Mr. Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-1633-P  
P.O. Box 8013  
Baltimore, MD  21244-1850

**RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System; Proposed Rule (80 Fed. Reg. 39200, July 8, 2015)**

Dear Mr. Slavitt:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on the proposed rule Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System; Proposed Rule (80 Fed. Reg. 39200, July 8, 2015).

The issues addressed in our comment are outlined as follows:

I. CMS Should Remove the Costly and Unnecessary Requirements Relating to Physician Supervision of CRNA Anesthesia Services

II. CMS Should Support Innovative Cost-Effective Models in Healthcare Delivery such as Non-medically Directed Anesthesia Services Performed by CRNAs

III. Support Ambulatory Surgical Center Quality Reporting (ASCQR) Program Normothermia Measure for Future Consideration and Keep Definition of Normothermia Consistent through all Quality Reporting Programs

IV. Include CRNAs in the List of Providers who Can Bill for Chronic Care Management Services
Background of the AANA and CRNAs

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists. AANA membership includes over 48,000 CRNAs and student registered nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. CRNAs are APRNs and anesthesia professionals who safely administer more than 38 million anesthetics to patients each year in the United States. Nurse anesthetists have provided anesthesia care to patients in the U.S. for over 150 years, and high quality, cost effective and safe CRNA services continue to be in high demand. CRNAs are Medicare Part B providers and since 1989, have billed Medicare directly for 100 percent of the physician fee schedule amount for services.

CRNAs practice in every setting in which anesthesia is delivered: traditional hospital surgical suites and obstetrical delivery rooms; critical access hospitals; ambulatory surgical centers; the offices of dentists, podiatrists, ophthalmologists, plastic surgeons, and pain management specialists; and U.S. military, Public Health Services, and Department of Veterans Affairs healthcare facilities. CRNA services include providing a pre-anesthetic assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery. CRNAs also provide acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities.

Peer-reviewed scientific literature shows CRNA services ensure patient safety and access to high-quality care, and promote healthcare cost savings. According to a May/June 2010 study published in the journal of *Nursing Economic*, CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery
model. Furthermore, an August 2010 study published in *Health Affairs* shows no differences in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians. Researchers studying anesthesia safety found no differences in care between nurse anesthetists and physician anesthesiologists based on an exhaustive analysis of research literature published in the United States and around the world, according to a scientific literature review prepared by the Cochrane Collaboration.

According to a 2007 Government Accountability Office (GAO) study, CRNAs are the predominant anesthesia provider where there are more Medicare beneficiaries and where the gap between Medicare and private pay is less. Nurse anesthesia predominates in Veterans Hospitals, the U.S. Armed Forces and Public Health Service. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management facilities and the offices of dentists, podiatrists, and all types of specialty surgeons. As colleagues and competitors in the provision of anesthesia and pain management services, CRNAs and anesthesiologists have long been considered substitutes in the delivery of surgeries.

I. **AANA Recommendation: CMS Should Remove the Costly and Unnecessary Requirements Relating to Physician Supervision of CRNA Anesthesia Services.**

We support the agency’s solicitation of comments on the regulatory impact analysis of this proposed rule. Regulatory reforms that reduce barriers to CRNA practice can help improve

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1 Paul F. Hogan et. al, “Cost Effectiveness Analysis of Anesthesia Providers.” *Nursing Economic*$ 2010; 28:159-169, available at [http://www.aana.com/resources2/research/Documents/nec_mj_10_hogan.pdf](http://www.aana.com/resources2/research/Documents/nec_mj_10_hogan.pdf).


healthcare quality, reduce healthcare expenditures and increase access for patients; among these reforms is a recommendation to eliminate the Medicare requirement for physician supervision of Certified Registered Nurse Anesthetists.\(^6\)

The requirement for physician supervision of CRNA services is costly and unnecessary, and eliminating the requirement supports delivery of healthcare in a manner allowing states and healthcare facilities to make their own decisions based on state laws and patient needs, thus controlling cost, providing access and delivering quality care. The cost benefits associated with eliminating this barrier are underscored in a new publication. Based upon analysis conducted by the Duke University Center for Health Policy & Inequalities Research,\(^7\) a 2015 paper by the AANA shows that eliminating regulatory barriers to the use of CRNAs nationwide will save the U.S. healthcare system approximately $954 million annually in reduced costs for anesthesia services.\(^8\) This requirement is more restrictive than the vast majority of state laws and impedes local communities from implementing the most innovative and competitive model of providing quality care.

