September 25, 2019

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
CMS–1717–P  
PO Box 8013  
Baltimore, MD 21244-1850

RE: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children’s Hospitals-Within-Hospitals (84 Fed. Reg. 39398, August 9, 2019)

Dear Ms. Verma:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on the proposed rule Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children’s Hospitals-Within-Hospitals (84 Fed. Reg. 39398, August 9, 2019). The issues addressed in our comment are outlined as follows:

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

II. Changes to the Hospital Inpatient Only List

• Include Strategic Consideration of the Role of Anesthesia in Enhanced Recovery after Surgery Protocol as an Innovative Healthcare Delivery Model

III. Supervision of Hospital Outpatient Therapeutic Services

• Agree that Direct Supervision Requirement for Outpatient Therapeutic Services in Critical Access Hospitals and Small Rural Hospitals Places an Additional Burden on Providers that
IV. Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges

- Support Proposal that Hospitals Make Public the List of their Standard Charges and Request Inclusion of Anesthesia Care as Ancillary Services in a Shoppable Service Situation
- CMS Can Address Underlying Causes of Surprise Billing by Issuing a Proposed Rule on Provider Non-Discrimination Provision and by Promoting Adequate Provider Networks in Medicare Advantage Plans and Health Plans Inside the Marketplace
- CMS Can Work with Health Care Stakeholders in Developing Guidance to Educate Consumers on Questions to Ask Their Insurance Companies to Help Avoid Surprise Billing

V. Request for Information (RFI): Quality Measurement Relating to Price Transparency for Improving Beneficiary Access to Provider and Supplier Charge Information

- Support the Creation of an Anesthesia Specific Survey that will Collect Information on Relevant Anesthesia Quality Measures, Including the Modification of S-CAHPS to Accurately Reflect the Role of CRNAs

VI. Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

- Include in the Final Rule Further Guidance or Information on the Proposal for a Prior Authorization Process for Certain OPD Services

VII. Non-Opioid Pain Management Therapy

- Use of Non-Opioid Alternatives, Such as Multi-Modal Pain Management ERAS® Protocols, Do Lead to a Decrease in Prescription Opioid Use and Addiction

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 nearly 54,000 CRNAs and SRNAs, representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 49 million anesthetics to patients each year in the United States. 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 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. 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*$, CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.$^1$ 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.$^2$ 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.$^3$ Most

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1. 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)


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.\(^4\)

CRNAs 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. 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.\(^5\) 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.\(^6\)

II. CHANGES TO THE HOSPITAL INPATIENT ONLY LIST


As CRNAs personally administer more than 49 million anesthetics to patients each year in the United States, including anesthesia for procedures such as total hip arthroplasty (THA), CRNA services are crucial to the successful development and implementation of the use of techniques such as anesthesia enhanced recovery after surgery (ERAS\(^\text{®}\)) programs. ERAS\(^\text{®}\) is a patient-centered, evidence-based, pain management strategy employed by CRNAs to reduce the need for opioids, improve patient outcomes and reduce costs.\(^7\) Using specific protocol-driven enhanced recovery after surgery 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. Enhanced recovery pathway for total hip arthroplasty engages the entire

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\(^6\) Liao, op cit.

perioperative team with the patient to limit care variation that improves outcomes and patient satisfaction. A total hip arthroplasty that includes minimally invasive surgical techniques and multimodal pain management with motor sparing regional anesthesia allow the patient to eat, drink and walk/exercise soon after recovery from anesthesia. The patient’s pain management plan of care begins pre-procedure and continues through post-discharge using techniques such as regional anesthesia including placement of epidural catheters, targeted peripheral nerve blocks, non-pharmacologic approaches, and non-opioid based pharmacologic measures.

As ERAS® pathways have been implemented, patient engagement in their own plan of care has improved return to preprocedure health on the day of surgery. CRNAs play an integral role in these episodes of care, in both inpatient and outpatient settings, as proper anesthesia services management can make a tremendous difference in terms of improving patient flow, patient safety, and ultimately in cost savings. Conversely, research shows that suboptimal care in the preoperative, intraoperative, or postoperative phases of surgery may compromise care, resulting in poor patient outcomes and unnecessarily higher healthcare costs. Facility and population specific ERAS® protocols engages the patient and the multidisciplinary team in the plan of care and continued assessment of patient status to optimize care, decrease complications, decrease time to discharge, improve outcomes and lower cost of care by limiting variation in care. CRNAs provide many ERAS® elements of care to optimize the patient to return to normal activity and diet, including minimally invasive surgical techniques, giving the patient a carbohydrate beverage at least two hours before surgery, maintaining patient warmth during the procedure and also providing multimodal pain management services to minimize or eliminate use of opioids. We urge that the agency emphasize the strategic consideration of the role of anesthesia delivery that is safe and cost-efficient and include the use of techniques such as ERAS® programs, which help reduce costs and improve patient outcomes. In addition, we ask that the final rule

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include language to assure CRNs are not restricted from providing anesthesia for THA in both the hospital outpatient and ambulatory surgical settings.

