American Association of
NURSE ANESTHESIOLOGY

September 12, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS–1772–P
PO Box 8010
Baltimore, MD 21244-1810

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating (87 Fed. Reg. 44502, July 26, 2022)

Dear Ms. Brooks-LaSure:

The American Association of Nurse Anesthesiology (AANA) welcomes the opportunity to comment on the proposed rule: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating. The issues addressed in our comment are outlined as follows:

I. CRNAs Provide Safe, High Quality and Cost-Effective Care

II. Nonrecurring Policy Changes

- Support Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients
- Provide Priority PPE Funding to Areas Where Providers Would be in the Highest Risk

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III. ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals That Function as Surgical Supplies

- Use of Non-Opioid Alternatives, Such as Multi-Modal Pain Management ERAS® Protocols, Do Lead to a Decrease in Prescription Opioid Use and Addiction and Can Help Decrease Barriers to Access to Non-Opioid Pain Management Products
- Proposed Criteria for Non-Opioid Pain Management Drugs and Biologicals to be Eligible for Payment Would Limit Access to Newer Treatment Modalities for Pain Management
- Support Payment for Non-Opioid Care in the Hospital Outpatient Setting

IV. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

- Collect Information About Patients' Lived Experiences as Part of Data Collection Efforts to Reduce Healthcare Disparities

V. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

- For Anesthesia, Interoperability of Health Information Should Communicate Across the Continuum of Patient Care and EHRs Should Use Standardized Taxonomies Across Technology Platforms
- The Focus of Measurement of Interoperability Should Not Be Limited to Only Use of Certified EHR Technology
- Additional Anesthesia Data Sources Should be Used to Evaluate Interoperability

VI. Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

- Prohibit the Use of Wasteful Tele-Supervision of CRNA Services Reducing Regulatory Barriers for CRNAs Increases Access to Anesthesia Care in Rural Communities
- Reducing Regulatory Barriers for CRNAs Increases Access to Anesthesia Care in Rural Communities
- Ensure Availability of Obstetrical Anesthesia Services Provided by CRNAs Who Are Working at the Top of Scope, Education, and Licensure

VII. Rural Emergency Hospital (REH) Provider Enrollment

- Include in the Final Rule, Further Guidance or Information Rural Pass through Status as Critical Access Hospitals Covert to REHs

VIII. Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

- Requiring Prior Authorization for Facet Joint Injections Might Delay Access to Pain Management Services

I. CRNAS PROVIDE SAFE, HIGH QUALITY AND COST-EFFECTIVE HEALTHCARE

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 89 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 among the nation's most trusted professions according to Gallup[1]. Nurse anesthetists have 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 assuring 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

[1] 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

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.[2] An August 2010 study published in *Health Affairs* showed no differences in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.[3] 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.[4] 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.[5]

II. **NONRECURRING POLICY CHANGES**

AANA Comment: Support Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients

We are pleased to see that the agency is proposing to allow nonphysician practitioners, including CRNAs, to provide general, direct and personal supervision of diagnostic testing services furnished to outpatients by hospitals or Critical Access Hospitals (CAHs) to the extent that they are authorized to do so under their scope of practice and applicable State law. This policy was already finalized in the CY 2021 CMS Physician Fee Schedule final rule and the agency also finalized a rule in November 2012 indicating Medicare coverage of all Medicare CRNA services within their state scope of practice.[6] CRNAs have continuously practiced autonomously and are well-qualified to make independent judgments based on their education, licensure and certification. And with the advent of the current COVID-19 pandemic, CRNAs have been even more vital to the nation's critical care response. CRNAs comprise over 50 percent of the U.S. anesthesia workforce and

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[2] 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

[3] 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

[4] 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

[5] 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.

[6] 77 Fed. Reg. 68892, 69005 et seq., Nov. 16, 2012, amending 42 CFR §410.69(b). Certified Registered Nurse Anesthetists scope of benefit. http://www.gpo.gov/fdsys/pkg/FR-2012-11-16/pdf/2012-26900.pdf.

are expert clinicians with highly specialized skills such as airway management, ventilator support, vascular volume resuscitation, and advanced patient assessment. Allowing CRNAs to supervise diagnostic tests in the hospital outpatient and CAH setting will help with CMS' goal of ensuring that an adequate number of health care professionals are available to support critical COVID–19-related and other diagnostic testing needs and provide access to needed medical care.