As we have previously stated, there is no evidence that physician supervision of CRNAs improves patient safety or quality of care. In fact, there is strong and compelling evidence showing that physician supervision does not have any impact on quality, and may restrict access and increase cost. Studies have repeatedly demonstrated the high quality of nurse anesthesia care, and a 2010 study published in *Health Affairs*\(^9\) led researchers to recommend that costly and duplicative supervision requirements for CRNAs be eliminated. Examining Medicare records

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\(^6\) See 42 CFR §§ 482.52, [http://www.ecfr.gov/cgi-bin/text-idx?SID=fc767c3bd4a62741e976f0ae03464e62&node=42:5.0.1.1.1&rgn=div5#42:5.0.1.1.1.4.4.2](http://www.ecfr.gov/cgi-bin/text-idx?SID=fc767c3bd4a62741e976f0ae03464e62&node=42:5.0.1.1.1&rgn=div5#42:5.0.1.1.1.4.4.2), 482.639 [http://www.ecfr.gov/cgi-bin/text-idx?SID=fc767c3bd4a62741e976f0ae03464e62&node=42:5.0.1.1.4&rgn=div5#42:5.0.1.1.4.4.7.16](http://www.ecfr.gov/cgi-bin/text-idx?SID=fc767c3bd4a62741e976f0ae03464e62&node=42:5.0.1.1.4&rgn=div5#42:5.0.1.1.4.4.7.16), and 416.42, [http://www.ecfr.gov/cgi-bin/text-idx?SID=fc767c3bd4a62741e976f0ae03464e62&node=42:3.0.1.1.3&rgn=div5#42:3.0.1.1.3.3.1.3](http://www.ecfr.gov/cgi-bin/text-idx?SID=fc767c3bd4a62741e976f0ae03464e62&node=42:3.0.1.1.3&rgn=div5#42:3.0.1.1.3.3.1.3).


\(^9\) Dulisse, op cit.
from 1999-2005, the study compared anesthesia outcomes in 14 states that opted-out of the Medicare physician supervision requirement for CRNAs with those that did not opt out. (To date, 17 states have opted-out.) The researchers found that anesthesia has continued to become safer in opt-out and non-opt-out states alike. In reviewing the study, the New York Times stated, “In the long run, there could also be savings to the healthcare system if nurses delivered more of the care.”

CRNA safety in anesthesia is further evidenced by the significant decrease in premiums for their own liability coverage. In 2015, self-employed CRNAs paid 33 percent less for malpractice premiums nationwide when compared to the average cost in 1988. When adjusted for inflation through 2015, the reduction in CRNA liability premiums is an astounding 65 percent less than approximately 25 years ago according to Anesthesia Insurance Services, Inc.

Furthermore, peer-reviewed scientific literature shows CRNA services ensure patient safety and access to high-quality care, and promote healthcare cost savings. According to a May/June 2010 study published in the journal of Nursing Economics, CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery without any measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model. Also, a study found that anesthesiologist supervision frequently lapses, increasing to over 90 percent of the time when supervision ratios are 1:3 or greater.

Further evidence that demonstrates the high costs of supervision is shown through anesthesiologist interpretation of this requirement. CMS requires supervision of CRNAs (except in opt-out states) by an operating practitioner or by an anesthesiologist who is immediately available if needed, and hospitals and healthcare facilities often misinterpret this requirement as a quality standard rather than a condition of participation. The AANA receives reports from the field that anesthesiologists suggest erroneously that supervision is some type of quality standard,

11 Hogan, op cit.
an assertion bearing potential financial benefit for anesthesiologists marketing their medical direction services as a way to comply with the Medicare supervision condition of participation. When this ideology is established, anesthesiologist supervision adds substantial costs to healthcare by requiring duplication of services where none is necessary. Further, as stated earlier, the Medicare agency has clearly noted that medical direction is a condition for payment of anesthesiologist services and not a quality standard. But there are even bigger costs involved if the hospital administrator believes that CRNAs are required to have anesthesiologist supervision.

