable level of supervision for both patient and provider."

Last year, Governor Hoeven's office conducted informal discussions with the various groups involved and also consulted with the North Dakota State Board of Medical Examiners and, I understand, the North Dakota State Board of Nursing.

In this consultation process, the North Dakota State Board of Medical Examiners informed the Governor of its position on his new opt out authority. The Board recommended on January 2, 2002, that "no North Dakota facilities be opted out of the supervision requirement. Frankly, we see no reason to change the status quo. The opt out provision does not improve access to health care in any way nor does it improve patient safety." The Board's recommendation went on further to state:

> "It seems clear that while the regulations require physician supervision of a nurse anesthetist, those regulations do not require that such supervision be provided by an anesthesiologist. In those circumstances in which no anesthesiologist is present, the operating surgeon acts as the supervising physician. In other words, there is never a circumstance when there is no supervising physician available. As you know, weighing practical considerations regarding access to health care against the ideal standards of patient safety can be a very difficult and delicate task. It is our position that in

almost every circumstance the patient's safety considerations should be given far more weight than the practical considerations but that dilemma does not present itself here. Opting out of the supervision requirement would not improve access to health care in any way."

In the months after the new CMS rule took effect, other organizations in North Dakota indicated their recommendation to the Governor that he not exercise his opt out authority to remove the longstanding physician-CRNA team approach. I've provided in Appendix B to my written testimony a number of letters delivered to the Governor by the North Dakota Medical Association, surgeons, including the State Chapter President for the American College of Surgeons, Dr. Wayne Anderson, who will also speak with you this morning, the chair of the North Dakota Section of the American College of Obstetricians and Gynecologists, and others, as well as the letter from the North Dakota State Board of Medical Examiners.

In our efforts to urge the Governor not to exercise his opt out authority, several basic arguments were made that can be summarized briefly:

(1) As noted by the Centers for Medicare and Medicaid Services in its own comments to the rule, North Dakota's laws and regulations were developed under the assumption that the Medicare physician supervision requirement would continue. The federal standards have provided an essential balance in North Dakota between appropriate practice by CRNAs and appropriate medical direction and oversight of CRNA practice. We have always suggested that any consideration for an opt out should be preceded by a comprehensive review of North Dakota statutes and rules to identify the implications of removing the regulatory assurances that now are afforded by the federal supervision standards, and determine whether further state protections should be implemented.

(2) We have consistently suggested that no compelling reason exists to move away from an approach to anesthesia care that has produced successful outcomes for North Dakota patients. We suggested to the Governor that an immediate opt out would unfairly shift the "burden of proof" to patients and the medical community to maintain the status quo, either through legislation, professional board regulations, or other means, even though the status quo has produced successful outcomes for North Dakota patients. We've argued that the burden of proof would shift with no assurance of continued anesthesia safety. We suggested that the

presumption should remain with the status quo, and the burden of proof should be on those who favor an opt out to show that changes would be in the best interest of the people of North Dakota. (3) The final rule adopted by CMS included a provision for a study of anesthesia outcomes. We also suggested that there was no compelling reason to opt out and place North Dakota patients at potential risk prior to the completion of that federal study. We suggested there was a clear consensus in medicine that removal of the physician supervision requirement should not occur until scientific proof of safety exists.

After the initial flurry of activity early last year, this issue of the Governor's opt out authority was put on the "back burner," until this past December, 2002. At that time, we were informed by the Governor's office that the Governor was "inclined" to exercise his opt out authority to remove the physician supervision requirements in our state. At that time, we again restated our views in discussions with the Governor's office and in discussions with the State Health Officer, who also expressed opposition to the opt out, and with the office of the North Dakota State Board of Medical Examiners. Further discussions resulted in no change in the Governor's "inclination" to opt out; therefore, it was suggested by the Governor's office that the medical community introduce state legislation. Faced with this dilemma on the last day of the Senate bill introduction deadline, SB 2413 was introduced in an attempt to anticipate a gubernatorial opt out by placing language in the Century Code that would maintain the status quo. That is our intent – to maintain the status quo. That is, we are not seeking to in any way diminish the physician-CRNA team approach, nor to increase the physician's supervisory role.

We understand that there have been various interpretations applied to the current language in SB 2413, including a suggestion that the collaborative agreement language would require that CRNA collaborative agreements could only be entered into with anesthesiologists. That is not our intent. Our intent is to simply incorporate the language of the present federal regulations, which would then incorporate as a matter of state law the longstanding physician supervision requirements that have been in place in the past and were relied upon in this state for many years in defining the relationship among professionals in providing anesthesia services.

Last week Thursday we met with representatives of the CRNAs to discuss the language used in SB 2413, as well as the possibility of using better language to describe our intent. We appreciated the opportunity to sit down and explore our diverse views on this issue. While we were not able to come to any agreement on whether our state law should be changed to maintain the status quo, we have prepared amendments that we believe more closely describe our intent. The proposed amendments to SB 2413 would incorporate the language from the federal regulation that we would lose in this state if the governor would opt out.

The proposed amendments I handed out would require the North Dakota Board of Nursing in setting standards for nurse practice to require that a certified registered nurse anesthetist who administers anesthesia must be under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed. This is the language used in the federal regulations relating to hospitals. The operating practitioner would be the individual actually performing the surgery, and would supervise the CRNA. Again, it is our intent not to change relationships among professionals but to maintain the status quo. We believe the proposed amendments more closely describe the status quo for this purpose.

The status quo provides the greatest opportunity for continued patient safety.

Although it may be contended that the Medicare requirements were established primarily to address matters of reimbursement, one cannot deny the profound affect its rules of participation have had on shaping the anesthesia care team model. These rules have contributed in a large part to the legacy of safe anesthesia care provided to the citizens of North Dakota.

The Institute of Medicine's 1999 study "To Err is Human" cites the medical specialty of anesthesiology as making great safety advances and improving the outcomes of those patients undergoing anesthesia. These current practices are the foundation of the legacy of safety in anesthesia.

Our state's longstanding record of successful outcomes under the anesthesia care team approach has served North Dakota patients well. Even the Institute of Medicine's call for professional

societies and groups to demonstrate a visible commitment to reducing errors in health care included, as a "notable exception," the work done by anesthesiologists to improve safety and outcomes for patients:

> "Anesthesiology has successfully reduced anesthesia mortality rates from two deaths per 10,000 anesthetics administered to one death per 200,000—300,000 anesthetics administered .... This success was accomplished through a combination of:
> - technological changes (new monitoring equipment, standardization of existing equipment);
> - information-based strategies, including the development and adoption of guidelines and standards;
> - application of human factors to improve performance, such as the use of simulators for training;
> - formation of the Anesthesia Patient Safety Foundation to bring together stakeholders from different disciplines (physicians, nurses, manufacturers) to create a focus for action; and
> - having a leader who could serve as a champion for the cause." Institute of Medicine, *To Err Is Human: Building a Safer Health System*, National Academy Press 1999, pp. 124-25.

These improvements in anesthesia care were developed in the context of the federal physician supervision requirements. There is no compelling reason to now retreat from an approach that has produced a longstanding record of successful outcomes in North Dakota under the anesthesia care team approach.

Maintaining the status quo will also maintain the current reimbursement structure.

We understand that SB 2413 as introduced initially raised some concerns regarding the reimbursement of anesthesia services. Again, it is not our intent to impact the current payment methodologies used by federal or private insurers, and the proposed amendments should maintain the present reimbursement structure.

Reimbursement for the provision of anesthesiology services to Medicare-participating providers is currently calculated using a base unit for each specific anesthesia service, added to a national average time unit for that service, and multiplied by a North Dakota anesthesia conversion factor of $15.25. In 1998, Medicare completed a phased-in reduction in reimbursement for anesthesia services, and recognized the anesthesia care team approach. Services are paid appropriately whether provided by a single anesthesiologist, by a single CRNA working with a surgeon, or under an anesthesiologist-CRNA care team. Employment agreements governing reimbursement would not be affected.

The people of North Dakota express a desire to maintain the status quo.

In a poll taken in North Dakota this spring, an overwhelming majority (67%) of the North Dakota adult population said they oppose action by the Governor to waive the current anesthesia supervision requirement (The Terrance Group, April 12, 2002). An executive summary of the poll is attached as Appendix C.

Those North Dakotans who oppose waiving the current supervision requirement include both senior citizens (71% oppose) as well as young adults (63% oppose). The opinion of North Dakotans has been particularly important in our discussions with the Governor's office because one of the findings the Governor must make in consideration of an "opt-out" is that an opt out is in the best interests of the people of the state. The poll shows that the people of North Dakota do not believe that an opt out is in their best interests.

Only six state Governors have decided to opt out. However, each state must examine its own state law to determine what is in the best interests of the citizens of their state.

To date, only six state Governors have opted out of the longstanding physician supervision requirements set forth in the Medicare conditions of participation: *Idaho, New Hampshire, Iowa, Minnesota, New Mexico, and Nebraska.* I've attached summaries of the laws of each of those states in Appendix D.

These states take varying approaches, which likely coincide with their own practice environments. For example, in our region Minnesota CRNAs may prescribe and administer drugs and therapeutic devices within the scope of a written agreement with a physician based on standards established by the Minnesota Nurses Association and the Minnesota Medical Association [Mn. Stat. 148.235]. "Registered nurse anesthetist practice" is defined in Minnesota law as the "provision of anesthesia care and related services *within the context of collaborative management*, including selecting, obtaining, and administering drugs and therapeutic devices to facilitate diagnostic, therapeutic, and surgical procedures, *upon request, assignment, or referral by a patient's physician, dentist, or podiatrist* [Mn. Stat. 148.171(21)]." The definition of "collaborative management" makes it very clear that CRNAs in Minnesota must provide

anesthesia services at the same hospital, clinic, or health care setting as the physician, surgeon, podiatrist, or dentist [Mn. Stat. 148.171(6)]. In general, all advanced practice registered nurses in Minnesota must have a plan with one or more surgeons or physicians that have experience in providing care to patients with the same or similar medical problems; however, there is a specific exception for CRNAs in that they can provide anesthesia services with physicians, surgeons, dentists and podiatrists. In other words, the collaborating physician does not have to be an anesthesiologist.

The Minnesota language is interesting because it generally takes the approach of SB 2413 as introduced and recognizes the interpretation that some have placed on SB 2413 – that it would somehow require that only anesthesiologists can provide supervision because of the "same or similar medical problems" language that applies to prescriptive authority in our state. That is not our intent. The proposed amendments would make that absolutely clear in using the present federal language. The proposed language would not create access issues in places where there are no practicing anesthesiologists.

