AANA
American Association of
NURSE ANESTHESIOLOGY

September 7, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS–1786–P
PO Box 8010
Baltimore, MD 21244-1810

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction (88 Fed. Reg. 49522, July 13, 2023)

Dear Ms. Brooks-LaSure:

The American Association of Nurse Anesthesiology (AANA) welcomes the opportunity to comment on the above proposed rule. The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs). AANA membership includes more than 61,000 CRNAs and SRNAs, representing 86 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. For further information, see: https://www.aana.com/about-us.

The issues addressed in our comment are outlined as follows:

- Support Establishing Payment under Medicare Part B for IOP services furnished by OTPs for Treatment of OUD
- Support Proposal to Continue Making Separate Payment for Four Non-Opioid Pain Management Medications
- Create Separate Billing Codes for Non Opioid Anesthesia Services and Treatments for Pain
- CMS Should Increase Access to Non-opioid Pain management Options to all Patients Beginning on January 1, 2024
- Include Behavioral Health as a Measure Topic in the Hospital OQR Program
- List of Gaps in Care that Telehealth Can Address in the Hospital OQR Program

- Prohibit the Use of Wasteful Tele-Supervision of CRNA Services in Measure Development for REHQP
- Reducing Regulatory Barriers for CRNAs Increases Access to Anesthesia Care in Rural Communities
- Support Separate Payment under the OPPS and IPPS for Establishment and Maintenance of a Buffer Stock of Essential Medicines

I. MODIFICATIONS RELATED TO MEDICARE COVERAGE FOR OPIOID USE DISORDER (OUD) TREATMENT SERVICES FURNISHED BY OPIOID TREATMENT PROGRAMS (OTPS)

AANA Request: Support Establishing Payment under Medicare Part B for IOP services furnished by OTPs for Treatment of OUD

AANA applauds the agency's exploration of potential gaps in coding under Medicare payment systems may be limiting access to needed levels of care for treatment of both behavioral health and substance use disorders (SUD) and how those gaps would best be addressed by the creation of new codes or billing rules. AANA supports the agency's proposal to establish payment under Medicare Part B for Intensive Outpatient Programs (IOP) services furnished by OTPs for the treatment of OUD for CY 2024 and subsequent years. Addressing the opioid crisis by expanding coverage for quality treatment options and reducing barriers to care continues to remain a high priority for AANA, and we know this is also a high priority for CMS. We agree that expanding access to coverage and payment under Medicare for (IOP) services provided by Outpatient Treatment Programs (OTPs) will have a meaningful and positive impact in a number of ways including ensuring Medicare beneficiaries have access to this care and also ensuring health equity for Medicare beneficiaries that may face barriers in accessing treatment, such as in rural and underserved areas. In addition, expanding access to coverage and payment under Medicare for IOP services provided by OTPs may help strengthen access to SUD prevention, evidence-based treatment, and recovery services, as well as advance the equity and quality of behavioral health services, which are consistent with the goals of CMS' Behavioral Health Strategy.

II. PROPOSED CY 2024 QUALIFICATION EVALUATION FOR SEPARATE PAYMENT OF NON-OPIOID PAIN MANAGEMENT DRUGS AND BIOLOGICALS THAT FUNCTION AS A SURGICAL SUPPLY

AANA Request: Support Proposal to Continue Making Separate Payment for Four Non-Opioid Pain Management Medications

We appreciate that the agency is proposing 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 for CY 2024, to ensure there are not financial disincentives to using these non-opioid pain management drugs in the ASC setting. As a main provider of pain management services in all types of settings including hospital outpatient departments, CRNAs have been on the front lines of developing novel non-opioid based treatments for chronic, interventional and acute pain. We support CMS' proposal to continue making separate payment for four non-opioid pain management drugs: Exparel, Omidria, Xaracoll, and Dextenza, because they all function as a supply in a surgical procedure under the ASC payment system for CY 2024.

Continued use of these non-opioid pain medications would help decrease the use of opioids to treat pain, cause better patient outcomes and also help control post-operative pain for patients.

