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Electronic Submission via [ProposedLCDComments@novitas-solutions.com](mailto:ProposedLCDComments@novitas-solutions.com)

Novitas Solutions  
Medical Affairs  
2020 Technology Parkway  
Mechanicsburg, PA, 17050

**RE: Draft Local Coverage Determination for Nerve Stimulators for Chronic Intractable Pain (DL39404)**

To Whom It May Concern:

The American Association of Nurse Anesthesiology (AANA) welcomes the opportunity to comment on the draft local coverage determination (LCD) for Nerve Stimulators for Chronic Intractable Pain (DL 39404). The AANA offers comments in the following area:

- Ensure that the Training Programs Recognized are Inclusive of Those Current and Future Programs Available to CRNAs

**Background of the AANA and CRNAs**

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs). AANA membership includes more than 59,000 CRNAs and SRNAs, representing about 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 50 million anesthetics to patients each year in the United States and are included among the nation's most trusted professions according to Gallup<sup>1</sup>. Nurse anesthetists have

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<sup>1</sup> Gallup "U.S. Ethics Ratings Rise for Medical Workers and Teachers (December 22, 2020), <https://news.gallup.com/poll/328136/ethics-ratings-rise-medical-workers-teachers.aspx>.

provided anesthesia in the United States for 150 years, and high-quality, cost-effective CRNA services are 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 also play an essential role in ensuring that rural America has access to critical anesthesia services, often serving as the sole anesthesia provider in rural hospitals, affording these facilities the capability to provide many necessary procedures.

CRNAs are involved in every aspect of anesthesia services including a pre-anesthesia patient 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 and recovery. CRNAs also provide acute, chronic, and interventional pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. Nurse anesthesia predominates in Veterans Hospitals and in the U.S. Armed Services. 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.

Numerous peer reviewed studies have shown that CRNAs are safe, high-quality and cost-effective anesthesia professionals who should practice to the full extent of their education and abilities. According to a May/June 2010 study published in the journal *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.<sup>2</sup> An August 2010 study published in *Health Affairs* showed no differences in patient outcomes when anesthesia services are provided

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<sup>2</sup> Paul F. Hogan et al., "Cost Effectiveness Analysis of Anesthesia Providers." *Nursing Economic\$*. 2010; 28:159-169. [http://www.aana.com/resources2/research/Documents/nec\\_mj\\_10\\_hogan.pdf](http://www.aana.com/resources2/research/Documents/nec_mj_10_hogan.pdf)

by CRNAs, physicians, or CRNAs supervised by physicians.<sup>3</sup> 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, the internationally recognized authority on evidence-based practice in healthcare.<sup>4</sup> Most recently, a study published in *Medical Care* (June 2016) found no measurable impact in anesthesia complications from nurse anesthetist scope of practice or practice restrictions.<sup>5</sup>

The importance of CRNA services in rural areas was highlighted in a recent study which examined the relationship between socioeconomic factors related to geography and insurance type and the distribution of anesthesia provider type.<sup>6</sup> The study correlated CRNAs with lower-income populations and correlated anesthesiologist services with higher-income populations. Of particular importance to the implementation of public benefit programs in the U.S., the study also showed that compared with anesthesiologists, CRNAs are more likely to work in areas with lower median incomes and larger populations of citizens who are unemployed, uninsured, and/or Medicaid beneficiaries.<sup>7</sup> This information highlights the importance of CRNAs who provide high-quality, evidence-based care to millions of Americans living and working in rural and underserved areas. Allowing them to participate in rural emergency hospitals will increase needed access to care for patients who live in these areas.

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<sup>3</sup> B. Dulisse and J. Cromwell, "No Harm Found When Nurse Anesthetists Work Without Physician Supervision." *Health Affairs*. 2010; 29: 1469-1475. <http://content.healthaffairs.org/content/29/8/1469.full.pdf>

<sup>4</sup> Lewis SR, Nicholson A, Smith AF, Alderson P. Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients. *Cochrane Database of Systematic Reviews* 2014, Issue 7. Art. No.: CD010357. DOI: 10.1002/14651858.CD010357.pub2. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010357.pub2/abstract>

<sup>5</sup> Negrusa B et al. Scope of practice laws and anesthesia complications: No measurable impact of certified registered nurse anesthetist expanded scope of practice on anesthesia-related complications. *Medical Care* June 2016, [http://journals.lww.com/lww-medicalcare/Abstract/publishahead/Scope\\_of\\_Practice\\_Laws\\_and\\_Anesthesia.98905.aspx](http://journals.lww.com/lww-medicalcare/Abstract/publishahead/Scope_of_Practice_Laws_and_Anesthesia.98905.aspx).

<sup>6</sup> Liao CJ, Qurashi JA, Jordan LM. Geographical Imbalance of Anesthesia Providers and its Impact on the Uninsured and Vulnerable Populations. *Nurs Econ*. 2015;33(5):263-270. <http://www.aana.com/resources2/research/Pages/NursingEconomics2015.aspx>

<sup>7</sup> Liao, op cit.