AANA Request: Provide Priority PPE Funding to Areas Where Providers Would be in the Highest Risk

The AANA supports the need to provide appropriate protection for healthcare providers and ensure that facilities have the resources to be able to secure required equipment and personal protective equipment (PPE). We recommend priority funding to areas where providers would be in the highest risk. During this pandemic, CRNAs have played a role providing critical, lifesaving care to patients by using their expertise in rapid systems assessment, airway management, managing ventilators, vascular volume resuscitation, placing of invasive lines and monitors, overseeing complex hemodynamic monitoring, emergency preparedness, and resource management. believe that the safety of anesthesia professionals is of utmost importance in developing policies related to PPE. CRNAs need access to proper equipment due to close patient contact and the need for airway instrumentation, perioperative professionals are at increased risk of exposure and infection for all diagnostic, therapeutic, and surgical procedures during the COVID pandemic in the U.S. Appropriate PPE to treat COVID-19 patients includes fitted N95 masks; powered air purifying respirators (PAPRs);[7] and may include other NIOSH or CDC approved respirators.[8] Personnel participating in aerosol-generating procedures also wear eye protection (goggles or a disposable face shield that covers the front and sides of the face), a gown, and gloves, in addition to airway protection with N95 masks or PAPRs.

We believe infectious disease payment should account for the equipment and resources used directly for care situations that are directly related to the PHE. Some examples include: 1) there is a surge of COVID-19 patients requiring anesthesia care, and also necessitating the use of all the required PPE to protect providers, which would not have been needed without the surge in the number of infected patients; 2) the anesthesia

[7] PAPRs should be used by individuals who are not N95 fit-tested, have facial hair, or fail N95 fit-testing.

[8] AANA, ASA, APSF and AAAA Issue Joint Statement on Use of Personal Protective Equipment During COVID-19 Pandemic, see: https://www.aana.com/docs/default-source/practice-aana-com-web-documents- (all)/update-the-use-of-personal-protective-equipment-by-anesthesia-professionals-during-the-covid-19-pandemic.pdf?sfvrsn=201caffe_6

provider or department has decided to use PPE and protective devices for all patients, infected or not infected, due to the risk of COVID-19 infection, regardless of the patients' COVID-19 infection status, because of the pandemic conditions. Before the pandemic, this additional PPE and/or protective equipment would not have been used for all patients.

CRNAs involved in care during the pandemic may either be employed by facilities or work in independent practice, which typically involves providing care under a contractual agreement with a health care facility. Employers typically bear the additional costs of equipment and resources for CRNAs who are employed by these facilities, including additional employee protections as mandated by CDC and OSHA during the pandemic. The additional costs of providing care for CRNAs who work in independent practice will depend on the contractual provisions between the provider and health care facilities using their services. To a greater or lesser degree, depending upon the contract conditions, either the CRNA and or the facility will be responsible for the costs of gowns, PAPRs, eye protective goggles, and N95 masks, and any additional anesthesia equipment such as clear plastic shields around the patient's head, and any other protective items that would not have been used in a typical case prior to pandemic conditions. Furthermore, there may be additional costs to clinicians of an increase in non-COVID-19 infections during the pandemic. There is a concern that hospital acquired infection rates have been going up as there has been potential rebound in the numbers of non-COVID-19 infections during the pandemic.[9] COVID-19 patients are more at risk for CLABSIs and CAUTIs than non-COVID-19 patients.[10]

III. ASC PAYMENT SYSTEM POLICY FOR NONOPIOID PAIN MANAGEMENT DRUGS AND BIOLOGICALS THAT FUNCTION AS SURGICAL SUPPLIES

AANA Comment: Use of Non-Opioid Alternatives, Such as Multi-Modal Pain Management ERAS® Protocols, Do Lead to a Decrease in Prescription Opioid Use and Addiction and can Help Decrease Barriers to Access to Non-Opioid Pain Management Products

We support the agency's continued review of payments for opioids and evidence-based non-opioid alternatives for pain management with the goal of ensuring that there are not financial incentives to use opioids instead of nonopioid alternatives. CRNAs have been on the front lines of developing novel non-

[9] McMullen KM, Smith BA, Rebmann T. Impact of SARS-CoV-2 on hospital-acquired infection rates in the United States: Predictions and early results. Am J Infect Control. 2020;48(11):1409-1411.

[10] See: https://nurseanesthesiology.aana.com/impacts-on-hospital-acquired-infection-rates-due-to-thesars-cov-2-pandemic

opioid based treatments for both chronic and acute pain and we support maximum flexibility in allowing pain treatment plans that rely on the clinical judgment of the practitioner directing care.