III. SUPERVISION OF HOSPITAL OUTPATIENT THERAPEUTIC SERVICES

AANA Recommendation: Agree that Direct Supervision Requirement for Outpatient Therapeutic Services in Critical Access Hospitals and Small Rural Hospitals Places an Additional Burden on Providers that Reduces their Flexibility to Provide Medical Care and Request Clarity on the Definition of “General” Supervision

CRNAs predominately work in these types of facilities in rural areas and we support the change in supervision level to free up resources for the rural hospitals who employ CRNAs. Research evaluating type of facility, size, and anesthesia staffing by rural location shows that 55.5% of small rural hospitals and 61.2% of rural ambulatory surgery centers were predominately staffed by CRNAs. Further research has shown that there is significant geographic variation in anesthesia provider supply and lower supply in rural communities raises concerns about access to procedures that require anesthesia in rural areas. The study found that enforcing state policies related to CRNA practice, such as less restrictive scope of practice regulations, were consistently correlated with a greater supply of CRNAs, especially in rural counties.

We agree with the agency that the direct supervision requirement for hospital outpatient therapeutic services places an additional burden on providers that reduces their flexibility to provide medical care. We appreciate and support the agency’s recommendation to reduce the level of supervision for outpatient therapeutic services in these facilities, however, changing the supervision term from “direct” to “general” provides no guidance or clarification as to what an enforceable minimum level of supervision is. The AANA opposes superfluous Medicare requirements for physician supervision or on-site general oversight that are not linked to demonstrated patient safety benefits, because they impose costs that waste scarce healthcare resources, impair patient access to quality care and do not allow advanced practice professionals to practice to their full scope of practice and licensure in collaboration with the healthcare team and patient. If a regulatory

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11 Coomer N. et al. (2019). Anesthesia staffing models and geographic prevalence post-Medicare CRNA/physician exemption policy. *Nursing Economic*, 37(2), 86-91. [https://search.proquest.com/openview/3f55b0d94533f910b7c0c1dc5d7202bc/1?pq-origsite=gscholar&cbl=30765](https://search.proquest.com/openview/3f55b0d94533f910b7c0c1dc5d7202bc/1?pq-origsite=gscholar&cbl=30765)


13 Martsolf, op cit.
requirement is meaningless in practice, contributes to greater healthcare costs, and is contrary to existing evidence regarding patient safety and access to care, it is obsolete and unnecessary and should be eliminated. CMS has correctly highlighted the impact that supervision requirements have on critical access hospitals (CAHs) and small rural hospitals. The AANA believes that any supervision standards that may impact the provision of CRNA anesthesia services under the misguided interpretation of an “enforceable supervision standard” warrants further examination. We request the agency provide in the final rule, further guidance or clarification on their interpretation of the definition of the term “general supervision.” We also request that the final rule include language that ensures CRNAs can continue to provide anesthesia services with these supervised personnel, perhaps through a similar request for anesthesia services from the general supervising practitioner.

IV. PROPOSED REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC A LIST OF THEIR STANDARD CHARGES

AANA Comment: Support Proposal that Hospitals make Public the List of their Standard Charges and Request Inclusion of Anesthesia Care as Ancillary Services in a Shoppable Service Situation

As health care costs continue to rise, health care affordability has become an area of focus for both patients and healthcare stakeholders. The AANA agrees that there is a lack of pricing information consumers have when they need to choose the healthcare services they want, which can place the patient at risk of paying huge medical bills. There is no transparency on cost of procedures prior to care and there is also no transparency of what procedures are covered or not covered by the patient’s insurance plan. In addition, patients also do not usually have an opportunity to know if their providers are in or out of their network. Therefore, we support the agency’s proposal to expand hospital charge display requirements to include charges and information based on negotiated rates and for common shoppable items and services, in a manner that is consumer-friendly.