Again, the states are different in how state law approaches the issue. On the other end of the spectrum, in New Hampshire, there doesn't appear to be any state law that addresses supervision now that the Governor in that state has recently opted out. Nevertheless, North Dakota needs to review its own situation and do what is in the best interests of the people of our own state. An environment where supervision or collaboration is lacking is certainly not the norm across this country, and should not be the norm here in North Dakota.

North Dakota's current law standing alone does not provide clear assurances of Medicare safety in the provision of anesthesia services. No assurances exist in the statutes and rules relating to CRNA scope of practice, hospital regulations appear vague in their application to this issue, and no regulations exist at all for ambulatory surgery centers. SB 2413 as amended provides an opportunity for filling this vacuum, which would exist if the federal regulations no longer apply to our state. In fact, regardless of what the Governor decides to do with his "opt-out" authority, it is better to define our relationships as a matter of state law, so we can all move forward without the constant consideration of "opt in" and opt out."

In conclusion, we urge the Committee to amend SB 2413, and recommend a "do pass" on the bill as amended.

This is a matter of extreme importance. We believe that SB 2413 as amended provides the most reasonable approach – simply incorporating the current federal supervision requirements in order to maintain the status quo. The status quo should enjoy a presumption of safety. Any other approach, including an "opt out" without any corresponding change in state law, should only be implemented if it is shown that it would improve our current successful record of patient safety. In our view, an opt out would present a serious threat to our record of safety. That is why we asked that SB 2413 be introduced during that last minute before the bill introduction deadline when we did not have assurances that the rules would not be changed. The language of the bill as introduced is not perfect, and has resulted in varying interpretations. That is why we present the proposed amendments for you to consider.

We urge you to support the proposed amendments to SB 2413 and, as amended, to recommend a "DO PASS" on the bill.

APPENDIX A

[Code of Federal Regulations]
[Title 42, Volume 3]
[Revised as of October 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR482.52]

[Page 490-491]

TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 482--CONDITIONS OF PARTICIPATION FOR HOSPITALS--Table of Contents

Subpart D--Optional Hospital Services

Sec. 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) Standard: Organization and staffing. The organization of anesthesia services must be appropriate to the

[[Page 491]]

scope of the services offered. Anesthesia must be administered only by--

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c)of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) Standard: Delivery of services. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

(2) An intraoperative anesthesia record.

(3) With respect to inpatients, a postanesthesia followup report by the individual who administers the anesthesia that is written within 48 hours after surgery.

(4) With respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

(c) Standard: State exemption. (1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is

located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[51 FR 22042, June 17, 1986 as amended at 57 FR 33900, July 31, 1992; 66 FR 56769, Nov. 13, 2001]

[Code of Federal Regulations]
[Title 42, Volume 2]
[Revised as of October 1, 2002]
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[CITE: 42CFR416.42]

[Page 675-676]

TITLE 42--PUBLIC HEALTH

HUMAN SERVICES

PART 416--AMBULATORY SURGICAL SERVICES--Table of Contents

Subpart C--Specific Conditions for Coverage

Sec. 416.42 Condition for coverage--Surgical services.

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(a) Standard: Anesthetic risk and evaluation. A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

(b) Standard: Administration of anesthesia. Anesthetics must be administered by only--

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in Sec. 410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in

[[Page 676]]

which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

(c) Standard: Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

(d) Standard: State exemption. (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[57 FR 33899, July 31, 1992, as amended at 66 FR 56768, Nov. 13, 2001.]

[Code of Federal Regulations]
[Title 42, Volume 3]
[Revised as of October 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR485.639]

[Page 596-597]

TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 485--CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS--Table of Contents

Subpart F--Conditions of Participation: Critical Access Hospitals (CAHs)

Sec. 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) Designation of qualified practitioners. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by--

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

(b) Anesthetic risk and evaluation. (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

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(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) Administration of anesthesia. The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only--

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as

described in Secs. 413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(e) Standard: State exemption. (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[60 FR 45851, Sept. 1, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 66 FR 39938, Aug. 1, 2001; 66 FR 56769, Nov. 13, 2001]

APPENDIX B

North Dakota State Board of Medical Examiners

ROLF P. SLETTEN
Executive Secretary and Treasurer

LYNETTE LEWIS
Administrative Assistant

January 2, 2002

Honorable Governor John Hoeven
Office of the Governor
600 East Boulevard Avenue
Bismarck, ND 58505

Re: Supervision of Certified Registered Nurse Anesthetists

Dear Governor Hoeven:

Last month the federal Centers for Medicare and Medicaid Services (CMS) issued a new regulation that provides some state governors with an opportunity to determine whether nurse anesthetists must continue to work under federally mandated physician supervision when the nurse anesthetist administers anesthesia in a Medicare-approved hospital or an ambulatory surgical center. Historically the CMS regulations have required physician supervision of nurse anesthetists working in these facilities. The new regulation retains that general rule, but permits governors to opt individual facilities out of the federal supervision requirement.

The purpose of this letter is to recommend that no North Dakota facilities be opted out of the supervision requirement. Frankly we see no reason to change the status quo. The opt-out provision does not improve access to health care in any way nor does it improve patient safety.

It seems clear that while the regulations require physician supervision of a nurse anesthetist, those regulations do not require that such supervision be provided by an anesthesiologist. In those circumstances in which no anesthesiologist is present, the operating surgeon acts as the supervising physician. In other words, there is never a circumstance when there is no supervising physician available. As you know, weighing practical considerations regarding access to health care against the ideal standards of patient safety can be a very difficult and delicate task. It is our position that in almost every circumstance the patient safety considerations should be given far more weight than the practical considerations but that dilemma does not present itself here. Opting out of the supervision requirement would not improve access to health care in any way.

It seems obvious to us that patient safety cannot possibly be improved by opting out of the supervision requirement and indeed we have heard no one make that argument. In short, there seems to be no reason to disturb the status quo.

Sincerely,

Rolf P. Sletten
Executive Secretary

RPS/js

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January 13, 2002

Honorable John Hoeven
Governor of the State of North Dakota
600 East Boulevard Avenue
Bismarck, ND 58505

RE: Physician Supervision of Certified Nurse Anesthetists

Dear Governor Hoeven:

The recent ruling adopted by the Centers for Medical and Medicaid Services (CMS) of the Department of Health and Human Services allows governors to let their states "opt out" of the requirement that certified nurse anesthetists (CRNAs) be supervised by physicians. The North Dakota section of the American College of Obstetricians and Gynecologists (ACOG) opposes this ruling and feels that unsupervised CRNA practice has not been proven to provide the uniformly high quality of anesthesia care North Dakota patients enjoy at this time. Therefore, the North Dakota Section of the ACOG, at this time, urges you to not "opt out" of the requirement that North Dakota CRNAs be supervised by physicians.

The present system of the anesthesia care team involving nurse anesthetists with physician supervision has proven itself to be a very effective and safe mechanism by which the patients of North Dakota receive anesthesia for their surgical needs. This system, its safeguards and quality checks, were designed to include the physician as a vital part of the team. Their inclusion was considered imperative because of the significantly different levels of training and experience that exist between the physician and the CRNA, in addition to the fact that the physician possess the knowledge of the unique needs of the specific surgical case being done.

The reasons proposed by CRNAs around the State in support of "opting out" of physician supervision of their services are multiple, but not based on sound, supportable reasoning. Their first assertion is that patients will have easier access to surgical services. By law, surgical services requiring CRNA provision of anesthesia also require the surgery to be performed by a licensed physician. Presently the CRNA can practice under the authority of not just a physician anesthesiologist, but any licensed physician doing the surgical case. There are no situations currently or lawfully conceivable when a CRNA could

provide anesthesia for a non-licensed individual to perform surgery. A second assertion is that obstetric practice could be provided more easily in the remote parts of our state if physician supervision was not required. State law at this time requires involvement of the physician even if nurse midwives are involved. It also is not in line with the philosophy of the American College of Obstetricians and Gynecologists provision that obstetric delivery services be provided in institutions able to do emergent Caesarean section delivery within a reasonable time the decision is made to do so. Therefore, there does not appear to be a situation where standalone practicing CRNAs would benefit North Dakota as far as access of patients to obstetric services is concerned. Yet another point CRNAs use to promote "opting out" is that recruitment of needed physicians to small, remote locations in North Dakota would be easier. Provision of anesthesia could be done without liability being placed on the operating physician. In reality, the perspective of most surgeons is that the CRNAs should practice only under the authority of a licensed physician, as exemplified by the support of all fifty state medical societies, the membership of the ACOG and numerous other specialty organizations. Physicians are legally and ethically obligated to ensure that services provided to their patients are appropriate and meet acceptable standards. If CRNAs are allowed to practice alone, this time proven physician insurance of provision of quality care is not guaranteed. The proposed "release from liability" for an operating physician under the "opting out" arrangement has not been tested at this time. With the current state of societal thought placing ultimate responsibility of the case on the surgeon, many feel this "release of liability" is more CRNA perception and less reality.

The provision of Medicaid and Medicare services historically has been under the policy that CRNAs would be supervised by physicians. This has, by its own virtue, allowed states to forego creating their own standards and requirements for free standing CRNA practice and implementing a system ensuring quality performance. This function is done by measures already in place to evaluate and regulate the physician's performance as head of the anesthesia team. Uncoupling the CRNA from the physician supervised anesthesia team has not been proven to maintain the same quality of services North Dakotans have become accustomed to.

At this time the North Dakota section of ACOG feels that multiple concerns exist concerning the ability to continue providing safe, state of the art anesthesia care our patients presently enjoy if uncoupling of the CRNA from physician supervised anesthesia team occurs. Therefore we recommend at this time that the State decide to not "opt out" of the requirement that certified nurse anesthetists be supervised by physicians.

I appreciate the opportunity to share the views of the North Dakota section of the ACOG concerning this very important issue.

Sincerely,

Thomas F. Arnold, M.D., FACOG, FACS
Chair, North Dakota Section of the American College of Obstetricians and Gynecologists

TFA/sl

Wayne L. Anderson, M.D., FACS
Diplomate, American Board of Surgery
1213 15th Ave. West
Williston, ND 58801
Ph. (701)572-4003
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December 27, 2001

The Honorable John Hoeven, Governor
State of North Dakota
ND State Capitol
Bismarck, ND 58505

Dear Governor Hoeven,

I am writing to you regarding the November 2001 Medicare rule change, which might affect the future provision of anesthesia services in North Dakota. Although the new rule maintains the current requirement that a nurse anesthetist(CRNA) may administer anesthesia only under the supervision of a physician or anesthesiologist, it would also allow the governor to seek a state exemption from this requirement, after consulting with the Boards of Nursing and Medicine.