As a main provider of pain management services in all types of settings including hospital outpatient departments, 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.[11] Furthermore, the holistic approach that CRNA pain management practitioners employ when treating their chronic pain patients may reduce the reliance on opioids as a primary pain management modality, thus aiding in the reduction of potential adverse drug events related to opioids.

As the risk of opioid dependence and addiction begins with the first exposure, we recommend that CMS promote comprehensive multimodal pain management and ERAS® protocols as a non-opioid alternative to treat pain in all clinical settings. Many pharmacologic treatments can be used to manage pain. While each nonopioid alternative has its own indications and risks, some are likely to be as effective as opioids or more so for reducing pain associated with the conditions for which they are indicated and when used appropriately, carry lower risk of adverse outcomes. Careful assessment, evaluation, and treatment of acute pain, with appropriate prescribing of an opioid, may prevent access to unused opioids and development of opioid dependency and abuse.

CRNAs play a critical role by ensuring proper anesthesia services management which can make a tremendous difference in terms of improving patient flow, patient safety, and cost savings. Interventional pain management involves the use of invasive techniques, such as joint injections, nerve blocks, spinal cord stimulation, and other procedures, to reduce pain. Such techniques are best performed in the context of a multimodal treatment regimen, including physical therapy to maximize functional restoration. There has been a significant increase in the volume of certain interventional procedures over the past 10 years, much of it focused on low back and neck pain with or without radiation to the hip and other lower extremities.[12]

[11] AANA Chronic Pain Management Guidelines, September 2021, available at: https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/professional-practice-manual/chronic-pain-management-guidelines.pdf?sfvrsn=d40049b1_8, AANA Regional Anesthesia and Analgesia Techniques - An Element of Multimodal Pain Management Guidelines, https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/regional-anesthesia-and-analgesia-techniques-an-element-of-multimodal-pain-management.pdf?sfvrsn=8aac5eb1_6, and AANA Guidelines on A Holistic Approach to Pain Management: Integrated, Multimodal, and Interdisciplinary Treatment https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/a-holistic-approach-to-pain-management-integrated-multimodal-and-interdisciplinary-treatment.pdf?sfvrsn=f40049b1_4

[12] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse; Phillips JK, Ford MA, Bonnie RJ, editors. Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription

Multimodal analgesia describes the use of more than one modality or techniques to achieve effective pain control from the preoperative period through initial recovery and return home.[13] A multimodal, instead of the traditional unimodal opioid approach involves the administration of several analgesics with separate mechanisms of action across the perioperative period and/or concurrent field block using local anesthetic, regional or neuraxial analgesia (e.g., paravertebral block with non-opioid analgesia).[14] It is important to take into consideration the complexity of the surgical procedure, patient pain experience history and preferences, anticipated level of postoperative pain, and duration of action of analgesics and local anesthetics when deciding on pain management options for pathway development and for individual patients. Multimodal analgesia may eliminate or significantly reduce the use of opioids and adverse side effects such as respiratory depression, postoperative nausea and vomiting (PONV), and delayed return of gastrointestinal function.[15]

Non-opioid medications include acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), systemic lidocaine or ketamine infusion, long-acting local anesthetics, and gabapentinoids (gabapentin/pregabalin).[16] Other modalities using local anesthetics of varying durations of action include surgical site local anesthetic infiltration, field blocks (e.g., transversus abdominis plane (TAP) block), central neuraxial techniques (e.g., epidural and spinal analgesia), and regional blocks.[17] Non-pharmacological analgesia (e.g., acupuncture, music therapy) as well as cognitive-behavioral techniques (e.g., guided imagery, relaxation), may be used as an adjunct to pharmacological methods to support the patient to reduce postoperative pain, anxiety, and use of pain medication.[18,19]

Opioid Use. Washington (DC): National Academies Press (US); 2017 Jul 13. 2, Pain Management and the Intersection of Pain and Opioid Use Disorder. Available from: https://www.ncbi.nlm.nih.gov/books/NBK458655/

[13]. Optimizing pain management to facilitate Enhanced Recovery After Surgery pathways. *Can J Anaesth.* Feb 2015;62(2):203-218.

[14] Tan M, Law LS, Gan TJ, op cit.

[15] Miller ET, Gan TJ, Thacker JK. Enhanced Recovery pathways for major abdominal surgery *Anesthesiology News* 2014.

[16] Siu-Chun Law L, Ah-Gi Lo E, Gan TJ. Preoperative Antiemetic and Analgesic Management In: Gan TJ, Thacker JK, Miller TE, Scott MJ, Holubar SD, eds. *Enhanced Recovery for Major Abdominopelvic Surgery.* West Islip, NY: Professional Communications, Inc; 2016:105-120.