The services listed in the draft LCD relate to techniques that reflect current evidence-based, pain management practice. Pain management is central to the scope and practice of a CRNA, and CRNAs play a vital role by providing patient focused, comprehensive pain care in communities throughout the United States. As APRNs, CRNAs are uniquely skilled to deliver pain treatment in a compassionate and holistic manner. By virtue of education and individual clinical experience and competency, a CRNA may practice chronic pain management utilizing a variety of therapeutic, physiological, pharmacological, interventional, and psychological modalities in the management and treatment of pain. Fellowship training along with subspecialty certification is available to those who like further recognition in the field of pain management. Several chronic pain education pathways are available to the CRNA including formalized education and mentored practice. The AANA has partnered with academia to develop Advanced Chronic Pain Management Fellowships that are accredited by the Council on Accreditation of Nurse Anesthesia Programs (COA) to attain focused learning and recognition as advanced, subspecialty practitioners beyond that required for initial certification of nurse anesthetists.<sup>8</sup> Furthermore, the National Board of Certification and Recertification for Nurse Anesthetists (NBCRNA) offers a voluntary nonsurgical pain management (NSPM) subspecialty certification for CRNAs.<sup>9</sup>

**AANA Comment: Ensure that the Training Programs Recognized are Inclusive of Those Current and Future Programs Available to CRNAs**

We support Novitas’ proposed local coverage determination (LCD) to broaden the list of covered indications. As the draft LCD includes peripheral nerve stimulators, and not just spinal cord stimulators, which was the sole subject in the previous LCD L36035, we request that Novitas ensure that “accredited interventional pain medicine training program” and “accredited surgical training program” be inclusive of nursing and other allied health programs available to CRNAs and not just be limited to programs offered by medical societies and accredited by Accreditation Council for Graduate Medical Education (ACGME). Qualified healthcare professionals include those from the specialty of nursing in addition to medicine, and, as such, each profession’s

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<sup>8</sup> See: <https://www.coacrna.org/wp-content/uploads/2022/07/List-of-Accredited-Fellowships-July-18-2022.pdf>

<sup>9</sup> See: <http://www.nbcrna.com/NSPM/Pages/NSPM.aspx>

education program accrediting and credentialing bodies should be equally recognized. Lack of reimbursement would limit access to necessary chronic pain management services for Medicare beneficiaries, especially in rural areas. For the same reasons, we also request that Novitas delete the word “medicine” after “accredited interventional pain.”

We agree with Novitas’ statement that there have been significant advancements to the field since the publication of the Spinal Cord Stimulators LCD. The technology for the peripheral stimulators has simplified the procedure performance and improved safety. As noted by Nayak and Banik, “a new generation of peripheral nerve stimulation devices has been developed; these allow external pulse generators to transmit impulses wirelessly to the implanted electrode, and their implantation is significantly less invasive.”<sup>10</sup> Within a CRNA’s professional scope and practice, CRNAs are trialing, implanting and managing peripheral and central neuromodulation therapies now more than ever in the care of acute and chronic pain syndromes. As a primary provider of pain management services and as APRNs, CRNAs are uniquely skilled to provide both acute and chronic pain management in a patient centered, compassionate and holistic manner across the pain continuum in all clinical settings. By virtue of education and individual clinical experience and competency, a CRNA may practice chronic pain management utilizing a variety of therapeutic, physiological, pharmacological, interventional, and psychological modalities in the management and treatment of pain, including for neurostimulating systems. Fellowship training along with subspecialty certification is available to those who like further recognition in the field of pain management. Several chronic pain education pathways are available to the CRNA including formalized education and mentored practice. We therefore request that Novitas recognize nursing and other allied health training programs available to CRNAs, such as advanced chronic pain management fellowships that are accredited by the Council on Accreditation of Nurse Anesthesia Programs (COA) amongst others. Finally, as technology in neuromodulating systems continue to advance and given the fluid nature of

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<sup>10</sup> Nayak R, Banik RK. Current Innovations in Peripheral Nerve Stimulation. *Pain Res Treat.* 2018;2018:9091216. Published 2018 Sep 13. doi:10.1155/2018/9091216.

practice evolution,<sup>11</sup> we request that Novitas acknowledge and recognize future training programs available to CRNAs as well.

We thank you for the opportunity to comment on this draft local coverage determination. Should you have any questions regarding these matters, please feel free to contact AANA Senior Associate Director, Federal Regulatory and Payment Policy, Romy Gelb-Zimmer at 202-484-8400, [rgelb-zimmer@aana.com](mailto:rgelb-zimmer@aana.com).

Sincerely,

A handwritten signature in black ink that reads "Angela Mund". The signature is written in a cursive, flowing style.

Angela Mund, DNP, CRNA  
AANA President

cc: William Bruce, MBA, CAE, AANA Chief Executive Officer  
Lorraine Jordan, PhD, CRNA, CAE, FAAN, AANA Chief Advocacy Officer and AANA Foundation CEO  
Romy Gelb-Zimmer, MPP, AANA Senior Associate Director Federal Regulatory and Payment Policy

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<sup>11</sup> Levy R. Evidence Based Medicine vs. Expert Consensus in Medical Guidelines: An Artificial Conflict. *Neuromodulation*. 2017 Feb;20(2):93-95. doi: 10.1111/ner.12578.