Under this proposal hospitals would include anesthesia providers, such as CRNAs and anesthesiologists, as employees of the hospital thereby including their professional fees as ancillary services under shoppable services. It is important to note that under Medicare Part B, Medicare recognizes CRNAs as qualified providers and CRNAs must accept assignment as a condition for payment.14 Therefore, payment for professional fee services is already public and based on the anesthesia fee schedule. In addition, the cost and

14 See 42 §414.60 (c).
risk factors noted above would no longer have to be calculated into the cost of anesthesia care services since they would be borne by the hospital for an inpatient admission or an outpatient procedure. Also, this proposal may encourage hospitals to be more price conscious about the cost of their procedures if they know similar hospitals in the same geographic area are charging less for a procedure such as MRI. This proposal can also add to the growing surprise billing problem. Hospitals may be encouraged to only have in-network providers working in their departments to mitigate the potential for patients to receive a surprise bill. One method to solve this challenge would be where a hospital would contract with an independent anesthesia provider group whose professional fees are determined by the provider group based on individual provider compensation rates and as well as the other variables noted above. Therefore, additional considerations will be needed with regards to contracted clinician groups.

**AANA Comment: CMS Can Address Underlying Causes of Surprise Billing by Issuing a Proposed Rule on Provider Non-Discrimination Provision and by Promoting Adequate Provider Networks in Medicare Advantage Plans and Health Plans Inside the Marketplace**

As stated above, the AANA shares the agency’s concern regarding the issues with insufficient price transparency, particularly with regards to patients being surprised by out-of-network bills and extra facility fees. The economic burden of receiving care out-of-network can be substantial for patients. Furthermore, knowing which providers and services are in-network and out-of-network is a huge burden for the patient as well as the provider and the facility. Allowing patients to know both in and out-of-network information would let them make more meaningful decision regarding their care.

CMS can address this issue best by helping to resolve the underlying causes of surprise billing, such as addressing inadequate networks offered by insurance plans that refuse to contract or work with certain providers and addressing health insurance plans engaging in discrimination against providers based on their licensure or certification. While this is not an issue under Medicare Part B, as Medicare recognizes CRNAs as qualified providers and CRNAs must accept assignment as a condition for payment, this is an issue with private health plans, thus potentially affecting the private payer market and Medicare Advantage plans.

Therefore, it is important to highlight the harms of discrimination CRNAs currently face in the selection criteria that certain health plans develop, which determines the selection of providers that participate in their

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15 See 42 §414.60 (c).
networks. CRNAs, acting within the scope of their license or certification under applicable state law or regulation, have experienced discrimination with respect to participation in qualified health plans, thus forcing them to become an out-of-network provider. Such discrimination may exacerbate surprise billing, impair consumer choice, reduce competition, and affect healthcare costs.

We recommend that CMS use its authority to further implement the federal provider nondiscrimination law by issuing a proposed rule. In 2010, Congress passed this provision in the Patient Protection and Affordable Care Act (Sec. 1201, Subpart 1, creating a new Public Health Service Act Sec. 2706(a), “Non-Discrimination in Health Care, 42 USC §300gg-5),16 which prohibits health plans from discriminating against qualified licensed healthcare professionals, such as CRNAs, solely on the basis of their licensure. This law promotes access to healthcare and consumer choice of healthcare professionals and helps reduce healthcare costs through competition. It prohibits discrimination based on provider licensure that keeps patients from getting the care they need.

To promote patient access to high quality healthcare, market competition and cost efficiency, all qualified health plans must all avoid discrimination against qualified, licensed healthcare professionals, such as CRNAs, solely on the basis of licensure or certification. Proper implementation of the provider nondiscrimination provision is crucial because health plans have wide latitude to determine the quantity, type, and geographic location of healthcare professionals they include in their networks, based on the needs of their enrollees. However, when health plans organize their healthcare delivery in such a way that discriminate against whole classes of qualified licensed healthcare professionals by licensure or certification, for example, by prohibiting reimbursement for anesthesia and pain management services provided by CRNAs, patient access to care is impaired, consumer choice suffers, and healthcare costs climb for lack of competition. Additionally, such discrimination provides incentives for the use of higher-cost providers without improving quality or access to care. Promoting nondiscrimination encourages the use of qualified, licensed, and certified

16 Patient Protection and Affordable Care Act, Sec. 1201, Subpart 1, creating a new Public Health Service Act Sec. 2706(a), Non-Discrimination in Healthcare (42 U.S.C. §300gg-5). The statutory provision reads as follows: “(a) Providers.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any healthcare provider who is acting within the scope of that provider’s license or certification under applicable State law. This section shall not require that a group health plan or health insurance issuer contract with any healthcare provider willing to abide by the terms and conditions for participation established by the plan or issuer. Nothing in this section shall be construed as preventing a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures.”
healthcare professionals such as CRNAs who perform the same services to the same high level of quality as other qualified providers.