[17] Montgomery R, McNamara SA. Multimodal Pain Management for Enhanced Recovery: Reinforcing the Shift From Traditional Pathways Through Nurse-Led Interventions. *AORN J.* Dec 2016;104(6S):S9-S16.

[18] Tan M, Law LS, Gan TJ, op cit.

[19] Montgomery R, McNamara SA, op cit

Using a multimodal approach and specific protocol-driven ERAS® pathways improves patient outcomes by reducing the patient's stress response to surgery, shortening the overall hospital length of stay, and accelerating the return to normal daily function. The anesthesia professional plays a pivotal role in patient/family education by engaging the patient as an active participant in his or her care and the recovery process.[20] Anesthesia professionals continue to build on these activities throughout the Prehospital/Preadmission Phase through patient assessment and evaluation to identify unique elements of the patient's health, pain and anesthesia history that may require modification of the ERAS® pathway to coordinate development of the plan of care with the patient and their primary care and specialty team, as appropriate. The patient's pain management plan of care begins pre-procedure and continues through post-discharge using opioid-sparing techniques such as regional anesthesia including placement of epidural catheters, targeted peripheral nerve blocks, non-pharmacologic approaches, and non-opioid based pharmacologic measures. Collaboration with the patient's advanced pain management team and utilizing multi-modal pain management strategies can improve outcomes, especially for patients with difficult to control pain (e.g., chronic pain patient, substance use disorder).[21,22, 23]

The evidence is quite clear that careful assessment, evaluation, and treatment of acute pain may prevent access to unused opioids and development of opioid dependency and abuse in the following AANA documents: Chronic Pain Management Guidelines (2021); Analgesia and Anesthesia for the Substance Use Disorder Patient (2019); Ketamine Infusion Therapy for Psychiatric Disorders and Chronic Pain Management (2019); Regional Anesthesia and Analgesia Techniques - An Element of Multimodal Pain Management (2018); A Holistic Approach to Pain Management Integrated Multimodal and Interdisciplinary Treatment (2016); Enhanced Recovery after Surgery, Considerations for Pathway Development and Implementation (2017). In addition, organizations such as SOFA (the Society for Opioid Free Anesthesia), a nonprofit organization formed to research, promote and educate anesthesia professionals and the general public on opioid free pain management techniques, may also have additional data regarding evidence-based non-opioid pain management therapies used in the outpatient and ASC setting. All of this evidence shows

[20] Brady KM, Keller DS, Delaney CP. Successful Implementation of an Enhanced Recovery Pathway: The Nurse's Role. *AORN J.* Nov 2015;102(5):469-481.
[21] Vadivelu N, Mitra S, Kaye AD, Urman RD. Perioperative analgesia and challenges in the drug-addicted and drug-dependent patient. *Best Pract Res Clin Anaesthesiol.* Mar 2014;28(1):91-101.
[22] Shah S, Kapoor S, Durkin B. Analgesic management of acute pain in the opioid-tolerant patient. *Curr Opin Anaesthesiol.* Aug 2015;28(4):398-402.
[23] Pulley DD. Preoperative Evaluation of the Patient with Substance Use Disorder and Perioperative Considerations. *Anesthesiol Clin.* Mar 2016;34(1):201-211.

that CRNAs play a critical role by ensuring proper anesthesia services management which can make a tremendous difference in terms of improving patient flow, patient safety, and cost savings.

In addition, we support the proposal to continue the policy to unpackage and pay separately at ASP+6 percent for the cost of nonopioid pain management drugs that function as surgical supplies in the performance of surgical procedures furnished in the ASC setting and to continue to package payment for nonopioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. These payment strategies are beneficial to clinicians, such as CRNAs, who are trained to administer non-opioid pain management, including the ERAS® protocols mentioned previously. As the agency continues to work on payment policies for nonopioid pain management treatments, we ask to consider including reimbursement for ERAS® procedures performed by CRNAs, who provide expert, non-opioid based care.

AANA Comment: Proposed Criteria for Non-Opioid Pain Management Drugs and Biologicals to be Eligible for Payment Would Limit Access to Newer Treatment Modalities for Pain Management

We support CMS' proposal for separate payment in the ASC setting for four non-opioid pain management drugs that function as surgical supplies, including certain local anesthetics and ocular drugs as CRNAs use these medications often in practice. We do caution the criteria that non-opioid pain management drugs and biologicals would be required to meet to be eligible for separate payment under the ASC payment system. Specifically, the proposed requirement that non-opioid pain management drugs and biologicals must have Food and Drug Administration (FDA) approval and an FDA-approved indication for pain management or analgesia in order to be approved for separate payment should not be approved because it would severely limit patient access to newer treatment modalities for pain management. CRNAs play a vital role in providing accessible, safe, cost-effective pain management services and as advanced practice registered nurses, CRNAs are exceptionally skilled to deliver non-opioid treatments for pain in a compassionate and holistic manner.