As a member of the American College of Surgeons, currently serving as our state chapter President, I am aware that the College, together with the American Society of Anesthesiologists, the American Medical Association, and dozens of other national medical specialty organizations, has expressed grave concerns for the safety of our surgical patients if physician supervision of anesthesia services would be preempted by action of a state's governor. I have visited with many of my surgical colleagues around the state, and we feel that the current physician/nurse anesthetist team approach in the provision of anesthesia services, which has worked so well for decades under the Medicare rules, is the safest for our patients.

As you know, not all surgeries in North Dakota are performed with the involvement of an anesthesiologist. Many of us work well with either anesthesiologists or CRNAs under the current team concept, and our patient safety record has been extremely positive. Patient safety has been exemplary precisely because of the professional team approach, and I am concerned that any change in this process will result in patients facing unnecessary or greater risk. We also recognize that many of the higher-risk surgical procedures are not done in our rural hospital facilities, but only in the tertiary-care centers where involvement by anesthesiologists is available and at times mandated by hospital policy. It is also evident that patient access is not at issue, since surgery may only be performed if a surgeon is available, regardless of the setting or who is providing the anesthesia services.

In summary, as a practicing surgeon I can find no reason to support any change to the current team approach in the provision of anesthesia services, and would certainly oppose a state exemption to the Medicare rule on this issue.

Sincerely,

Wayne L. Anderson, M.D., FACS
Suite 200
1213 15th Ave West
Williston, ND 58801

January 9, 2002

Honorable Governor John Hoeven
Office of the Governor
600 East Boulevard Avenue
Bismarck, ND 58505

RE: Supervision of Certified Registered
Nurse Anesthetists

Dear Governor Hoeven:

The Third District Medical Society strongly recommends that no North Dakota facilities be opted out of the supervision requirement.

The federal supervision standard represents uniform National Standard of Protection for Medicare and Medicaid beneficiaries. Opting certain facilities out of the federal requirement will result in different standards of care for patients within the state. This will establish a lower standard of care and certainly will not improve access to Anesthesia care. By definition the Operating Physician is always present; claims that "opting out" is necessary to improve access to Anesthesia care, especially in rural areas, are without merit.

We, The Third District Medical Society, are in strong support of the North Dakota Society of Anesthesiologists, The North Dakota Medical Society, The American Society of Anesthesiologists, and all other medical societies, and we are strongly urging Governor Hoeven to consider any request for an "opt-out" carefully. We strongly believe that for the best interest of the citizens of North Dakota, it is optimal to have the involvement of the Physician in their Anesthesia care.

There is a strong urge by a few people to take the fences down without thinking why those fences were put there in the first place. We see no reason to "opt-out" the supervision requirement by a Physician.

Sincerely,

Paul Jahn, M.D.
President, Third District Medical Society
Grand Forks, ND 58201

Jitendra R. Parikh, M.D.
Chairman, Department of Anesthesiology
Altru Health System
Grand Forks, ND 58201

cc North Dakota Medical Association

Physicians Dedicated to the Health of North Dakota

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Bruce Levi
Executive Director

David Peske
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Leann Tschider
Director of Membership
Office Manager

January 4, 2002

Honorable John Hoeven
Governor of the State of North Dakota
600 East Boulevard Avenue
Bismarck, ND 58505

RE: Medicare Conditions of Participation – CRNA Supervision

Dear Governor Hoeven,

The North Dakota Medical Association appreciates your efforts to seek input from the medical community about the final rule recently adopted by the federal Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services that provide you with new authority in addressing physician supervision of certified registered nurse anesthetists (CRNAs) in Medicare certified hospitals, including critical access hospitals and ambulatory surgery centers. Under that authority, the governor of a state, after consultation with that state's boards of medicine and nursing, may "opt out" of the longstanding physician supervision requirements set forth in the Medicare conditions of participation upon a finding that such action is (1) consistent with state law, and (2) in the best interests of the people of the state.

While a governor is required to consult with state boards of nursing and medicine "about issues related to access to and the quality of anesthesia services in the state," the new regulation gives you "discretion and maximum flexibility" to consult with others as you deem necessary [Federal Register, Nov. 13, 2001 (Fed Reg), p. 56764]. We appreciate the opportunity to provide the views of North Dakota's physicians. The North Dakota Medical Association is the professional membership association for active and retired physicians, residents, and medical students in North Dakota. The NDMA membership is comprised of almost 1,100 members who represent all medical specialties and all practice settings. The mission of the Association is to promote the health and well-being of the citizens of North Dakota and to provide leadership to the medical community.

The Association is deeply concerned that CRNAs in North Dakota are actively encouraging you to exercise your opt-out authority. Our knowledge of the nature of their request is based on a form letter and "fact sheet" that has been provided by CRNAs to many physicians in the state. Several physicians provided those materials to us, in expressing concerns about the CRNA effort.

North Dakota physicians are subject to various ethical obligations – ***when practicing in concert with allied health professionals such as CRNAs, physicians are obligated to ensure that those professionals are appropriately trained to perform the activities requested, and owe an ethical duty to their patients***

to ensure that medical and surgical conditions are appropriately evaluated and treated. *See* American Medical Association Code of Professional Ethics, Opinion 3.03 (2000-01 Edition). While there appears to be an inordinate focus by CRNAs on the "perceived liability" issues associated with an opt out and the implications of legal liability to physician recruitment and hospital administrative "flexibility," physicians view their ethical obligations to patients as the paramount consideration. This view is similar to the standard used in the opt-out mechanism – *what is in the best interests of the people of North Dakota?* The standard is not what is in the best professional interests of CRNAs or physicians, or the best institutional interests of hospitals, professional boards or other health care facilities.

On December 19, 2001, the Board of Directors (Council) of the North Dakota Medical Association discussed this issue at length, and unanimously agreed that an "opt out" in North Dakota at this time would have serious implications for our state's longstanding record of successful outcomes under the anesthesia care team approach. The Board also expressed concerns for the safety of surgical patients, and the absence of clarity in North Dakota statutes to govern the practice of CRNAs if the minimal standards of quality and safety provided in the Medicare conditions of participation are removed. Underlying all their discussion is uncertainty over what an opt out would accomplish – how would quality of care or patient safety be improved for North Dakota patients?

I. ***North Dakota's laws and regulations were developed under the assumption that the Medicare physician supervision requirement would continue. The federal standards have provided an essential balance in North Dakota between legitimate practice by CRNAs and appropriate medical direction and oversight of CRNA practice. Any consideration for an opt out should be preceded by a comprehensive review of North Dakota statutes and rules to identify the implications of removing the regulatory assurances that now are afforded by the federal supervision standards, and determine whether further state protections should be implemented.***

One impetus for CMS' abandonment of the effort to entirely eliminate all physician supervision requirements in favor of a discretionary "opt-out" mechanism concerned states' reliance on the Medicare requirements in establishing state scope of practice laws and monitoring practices:

> In some cases, State laws and regulations may have been written with the assumption that Medicare would continue its longstanding policy requiring physician supervision of the anesthesia care provided by CRNAs. Eliminating Medicare requirements now could change supervision practices in some States without allowing States to consider their individual situations. In the absence of Federal regulations, we were concerned that States might have promulgated different laws or different monitoring practices. CMS Comments, Fed Reg, p. 56762.

The federal CRNA supervision requirements have long existed and have not been a deterrent to effective CRNA practice in North Dakota. In fact, the standards have provided an essential balance between legitimate practice by CRNAs and appropriate medical direction and oversight of CRNA practice. Consideration of an opt-out, thereby relying solely on North Dakota law, should include a review of North Dakota statutes and rules to identify state regulatory assurances, or a lack thereof, that now are afforded by the federal supervision standards.

Current medical hospital licensure laws [ND Admin. Code 33-07-01.1-32] address anesthesia services, but do not provide clear assurances. On one hand, the rules provide that a hospital's anesthesia service must be under the direction of a qualified physician who is a member of the medical staff [ND Admin. Code 33-07-01.1-32(1)(a)]. Additionally, the rules require that hospital anesthesia departments establish policies, procedures, rules and regulations regarding personnel permitted to administer anesthesia. *See id.* at (d). On the other hand, while anesthesia services may only be initiated when ordered by a member of the medical staff, the term "medical staff" appears to be defined broadly. *See* ND Admin. Code 33-07-01.1-01(4)(j). Ambulatory surgery centers are not licensed and, as such, the Medicare conditions of participation are critical to assuring that these facilities meet minimal standards of quality and safety.

In addition, consideration of the CMS rule raises new interpretation issues with respect to North Dakota law that may not have been previously considered in light of the federal supervision requirement. A reasonable interpretation of North Dakota law is that CRNAs are not specifically empowered by statute to select and administer anesthesia. Inasmuch as a CRNA is "assessing the need for drugs," the CRNA may be required to first apply to the Board of Nursing for general prescriptive authority in collaboration with a physician [*see* NDCC 43-12.1-02(6); 43-12.1-08(6)(b)]. If a CRNA applies for general prescriptive authority, the scope of that authority must be appropriately related to the collaborating physician's medical specialty or practice [*see* ND Admin. Code 54-05-03.1-09(6)].

While Iowa's Governor Thomas Vilsack recently elected to opt out on a "fast-track" basis, each state's law must be analyzed independently to determine whether an opt out is consistent with state law and in the best interests of the people of the state. Iowa law requires physician collaboration and consultation for <u>all</u> CRNAs [Ia. Admin. Code r. 655-7.1]. Iowa's Governor chose to opt out in the face of strong concerns expressed by the Iowa Medical Society and the Iowa Board of Medical Examiners that basic facts were unknown and that remaining state regulation was inadequate, and indications of strong public sentiment against the opt out.

Standing alone, North Dakota's laws relating to CRNA practice may not provide assurances for minimal quality and safety in light of the states' longstanding reliance on the federal supervision requirements. If you do, in fact, intend to consider this issue further, the Association encourages you to first undertake a comprehensive review of North Dakota statutes and rules to identify the implications of removing the regulatory assurances that now are afforded by the federal supervision standards, and determine whether further state protections should be implemented.

II. Since it is impossible to definitively document outcomes related to independent CRNA practice, the final rule promulgated by CMS includes provision for a study on anesthesia outcomes. There is no compelling reason to opt out and place North Dakota patients at potential risk prior to the completion of that study.

In the "fact sheet" being circulated by CRNAs around the state, it is asserted that an "opt out" would not impact quality of care or patient safety. Even the CMS in its comments to the final rule noted that although the anesthesia-related death rate is extremely low, "it is impossible to definitively document outcomes related to independent CRNA practice [Fed Reg, p. 56762-3]." In that light, the Agency for Healthcare Research and Quality (AHRQ) will "conduct a study of

anesthesia outcomes in those states that choose to opt out of the CRNA supervision requirement compared to those states that have not [*Id.* at p. 56763]."