The AANA supports the agency’s objective of achieving the triple aim of healthcare which includes, improving the experience of care, improving the health of populations, and reducing per capita costs of healthcare. CRNAs are an important component in helping achieve the triple aim because they ensure patient safety and access to safe, high-quality care, and promote healthcare cost savings. The physician supervision requirement contradicts the triple aim of healthcare by increasing healthcare costs and decreasing patient access to safe and high quality care. Therefore, the AANA recommends the agency remove the regulatory barrier of physician supervision of CRNAs in the Medicare program. Removing this barrier is also consistent with the findings and recommendations of the Institute of Medicine, whose landmark publication titled *The Future of Nursing: Leading Change, Advancing Health* calls for removing barriers so that APRNs, including CRNAs, can practice to the full extent of their education and training, indicating that APRNs play a critical role in the future of healthcare.

II. **AANA Recommendation: CMS Should Support Innovative Cost-Effective Models in Healthcare Delivery such as Non-medically Directed Anesthesia Services Performed by CRNAs**

This proposed rule recommends advancing innovative healthcare delivery models to improve care and achieve cost savings. The AANA supports the agency’s overall effort; in the


anesthesia and pain management arena, one innovative model that the agency should study as a cost-efficient model in healthcare delivery is non-medically directed CRNA anesthesia services.

In most respects, Medicare reimburses CRNAs and anesthesiologists the same rate for the same high quality service -- 100 percent of a fee for providing non-medically directed (CRNA) or personally performed (anesthesiologist) services. However, Medicare Part B also authorizes payment for “anesthesiologist medical direction”¹⁵ that provides a financial incentive for anesthesiologists to “medically direct” CRNAs who are capable of and are often providing patient access to high quality anesthesia care unassisted. An anesthesiologist claiming medical direction services may be reimbursed 50 percent of a fee in each of up to four concurrent cases, a total of 200 percent over a given period of time, twice what the anesthesiologist may claim when personally performing anesthesia services in one case. Under medical direction, the CRNA may claim the remaining 50 percent of a fee for his or her case. Peer-reviewed evidence demonstrates anesthesiologist medical direction increases healthcare costs without improving value.¹⁶ The CMS has also stated that medical direction is a condition of payment of anesthesiologist services and not a quality standard.¹⁷

In demonstrating the increased costs associated with anesthesiologist medical direction, suppose that there are four identical cases: (a) has anesthesia delivered by a non-medically directed CRNA; (b) has anesthesia delivered by a CRNA medically directed at a 4:1 ratio by a physician overseeing four simultaneous cases and attesting fulfillment of the seven conditions of medical direction in each; (c) has anesthesia delivered by a CRNA medically directed at a 2:1 ratio; and (d) has anesthesia delivered by a physician personally performing the anesthesia service. (There are instances where more than one anesthesia professional is warranted; however, neither patient acuity nor case complexity is a part of the regulatory determination for medically directed services. The literature demonstrates that the quality of medically directed vs. non-medically directed CRNA services is indistinguishable in terms of patient outcomes, quality and safety.) Further suppose that the annual pay of the anesthesia professionals approximate national market

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¹⁶ Hogan, op cit.

conditions, $170,000 for the CRNA\textsuperscript{18} and $540,314 for the anesthesiologist\textsuperscript{19}. Under the Medicare program and most private payment systems, practice modalities (a), (b), (c) and (d) are reimbursed the same. Moreover, the literature indicates the quality of medically directed vs. non-medically directed CRNA services is indistinguishable. However, the annualized labor costs (excluding benefits) for each modality vary widely. The annualized cost of practice modality (a) equals $170,000 per year. For case (b), it is ($170,000 + (0.25 \times $540,314) or $305,079 per year. For case (c) it is ($170,000 + (0.50 \times $540,314) or $440,157 per year. Finally, for case (d), the annualized cost equals $540,314 per year.

<table>
<thead>
<tr>
<th>Anesthesia Payment Model</th>
<th>FTEs / Case</th>
<th>Clinician costs per year / FTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) CRNA Non-medically Directed</td>
<td>1.00</td>
<td>$170,000</td>
</tr>
<tr>
<td>(b) Medical Direction 1:4</td>
<td>1.25</td>
<td>$305,079</td>
</tr>
<tr>
<td>(c) Medical Direction 1:2</td>
<td>1.50</td>
<td>$440,157</td>
</tr>
<tr>
<td>(d) Anesthesiologist Only</td>
<td>1.00</td>
<td>$540,314</td>
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</tbody>
</table>

Anesthesiologist mean annual pay $540,314 MGMA, 2014  
CRNA mean annual pay $170,000 AANA, 2014