While we agree that non-opioid drugs and biologicals used for pain management must be safe and effective, we recognize that this new requirement would cause a delay to access to pain treatment by limiting the types of medications used to treat pain. For example, the medication Naltrexone is used to treat fibromyalgia, chronic pain in the muscles and bones, but this medication does not currently have FDA approval to treat

pain. There are also many other off label medications used to treat this painful condition that would not be able to be used to treat pain if this new criterion were to be put into effect by the agency. In addition, it can take up to 10 years for a pain treatment to become FDA approved, further limiting access to newer treatment modalities for pain management. In order to help continue to treat the millions of patients who suffer from both acute and chronic pain, we ask that the proposed requirement that non-opioid pain management drugs and biologicals must have FDA approval and an FDA-approved indication for pain management or analgesia not be finalized.

AANA Comment: Support Payment for Non-Opioid Treatments for Pain in the Hospital Outpatient Setting

The AANA appreciates the opportunity to comment on strategies CRNAs use to more effectively address the opioid epidemic. In 2019, the agency adopted a policy to provide separate reimbursement for non-opioid options to patients undergoing procedures in the ambulatory surgery center (ASC) setting. Since then, use of non-opioid pain management approaches in ASCs increased by 120 percent.[24] We supported this policy change and now recommend that this policy also be adopted in the hospital outpatient setting. Non-opioid approaches, such as ERAS® protocols mentioned above, administered by highly trained professionals, such as CRNAs, offer patients many clinical and health benefits compared to traditional, opioid-based treatments. This also increases patient access to pain care. Providers, including CRNAs, who deliver non-opioid treatments for pain should receive reimbursement for those services, regardless of the setting. Therefore, recommend the agency provide patients increased access safe and effective non-opioid therapies to treat pain in all settings, including the hospital outpatient setting.

IV. OVERARCHING PRINCIPLES FOR MEASURING HEALTHCARE QUALITY DISPARITIES ACROSS CMS QUALITY PROGRAMS

AANA Comment: Collect Information About Patients' Lived Experiences as Part of Data Collection Efforts to Reduce Healthcare Disparities

We applaud that CMS is seeking input on ideas to revise the Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs to make reporting of health

[24] Centers for Medicare & Medicaid Services (2021). Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs proposed rule: https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center

disparities based on social risk factors and race and ethnicity more comprehensive and actionable for facilities, providers, and patients. The AANA supports the agency's efforts to reduce healthcare disparities and appreciates the opportunity to comment to help enable a more comprehensive assessment of health equity to further identify and develop actionable strategies, including the selection of quality measures and quality improvement, to promote health equity. The AANA believes that eliminating healthcare disparities remains a critical public health priority. Recent analysis highlights the possible consequences of disparities including annually adding approximately $93 billion to healthcare costs and $42 billion in lost productivity in addition to causing significant economic loss due to premature deaths.[25] Furthermore, the AANA has developed the position statement entitled, "The CRNA's Role in Addressing Racial and Ethnic Disparities in Anesthesia Care," for the purpose of highlighting "the impact of racial and ethnic disparities on outcomes of care and provide resources for CRNAs and facilities to develop effective policies and practices that promote equitable care for all patients."[26]

As CMS is seeking ways to address challenges of defining and collecting, accurate and standardized, self-identified demographic information, we would recommend that CMS collect information about patients' lived experiences as part of its data collection efforts. Emerging evidence suggests that healthcare disparities may be rooted in lived experiences. Therefore, CMS should include questions, which can be built into patient satisfaction surveys, that specifically address the experiences of racialized minorities within the healthcare system. For instance, questions could center around trust of the healthcare system and providers, experiences of microaggression, and perceived discrimination or injustices.

We also would recommend that CMS accommodate the literacy needs and linguistic barriers of patients during these data collection efforts. We believe it is important to recognize that patients from racial and ethnic backgrounds are more likely than other groups to experience limited health literacy and English proficiency potentially restricting their ability to obtain, process, and understand basic health information.