If the results of other studies are indicative of what the AHRQ study may find [*see, e.g.*, Silber *et al, Anesthesiologist Direction and Patient Outcomes*, Anesthesiology, July 2000 [Surgical outcomes in Medicare patients are associated with anesthesiologist direction – both 30-day mortality rate and mortality rate after complications (failure-to-rescue) were lower when anesthesiologists directed anesthesia care]], the assertion that an "opt out" would not impact quality of care or patient safety is clearly speculative. North Dakota patients should not be placed at potential risk while the federal study proceeds. The best interests of North Dakota people are met by waiting until the AHRQ completes its study, and deferring consideration of an opt out until that time.

III. No compelling reason exists to move away from an approach to anesthesia care that has produced successful outcomes for North Dakota patients.

Our state's longstanding record of successful outcomes under the anesthesia care team approach has served North Dakota patients well. Even the Institute of Medicine's 1999 call for professional societies and groups to demonstrate a visible commitment to reducing errors in health care included, as a "notable exception," the work done by anesthesiologists to improve safety and outcomes for patients:

> "Anesthesiology has successfully reduced anesthesia mortality rates from two deaths per 10,000 anesthetics administered to one death per 200,000—300,000 anesthetics administered … . This success was accomplished through a combination of:
> - technological changes (new monitoring equipment, standardization of existing equipment);
> - information-based strategies, including the development and adoption of guidelines and standards;
> - application of human factors to improve performance, such as the use of simulators for training;
> - formation of the Anesthesia Patient Safety Foundation to bring together stakeholders from different disciplines (physicians, nurses, manufacturers) to create a focus for action; and
> - having a leader who could serve as a champion for the cause." Institute of Medicine, *To Err Is Human: Building a Safer Health System*, National Academy Press 1999, pp. 124-25.

These improvements in anesthesia care were developed in the context of the federal physician supervision requirements. There is no compelling reason to now retreat from an approach that has produced a longstanding record of successful outcomes in North Dakota under the anesthesia care team approach.

The "if it ain't broke, don't fix it" adage we hear each session of the Legislative Assembly aptly applies here. Until the study of anesthesia outcomes is performed by AHRQ and if the results provide such a compelling reason, perhaps then consideration would be timely. Again, until such time, North Dakota patients should not be placed at potential risk by removal of physician supervision over anesthesia care. North Dakota should not be held to a <u>presumption of safety without scientific proof</u> – in light of the overall improvement of anesthesia safety over the past several years during which physician supervision has been required.

IV. "Perceived liability" assertions detract from the real issue of quality of care and patient safety.

The bald assertion by CRNAs that an opt out will eliminate any perceived liability of the supervising physician and thereby facilitate physician recruitment and retention is simply another speculative statement that has little relevance to the best interests standard to be used in determining whether to opt out. Nevertheless, issues relating to the shifting of legal liability are complex, and should be carefully examined as part of your review of North Dakota law.

V. An opt out will not improve <u>access</u> to health care.

The long-standing federal standard requires supervision of a nurse anesthetist by a physician, meaning that if a physician anesthesiologist is not available to supervise, the operating physician is permitted to do so. Because by definition the operating physician is always present, claims that opting out is necessary to improve access to anesthesia care, especially in rural areas, are simply without merit.

VI. There is a clear consensus in Medicine that removal of the physician supervision requirement should not occur until scientific proof of safety exists.

For many years, medicine in this country through national specialty societies and state medical societies has supported retaining the Medicare physician supervision requirement in the interest of patient safety, and has actively opposed federal efforts since 1997 to eliminate the requirement. One of the latest efforts occurred in February 2001 when medicine expressed concern to Secretary Tommy Thompson of the Department of Health and Human Services regarding the need for an alternative to the Clinton Administration's effort to eliminate physician supervision:

> "We support the position of the American Society of Anesthesiologists and Anesthesia Patient Safety Foundation that revision of the pre-existing physician supervision requirement should be considered only after development and review of current scientific outcomes data. *We are deeply troubled by the position of the Clinton Administration, set forth in the preamble to the final rule, that the elimination of physician supervision can be presumed to be safe – without scientific proof – in light of the overall improvement of anesthesia safety over the past several years during which physician supervision has been required. We believe Medicare and Medicaid beneficiaries deserve better than a mere presumption of safety that has no basis in the scientific literature.*"

In addition to being signed by all 50 state medical societies, including the District of Columbia and Puerto Rico, the letter was signed by over thirty national specialty societies, including the American Academy of Family Physicians, American Academy of Ophthalmology, American Academy of Orthopaedic Surgeons, American Association for Thoracic Surgery, American Association of Neurological Surgeons, American College of Cardiology, American College of Emergency Physicians, American College of Obstetricians and Gynecologists, American College of Physicians – American Society of Internal Medicine, American College of Surgeons, American Medical Association, American Psychiatric Association, American Society of General Surgeons, and Congress of Neurological Surgeons.

The American Medical Association last month adopted policy reaffirming this consensus, and urged state medical societies to inform all state Governors and regulatory agencies of AMA's policy position which requires physician supervision for CNRAs for anesthesia services in Medicare participating hospitals, ambulatory surgery centers, and critical access hospitals.

Governor, thank you for this opportunity. If you intend to consider this issue further, we encourage you to seek further advice and input from North Dakota's physicians.

Sincerely,

Bruce Levi

Bruce Levi, JD
Executive Director
North Dakota Medical Association

Physicians Dedicated to the Health of North Dakota

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December 19, 2002

Duane Houdek
Office of Governor
600 East Boulevard Avenue
Bismarck, ND 58505

Dear Duane,

Thank you for our conversation yesterday with Rolf Sletten, Chip Thomas, and Dr. Scott Klein regarding the ramifications of the CRNA opt-out issue.

You requested that I determine to what extent the Governors of other states (other than the current six opt-out states) have considered the opt out issue. According to the American Society of Anesthesiologists, the Governors of Texas and Missouri have, after considering the issue, said they are not going to opt out. The issue pends (that is, a Governor has sought advice) in Arkansas, Kansas, Kentucky, Oregon, Montana, Washington, and Wisconsin. With the exception of Montana; no further opt outs appear imminent among these other states; I understand that many of these Governors have put the issue on the back burner.

As suggested in our letter of January 4, 2002, as supplemented by the information we provided yesterday about the underlying state framework in the current six opt-out states, we believe Governor Hoeven should seek a broad spectrum of advice on whether state law is adequate to protect the public in the event an opt out occurs, and seek advice from the public, senior and consumer groups. As there are differing rules for hospitals, ambulatory surgery centers and critical access hospitals, the Governor should consider whether state standards are appropriate to each kind of facility. I also urge you to consult with the State Health Officer on this issue, particularly in light of the strong opposition expressed by the North Dakota Board of Medical Examiners and physician groups. In addition, the poll results we shared with you yesterday show that North Dakota people are greatly concerned about this issue, which ought to bear on consideration of whether an opt out is in the best interests of North Dakota people. As discussed, our concern is that high-risk anesthesia procedures not be performed by non-physician personnel functioning without the supervision of a medically-trained physician.

I appreciate your willingness to sit down and speak candidly about this issue. Please call if there is anything else we can do.

Sincerely,

Bruce

Bruce Levi

cc Rolf Sletten, Joanne Pearson, MD, ND Board of Medical Examiners
Arnold Thomas, ND Healthcare Association
Scott Klein, MD, President, ND Society of Anesthesiologists
Wayne Anderson, MD, American College of Surgeons, ND Chapter
North Dakota Medical Association Councillors and Officers

January 10, 2002

Honorable John Hoeven, Governor
State of North Dakota
600 E. Blvd. Ave.
Bismarck, ND 58505

Re: Supervision of CRNA's.

Dear Governor Hoeven:

This last month the Federal Centers for Medicare and Medicaid Services (CMS) issued a new regulation that allows state governors the opportunity to determine whether nurse anesthetists must continue to work under physician's supervision when the nurse anesthetist administers anesthesia in a Medicare approved hospital or ambulatory care surgery center. My understanding is that there has been an effort on behalf of CRNA's within the State of North Dakota to petition your office to allow the CRNA's in North Dakota to opt out of the supervision requirement.

As my understanding of the CRNA's argument for opting out of this supervision requirement, is the ability to provide North Dakota healthcare facilities with greater flexibility and to allow surgical and trauma stabilization care and access to pain relief during childbirth, to some of the rural areas within North Dakota. As the President of the Tenth District North Dakota Medical Association, which is made up entirely of rural hospitals in eastern North Dakota, I can assure you that having the CRNA's opt out of this supervision requirement will in no way change the access to healthcare. In all instances there is a supervising physician available that has been made available for consultation and any supervision needs. I do not believe that opting out of the supervision requirement would improve access to healthcare in any way. I believe that we are currently operating under a situation that has worked reasonably well given our rural environment and difficulties with health care access. I do not believe that changing the status quo would in any help. I am urging and recommending that you decide no change is necessary and that you do not exercise your authority to exempt North Dakota from the current Medicare supervision rules.

Thank you for the time spent in reviewing this issue and our concerns.

Sincerely,

Tim Luithle, MD
President, Tenth District North Dakota Medical Association

APPENDIX C

THE TARRANCE GROUP

EXECUTIVE SUMMARY

April 12, 2002

To: **American Society of Anesthesiologists**
From: **Brian Tringali, William Stewart and Brian Nienaber**
Subject: **Key findings from a survey of North Dakota adults regarding anesthesia services** [1]

- **An overwhelming majority (67%) of the North Dakota adult population would oppose an action by their governor to waive the current anesthesia supervision requirement in Medicare-approved hospitals.** The waiver option gives a governor the authority to allow nurse anesthetists to administer anesthesia in all cases without the supervision of a medical doctor.

- The percentage of people who oppose waiving the current supervision requirement stands at 55% or higher among every major demographic group, including both senior citizens (71% oppose) as well as young adults (63% oppose). Additionally, almost half of the entire North Dakota adult population indicates that it "strongly opposes" waiving the current supervision requirement (49%).

- In contrast, only 24% of North Dakota adults are in favor of waiving the current supervision requirement, while another 10% say they are unsure.

- Respondents who support waiving the current supervision requirement were informed that supervision normally does not cost the patient extra money. After this information was presented, opposition to waiving the supervision requirement climbs to 72%.

- All respondents were asked if they would be more likely or less likely to vote for Governor Hoeven if he decided to waive the supervision requirement. Nearly half (48%) of all "likely" voters statewide say they would be less likely to vote for the governor if he supported a waiver, while only 16% say they would be more likely to vote for him. One-in-four "likely" voters (25%) indicate that this issue has no impact on their voting decision.

