

# OPT-OUT- What does it mean to Missouri CRNAs?

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Until November of 2001, the Centers for Medicare and Medicaid Services (CMS) included physician supervision of all CRNAs as one of their conditions for hospital and surgery center participation in Medicare part A. This meant that if the hospital or surgery center wanted to be reimbursed by Medicare for the facility portion, (Medicare part A) of the billed services then, regardless of the individual state's CRNA scope of practice, they must be able to prove the CRNA was supervised by a physician. From a monetary standpoint, if the facilities wanted to be paid, the federal requirement for supervision trumped the states' ability to determine their own scope of practice. Of course if the state's CRNA scope of practice didn't require supervision, then CRNAs were legally able to provide unsupervised care, but the hospitals and surgery centers would not be reimbursed for the facility services. In summary, in order for a hospital/surgery center to be reimbursed for Medicare patients prior to November of 2001, all anesthesia services had to be performed by an anesthesiologist, a physician trained in anesthesia, or a CRNA under the supervision of a physician.

## Historical Insight

In 1982 the Health Care Financing Administration (HCFA) that later became know as the Centers for Medicare and Medicaid (CMS) revised the conditions of participation for ambulatory surgical centers (ASCs) to require physician supervision of CRNAs and in 1986 revised the conditions of participation for hospitals to require supervision of CRNAs.

### **What are “Conditions of Participation”?**

These are the conditions that ASCs and hospitals must meet in order to be reimbursed for providing services and care to Medicare patients under Part A of Medicare.

There are three parts to Medicare.

- 1) Part A is for facilities such as ASCs, hospitals and critical access hospitals.
- 2) Part B is for providers such as physicians, CRNAs and other providers that are allowed to bill Medicare directly.
- 3) Part D which is prescription drugs.

There are no requirements for CRNAs to be supervised by a physician under Part B of Medicare.

In 1990, the President of a state nurse anesthetist association wrote a letter to HCFA regarding concerns about the federal supervision requirement and requested a definition of the term “supervision”. HCFA responded with a general definition of supervision and a policy interpretation. This led to many meetings between HCFA and the AANA in which AANA requested that the physician supervision requirement be dropped, and that the federal government defer to the states.

In 1990 the Center for Health Economics Research (CHER) completed a report for the Health Care Financing Administration (HCFA), which states “anesthesia outcomes between CRNAs and anesthesiologists have not been shown to differ”. That same year, the Center for Disease Control (CDC) intended to conduct a study on mortality and morbidity relating to anesthesia but after reviewing the anesthesia data, concluded that morbidity and mortality in anesthesia was too low to warrant the study.

In 1994, legislation was introduced in both the House and Senate providing for fair anesthesia payment and deferral to state law on the issue of physician supervision. Also in the fall of that year, HCFA issued draft regulation in the Medicare Conditions of Participation for Hospitals, which includes the removal of physician supervision of nurse anesthetists.

During 1995, AANA continued to inquire of HCFA when the regulations would be released and members continued to lobby Congress for direct reimbursement and removal of the supervision requirement. Bills were introduced for removal of the supervision requirement, and direct reimbursement for CRNAs, but were not included in the final

Medicare package. In 1995, direct reimbursement was passed to become effective in 1998, but the supervision issue remained unresolved.

In December 1997, HCFA issued a proposed rule deferring to the states on the supervision issue. A comment period was held, and AANA members continued to lobby Congress during the Mid-Year Assemblies. Because of the lack of statistical evidence suggesting differences between the level of care and patient outcomes, in November 2001, the Centers for Medicare and Medicaid Services (CMS) ruled to lift the condition of supervision as a requirement for participation as a provider for Medicare part A deferring conditions for participation to actual state law.

On January 18, 2001, two days prior to President Clinton leaving office, HCFA and HHS published the rule to “defer to the states” in the Federal Register. The rule was scheduled to become effective March 18, 2001.

Prior to the above ruling, hospitals and surgery centers had to comply with federal requirements for CRNA supervision; but post ruling, if states didn’t require physician supervision of CRNAs, facilities in these states would still be considered participating Medicare providers without supervision of CRNAs. Unfortunately the rule never became effective. Due to challenges set forth by the lobbyists representing the American Society of Anesthesiologists (ASA), On March 18, 2001, President Bush froze the rule for 60 days pending further review. On May 18, 2001, the Bush Administration enacted a regulatory freeze to the final rule for 180 days. Subsequently, the ruling was modified to: CRNA supervision is required in order to be eligible as a participating provider, but states are allowed to “opt out” or exempt themselves from the requirement through a court petition issued by the governor of the state. This new rule would leave the conditions for supervision of CRNAs by a physician intact unless the state governors requested a waiver, (opt out) from the Secretary of HHS. There was a 60-day comment period and this final rule became truly final on November 13, 2001.