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[25] Artiga S, Orgera K, Pham O. Kaiser Family Foundation. Disparities in Health and Health Care: Five Key Questions and Answers. 2020; https://www.kff.org/racial-equity-andhealth-policy/issue-brief/disparities-in-healthand-health-care-five-key-questions-andanswers/. Accessed December 14, 2020.

[26] AANA, "The CRNA's Role in Addressing Racial and Ethnic Disparities in Anesthesia Care: Position Statement, Policy and Practice Considerations," adopted by AANA Board of Directors, February 2021, available at: https://www.aana.com/docs/default-source/2019-fall-spinal-epidural-with-obstetric-essentials-workshophandout-page/2021-disparities-position-statement-final-_bod.pdf?sfvrsn=ac7114a5_0

As an example, the AANA's Informed Consent for Anesthesia Care[27], includes practical recommendations on how to effectively facilitate communication with patients from diverse backgrounds.

V. REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM

AANA Comment: For Anesthesia, Interoperability of Health Information Should Communicate Across the Continuum of Patient Care and EHRs Should Use Standardized Taxonomies Across Technology Platforms

Electronic health record (EHR) interoperability is important for many reasons including supporting collaboration across clinical specialists and patient centered care, particularly in the area of chronic pain management. CRNA practice can be affected by a lack of standardization because CRNAs are frequently faced with collecting information from a variety of software platforms during pre-procedural interviews and subsequent referrals. CRNAs would also be affected by the use of medications and devices where vendors do not use a common language to describe the use and function of such products. We offer the following recommendations regarding interoperability and communication of patient information across technology platforms in the realm of anesthesia. For anesthesia measures, we recommend the interoperability of dQMs, EHRs and other information systems should communicate across the continuum of patient care. They should be designed in a way that measure data can be captured across the continuum of patient care, which is what providers really need.

We also recommend that EHR systems should include standardized taxonomy and fields and require providers to use these across various platforms to optimize communication of care and interoperability. In the major anesthesia information management systems, some standardized taxonomies are present; however, valuable patient specific information is entered as free text or in unstructured data hindering data sharing and communication, in addition to making this information difficult to extract for quality reporting without manually reading the fields.

AANA Comment: The Focus of Measurement of Exchange and Use of Interoperability Should Not Be Limited to Only Use of Certified EHR Technology

[27] AANA Informed Consent for Anesthesia Care, Policy and Practice Considerations, https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/professional-practice-manual/informed-consent-for-anesthesia-care.pdf?sfvrsn=8a0049b1_8#:~:text=Informed%20consent%20is%20grounded%20in,determination%20and%20self%2Ddecision).

In order to establish metrics that will assess the extent to which widespread exchange of health information through interoperable certified EHR technology nationwide has occurred, the health information technology needs to first define the scope of measurement. The AANA believes that the measurement of EHR interoperability is limited if the focus of this measurement is restricted only to use of certified EHR technology. Smaller facilities and anesthesia groups may not have the funds and resources necessary to participate in use of a certified, comprehensive EHR, but may purchase a standalone AIMS that is added to the facility EHR. If the agency's goal is to measure true interoperability, and if smaller EHR companies can construct an AIMS that is affordable for use by smaller provider groups, then these groups should be included in this measurement. Furthermore, use of non-certified EHRs in measurement of interoperable EHR technology will also encourage innovation in this field because having to get certified first will limit many programmers who are experimenting with novel methods of handling and accessing EHR data.

AANA Comment: Additional Anesthesia Data Sources Should be Used to Evaluate Interoperability

As stated above, CRNAs in some settings have continued to document on paper or used paper/EHR to document care because they have not been eligible for incentive payments for the adoption and meaningful use of certified EHR technology. As a result, electronic capture of point of care patient information is very difficult to collect. The AANA supports collection of meaningful data through interoperability across all patient care experiences to provide access to a complete and comprehensive healthcare record to improve patient satisfaction, outcomes and affordability of care. Not only would this data be used to provide care, but also to analyze care processes to continually improve outcomes. In evaluating the interoperability of systems across the patient care experience, we recommend development and participation in team and composite measures such as sharing patient health and medication history, communication of encounter information, and decrease in repeat diagnostic testing. Though we only have anecdotal information, sharing of information across platforms is currently very limited and hybrid paper and electronic records are used in many rural, ASC, clinic, and office practice locations.

