Regulatory Challenges to Emergency Medicine Procedural Sedation

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As currently written, national regulatory guidance on procedural sedation has elements that are contradictory, confusing, and out of date. As a result, hospital procedural sedation policies are often widely inconsistent between institutions despite similar settings and resources, putting emergency department (ED) patients at risk by denying them uniform access to safe, effective, and appropriate procedural sedation care. Many hospitals have chosen to take overly conservative stances with respect to regulatory compliance to minimize their perceived risk. Herein, we review and critique standards and policies from the Centers for Medicare & Medicaid Services, The Joint Commission, state nursing boards, the Food and Drug Administration, and others with respect to their effect on ED procedural sedation. Where appropriate, we recommend modifications of and enhancements to their guidance that would improve the access of ED patients to modern, safe, and effective procedural sedation care. [Ann Emerg Med. 2020;■:1-12.]

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INTRODUCTION

As a result of their acute illness or injury, emergency department (ED) patients frequently require urgent procedures, many of which are extremely painful (eg, cardioversion, abscess incision and drainage, fracture and dislocation reduction) or unduly frightening (eg, facial laceration repair, neuroimaging for a child). The timely and effective provision of pharmacologic sedation and analgesia to humanely facilitate such procedures is a standard, necessary, and integral component of emergency medicine practice.[1-12]

Despite pressing patient needs for procedural sedation, many emergency physicians face barriers to the provision of this vital service.[5-8] Procedural sedation practice is dictated and governed at the local hospital level, with policies often widely inconsistent between institutions despite similar settings and resources.[5-8] Such hospital procedural sedation policies are often written and updated without input from local emergency physicians, and are in many cases implemented despite emergency physician objections. In a recent survey,[5] 43% of responding California ED medical directors reported conditional or total limitations on their ability to offer their patients specific levels of procedural sedation or core sedatives; indeed, the practice of deep sedation was specifically and completely prohibited in 18% of responding EDs. Local anesthesia directors were the most frequently cited creators of these restrictions, and respondents noted adverse patient care consequences, including inadequate sedation and pain control, the use of less effective sedatives, and performance of uncomfortable procedures without sedation.[5]

Why are hospital procedural sedation policies so inconsistent? First, many institutions have chosen to take overly conservative stances with respect to regulatory compliance to minimize their perceived risk.[4-8] Such caution often prompts oversimplified interpretations of existing regulatory standards, which admittedly have elements that are contradictory, confusing, and out of date. Second, many hospital directives are founded on guidelines and policies from the American Society of Anesthesiologists (ASA),[13-16] which has crafted its procedural sedation practice and privileging recommendations[6,13-15] to apply equally to all "nonanesthesiologists"[17,18] and makes no accommodation for the advanced airway and resuscitation skills of emergency physicians. The ASA opposes deep sedation by nonanesthesiologists[6,13] and has recently sought to reclassify ketamine and propofol—the 2 most useful and safe ED sedation medications—as "intended for general anesthesia" and thus requiring anesthesia care.[6,13] Hospitals that use these justifications to restrict ED procedural sedation practice deny patients the benefits of humane procedural comfort and anxiolysis.[6]

Accordingly, the American College of Emergency Physicians (ACEP) appointed a work group to create this information article with the objective of ensuring that modern, safe, and effective procedural sedation is available to all ED patients. A clearer understanding of regulatory requirements can enhance consistency among hospitals in their oversight of ED procedural sedation and benefit patient care. Herein, we review and critique standards and policies from the Centers for Medicare & Medicaid Services (CMS), The Joint Commission (TJC), Det Norske Veritas Healthcare (DNV), Health Care Facilities Accreditation Program (HFAP), Food and Drug Administration (FDA) drug labeling, and state nursing boards with respect to their effect on ED procedural sedation. Where appropriate, we recommend regulatory changes.

EMERGENCY PHYSICIAN PROCEDURAL SEDATION SKILLS

Qualified emergency physicians possess the skills and training to safely and effectively provide all levels of procedural sedation (moderate, deep, and dissociative), and to provide emergency general anesthesia as part of rapid sequence intubation, as has been acknowledged by CMS.[19] Indeed, all hospitals automatically credential them for intubation procedures, but paradoxically most do not for procedural sedation, which is less complicated and risky than rapid sequence intubation. Indeed, despite the unusual attention paid by regulatory authorities, procedural sedation is far from the most challenging or complicated of routine emergency physician tasks.