## **OPT-OUT Essentials for Each State**

For a state to opt out of the federal requirement for supervision of CRNAs, the state’s governor must send a letter to the Secretary of HHS requesting that the state opt out of the supervision requirement. The letter must attest:

1. The state’s governor has consulted with the state boards of medicine and nursing about issues related to the access to and the quality of anesthesia services in the state; and,
2. That it is in the best interest of the state’s citizens to opt-out of the current federal physician requirement; and,
3. That the opt-out is consistent with state law.

The consultation with the boards of medicine and nursing is not defined by CMS and gives the governor flexibility and the boards do not have to submit comments. CMS believes that the governors are best suited to make the determination for an opt-out. Governors can at any time request that a previous opt-out be withdrawn as well. This happened in Montana where the governor later after a period of time, decided to continue the opt-out.

When a state has opted out of the federal requirement, it does not necessarily change the practice of CRNAs in the state. The facilities may still require physician supervision of the CRNAs in the bylaws of the facility. The opt-out would not permit a CRNA to practice outside the scope authority granted by state law.

A state opt-out takes a great deal of planning and each state needs to prepare for the battles to follow. It should be noted that lawsuits are most likely going to be filed, and legislation be introduced for strict supervision. Having a relationship with the Governor’s office is essential to the opt-out process.

## **Reimbursement Issue - Not legal Scope of Practice Issue**

There are those that would have facilities and other providers to believe that the requirement for physician supervision is a legal scope of practice requirement. ***It is not a legal scope of practice requirement***; it is a condition for participation that (if met by the facility) will result in reimbursement by Medicare for the services given to Medicare patients. To clearly summarize this point, a CRNA licensed in a state in which the scope of practice allows unsupervised care may provide this care legally to any patient regardless of type of insurance as long as the facility bylaws allow it. If the state has not opted out, then any services provided to Medicare patients by the

facility won't be reimbursed to the facility, however services provided by the CRNA will be reimbursed to the CRNA under Medicare part B.

At the present time, 17 states have opted out of the supervision requirement. [1, 2, 3] Some of the states have been faced with lawsuits being filed to reverse the opt-out but the outcomes have been positive. In addition there are 40 states that do not require CRNAs be "supervised" by a physician and 32 states do not have a physician supervision or direction requirement. The following are the 17 states that have opted out to date:

Iowa 2001

Nebraska 2002

Idaho 2002

Minnesota 2002

New Hampshire 2002

New Mexico 2002

Kansas 2003

North Dakota 2003

Washington 2003

Alaska 2003

Oregon 2003

**Montana 2004 -** *(Gov. Judy Martz opted-out; Gov. Brian Schweitzer reversed the opt-out in May 2005, without citing any evidence to justify the decision. Subsequently, after the governor and his staff became more familiar with the reasons justifying the January 2004 opt-out, Gov. Schweitzer restored the opt-out in June 2005. Montana's opt-out, therefore, is currently in effect.)*

S. Dakota 2005

Wisconsin 2005

California 2009

**Colorado 2010-** *(September 2010) (For Critical Access Hospitals (CAHs) and specified rural hospitals)*

Kentucky 2012

## **Study of Anesthesia Outcomes**

In its November 13, 2001 rule comments, CMS says that 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." CMS will not pursue a voluntary registry that assesses outcomes of care. To date, and to our knowledge, AHRQ has not initiated the study.

A well-known study, [8] was performed by Brian Dulisse, a health economist at the Research Triangle Institute, in Waltham, Massachusetts and Jerry Cromwell, a senior fellow in health economics at the Research Triangle Institute. In this study Medicare data from 1999-2005 was analyzed. This analysis found no evidence that opting out of the oversight requirement resulted in increased inpatient deaths or complications. Based on these findings, they recommend that CMS allow certified registered nurse anesthetists in every state to work without the supervision of a surgeon or anesthesiologist.