VI. REQUIREMENTS FOR THE RURAL EMERGENCY HOSPITAL QUALITY REPORTING (REHQR) PROGRAM

AANA Comment: Prohibit the Use of Wasteful Tele-Supervision of CRNA Services

Rural emergency hospitals (REHs) can utilize telehealth and other remote service capacities in serving rural communities in their vicinity. The AANA is supportive of telehealth and remote monitoring technology that improves the quality of care provided for all patients. However, we caution against the use of wasteful services in the name of telehealth that would increase costs without improving healthcare access or quality. We stress that one wasteful payment policy to avoid is to provide a pathway to reimbursing anesthesiologists that are not providing actual anesthesia care, through billing for remote so-called "supervision" services. This type of remote supervision would not improve access to healthcare for patients and would instead reward providers not actually furnishing healthcare services. Furthermore, there is no evidence of the efficacy and cost-effectiveness of in-person physician supervision requirements[28] and there is no evidence regarding the benefit for the use of supervision of anesthesia via telehealth.[29]

As evidence shows that in-person supervision by physicians does not improve anesthesia outcomes, while it significantly increase costs; it stands to reason that remote supervision would not improve outcomes, while also substantially increasing costs. In these instances, anesthesiologist telesupervision of anesthesia provider services would not meet CMS' current Category 2 criteria for Medicare telehealth services of providing a clinical benefit to the patient. As CMS has noted that Medicare Part B anesthesiologist medical direction is a condition for payment of anesthesiologist services[30] and not a quality standard,[31] we also would urge the agency against using interactive telecommunications technology as a way to fulfill any of the seven required steps for payment. We stress that the use of telehealth for these purposes would be wasteful, costly and would constitute inappropriate use.

AANA Comment: Reducing Regulatory Barriers for CRNAs Increases Access to Anesthesia Care in Rural Communities

[28] See B. Dulisse and J. Cromwell op cit. and Paul F. Hogan et. al, op cit.

[29] See: Applegate RL, 2nd, Gildea B, Patchin R, et al. Telemedicine pre-anesthesia evaluation: a randomized pilot trial. Telemed J E H ealth. 2013;19:211-6; Cone SW, Gehr L, Hummel R, Merrell RC. Remote anesthetic monitoring using satellite telecommunications and the Internet. Anesthesia and analgesia. 2006;102(5):1463-1467; Dilisio RP, Dilisio AJ, Weiner MM. Preoperative virtual screening examination of the airway. J Clin Anesth. 2014;26:315-7; and Galvez JA, Rehman MA. Telemedicine in anesthesia: an update. Curr Opin Anaesthesiol. 2011;24:459-62.

[30] 42 CFR §415.110 Conditions for payment: Medically directed anesthesia services.

[31] 63 FR 58813, November 2, 1998.

Rural hospitals are vital to providing health care to their communities and the increasing closure of rural hospitals limits access to care, produces long trips for emergency care and causes an increase in negative health outcomes for patients living in rural areas.[32] Over 130 rural hospitals have closed in the U.S. since 2010. As 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, it is vital that the agency help to promote access to the use of CRNA anesthesia services in rural America. Furthermore, the agency seeks to address quality of care using telehealth services in rural and rural emergency settings, we urge that these new policies do not create unintended barriers to the use of CRNA services and that CRNA are able to practice at their full professional education, skills, and scope of practice. Nurse anesthetists are experienced and highly trained anesthesia professionals who provide high-quality patient care, which has been proven through decades of scientific research.

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.[33] 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.[34] CRNAs play an essential role in assuring that rural America has access to critical anesthesia services and by removing regulatory barriers to CRNA practice and allowing CRNAs to practice to the full extent of their scope, licensure and training, patients in rural areas will receive consistently safe and high quality care delivery.

AANA Comment: Ensure Availability of Obstetrical Anesthesia Services Provided by CRNAs Who Are Working at the Top of Scope, Education, and Licensure

CRNAs play an essential role in ensuring that rural America has access to critical anesthesia services, including critical obstetrical anesthesia services, often serving as the sole anesthesia provider in rural

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[32] "The Health 202: Congress is throwing a lifeline to struggling rural hospitals." The Washington Post, June 29, 2021.