Furthermore, while we recognize that CMS has developed network adequacy standards in Medicare Advantage plans and in the Marketplace, CMS must do more to ensure that health carriers maintain networks that are sufficient in numbers and types of providers to assure that all services to covered persons will be accessible to them without unreasonable delay. CRNAs are an important type of provider with an integral role in providing anesthesia and analgesia-related care, including pain management services. They provide safe, high-quality and cost-effective anesthesia care and are advanced practice registered nurses who personally administer more than 49 million anesthetics to patients each year. Furthermore, in rural communities and other medically underserved areas of the United States, CRNAs can be the sole anesthesia professionals. The AANA believes that patients benefit the greatest from a healthcare system where they receive easily accessible care from an appropriate choice of safe, high quality and cost-effective providers, such as CRNAs. Therefore, we request that CRNAs be included in all health carrier network plans, which will help ensure network adequacy, access and affordability to consumers. Doing so would help establish appropriate minimum standards for ensuring sufficient choice of providers within health carrier networks.

**AANA Comment: CMS Can Work with Health Care Stakeholders in Developing Guidance to Educate Consumers on Questions to Ask Their Insurance Companies to Help Avoid Surprise Billing**

The AANA supports the agency’s goal that providers and suppliers of health care service should undertake efforts to engage in consumer-friendly communication of their charges to help patients what their potential financial liability might be for services they obtain and to enable patients to compare charges for similar services. We recommend that CMS work with healthcare stakeholders, such as CRNAs, in developing consumer guidance documents on surprise billing and out-of-network coverage and resources for assistance. For instance, this guidance could provide consumers with the education needed to know what questions to ask their insurance plans prior to procedures and where to go for help. We are happy to assist in the development of these patient tools.
V. REQUEST FOR INFORMATION: QUALITY MEASUREMENT RELATING TO PRICE TRANSPARENCY FOR IMPROVING BENEFICIARY ACCESS TO PROVIDER AND SUPPLIER CHARGE INFORMATION

AANA Comment: Support the Creation of an Anesthesia Specific Survey that will Collect Information on Relevant Anesthesia Quality Measures, Including the Modification of S-CAHPS to Accurately Reflect the Role of CRNAs

In this letter, we have previously stated our support for the proposal to expand hospital charge display requirements for common shoppable items and services and stated our recommendations about how the agency can address the underlying causes of surprise billing. For this RFI, the AANA appreciates the agency’s efforts to ask for healthcare stakeholder recommendations to help improve future policies related to increased transparency in healthcare charge information and how this can lead to increased access to care.

We welcome the opportunity to offer recommendations on improving the ability of health care providers and suppliers to communicate and share charge information with patients and also on improving access to existing quality of health care information for third parties and health care entities to use when developing price transparency tools in the area of anesthesia. Specifically, we support the creation of an anesthesia specific survey that will collect information on relevant anesthesia quality measures. This can include the modification of S-CAHPS to accurately reflect the role of CRNAs. Furthermore, we support the collection of quality measures specifically related to the provision of anesthesia care services and price transparency to improve beneficiary access to provider and supplier charge information.

Nurse anesthetists provide anesthesia to millions of patients annually and currently, there is not much existing literature or evidence that describes patient experiences with anesthesia. More qualitative research is needed particularly about what patients expect and how they interpret care delivery by anesthesia providers.

Although patient satisfaction survey results will likely continue to incentivize hospital payments, providers like CRNAs must advocate with administrators and regulatory agencies for inclusion of measures such as patient outcomes, safety measures, collegial communication, Anesthesia Department professionalism, surgeon satisfaction of anesthesia services, efficiency, and unplanned admissions. In addition, based on current evidence, patient satisfaction survey results used as a single measure of quality will not accurately evaluate

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17 Falco, Darlene et al, “Patient Satisfaction with Anesthesia Care: What do we Know” AANA Journal, August 2017 (Vol. 85, No. 4): 291 [https://pdfs.semanticscholar.org/5de2/cfac85bf5028b78ee975a98a6c25d8265578.pdf](https://pdfs.semanticscholar.org/5de2/cfac85bf5028b78ee975a98a6c25d8265578.pdf)
the quality of anesthesia care. Currently, there are no guidelines established for patient satisfaction and surveys that include anesthesia care.