III. COMMENT SOLICITATION ON ACCESS TO NON-OPIOID TREATMENTS FOR PAIN RELIEF UNDER THE OPPS AND ASC PAYMENT SYSTEM

AANA Request: Create Separate Billing Codes for Non Opioid Anesthesia Services and Treatments for Pain

CRNAs are helping to reduce the opioid crisis by their use of nonopioid treatments for anesthesia and also for chronic, acute and interventional pain management. CRNAs have been on the front lines of developing novel non-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. AANA recommends the agency further explore creation of payment for providers, including CRNAs, who provide opioid free techniques for anesthesia and treatments for pain. AANA commented to CMS in the CY 2023 Physician Fee Schedule proposed rule where we recommended that the Centers for Medicare and Medicaid (CMS) include separate coding and payment that supports the use of opioid free techniques and enhanced recovery after surgery (ERAS®) pathways available in all settings where these services are provided. We continue to recommend this. We also recommend that these be made available for use for direct reimbursement by providers, such as CRNAs. Currently, opioid free techniques and ERAS® pathways are not reimbursed. Therefore, we recommend that coding be developed and used as a stand-alone or a single unit specialty service in addition to the primary anesthetic. The AANA is concerned about the increases in opioid drug use, abuse and deaths and is committed to working collaboratively toward comprehensive solutions to help curb the opioid epidemic in the United States. The AANA believes that the use of opioid sparing techniques and ERAS® pathways in anesthesia and pain management services are essential since the risk of opioid dependence and addiction begins with the first exposure to the drugs.

As a main provider of pain management services, and as Advanced Practice Registered Nurses (APRNs), CRNAs are uniquely skilled to provide both acute and chronic pain management in a multimodal, patient centered and compassionate manner across the pain continuum in all clinical settings.[1] The approach that CRNA pain management practitioners employ when treating their 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. 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

[1] AANA Chronic Pain Management Guidelines, September 2014, available at: http://www.aana.com/resources2/professionalpractice/Pages/Chronic-Pain-Management-Guidelines.aspx, 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

pain, with appropriate prescribing of an opioid, may prevent access to unused opioids and development of opioid dependency and abuse.
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.[2] A multimodal treatment, 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).[3] 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.[4]

Non-opioid medications include acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), systemic lidocaine or ketamine infusion, long-acting local anesthetics, and gabapentinoids (gabapentin/pregabalin).[5] 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.[6] 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.[7]

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.[8] 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

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[2] Tan M, Law LS, Gan TJ, Optimizing pain management to facilitate Enhanced Recovery After Surgery pathways. Can J Anaesth. Feb 2015;62(2):203-218.

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

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

[5] 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.

[6] 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.

[7] See: Tan M, Law LS, Gan TJ, op cit. and Montgomery R, McNamara SA, op cit.

[8] 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.

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. AANA would like to remain a resource to CMS to further support the agency in the development of additional coding and payment.

AANA Request: CMS Should Increase Access to Non-opioid Pain management Options to all Patients Beginning on January 1, 2024

Over the past six months, thousands of patients[9], dozens of leading advocacy voices[10], and eleven Governors[11] representing 60 million Americans made clear their desire to see enhanced access to non-opioids in the outpatient surgery center. We are disappointed this proposed rule did not include a provision to increase access to non-opioid treatment options to all patients by January 1, 2024.

The opioid crisis in this country is showing no signs of abating anytime soon. In fact, opioid-related overdose deaths are higher than ever. In 2022, more than 82,000 Americans died due to an opioid related drug overdose[12].

In December 2022, the Administration signed into law a landmark spending agreement. Included in this legislation was a policy measure designed to prevent opioid addiction by increasing access to non-opioid pain management approaches in all outpatient surgical centers. The legislation mirrored a policy change put into place by the CMS starting in CY 2019[13] to increase access to and use of non-opioid pain measures in the ambulatory surgical center (ASC) setting to prevent postsurgical opioid misuse and addiction. This policy has been an indisputable success. From 2019 to 2020, use of non-opioid pain management approaches increased by 120 percent[14] – which created opportunities for providers to reduce opioid prescribing in this setting and, in turn, the risk of ASC patients misusing prescription opioids.

Unfortunately, such a policy change was never made for the hospital outpatient department (HOPD) setting, resulting in tens of millions of patients[15] who will not have access to non-opioid pain management

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[9] https://nonopioidchoices.org/wp-content/uploads/2023/07/Citizens-Petition-6.5.23.pdf

[10] https://nonopioidchoices.org/wp-content/uploads/2023/03/VoicesCMSimplementationsignonletter-03.23.23.pdf

[11] https://nonopioidchoices.org/wp-content/uploads/2023/05/Governor-Letter-to-Biden-Admin-NOPAIN-Act-05.17.23.pdf

[12] Centers for Disease Control and Prevention. (2023, May 18). *Provisional data shows U.S. drug overdose deaths top 100,000 in 2022*. Centers for Disease Control and Prevention. https://blogs.cdc.gov/nchs/2023/05/18/7365/#:~:text=The%2079%2C770%20reported%20opioid%2Dinvolved,80%2C997%20in%20the%20previous%20year.