- This survey also finds that three-in-four North Dakota adults (75%) have received general anesthesia in their lifetime. Among this subgroup, a vast majority (80%) indicates that they are either "extremely" satisfied or "very" satisfied with the quality of anesthesia care that they had received in the past.

- *The bottom line...* The results of this survey demonstrate that a strong majority of North Dakota adults are opposed to waiving the current supervision requirement in their state.

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[1] *These findings are drawn from telephone interviews with N=502 adults aged 18 and older throughout the state of North Dakota. The confidence interval associated with a sample of this type is ± 4.1%. Responses to this survey were gathered April 10-11, 2002.*

APPENDIX D

Six "Opt-Out" States – Summary of Laws

◆ ***Minnesota (MN)***

- Nurse anesthetists are recognized as advanced practice registered nurses (APRNs). *See* MINN. STAT. §148.171(3) (1999). The practice of advanced practice registered nursing "includes functioning as a direct care provider, case manager, consultant, educator, and researcher [and] ... also includes accepting referrals from, *consulting with, cooperating with*, or referring to all other types of health care providers, including but not limited to physicians, chiropractors, podiatrists, and dentists, provided that the advanced practice registered nurse and the other provider are practicing within their scopes of practice as defined in state law. The [APRN] *must* practice within a health care system that provides for *consultation, collaborative management*, and referral." *See* MINN. STAT. §148.171(13).

  Collaborative management is defined as "a mutually agreed upon plan between an [APRN] and one or more physicians or surgeons ... that designates the scope of collaboration necessary to manage the care of patients .... [CRNAs] may continue to provide anesthesia *in collaboration with physicians*, including surgeons, podiatrists licensed under chapter 153, and dentists ... [CRNAs] *must* provide anesthesia services *at the same hospital, clinic, or health care setting as the physician*, surgeon, podiatrist, or dentist." *See* MINN. STAT. §148.171(6).

  Registered nurse anesthetist practice is defined as "the provision of anesthesia care and related services *within the context of collaborative management*, including selecting, obtaining, and administering drugs and therapeutic devices to facilitate diagnostic, therapeutic, and surgical procedures *upon request, assignment, or referral by a patient's physician*, dentist, or podiatrist." *See* MINN. STAT. §148.171(21).

- In hospitals, anesthesia must be administered by "a person adequately trained and competent in anesthesia administration, or under the close supervision of a physician." MINN. REG. 4640.2500.1 (1998). Under the law setting out scope of practice, physician supervision is apparently not required for nurse anesthetists.

- Minnesota law regulates ambulatory surgical centers, but does not address the administration of anesthesia in ASCs

- CRNAs may prescribe and administer drugs and therapeutic devices within the scope of a *written agreement with a physician* and within practice as a CRNA. *See* MINN. STAT. §148.235(2a). "Within practice as a CRNA" is not specifically defined, but presumably has the meaning set out in Section 148.171 *See* §148.171(21) (defining registered nurse anesthetist practice). CRNAs with prescriptive authority can also dispense drugs subject to the same requirements established for the prescribing of drugs. The dispensing authority is limited to those drugs described in the *written agreement* and includes the authority to receive and dispense sample drugs. *See* MINN. STAT. §148.235(4b).

◆ ***Iowa (IA)***

- Under Board rule 1, a "certified registered nurse anesthetist" is "an [advanced registered nurse practitioner [ARNP]] educated in the disciplines of nursing and anesthesia who possesses evidence of current certification by a national professional nursing association approved by the board." IOWA ADMIN. CODE r. 655-6.1 (1999); IOWA CODE ANN. § 152.1(6)(d) (1997) (granting Board authority to recognize specialties within practice of registered nurse). The practice of "advanced nursing" occurs "within an interdisciplinary health care team which provide[s] for *consultation, collaborative management, or referral.*" Rule 655-7.1. "Collaboration" is "the process whereby an ARNP and physician jointly manage the care of a client." *Id.*

  Also, as an ARNP, the CRNA is subject to the general requirement that selected *medically delegated functions* be performed only in connection with a collaborative practice agreement. *See id.* A "*collaborative practice agreement*" means "an ARNP and physician practicing together within the framework of their respective professional scopes of practice," "reflects independent and cooperative decision making," and "is based on the preparation and ability of each practitioner." *Id.*

- In a hospital, anesthesia services shall be provided "under the direction of a qualified doctor of medicine or osteopathy." IOWA ADMIN. CODE r. 481-51.28(1)(b)(1).
- Iowa law regulates ambulatory surgical centers, but does not address the administration of anesthesia in ASCs
- ARNPs may prescribe substances or devices, apparently as an automatic feature of being an ARNP. *See* IOWA CODE ANN. § 147.107.9. Rules of the Nursing Board define this prescriptive authority as "the authority granted to an ARNP registered in Iowa in a recognized nursing specialty to prescribe, deliver, distribute, or dispense prescription drugs, devices, and medical gases when the nurse is engaged in the practice of that nursing specialty." IOWA ADMIN. CODE r. 655-7.1. To extend the authority to controlled substances, proper registration is necessary. *See id.* and r. 657-10.2. Nurses in noninstitutional settings must regularly consult with a licensed physician regarding the utilization of controlled substances. Rule 655-7.1 (defining "consultation"). The authority of registered nurses is referenced in the pharmacy provisions of the Iowa Code. IOWA CODE ANN. § 147.107(9) (1996).

◆ ***Idaho (ID)***

- Registered nurse anesthetists [RNAs] are classified as "advanced practice professional nurses." *See* IDAHO CODE § 54-1402(1) (1999); IDAHO ADMIN. CODE §§ 23.01.01.290 (1999) (rules of the Board of Nursing); § 23.01.01.310.04 (title protection). The practice of the advanced practice professional nurse "may include acts of diagnosis and treatment, and the prescribing, administering and dispensing of therapeutic pharmacologic and non-pharmacologic agents." IDAHO ADMIN. CODE. § 23.01.01.271.02. Specifically, an RNA is "a licensed professional nurse who has graduated from a nationally accredited nurse anesthesia program, passed a qualifying examination recognized by the board and, has current initial certification or current recertification ... from a national organization recognized by the board." § 23.01.01.271.14. *See also* IDAHO ADMIN. CODE § 23.01.01.285.04(c) (specifying that RNA candidates must have passed the certification examination of the AANA and maintain current certification with the appropriate AANA council); §§ 23.01.01.320.01 (recognizing the Councils on Certification and Recertification); 23.01.01.320.05 (specifying criteria for recognition of national certifying agencies).

  Licensed RNAs may "in *collaboration with a physician, dentist or podiatrist* authorized to practice in Idaho, provide anesthesia care services as defined by rules of the [Board of Nursing.]" IDAHO CODE § 54-1402(1)(d). By statute, "the scope of practice for [RNAs] shall incorporate acts identified in board rules, including *selecting, ordering, and administering medications appropriate for rendering anesthesia care services.*" *Id.* Collaboration means "the cooperative working relationship with another health care provider, each contributing his respective expertise in the provision of patient care, and such collaborative practice includes the discussion of patient treatment and cooperation in the management and delivery of health care." IDAHO ADMIN. CODE § 23.01.01.271.07.

- In "hospitals," as defined in Title 39 of the IDAHO CODE, anesthesia services "shall be under the *overall direction of a physician.*" *See* § 16.03.14.390.02. Also, the medical staff or appropriate committee must approve the granting of anesthesia privileges to any person. *See* § 16.03.14.390.02. However, nurse anesthetists are authorized to do many things, including performing the preanesthesia physical examination, *see* §16.03.14.390.01(b) (although the preoperative diagnosis of a physician must be reflected in patient's records), and general anesthetics, *see* § 16.03.14.390.02(a).

- Idaho law regulates ambulatory surgical centers, but does not address the administration of anesthesia in ASCs.

- Advanced nursing practice may include "the prescribing, administering and dispensing of therapeutic pharmacologic agents, as defined by board rules." IDAHO CODE § 54-1402(1). *See also* IDAHO ADMIN. CODE § 23.01.01.280.06. RNAs may apply for the authority to prescribe and dispense pharmacologic and non-pharmacologic agents. *See* IDAHO ADMIN. CODE § 23.01.01.315.01. Pharmacologic agents "include legend and Schedule II through V controlled substances." *See* IDAHO ADMIN. CODE § 23.01.01.271.12.

◆ ***Nebraska (NE)***

- CRNAs, also called nurse practitioner-anesthetists (NEB. REV. STAT. § 71-1729(1) (1999)), are treated as "advanced practice registered nurses [APRNs]" under the relevant statutes. *See, e.g.*, NEB. REV. STAT. § 71-1103 (15) (stating that nurse anesthetists practicing under and in accordance with the Advanced Practice Registered Nurse Act are not engaged in the unauthorized practice of medicine). However, as of the 1997 version of its APRN rules, which is the current version, the Board of Nursing has not listed the AANA certification council as a recognized certifying body. *See* NEB. ADMIN. R. & REGS. 172-100-002.04. The qualifications and scope of practice of CRNAs are treated at NEB. REV. STAT. §§ 71-1729 to 71-1737.

  The scope of practice for CRNAs is broad, but subject to a requirement of *collaboration and consultation*: "The determination and administration of total anesthesia care shall be performed by the CRNA or a nurse anesthetist temporarily certified pursuant to 71-1731 *in consultation and collaboration with and with the consent of* the licensed practitioner." NEB. REV. STAT. § 71-1734(1). "Consultation" and "collaboration," are defined in the Advanced Registered Nurse Practitioner's Act. "Consultation" means "a process whereby an advanced registered nurse practitioner seeks the advice or opinion of a physician or another health care practitioner." NEB. REV. STAT. § 71-1709.02. "Collaboration" means "a process and relationship in which an advanced registered nurse practitioner shall, together with other health professionals, deliver health care within the scope of authority of the various clinical specialty practices." § 71-1716.

  The practice of anesthesia for the CRNA means "the performance of or the assistance in any act involving the determination, preparation, administration, or monitoring of any drug used to render an individual insensitive to pain for procedures requiring the presence of persons educated in the administration of anesthetics or the performance of any act commonly the responsibility of educated anesthesia personnel." NEB. REV. STAT. § 71-1729(3). Specifically included within the scope of practice are such functions as conducting the preanesthetic evaluation; selection and application of appropriate monitoring devices; selection and administration of anesthetic techniques; and evaluation and direction of proper postanesthesia management and dismissal from postanesthesia care. *See* § 71-1734(2). Through written policies, the governing board of a hospital, acting jointly with the medical staff and nurse anesthetist personnel, may include in the CRNA's scope of practice duties that are normally considered medically delegated duties. *See id.* § (3).