The analysis of seven years of Medicare inpatient anesthesia claims suggests that the change in CMS policy allowing states to opt out of the physician supervision requirement for certified registered nurse anesthetist reimbursement was not associated with increased risks to patients. In particular, the absolute increase in the provision of anesthesia by unsupervised nurse anesthetists in opt-out states was virtually identical to the increase in non-opt-out states, and the proportional increase was smaller in opt-out states.

This lends no support to the belief that a meaningful shift in provider shares occurred as a consequence of the policy change. Similarly, the analysis found no evidence to suggest that there is an increase in patient risk associated with anesthesia provided by unsupervised certified registered nurse anesthetists.

Both a change in the proportion of anesthesia provided by the different groups—nurse anesthetists alone, anesthesiologists alone, and nurse anesthetists and anesthesiologists working in teams—and a difference in the outcomes of the different groups are necessary to conclude that the change in CMS policy led to changes in patient safety. Because the data provides no evidence to support either of these conditions, they concluded that patient safety was not compromised by the opt-out policy.

The recommendation called for CMS to return to its original intention of allowing nurse anesthetists to work independently of surgeon or anesthesiologist supervision without requiring state governments to formally petition for an exemption. This would free surgeons from the legal responsibility for anesthesia services provided by other professionals. It would also lead to more-cost-effective care as the solo practice of certified registered nurse anesthetists increases.

## **Why isn't Missouri a candidate for Opt-Out?**

Because Missouri doesn't meet the essential third requirement: *the opt-out must be consistent with state law*. Currently Missouri has a statute enacted under the physician chapter 334.104.7 which states in part, "...a CRNA as defined in subdivision (8) of section 335.016 shall be permitted to provide anesthesia services without a collaborative practice arrangement provided that he or she is under the *supervision* of an anesthesiologist or other physician, dentist, or podiatrist who is immediately available if needed...": see ([Mo Rev. Statute 334.104.7](#))

Because this language has already been legislatively approved and enacted in Missouri, CRNAs are required to adhere to state law, which requires them to be supervised by a physician. So opting out at the federal level would not change the state's current legal restrictive requirements. At the present time, there is no reference to supervisory language in either the nurse practice act (which governs and regulates the CRNA practice) or in any rules promulgated to regulate hospitals and surgery centers (6,7). To summarize; an opt-out at this time would not be *consistent with existing Missouri state law* and because of this inconsistency Missouri is ineligible to apply. Missouri would first have to seek a revision in the existing statute through the Missouri state legislative process in order to revise the requirement of supervision at the state statutory level. Once this has successfully been accomplished an opt-out could then be requested and pursued.

Sources can be found at the following links:

1. *AANA Fact Sheet Concerning State Opt-Outs and November 13, 2001 CMS Rule*  
<http://www.aana.com/advocacy/stategovernmentaffairs/Pages/Fact-Sheet-Concerning-State-Opt-Outs.aspx>
2. *Federal Supervision Rule/Opt-Out Information*  
<http://www.aana.com/advocacy/stategovernmentaffairs/Pages/Federal-Supervision-Rule-Opt-Out-Information.aspx>
3. *Final Federal Supervision Rule: Federal Register PDF Version*  
<http://www.aana.com/advocacy/stategovernmentaffairs/Documents/Federal%20Register%20Opt%20Out.pdf>
4. *Missouri Nurse Practice Act*  
<http://pr.mo.gov/boards/nursing/npa.pdf>
5. *Missouri Revised Statute- Physician Chapter 334.104.7*  
<http://www.moga.mo.gov/statutes/C300-399/3340000104.HTM>
6. *Rules of Department of Health and Senior Services, Division 30-Division of Regulation and Licensure, Chapter 20-Hospitals- begins on page 48.*  
<http://www.sos.mo.gov/adrules/csr/current/19csr/19c30-20.pdf>
7. *Rules of Department of Health and Senior Services, Division 30- Division of Regulation and Licensure, Chapter 30- Ambulatory Surgical Centers- begins on page 6.*  
<https://www.sos.mo.gov/adrules/csr/current/19csr/19c30-30.pdf>
8. *No Harm Found When Nurse Anesthetists Work Without Physician Supervision*  
[http://www.oana.org/pdf/No%20Harm%20Found%20Study%20article%20%20\(RTI\).pdf](http://www.oana.org/pdf/No%20Harm%20Found%20Study%20article%20%20(RTI).pdf)