If plans pay the same rate whether the care is delivered according to modalities (a), (b), (c) or (d), someone in the health system is bearing the additional cost of the medical direction service authorized under the Medicare regulations at 42 CFR §415.110. Pertinent to Medicaid, if a state Medicaid program reimburses for CRNA anesthesia services only to the extent that they are medically directed by an anesthesiologist (as is the case in Pennsylvania, for example), that policy is driving additional healthcare costs and waste without improving healthcare quality or access to care. This additional cost is shifted onto hospitals and other healthcare facilities, and ultimately to patients, premium payers and taxpayers. With CRNAs providing over 38 million anesthetics in the U.S., and a considerable fraction of them being “medically directed,” the additional healthcare costs driven by this medical direction service are substantial.

\textsuperscript{18} AANA member survey, 2014  
\textsuperscript{19} MGMA Physician Compensation and Production Survey, 2014. \url{www.mgma.com}
In addition, the most recent peer-reviewed literature makes clear that the requirements of anesthesiologist medical direction are often not met in practice – and if anesthesiologists submit claims to Medicaid for medical direction but did not perform all of the required services in each instance, then the likelihood of widespread Medicaid fraud in this area is high. Lapses in anesthesiologist supervision are common even when an anesthesiologist is medically directing as few as two CRNAs, according to a 2012 study published in the journal *Anesthesiology*,20 the professional journal of the American Society of Anesthesiologists. The authors reviewed over 15,000 anesthesia records in one leading U.S. hospital, and found supervision lapses in 50 percent of the cases involving anesthesiologist supervision of two concurrent CRNA cases, and in more than 90 percent of cases involving anesthesiologist supervision of three concurrent CRNA cases. This study raises critical issues about Medicare claims compliance in a common and costly model of anesthesia delivery at a time when quality, cost-effectiveness, and best use of Medicare resources are the focus of healthcare reform. In the interest of patient safety and access to care, these additional costs imposed by medical direction modalities more than justify the public interest in recognizing and reimbursing fully for non-medically directed CRNA services within Medicare, Medicaid and private plans in the same manner that physician services are reimbursed.

In conclusion, anesthesiologist medical direction reimbursement models contribute to increased healthcare system costs without improving access or quality, and also present fraud risk when medical direction requirements are not met by the anesthesiologist submitting a claim for such services. Therefore, CMS should consider such costs when developing and carrying out new systems for anesthesia reimbursement in new healthcare delivery models, and to favor reimbursement systems that support the most cost-effective and safe anesthesia delivery models such as for non-medically directed CRNA services.

III.  AANA Recommendation: Support Ambulatory Surgical Center Quality Reporting (ASCQR) Program Normothermia Measure for Future Consideration and Keep Definition of Normothermia Consistent through all Quality Reporting Programs

The AANA applauds the agency for seeking quality measures in the Ambulatory Surgical Center Quality Reporting Program (ASCQR), through future rulemaking, that help further the goal of achieving better healthcare and improved health for Medicare beneficiaries who receive healthcare in ASC settings. As determined advocates for patient safety and access to quality healthcare, CRNAs have been providing safe and high-quality anesthesia care in the United States for 150 years and provide anesthesia services in a wide variety of settings including ASCs.

We support the agency’s proposed future normothermia measure in the ASCQR program, which assesses the percentage of patients having surgical procedures under general or neuroaxial anesthesia of 60 minutes or more in duration who are normothermic (normal body temperature) within 15 minutes of arrival in the post-anesthesia care unit. The AANA believes this future measure in ASCs will help promote quality care in the ASCs where CRNAs contribute to each patient’s anesthetic and perioperative care. We regard it as an important outcome measure for CRNAs who provide general or neuroaxial anesthesia.

However, we note that a change in the definition of normothermia was recently approved from 36 degrees Celsius/96.8 degrees Fahrenheit to 35.5 degrees Celsius/95.9 degrees Fahrenheit by the 2015 Surgical Standing Committee of National Quality Forum (NQF), though it has not currently been NQF endorsed. In particular, we note that the January 2015 ASC Quality Collaboration’s ASC Quality Measures Implementation Guide 3.0 uses the former definition of normothermia (i.e., 36 degrees Celsius/96.8 degrees Fahrenheit). Given the potential for incongruency in the definitions of normothermia throughout all of the federal quality reporting programs (including ASCQR), we believe that using the more current definition for normothermia (i.e., 35.5 degrees Celsius/95.9 degrees Fahrenheit) is a non-substantive change to the ASC measures specification guide as it is an acceptable definition for normothermia by anesthesia professionals. Therefore, we recommend that this measure be adopted so long as the ASCQR definition of normothermia is consistent with the other quality reporting programs (e.g.