- In hospitals, "[a]nesthesia services shall be directed on a full-time, part-time or consulting basis by physician, preferably an anesthesiologist, licensed to practice medicine who is a member of the medical staff of the hospital. The qualifications of all personnel in the anesthesia service shall be reviewed by the director. . . ." Regulations and Standards for Hospitals, Title 175, Ch. 9, § 003.03J1.

- Nebraska law regulates ASCs, but does not address the administration of anesthesia in ASCs.

- The regulations do not expressly grant CRNAs authority to order anesthetics, and they are not granted general prescriptive authority. However, APRNs by statute have authority to prescribe therapeutic measures and medications, including controlled substances, related to health conditions within their scope of practice. *See* NEB. REV. STAT. § 71-1721(3). Schedule II controlled substances may be prescribed for pain control for a maximum of 72 hours. *See id.* As pointed out in a 1997 Attorney General opinion, however, the Department of Health and Human Services does not list APRNs among those persons who may obtain controlled substances registration. *See* 1997 Op. Atty. Gnrl. 34. "[A]pplicants for a Nebraska Controlled Substances Registration must ... [h]ave a current Nebraska license or permit in one of the following categories; pharmacy or pharmacist, hospital, medicine and surgery, osteopathic medicine and

surgery, dentistry, podiatry, optometry, and veterinary medicine." See Neb. Admin. R. & Regs. 172-129-003.01B.

- The State Board of Nursing has apparently interpreted the relevant sections pertaining to CRNA scope of practice as authorizing a CRNA to select, order and administer anesthetics (and related controlled substances) preoperatively, intraoperatively and postoperatively.

◆ <u>New Mexico (NM)</u>

- CRNAs are registered nurses licensed to engage in "advanced practice," beyond the ordinary scope of practice of the registered nurse, by virtue of their education and certification by the AANA. *See* N.M. STAT. ANN. § 61-3-3(A) and (D) (2001); § 61-3-23.3 (requirements for CRNA licensure); N.M. ADMIN. CODE tit. 16, § 12.2.14 (2002) (discussing CRNA practice). Among nurses, only properly licensed CRNAs may deliver anesthesia care. *See* STAT. § 61-3-6. CRNAs "may provide pre-operative, intra-operative and post-operative anesthesia care" in accordance with AANA guidelines. STAT. § 61-3-23.3(B); N.M. ADMIN. CODE tit. 16, § 12.2.14 (O)(1) (2002). CRNAs function "in an interdependent role as a member of the health care team in which the medical care of the patient is directed by a licensed physician, osteopathic physician, dentist or podiatrist." STAT. § 61-3-23.3(C). CRNAs must "*collaborate with the licensed physician*, osteopathic physician, dentist or podiatrist." *Id.* "Collaboration" is defined as the process by which each health care provider contributes his respective expertise. *Id.* Collaboration also "includes systematic formal planning and evaluation between the health care professionals involved in the collaborative practice arrangement." *Id.*

- In hospitals, "anesthesia must be administered only by a licensed practitioner permitted by the state to administer anesthetics." N.M. ADMIN. CODE tit. 7, § 7.2.33(C)(1)(c). Further, "if a general or regional anesthetic is used and an MD or DO is not a member of the operating team, an MD or DO shall be immediately available on the hospital premises." *Id.* at § 7.2.33(C)(1)(d). A health care facility may adopt policies relating to the provision of anesthesia care. N.M. STAT. ANN. §61-3-23.3(F).

- In ASCs, a nurse anesthetist may administer anesthesia, but only *under the supervision of the operating physician* N.M. ADMIN. CODE tit. 7, § 11.2.70.4.2 (2001).

- CRNAs have prescriptive authority if they have fulfilled the requirements for prescriptive authority in the area of anesthesia practice. *See* N.M. STAT. ANN. § 61-3-23.3(D & E). CRNAs, who have fulfilled the such requirements, are authorized to prescribe and administer therapeutic measures, including dangerous drugs and controlled substances included in Schedules II through V of the Controlled Substances Act within the emergency procedures, perioperative care or perinatal care environments and may prescribe such drugs in accordance with rules, regulations, and guidelines. *Id* The Board of Nursing and Medicine must "adopt rules concerning a prescriptive authority formulary for certified registered nurse anesthetists that shall be based on the scope of practice of certified registered nurse anesthetists." *Id.* CRNAs "who prescribe shall do so in accordance with the prescriptive authority formulary." *Id.*

- ***New Hampshire (NH)***
  - CRNAs are advanced registered nurse practitioners [ARNPs]. *See* N.H. CODE ADMIN. R. NURSE, § 304.05; N.H. REV. STAT. ANN. § 326-B:10 (1999) (requirements for ARNP certification). ARNPs are recognized as qualified to perform certain functions independently, such as performing physical examinations, implementing and managing treatment regimens, and prescribing pharmacological agents for identified health problems. *See id.* (b). CRNAs are authorized to perform additional functions, including to prescribe preanesthetic and perianesthetic, diagnostic, therapeutic, pharmacologic or anesthetic agents; initiate and manage regional and general anesthesia, including induction, intubation, maintenance, fluid support, and emergence; perform corrective action based on patient response and appropriate consultation; and evaluate and release patients from post-anesthetic care. *See id.* (e).
  - In ASCs, qualified anesthesia personnel, who include a nurse anesthetist, must administer all anesthetics. *See* N.H. CODE ADMIN. R., HE-P 812.03 § (f) & (h); HE-P 812.01(w) (defining qualified anesthesia personnel as a certified registered nurse anesthetist). Qualified anesthesia personnel must be on the premises during the post anesthetic recovery period until the patient is alert and has been approved for discharge by the physician. *Id.* Qualified anesthesia personnel must also be present in the room throughout the administration and conduct of all general anesthetics, regional anesthetics and monitored anesthesia and must evaluate the patient oxygenation, ventilation, circulation and temperature. *Id.*
  - An ARNP has plenary authority to possess, compound, prescribe, administer, dispense and distribute controlled and noncontrolled drugs from an official formulary distributed yearly to each licensed ARNP in the state. *See* N.H. REV. STAT. ANN. § 326-B:10 (II) (1999); N.H. CODE ADMIN. R. Nurse, § 326-B:10. The formulary is promulgated by the "Joint Health Council" which consists of members designated by the boards of nursing, medicine, and pharmacy and whose primary charge is to add to or alter the list of controlled and noncontrolled substances on the ARNP formulary. *See* N.H. REV. STAT. ANN. § 326-B:10-a. According to the most recent formulary, CRNAs are authorized to prescribe all anesthetics without exclusions. *See* 1999 General Formulary, *available at* http://www.state.nh.us/nursing/genform1299.html (stating that CRNAs' prescriptive authority as to anesthetics is "all routes, all drugs."). Other ARNPs have authority only to provide local anesthesia. ARNPs are specifically exempted from the provisions of statutes governing pharmacies. *See* N.H. REV. STAT. ANN. § 318:42(II).

NORTH DAKOTA BOARD OF NURSING

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HUMAN SERVICES COMMITTEE

TESTIMONY RELATED TO SB 2413

Chairperson Lee and members of the Human Services Committee, my name is Dr. Constance Kalanek, Executive Director of the North Dakota Board of Nursing.

On behalf of the board, I wish to offer testimony in opposition to SB 2413 relating to the proposed revisions to the Nurse Practices Act 43-12.1.-08. Board of Nursing members voted unanimously to oppose this legislation.

The North Dakota Board of Nursing recognizes the significant nature of this proposed legislation and it is not our intent to fracture our working relationship with the Board of Medical Examiners and the North Dakota Medical Association. The Board of Nursing values the collaborative relationship it has developed with the those organizations over the past several years and is severally disappointed that a change of this magnitude is offered via legislative means without consultation with the Board of Nursing.

The North Dakota Board of Nursing comes before you today because we believe in establishing good public policy that is consistent with our mission set forth by this legislature. In fact, it is interesting to note that 26 years ago, in 1977, the North Dakota Legislature was very visionary when it enacted legislation that recognized the performance of additional acts to be performed by registered nurses practicing in expanded roles and gave the board of nursing the power to set standards for nurses practicing in specialized roles.

When you passed the legislation in 1977 you affirmed that anesthesia was within the scope of nursing practice. For the past 26 years, nurse anesthetists have proven that they are competent providers of anesthesia.

The Board of Nursing believes that anesthesia practice is not exclusive to medicine. Instead, anesthesia practice is an "overlapping" or shared scope of practice between nursing and medicine. Overlapping scopes of practice do not imply hierarchical relationships. On the contrary, overlapping scopes of practice means

that each provider is educated and competent to perform the same prescribed functions.

In 1995 and in 1998 you may recall receiving a document form the PEW Health Professions Commission entitled Reforming Health Care Workforce Regulation or Strengthening Consumer Protection. This Commission was not comprised of individuals interested in protecting their professional turf. The PEW Commission Task Force was composed of health policy analysts and consumers who strongly affirmed the need to reform health care workforce regulations.

One of the 10 recommendations encourages states to base practice acts on demonstrated competency and to allow and expect different professions to share overlapping scopes of practice. The PEW commission suggests that states eliminate exclusive scopes of practice which unnecessarily restrict other professions from providing competent, effective and accessible care.

The PEW Report concluded that "a regulatory system that maintains its priority of quality care, while eliminating irrational monopolies and restrictive scopes of practice would not only allow practitioners to offer the health services they are competent to deliver, but would be more flexible, efficient, and effective".

The effect of SB 2413 does just the opposite. It restricts practice of the nurse anesthetist in this very rural state. North Dakota currently licenses only 217 CRNAs. Of that number, 70 have an out of state address and enter the state periodically to provide locum tenens services or part-time services to the rural and urban communities. Many provide services in North Dakota, Minnesota, Montana, and South Dakota.

The question that legislators will need to answer today is whether supervision of nurse anesthetists by physicians through the mandate of a collaborative agreement is necessary to protect the public or does it only serve to protect the established medical profession? This legislation is intended to restrict the practice of anesthesia services in this state. CRNAs have compiled an enviable safety record. No studies to date that have addressed anesthesia care outcomes have found that there is a significant difference in patient outcomes based on whether the anesthesia provider is a CRNA or an anesthesiologist.

In summary, the North Dakota Board of Nursing will continue to critically evaluate the implication this change in regulation of advanced practice nursing would make for the citizens of ND. CRNAs provide superb anesthesia care. The studies on their services demonstrates overwhelming that anesthesia care is very safe, regardless of whether the care is given by a CRNA or anesthesiologist. In addition, malpractice insurance premiums (as shown by St. Paul Fire and Marine

Insurance company statistics) for CRNAs have decreased significantly over the past 10 years, further demonstrating that CRNAs provide safe anesthesia care.