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

34 Liao, op cit.

hospitals, affording these facilities the capability to provide many necessary procedures. The AANA has several resources with respect to obstetrical anesthesia that the agency may want to take into account with respect to future quality measures for maternal health services in rural and rural emergency settings, including the AANA *Analgesia and Anesthesia for the Obstetric Patient Practice Guidelines Analgesia and Anesthesia for the Obstetric Patient Practice Guidelines.*[35] These guidelines promote safe and effective anesthesia care for obstetrical patients and provide guidance for anesthesia professionals and healthcare institutions. As stated in the guidelines, ideal medications for labor analgesia provide effective analgesia with minimal motor blockade, minimal risk of maternal and fetal toxicity, and negligible effect on uterine activity and uteroplacental perfusion. Other important aspects of these guidelines that could be part of best practices include:

- CRNAs conduct a pre-anesthesia assessment and evaluation. CRNAs complete an assessment and evaluation criteria regarding general health, allergies, medication history, preexisting conditions, and anesthesia history in order to develop a patient-specific plan for analgesia and anesthesia. Patients whose obstetric anesthesia care may be challenging or are known to be at risk of significant morbidity should be evaluated for analgesia and anesthesia prior to labor in collaboration with the interprofessional team.
- The anesthesia professional, in partnership with the interprofessional healthcare team, develops the plan of anesthesia care with the patient as an engaged, informed and active decision-maker. The informed consent process provides an opportunity for the anesthesia professional and the patient to share information and explore patient needs, preferences, previous experiences, and concerns to develop the plan for anesthesia care.
- It is ideal to discuss options for analgesia and anesthesia as early as possible. When obtaining informed consent during active labor, time the discussion to occur between contractions to allow the patient to best participate in the discussion. With the patient's consent, conduct discussions when the patient's family or other support persons are present in compliance with the patient's wishes and applicable healthcare privacy laws.

[35] See: https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/professional-practice-manual/analgesia-and-anesthesia-for-the-obstetric-patient.pdf?sfvrsn=be7446b1_10

- Choice of pain relief should be based on patient condition, provider skill set and the resources available at the practice setting. Analgesia and anesthesia considerations are unique for each patient during the three stages of labor, beginning prior to regular uterine contractions, through vaginal or surgical delivery, and continuing after delivery to address any acute pain management needs. Analgesia is individualized to address the stage of labor, maternal discomfort and fetal status.[36] A multimodal plan for labor and, when necessary, surgical analgesia, limits the use of opioids through a patient-specific plan of care that integrates non- pharmacologic, parental opioid, non-opioid, neuraxial and surgical field block. Refer to facility policy for guidance regarding family member presence during analgesia and anesthesia procedures.

VII. RURAL EMERGENCY HOSPITAL (REH) PROVIDER ENROLLMENT

AANA Comment: Include in the Final Rule, Further Guidance or Information Rural Pass through Status when Critical Access Hospitals Covert to REHs

The current proposed rule allows rural hospitals that are currently deemed as Critical Access Hospitals (CAHs) or hospitals to convert to REHs by submitting a Form CMS–855A change of information instead of an initial enrollment. It is unclear in the proposed rule with what happens to the rural pass through status when CAHs convert to REHs. We request that the agency include in the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs final rule further information on what will happen to the pass through status after the hospital conversion.

VIII. ADDITION OF A NEW SERVICE CATEGORY FOR HOSPITAL OUTPATIENT DEPARTMENT (OPD) PRIOR AUTHORIZATION PROCESS

AANA Comment: Requiring Prior Authorization for Facet Joint Injections Might Delay Access to Pain Management Services

We have concerns that the proposed requirement for provider authorization facet joint injections will cause a delay of care especially in rural America, where patients must travel further to receive pain management services. In addition, we request that the agency include in the Hospital Outpatient Prospective Payment

[36] See: Committee on Practice B-O. Practice Bulletin No. 177: Obstetric Analgesia and Anesthesia. Obstet. Gynecol. Apr 2017;129(4):e73-e89 and Orejuela FJ, Garcia T, Green C, Kilpatrick C, Guzman S, Blackwell S. Exploring factors influencing patient request for epidural analgesia on admission to labor and delivery in a predominantly Latino population. J. Immigr. Minor. Health. Apr 2012;14(2):287-291.

and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs final rule, further guidance or information on what must be included in the proposed prior authorization process for facet joint injections. The procedures involved for these injections require anesthesia care and we highlight that these procedures are not always elective in nature and could be medically necessary. In instances when these procedures are used for legitimate medical reasons, we are concerned that patients might experience a delay in care with an additional prior authorization process and that the cost of care will increase if providers are required to submit requests for prior authorization. We would like to have further information on how this prior authorization process would work for our members who participate in these services and for the patients who experience these procedures. In addition, we also ask for further clarification that if the procedures mentioned above receive prior approval, associated anesthesia care would also automatically receive prior approval as well.

The AANA appreciates the opportunity to comment on this proposed rule. Should you have any questions regarding our comments, please feel free to contact the AANA Senior Associate Director, Federal Regulatory and Payment Policy, Randi Gold, at 202-741-9082 or rgold@aana.com.

Sincerely,

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