Anesthesia is a complex subject as it is integral in most of the top surgical procedures performed, yet it accounts for a small part of the top surgical procedures. CMS, CRNAs and patients would all greatly benefit from the creation of an anesthesia specific survey based on the suggested quality measures noted above. Current surveys such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), a patient satisfaction survey required by CMS for all hospitals in the United States and the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey (S-CAHPS), which asks patients to report on surgical care, surgeons, the surgical staff, and anesthesiologists inadequately reflect the key contributions that CRNAs make every day. States such as California, \(^{18}\) Minnesota\(^{19}\) and North Carolina\(^{20}\) have already established methods on how to collect price transparency data. CMS should follow their lead and created a national repository of prices, quality and outcomes for medical specialties that includes the top 35 procedures that will be used to inform consumers. This price transparency can demonstrate a significant link, through evidence-based research, between lower costs/price and increased quality and could also help improve CRNA practice by incorporating processes and initiatives that lower cost and improve patient outcomes.

In addition, we would like to include our recommendations for what types of existing quality of health care information would be most beneficial to patients to help enhance future efforts to improve policies related to transparency in health care charges. We recommend the following information: Infection rate, percent of increase or decrease in final billing over estimated cost, length of stay comparison, morbidity (exacerbation of prior existing medical conditions) requiring increased length of stay or cost 30 days, 60 days, long term quality outcome that would clarify differences in prosthetics, choice of surgical procedure, ERAS or discharge protocols.

### VI. PROPOSED PRIOR AUTHORIZATION PROCESS AND REQUIREMENTS FOR CERTAIN HOSPITAL OUTPATIENT DEPARTMENT (OPD) SERVICES

\(^{18}\) California Health and Safety Code sections 1339.55; sec. 1339.056; sec. 1339.58; sec.1339.585

\(^{19}\) Minn. Stat. sec 62U.04

AANA Comment: Include in the Final Rule, Further Guidance or Information on the Agency’s Proposal for a Prior Authorization Process for Certain OPD Services

The AANA requests that the agency including in the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs final rule, further guidance or information on what specific procedures are included in the proposal for prior authorization of certain hospital outpatient department (OPD) services. These proposed rules state that the certain services fall within the following five categories: blepharoplasty; botulinum toxin injections; panniculectomy; rhinoplasty; and vein ablation. We highlight that these procedures are not always cosmetic in nature and could be medically necessary. In instances when these procedures are used for legitimate medical reasons, we have concerns that patients might experience a delay in care and also that cost of care will increase if providers are required to submit requests for prior authorization. Anesthesia could be tied to these procedures and as a result, 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.

VII. NON-OPIOID PAIN MANAGEMENT THERAPY

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

The AANA appreciates the opportunity to comment on strategies to improve existing requirements to more effectively address the opioid epidemic. Furthermore, the AANA appreciates that the agency is asking for peer-reviewed evidence to describe existing evidence-based non-opioid pain management therapies used in the outpatient and ASC setting. We support the agency’s interest in reviewing peer-reviewed evidence that demonstrates that use of non-opioid alternatives in the outpatient setting and contend that these alternatives do lead to a decrease in prescription opioid use and addiction. 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 (discussed at the beginning of the letter) as a non-opioid alternative to treat pain in all clinical settings. 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. 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\textsuperscript{21}. 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 mitigating the risk of dependency and aiding in the reduction of potential adverse drug events related to opioids.

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.\textsuperscript{22} 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).\textsuperscript{23} 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.\textsuperscript{24}

Non-opioid medications include acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), systemic lidocaine or ketamine infusion, long-acting local anesthetics, and gabapentinoids (gabapentin/pregabalin).\textsuperscript{25} 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.\textsuperscript{26} Non-pharmacological analgesia (e.g., acupuncture, music therapy) as well as cognitive-behavioral techniques (e.g., guided imagery, relaxation), may be used as

\textsuperscript{23} Tan M, Law LS, Gan TJ, op cit.
\textsuperscript{24} Miller ET, Gan TJ, Thacker JK. Enhanced Recovery pathways for major abdominal surgery \textit{Anesthesiology News} 2014.
an adjunct to pharmacological methods to support the patient to reduce postoperative pain, anxiety, and use of pain medication.²⁷,²⁸

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.²⁹ 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).³⁰,³¹,³² 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 (2014); 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

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²⁸ Montgomery R, McNamara SA, op cit
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 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.

The AANA appreciates the opportunity to comment on this proposed rule. Should you have any questions regarding this matter, please feel free to contact the AANA Senior Director of Federal Government Affairs, Ralph Kohl, at 202-741-9080 or rkohl@aanadc.com.

Sincerely,

Kathryn Jansky, MHS, CRNA, APRN, USA LTC (ret)
AANA President

cc: Randall D. Moore, DNP, MBA, CRNA, AANA Chief Executive Officer
Ralph Kohl, AANA Senior Director of Federal Government Affairs
Randi Gold, MPP, AANA Senior Associate Director Federal Regulatory and Payment Policy