[13] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1678-FC-2018-OPPS-FR-Claims-Accounting.pdf

[14] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals. Federal Register. Available at: https://www.federalregister.gov/documents/2021/08/04/2021-15496/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment

[15] McDermott, K. W., & Liang, L. (n.d.). *Overview of major ambulatory surgeries performed in hospital-owned …* Overview of Major Ambulatory Surgeries Performed in Hospital-Owned Facilities, 2019. https://hcup-us.ahrq.gov/reports/statbriefs/sb287-Ambulatory-Surgery-Overview-2019.pdf

approaches in any given year simply because of their site of care. The legislation signed into law by President Biden[16] fixed this discrepancy and would ensure that all patients undergoing an outpatient surgical procedure would have access to non-opioid pain management options, but the legislation would not go into effect until 2025.

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 patients' 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, we recommend the agency provide patients with increased access to safe and effective non-opioid therapies to treat pain in all settings, including the hospital outpatient setting. We urge CMS to act with the urgency this crisis demands and increase access to non-opioid pain management options to all patients beginning on January 1, 2024 in the final rule.

IV. HOSPITAL OUTPATIETN QUALITY REPORTING (OQR) PROGRAM QUALITY MEASURE TOPICS FOR POTENTIAL FUTURE CONSIDERATION

AANA Comment: Include Behavioral Health as a Measure Topic in the Hospital OQR Program

We appreciate CMS's dedication to expanding access to behavioral health services and for including pain treatment and management in the agency's Behavioral Health strategy. We think it's important to include behavioral health topics for measure development in the hospital outpatient quality program to decrease the quality gaps in care coordination across settings, availability of services, prevention and treatment of chronic conditions and barriers to accessing these services. 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 a main 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 in all clinical settings. [17] 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.[18]

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. CRNAs are involved in every aspect of anesthesia services and work in many types of facilities and also provide acute,

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[16] Carvajal, N. (2022, December 30). *Biden signs $1.7 trillion government spending bill into law | CNN politics*. CNN. https://www.cnn.com/2022/12/29/politics/joe-biden-omnibus/index.html

[17] AANA Chronic Pain Management Guidelines, op cit and AANA, Regional Anesthesia and Analgesia Techniques - An Element of Multimodal Pain Management. Guidelines, https://issuu.com/aanapublishing/docs/15_-_regional_anesthesia_and_analgesia_techniques_ and AANA Guidelines on A Holistic Approach to Pain Management: Integrated, Multimodal, and Interdisciplinary Treatment, https://issuu.com/aanapublishing/docs/1_-_a_holistic_approach_to_pain_management-_integr.

[18] Ibid.

chronic, and interventional pain management services. In some states they are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. As stated above, CRNAs have been on the front lines of developing novel non-opioid based treatments for both chronic and acute pain and the AANA supports maximum flexibility in allowing pain treatment plans that rely on the clinical judgment of the practitioner directing care.

Related to behavioral health, CRNAs are educated and trained to administer ketamine both for sedation and general anesthesia, chronic pain management and also ketamine infusion therapy for psychiatric disorders. Ketamine infusion clinics are becoming more available, and this therapy has been shown to have antidepressive properties and is increasingly becoming used to treat psychiatric disorders, including major depressive disorder (MDD), bipolar disorder, treatment-resistant depression, and post-traumatic stress disorder (PTSD). The AANA supports a patient-centered, interdisciplinary approach to managing patients who suffer from psychiatric disorders and may benefit from ketamine infusion therapy and practice in accordance with professional ethics, scope and standards of practice, sound professional judgment, available evidence, interests of the patient, and applicable law. When administering ketamine for the treatment of psychiatric disorders, CRNAs collaborate with healthcare professionals whose practice includes focusing on and diagnosing mental health and psychiatric disorders within their professional and scope of practice.[19] As part of the collaboration, CRNAs may obtain a referral to provide ketamine infusion therapy for psychiatric disorders. The CRNA's role in ketamine infusion therapy may include, but is not limited to, reviewing healthcare records, obtaining a health history and assessment, performing a history and physical, conducting pre-infusion assessment and evaluation, ordering and evaluating diagnostic tests, ordering or prescribing medications, initiating the infusion, monitoring the patient, conducting post-infusion assessment and evaluation, and managing infusion-related adverse events or complications.[20]

In addition, AANA supports increased patient access to safe, responsible use of medication assisted treatment (MAT) for the comprehensive treatment of substance and opioid use disorders. There are more than 59,000 CRNAs who can now treat opioid addictions with medications such as buprenorphine. These medications ease withdrawal symptoms and improve treatment outcomes. Many of these CRNAs are practicing in rural and underserved communities where access to these services is limited—there are either no qualified providers currently working in the area or they're overwhelmed by the large number of patients, which results in extended wait times.