In the United States, emergency medicine is a well-established, highly sought specialty choice, and the core curricula of emergency medicine residencies and pediatric emergency medicine fellowships include broad training in advanced resuscitation skills, airway management and intubation, critical care and vascular access, monitoring, pharmacology, minor surgical techniques, and training and practice in moderate, deep, and dissociative sedation and pain management.[1-4] The safety of ED procedural sedation is supported by a large and robust literature.[1,2,4,6,9-11] Serious adverse events, although rare, are managed effectively by emergency physicians and are no more frequent than with sedation provided by anesthesiologists.[11] The specialty of emergency medicine has fostered a strong procedural sedation safety culture after decades of close attention to practitioner training, patient evaluation, cardiopulmonary monitoring, and other critical safeguards.

Emergency physicians are procedural sedation research leaders and have contributed relevant clinical practice guidelines,[1,3,9,10,20,21] methodological guidelines for research,[12,22-24] and high-profile articles regarding the state of the art and future of sedation.[25-29]

MATERIALS AND METHODS

ACEP appointed a 3-member writing committee with substantial procedural sedation research, administrative experience, or both, and with representation from pediatric emergency medicine and the ACEP Federal Government Affairs Committee. The Emergency Nurses Association and the Society for Pediatric Sedation were each invited and agreed to appoint an additional member to this group, for a total of 5 members.

The committee first performed a foundational review, reconsidering the current pertinent regulatory documents that affect ED procedural sedation practice in the United States. We asked our members to identify and informally outline perceived strengths, weaknesses, and areas of confusion with these documents. We then aggregated our initial appraisals, using the principles of nominal group technique, while soliciting relevant opinions from various thought leaders in ED procedural sedation. We then collated this exploratory feedback and generated work lists of topics to be included and recirculated this listing to the committee for iterative comment and refinement.

We used these work lists to draft document segments, which each then independently underwent repeated, iterative group review using the Delphi method until strong agreement was achieved. The draft document was then assembled and sent for review and critique by the ACEP Federal Government Affairs Committee, State Legislature/Regulatory Committee, and Quality and Patient Safety Committee. We revised the document by using this feedback and finalized it with additional Delphi review.

CMS

In 2010, CMS issued[30] and then in 2011 revised[19,31] its interpretive guidance on §482.52 "Condition of Participation: Anesthesia Services" to include procedural sedation.

In their 2011 revision, CMS specifically acknowledged the unique setting of the ED and the distinctive training of emergency physicians: "The ED is a unique environment where patients present on an unscheduled basis with often very complex problems that may require several emergent or urgent interventions to proceed simultaneously to prevent further morbidity or mortality. In addition, emergency medicine-trained physicians have very specific skill sets to manage airways and ventilation that is necessary

Table 1. Examples of pertinent regulatory guidance from CMS.