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PQRS) to maintain uniformity in anesthesia quality improvement. This is consistent with the agency’s interests in promoting improved safety, quality, access and cost-effectiveness in the healthcare marketplace.

IV. **AANA Recommendation: Include CRNAs in the List of Providers who Can Bill for Chronic Care Management Services**

The AANA supports CMS’ newly designated chronic care management (CCM) service (CPT Code 99490) as we recognize that chronic care management as one important component of primary care that contributes to the delivery of high-quality healthcare services, expanding access to care, and improving health outcomes for patients, as well as reduced healthcare spending. These priorities correspond with the principles advocated by the AANA, which are to provide safe, high-quality and cost effective anesthesia care for patients. However, in a Medlearn Learning Network brochure, the agency did not include CRNAs on the list of non-physician providers who can bill for this code.\(^2\) For reasons that go to patient access to care, clinical practicality, and existing Medicare payment policy governing coverage of CRNA services, we believe that Medicare should include CRNAs on the list of providers who can bill for chronic care management services.

With regard to patient access to care, the agency is aware that CRNAs provide anesthesia and related care, including pain management services, in every type of setting, and predominate in rural and medically underserved America. Within their state scope of practice, CRNAs may provide services that meet the definition of chronic care management which include dedicating “at least 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month” treating “multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; and a comprehensive care plan established, implemented, revised, or monitored.”

CRNAs may be involved in chronic care management services insofar as they are also involved in chronic pain management services, a specialized field relating to the treatment of persistent intractable pain. As the agency is aware, CRNA provision of pain management services increases the availability and ease of obtaining of pain management services, expanding consumer access to high quality, safe and cost-effective healthcare. Patient need for such services is significant: the Institute of Medicine (IOM) reported in *Relieving Pain in America* (2011) that 100 million Americans suffer from chronic intractable pain at an annual cost exceeding $600 billion from healthcare expenditures and lost productivity. The IOM also reported an insufficient supply of healthcare professionals treating pain patients, and concluded that more professionals and more training are needed to meet the needs of a growing population of U.S. retirees. Particularly in rural and frontier areas, CRNAs often are the only healthcare professionals trained in pain management in these communities, the patient’s alternative being travel of hundreds of miles to access care or to go without these needed benefits. Customarily, referring practitioners choose to refer their patients to CRNAs for high-quality pain care, and patients choose to receive their care from a CRNA in their local community rather than traveling long distances. Without CRNAs to administer chronic pain management services, Medicare beneficiaries in vast rural and frontier areas would lose access to vital treatment, which could result in poor healthcare outcomes, lower quality of life, and unnecessary costs to patients, Medicare, and the healthcare system. A second area of chronic care management where CRNAs may practice is palliative care, defined by the World Health Organization in part as “an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.” Although palliative care is not a prevalent area of practice for CRNAs, the knowledge and skills necessary to provide knowledgeable palliative care are present in many CRNAs. Persons needing palliative care may benefit from the years of experience in acute and critical care nursing and extensive pain and symptom management skills.

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that CRNAs bring.\textsuperscript{26} Such services may lie within CRNA scope of practice in a state and thus be covered services by Medicare when provided by a CRNA.\textsuperscript{27}

Thus, including CRNAs in the list of providers who may bill Medicare for chronic care management services and be reimbursed by the Medicare program would promote patient access to care by supporting consumer choice and competition, be consistent with patient safety, and be supported by existing Medicare policy.

We thank you for the opportunity to comment on this proposed rule. Should you have any questions regarding these matters, please feel free to contact the AANA Senior Director of Federal Government Affairs, Frank Purcell, at 202.484.8400, fpurcell@aanadc.com.

Sincerely,

\textbf{Sharon P. Pearce, CRNA, MSN}  
AANA President

cc: Wanda O. Wilson, CRNA, MSN, PhD, AANA Executive Director  
Frank J. Purcell, AANA Senior Director of Federal Government Affairs  
Randi Gold, MPP, AANA Associate Director Federal Regulatory and Payment Policy