AANA Request: List of Gaps in Care that Telehealth Can Address in the Hospital OQR Program

Telemedicine has the potential to improve patient experience, outcomes, and access to healthcare, including access to anesthesia, pain management and treatment for mental health and substance use disorders. It is also associated with cost-savings for both patients and healthcare systems. Utilization of telehealth expanded greatly in the outpatient setting during the COVID-19 epidemic and while it does provide a variety of benefits to patients and health systems, there is variability in telehealth's effectiveness across different

[19] AANA and APNA Joint Position Statement on Ketamine Infusion Therapy for Psychiatric Disorders (2019), https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/professional-practice-manual/apna-aana-joint-statement-on-ketamine.pdf?sfvrsn=8ecfb9bb_10

[20] AANA and APNA Joint Position Statement on Ketamine Infusion Therapy for Psychiatric Disorders op. cit

outpatient services. We appreciate that CMS is seeking comments on development of quality measurement topics in the area of telemedicine for the Hospital OQR Program. Our comments below pertain to the specific question regarding the most relevant clinical issues addressable through telehealth in outpatient settings, including quality gaps in outpatient telehealth-related care across HOPD settings and services.

One relevant clinical issue would be better monitoring of people diagnosed with diabetes mellitus. According to the CDC, as of June 2022, 37.3 million or 11.3% of the U.S. population has diabetes and additionally, another 96 million, or 38% of adults 18 years or older, have prediabetes[21]. Diabetes can lead to life-threatening consequences for patients undergoing anesthesia. Traditionally, patients with diabetes had to prick themselves with a needle multiple times daily to determine their glucose levels and subsequent medication requirements. This process contributed to inconsistent monitoring, suboptimal medication administration, and therapeutic non-compliance. Currently, technology and telehealth have created a number of continuous glucose monitoring systems that measure glucose levels continuously to be measured and treated more efficiently[22]. The blood glucose readings are continuously available to the patient and the health care providers as the patient chooses. CMS should consider expanding access to continuous glucose monitors to patients and approving a system supporting interoperability between the patient's phone application that houses the glucose results and the electronic health record used by the rural hospital system where patients seek health care.

A second relevant issue that CMS could address via telehealth is mental health support for young adults aged 18 - 25. Many young adults are navigating through an emotional time of life while dealing with the stress of post-pandemic uncertainties. Some measures that may be addressed in part by telehealth are counseling for anxiety, depression, substance abuse, and several types of personality disorders.[23] CMS could vet and support online mental health support for young adults who could establish a professional relationship with a licensed mental health provider[24]. Most young adults own and engage with their cell phones and other online devices daily. The young adults could obtain professional therapy via telehealth via email, video conference, online chat, or phone call. This target population would be less likely to show up for face-to-face appointments for these services. If CMS would develop a payment structure for such care this process may provide a bridge for young adults contemplating more serious acts such as harming themselves or harming others. CMS's support will be most helpful because many of this target age group may lack medical insurance.

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[21] Centers for Disease Control and Prevention, 2020 National Diabetes Statistics Report, https://diabetesresearch.org/wp-content/uploads/2022/05/national-diabetes-statistics-report-2020.pdf

[22] Funtanilla, V. D., Candidate, P., Caliendo, T., & Hilas, O. (2019). Continuous Glucose Monitoring: A Review of Available Systems. *Pharmacy and Therapeutics*, *44*(9), 550-553, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6705487/

[23] Anxiety and Depression Association of America, Facts and Statistics, https://adaa.org/understanding-anxiety/facts-statistics#Facts%20and%20Statistics

[24] Cadigan, J.M., Lee, C.M. & Larimer, M.E. Young Adult Mental Health: a Prospective Examination of Service Utilization, Perceived Unmet Service Needs, Attitudes, and Barriers to Service Use. *Prev Sci* **20**, 366–376 (2019). https://doi.org/10.1007/s11121-018-0875-8