The Board prides itself in making decision based on public safety that is truly data driven. This type of battle is costly and time-consuming for the professions and for the state legislators involved. Such decisions regarding who can competently provide what types of care demands a more empirical foundation and a less political venue. And I hope common sense will prevail when you consider this piece of legislation in its totality.

Thank you for the opportunity to present testimony. I am now open to questions.

TESTIMONY

BY
CALVIN N. ROLFSON
IN OPPOSITION TO
SENATE BILL NO. 2413

My name is Cal Rolfson. I am an attorney here in Bismarck. I represent the North Dakota Association of Nurse Anesthetists . I appear on their behalf speaking in opposition to Senate Bill No. 2413.

Senate Bill 2413 has been described by some as a classic case of throwing the baby out with the bathwater. It is a bit of a Johnny-come-lately Bill where there was some scrambling to have it introduced at the last minute.

I do not doubt the laudable reasons of the Bill sponsor to introduce this Bill. However, I believe the Bill will have a significant adverse impact on health care in North Dakota, most particularly at the rural hospital level. Let me explain why.

As a significantly rural and sparsely populated state, North Dakota has been blessed to have decades of superb hospital and outpatient anesthesia services in surgical cases throughout the state. We have a total of 35 anesthesiologists serving North Dakota and 160 CRNAs across the state.

You will note in the map attached to my testimony, the locations at which

anesthesiologists practice, and the locations at which CRNAs practice. You will also note that the CRNAs of North Dakota work in both urban and rural settings, but most particularly they are essentially the only ones serving rural North Dakota with anesthesia services in surgical cases. Those surgical cases include patient populations in all risk categories, including relatively minor surgeries such as I experienced in the last two years with the removal of a growth on my eyelid, and rhinoplasty (clearing out nasal passages), and cases as complex as obstetrical deliveries, major abdominal and orthopedic surgery, colonectomys and the like.

In North Dakota, 80% of all anesthesia is delivered by CRNAs, with nearly two-thirds delivered exclusively by CRNAs without any supervision, direction or involvement by anesthesiologists. [See red dots on map].

You have heard or will hear in your hearing today, testimony from CRNAs describing their practice to you. I would like to tell you one personal story that will hopefully drive home a point.

In October, 2001, I had rhinoplasty surgery at Medcenter One here in Bismarck. The surgery and supporting anesthesiology was successful in every respect. However, the anesthesia services were interesting.

I was served from beginning to end by a CRNA. Before surgery, the CRNA went through a broad series of questions to determine my allergies, what I had

eaten, what medications I was taking, my weight, etc. Those questions lasted some time. The CRNA inserted the needle into my hand to administer the anesthesia. The CRNA was the only one administering the anesthesia during surgery. The CRNA was there to "wake me up" following surgery and monitor my brief recovery period.

Now during the time I was awaiting surgery in the waiting room, and while I was sitting there with my CRNA, an anesthesiologist walked by with a clipboard, introduced himself to me for the first time, and asked two questions: 1) "Have you had anything to eat today?" - to which I replied, "No."; 2) "Have you taken any medications today?" - to which I replied, "No." The introductions and questions took less than one minute. He thanked me and went on to the next patient in the adjacent screened-in area of the preoperative waiting room.

I have confirmed that at no time other than when those two questions were asked, was the anesthesiologist involved, in any way, in the surgery. Of course, if that same surgery had been performed in Bowman or Jamestown or Harvey or Rugby, there would have been no anesthesiologist present to ask the two questions. Of course, those were the same two of the many other questions previously asked of me by my CRNA. The surgery lasted about 40 minutes. The CRNA charged $116.96. The anesthesiologist charged $418.88. That amount was

discounted by Blue Cross/Blue Shield by $249.65, leaving a balance due to the anesthesiologist, of $169.23. Of that amount, Blue Cross Blue Shield paid $135.38, and my twenty percent responsibility for the anesthesiologist was $33.85.

What this Bill would do is not only perpetuate a requirement for a collaborative agreement between CRNAs and anesthesiologists in Medicare cases, but most likely give them the statutory responsibility to contractually involve themselves in every surgery in which a CRNA involved. They would presumably bill for that service. At a time when the governor intends to opt out of the Medicare requirement, in order to save money, this is not the time to use governmental public policy to regulate where no regulation has ever existed in North Dakota before.

Approximately ten years ago, the cost for liability insurance for CRNAs in North Dakota averaged approximately $2,500 per year. Ten years later, the average premium is about $800 per year. I know of no insurance company that would reduce by three times over ten years, the malpractice premium rates for CRNAs if there was any question of a safety problem with their surgical practice. That simply means that safety, with regard to anesthesia administered by CRNAs, is simply not an issue.

Significantly, if this Bill passes, the right of citizens in rural North Dakota

to have access to surgical procedures by their local surgeons and at their local hospital, in my view, will be significantly diminished. If this Bill passes, it is unlikely to me that an anesthesiologist will get out of bed at 2:00 in the morning to drive to Bowman, North Dakota, to administer anesthesia for an appendectomy. That is routinely done by CRNAs, driving from Bismarck to Bowman, for example, at 2:00 in the morning, at the call of the local surgeon.

It would be a rural concern if this Bill passes, that there will be an effort to require rural surgical cases, and rural surgery patients to have their surgery in the state's urban centers where anesthesiologists are located, either requiring their rural surgeon to travel to those urban centers to do the surgery, or having the urban center surgeons perform the surgery. Either way, the rural patient and the rural surgeon may lose the rural choice they now have, and have had, for decades.

I am also aware that many hospitals – rural and urban do not favor the more expensive anesthesia services collaboration if this Bill is passed.

The proponents of this Bill are claiming it maintains the status quo. Nothing is further from the truth. The only requirement now for a collaborative agreement between an anesthesiologist and a CRNA, is in federal Medicare regulations. Probably to reduce Medicare costs, over one year ago CMS changed its rules to allow governors to opt out of Medicare. Governor Hoeven has

informed us he is planning to opt out. However, Senate Bill 2413 would require all surgeries – rural, urban, Medicare, Medicaid, and all others–to have anesthesia services delivered under a state mandate requiring a collaborative agreement in all surgeries. There is no qualifier in the Bill. I understand not even the Board of Nursing, to which this Bill is directed, wants this Bill.

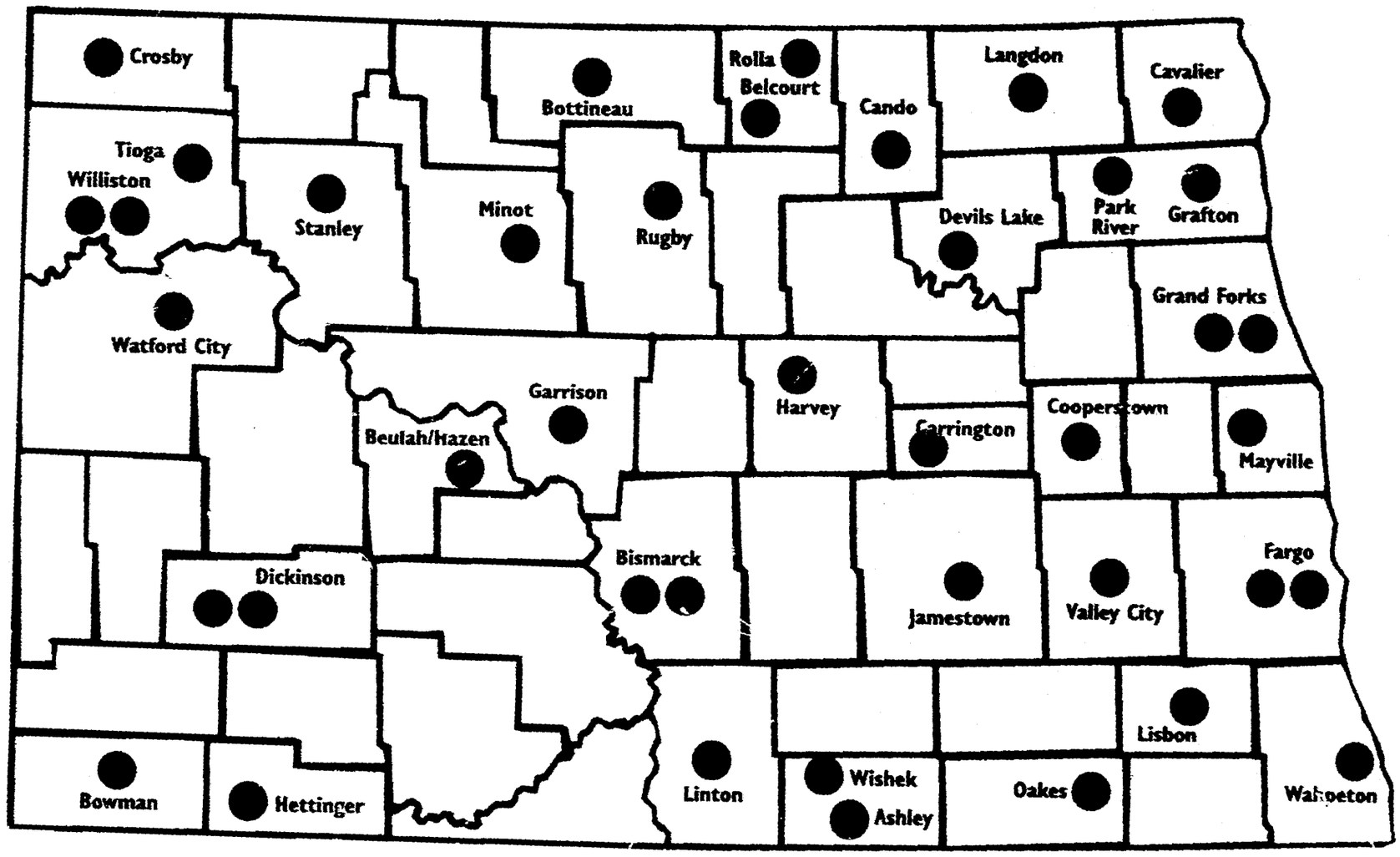
Patient safety is not an issue, and never has been with nurse anesthetists.

Rural choice is an issue. Patient choice is an issue. Hospital choice is an issue.

I urge a do not pass on Senate Bill 2413.

Calvin N. Rolfson
Legislative Counsel
CRNA Association
(Lobbyist No. 144)

ND ANESTHESIA COVERAGE BY CITY



● Red: CRNA only ● Green: CRNA & MDA Yellow: MDA only

North Dakota Surgery Center

OPHTHALMIC SURGERY
Gary L. Karlstad, M.D., F.A.C.S.
Gerald N. Gaul, M.D., F.A.C.S.

SPORTS MEDICINE/ARTHRITIS SURGERY
Brian T. Briggs, M.D.
Joffrey G. Thompson, M.D.
David M. Schall, M.D.
UROLOGIC SURGERY
Steven E. Schultz, M.D.

Chairman Lee and members of the Senate Human Services Committee

I am Ross Gonitzke from Grand Forks, ND. I am the administrator for, GG Properties, the North Dakota Eye Clinic and the North Dakota Surgery Center. I am submitting this today to ask you to give SB 2413 a Do Not Pass recommendation.

Our surgery center offers outpatient orthopedic, urological and ophthalmology surgery services. We do approximately 1200 cases per year. CRNAs currently provide the anesthesia services. I and the physicians of our facility rely on the CRNA for their expertise in anesthesia care. I do not feel this should be the responsibility of the operating physician. The "evidence of a collaborative agreement" stated in SB 2413 can potentially place this responsibility within the realm of the surgeon with whom our CRNAs provide services for. Within the current system of surgical services, there already exists a great deal of consultation between the CRNA, the surgeon and the appropriate resources. It is part of the inherent process of surgical services. The surgeon schedules a surgical procedure, thereby requesting the services of anesthesia as needed for the patient. The anesthesia provider is expected using their anesthesia expertise, to provide whatever anesthesia they deem appropriate utilizing their resources as needed. This may be the surgeon, but also more appropriately may be another healthcare member. To place this responsibility solely on the physician as a surgeon is not only inappropriate, but burdens them with the potential of anesthesia liability which is an area they are not trained.

Again, I ask for a Do NOT Pass recommendation on SB 2413.

Ross Gonitzke

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North Dakota Association of Nurse Anesthetists

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Chairperson Lee and members of the Senate Human Services Committee: Thank you for the opportunity to voice my opposition to SB 2413. My name is Rob Schmieg, I am a Certified Registered Nurse Anesthetist and Past-President and current Government Relations Committee Chairman of the North Dakota Association of Nurse Anesthetists. I am presently employed as a staff Nurse Anesthetist in Fargo. I also work occasionally at the hospitals in Jamestown, Rugby, Belcourt, and Rolla. On behalf of the North Dakota Association of Nurse Anesthetists and our 195 members, I am testifying this morning in opposition to this legislation and respectfully encourage your **Do Not Pass** recommendation on this bill.

I would like to start by giving you by brief history of the evolution of Nurse Anesthesia. Nurse Anesthetists have been practicing for well over 100 years. Initially, surgical residents and medical students were utilized to administer anesthesia. They were, however, more pre-occupied with observing the surgical procedure and because of this, mortality rates were high. Surgeons then turned to nurses they felt had the experience and aptitude and gave them specialized training to become Nurse Anesthetists. In about the 1950's, physicians began to see anesthesia as a specialty and more abundantly entered the field. In ND today there are two anesthesia providers: CRNAs; and anesthesiologists.

Presently, to become a Certified Registered Nurse Anesthetist (CRNA) it requires a bachelor's degree in nursing, at least one year of critical care nursing experience in an intensive care or cardiac care unit (though most have at least three years), and 27-36 months of post-graduate education in anesthesia.

This legislation before you this morning has a bit of a history. It begins with a recent Federal CMS (formerly HCFA) rule which allows states to "opt-out" of the rule and defer to state law on the issue of physician supervision of nurse anesthetists for the hospital portion of Medicare reimbursement. In the mid 1980's, a supervision rule was put in place so that anesthetists could be directly reimbursed by Medicare. As the Federal Medicare Rule now stands, a CRNA doing anesthesia on a Medicare patient must be supervised by a physician (usually the operating surgeon) for the facility to be reimbursed for the procedure. Therefore, if a CRNA does an anesthetic on a Medicare patient, unsupervised, Medicare will pay the bill for the CRNA, but not the hospital bill. The Medicare physician supervision requirement is for reimbursement only, not for practice.

What is meant by physician supervision under the Medicare rules? It essentially requires that prior to the start of the anesthetic, the surgeon agrees with the CRNA's pre-op assessment and that both agree on the anesthesia plan of care. Again, I would like to stress that the Federal Medicare Physician Supervision rule applies only to reimbursement, not practice. It applies only to Medicare patients, not non-Medicare patients. There is not now, nor has there ever been mandated physician supervision of CRNAs for practice.

What does this "opt-out" accomplish?

1) It provides hospitals with more flexibility in staffing.
2) It removes the "perceived" liability of surgeons supervising CRNAs.
3) It increases the facility's compliance rate of Medicare rules.

This "opt-out" removes the decision of supervision from the Federal Government and places it at the state and local control.

Nurse Anesthetists deliver safe, high quality, cost effective care. As a testament to this, CRNA's have seen their malpractice insurance premiums cut in half. There have been no studies to date that have shown a difference in the quality of care between a CRNA and an anesthesiologist, or a supervised versus unsupervised CRNA.

What impact would SB 2413 have?

1) Preempt an "opt-out" and deference to current ND state law
2) Restrict CRNA practice and anesthesia delivery by mandating a collaborative agreement

With or without the presence of the "opt-out," this bill changes ND law and significantly increases a regulatory burden which is unnecessary. Clearly, the rule provided the opt-out option for those states who may choose to do so to make compliance with Medicare rules less complex. This bill does not return the status quo, it is wholly restrictive of our practice. As I said before, there is not now nor ever has been a legislative mandate for MD supervision or a collaborative agreement for CRNAs for practice in ND.

It is unreasonable to believe that without this bill, CRNAs would be offering anesthesia to anyone at anytime – that is simply not possible. Realistically, we do nothing that isn't initiated by a physician. We only provide anesthesia for individuals for which surgeons or physicians request our services. Pregnant women delivering under a doctor's care, patients referred to us by their primary care physician for epidural steroid or trigger point injections,

airway management or IV therapy in emergency rooms, and, of course, peri-operative anesthesia. There are already safety checks in place.
For example, all hospitals require a recent history and physical by a surgeon or primary care physician prior to surgery.

As one of many non-physician providers, it is difficult to understand why, at time when anesthesia is safer than ever before, CRNAs are being singled-out for a specific collaborative practice agreement.

Additionaly, SB 2413 raises significant questions:

1) Must the physician collaborator be of the same specialty? How will that be possible in Bowman, Rugby, etc? They have no anesthesiologists there.
2) If the operating surgeon, whose specialty is not anesthesia, were able to sign the collaboration agreement, why would he or she want to? A collaboration agreement states that the MD vouches for the practitioners character, knowledge and skill. That also then makes them liable for the CRNAs actions, increasing their already burdensome malpractice insurance premiums.
3) Which surgeon or MD would you have sign the collaborative agreement? Even in a small rural facility, by nature of the practice, a CRNA may work with 5 or more physicians in a day.

I am not here today asking you to expand or increase our scope of practice. **I am here to keep our practice from being unfairly restricted.**

There is now a national shortage of anesthesia providers, both CRNAs and anesthesiologists. It is becoming increasingly harder to recruit CRNAs to practice here, by making that practice more restrictive, it makes it even more difficult to recruit those CRNAs, especially in the rural settings.

CRNAs are already regulated by a national certifying board and the North Dakota Board of Nursing, we don't need another level of regulation. Please give SB 2413 a **do-not pass** recommendation. Thank you for your time, I will try and answer any questions you may have.

Chairperson Lee and members of the Senate Human Services Committee, my name is Paula Schmalz; I currently reside in Fargo and I am a Certified Registered Nurse Anesthetist (CRNA) licensed and practicing in North Dakota for 20 years in rural and urban settings. I appear before you this morning on my own behalf as a CRNA in opposition to SB 2413 and ask this committee for a **Do Not Pass** recommendation.

CRNAs work as an employee of a hospital, as an independent contractor with a health care facility, or as an employee of a group. Regardless, a CRNA does not begin their services unless initially ordered by a physician. By the very nature of our anesthesia practice, CRNAs use both independent and cooperative decision making skills with other health professionals as they deliver anesthesia services. We confer with general practitioners, pharmacists, laboratory specialists to name a few and certainly the surgeon(s) with which we work on a minute to minute basis. The very nature of working in conjunction with one another in health care goes on every day of the year by all practitioners. I ask why single out only the CRNA for collaborative agreement when in actuality all medical professionals confer with one another in order to deliver high quality care. Conferring is not a new concept. It is the nature of what we do. Legislative language is not warranted in order for this to occur.

CRNAs work with many surgeons. In fact, in any given week, I may work with 10 or more surgeons. The concept of a collaborative agreement simply does not fit. Would it require a cumbersome process of establishing written agreements with every surgeon I work (whom I already confer with as the surgery unfolds minute by minute)? Or does it

mean establishing a written agreement with an anesthesiologist far removed from my location of practice? Am I now liable not only for the patient but also to this anesthesiologist miles away for every decision I make?

This amendment raises serious concerns associated with additional physician liab'lity especially when functioning in the collaborating role pertaining to anesthesia. Most physicians have a limited background in the actual delivery of anesthesia.

SB 2413 could have a negative impact on overall healthcare accessibility. In North Dakota anesthesiologists are located in only the most urban communities. For the remaining health care facilities all anesthesia services are rendered by Certified Registered Nurse Anesthetists. Requiring a collaborative agreement with any licensed physician may trend toward such an agreement with a physician specialist, that being an anesthesiologist. In reality, such a trend may force citizens to travel significant distances to the urban community for surgical, obstetrical, and trauma stabilization services.

CRNAs administer **at least** 85% of all anesthetics and are the **sole** providers in 64% of health care facilities in this state serving 30 counties including the largest urban communities and some of the most rural. Often the CRNA has been and continues to be the only anesthesia provider in many rural areas. SB 2413 would restrict healthcare and anesthesia delivery in our state and would only further constrain the safe and efficient flow of anesthesia services. SB 2413 is restrictive, regressive and simply does not fit the healthcare needs of the citizens of North Dakota.

The scope of practice of a CRNA in North Dakota does not and never has required a collaborative agreement. What indicates this amendment is needed? CRNAs have the knowledge and expertise in the field of anesthesia, are a vital component of the surgical team and provide anesthesia care to patient populations in all risk categories. No difference in mortality or morbidity exists when anesthesia care is administered by an anesthetist verses an anesthesiologist.

The real question is What will this legislation accomplish? Will service be better? No. Safer? No. Will costs be potentially increased? Very possibly.

I appreciate the opportunity to testify before you this morning and again urge a **Do Not Pass** recommendation on Senate Bill 2413.

I am open to any questions you may have.