In addition, CMS has also asked for feedback on the priority concerns regarding disparities in access, use, or outcomes related to telehealth in the outpatient setting. Maternal health morbidity and mortality is an issue that should be prioritized on the agency's health agenda. According to the CDC's Maternal Mortality Rates in the U.S. in 2021 report states "the maternal mortality rate for non-Hispanic Black women was 69.9 deaths per 100,000 live births, 2.6 times the rate for non-Hispanic White women (26.6). Rates for Black women were significantly higher than rates for White and Hispanic women. The increases from 2020 to 2021 for all race and Hispanic-origin groups were significant."[25] According to the CDC, methods hospital systems can work to prevent these deaths include: standardizing coordination of care and response to emergencies, improving delivery of quality prenatal and postnatal care and also training non-obstetric care providers to ask about pregnancy history in the preceding year.[26] CMS should prioritize access to quality maternal health during the perinatal period to decrease the number of maternal deaths among all women. Evidence and research point to the special need to improve access and treatment for Black women who may have experience disparities in maternal care since the first trimester of pregnancy.

V. REHQR PROGRAM MEASURES AND TOPICS FOR FUTURE CONSIDERATION

AANA Recommendation: Prohibit the Use of Wasteful Tele-Supervision of CRNA Services in Measure Development for REHQP

We appreciate that CMS is considering adding measures to the Rural Emergency Hospital Quality Program (REHQP). As part of future rulemaking, CMS should consider adding measures to the REHQR Program measure set that are relevant to the coordination of care between REHs and other kinds of healthcare providers. Health information exchange has the potential to improve the healthcare system in numerous ways by advancing interoperability and health information exchange between patients, providers and health care settings is an important step toward realizing this potential. 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, when developing measures, 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[27] and there is no evidence regarding the benefit for the use of supervision of anesthesia via telehealth.[28]

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[25] Centers for Disease Control and Prevention, Maternal Mortality Rates in 2021, https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.pdf

[26] Centers for Disease Control and Prevention, Working Together to Reduce Black Maternal Mortality (2023), https://www.cdc.gov/healthequity/features/maternal-mortality/index.html

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

[28] 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.

As evidence shows, 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[29] and not a quality standard,[30] we also would urge the agency against using interactive telecommunications technology 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

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.[31] 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. The agency should ensure that future Health IT strategies 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. 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.[32] 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.[33] CRNAs play an essential role in assuring that rural

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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.

[29] 42 CFR §415.110 Conditions for payment: Medically directed anesthesia services.

[30] 63 FR 58813, November 2, 1998.

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

32 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

33 Liao, op cit.

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.

V. POTENTIAL HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS) AND OPPS PAYMENT ADJUSTMENTS FOR THE ADDITIONAL COSTS OF ESTABLISHING AND MAINTAINING A BUFFER STOCK OF ESSENTIAL MEDICINES

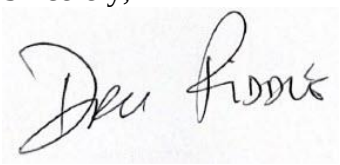
AANA Comment: Support Separate Payment under the OPPS and IPPS for Establishment and Maintenance of a Buffer Stock of Essential Medicines

Drug shortages have been a long-standing problem reported by hospitals and the frequency and severity of these supply disruptions has only been exacerbated over the last few years with the COVID-19 epidemic. They also decrease access to health care. We agree with CMS and also believe it is necessary to support practices that can help to curtail shortages of essential medicines to safeguard and improve the care hospitals are able to provide to patients. This includes establishing and maintaining a buffer stock of essential medicines. With respect to shortages, supply chain resiliency includes having sufficient inventory that can be leveraged in the event of a supply disruption or demand increase. This concept is especially true for essential medicines, which generally comprise of products that are medically necessary to have available at all times and in an amount adequate to serve patient needs and in the appropriate dosage forms. The U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) developed a report on Essential Medicines Supply Chain and Manufacturing Resilience Assessment, which prioritized 86 essential medicines. Anesthesia medications, which are central to many procedures performed in the hospital outpatient setting, are included on this essential medicine list.[34]

We agree that hospitals can and should adopt procurement strategies that foster a consistent, safe, stable, and resilient supply of these essential medicines. We support measures taken to ensure the supply chain can help deliver safe and high-quality health care and would support separate payment under the OPPS and IPPS for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines.

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,



[34] U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response report on Essential Medicines Supply Chain and Manufacturing Resilience Assessment (May 2022), https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

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