CMS Regulatory Guidance	Task Force Comment	Task Force Recommendation
"The anesthesia services must be under the direction of one individual who is a qualified doctor of medicine (MD) or doctor of osteopathic medicine (DO)."[31]	The CMS paradigm is an "anesthesia service" directed by a single physician—in practice almost always an anesthesiologist—in contrast to a multidisciplinary, hospitalwide sedation committee.	CMS regulations should encourage procedural sedation oversight in the form of a collaborative, multidisciplinary sedation committee.
"Although *not required* [emphasis added] under the regulation to do so, a well-organized anesthesia service would develop the hospital's anesthesia policies and procedures in collaboration with several other hospital disciplines (e.g., surgery, pharmacy, nursing, safety experts, material management, etc.) that are involved in delivering these services to patients in the various areas in the hospital." [31] "These collaborative approaches are not, however, a regulatory requirement. A hospital may therefore allow the director to develop the policies alone." [19]	The CMS stipulation of a single anesthesia leader grants that individual wide latitude to create policies based on specialty-driven and personal biases that may be at variance with evidence-based practice, accepted standards of care (such as ACEP procedural sedation guidelines), and the appropriate needs of patients outside of the operating room. Because of the reimbursement for providing procedural sedation, single-specialty oversight is fraught with potential conflicts of interest.	Although CMS permits hospitals to use ACEP guidelines in the ED setting, they currently provide emergency physicians no recourse on behalf of their patients when hospital and anesthesia leaders disallow such optimal procedural sedation care.
"The additional definitions below illustrate distinctions among the various types of 'anesthesia services' that may be offered by a hospital." [31]	CMS defines procedural sedation as an anesthesia service despite clear differences in definitions between the various sedation states and with that of general anesthesia.	Procedural sedation is not general anesthesia, nor is it a subset of general anesthesia. CMS should reconcile the existing language that conflates the two and differentiate procedural sedation from anesthesia services.
"'Anesthesia' involves the administration of a medication to produce a blunting or loss of pain perception (analgesia); voluntary and involuntary movements; autonomic function; and memory and/or consciousness, depending on where along the central neuraxial (brain and spinal cord) the medication is delivered. In contrast, 'analgesia' involves the use of a medication to provide relief of pain through the blocking of pain receptors in the peripheral and/or central nervous system. The patient does not lose consciousness, but does not perceive pain to the extent that may otherwise prevail." [31] "As previously mentioned, there is often no bright line, i.e., no clear boundary, between anesthesia and analgesia." [31]	Sedation is well recognized as a continuum; however, CMS has, in nonstandard fashion and in variance with common sedation guidelines, dichotomized this continuum into "anesthesia" versus "analgesia." Despite incompatibilities in their accepted definitions, CMS classifies deep sedation as a form of anesthesia, and minimal sedation and moderate sedation as forms of analgesia. Sedation is not analgesia, and analgesia is not sedation. This binary anesthesia versus analgesia oversimplification is confusing and at odds with the core construct of procedural sedation as a continuum with graded expectations and precautions based on progressive sedation depth.	CMS should amend their binary anesthesia versus analgesia oversimplification to instead comply with the well-established, core construct of procedural sedation as a continuum, with graded expectations and precautions based on progressive sedation depth.

to provide patient rescue. Therefore, these practitioners are uniquely qualified to provide all levels of analgesia/sedation and anesthesia (moderate to deep to general)."[19]

CMS also noted that various specialty society guidelines "may not always fully agree with each other," but affirmed that "[a] hospital could use multiple guidelines, for example, ACEP for sedation in the emergency department and ASA for anesthesia/sedation in surgical services, etc."[19]

Despite the supportive wording, many emergency physicians remain unable to provide optimal procedural sedation for their patients in accordance with ACEP guidelines.[5-8] Many hospital and anesthesia leaders continue to maintain barriers to such care according to the local interpretations of CMS language, as discussed later and summarized in Table 1. We provide recommendations in the Figure.

THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- CMS should clarify and modernize their procedural sedation regulations to mitigate the unintended consequence of hospitals restricting appropriate, evidence-based sedation practices.
- Procedural sedation is not general anesthesia, nor is it a subset of general anesthesia. CMS regulations should reconcile the existing language that conflates the two, and differentiate procedural sedation from anesthesia services.
- Sedation is not analgesia, and CMS regulations should reconcile the existing language that conflates the two.
- CMS regulations should encourage appropriate and patient-centric oversight for the multidisciplinary practice of procedural sedation in the form of a collaborative, multidisciplinary sedation committee. Although CMS permits hospitals to use ACEP guidelines in the ED setting, they provide emergency physicians no recourse on behalf of their patients when the hospital and anesthesia leaders disallow such optimal procedural sedation care.
- The current CMS focus on scheduled, elective sedation encounters should be amended to additionally acknowledge the unique issues and needs of unscheduled, urgent sedation.
- CMS should amend their binary "anesthesia versus analgesia" oversimplification to instead comply with the well-established, core construct of procedural sedation as a continuum, with graded expectations and precautions based upon progressive sedation depth.
- To address and resolve the existing high variance in hospital classification of ketamine, CMS should acknowledge that the clinical effects of this dissociative agent are incompatible with their existing sedation state definitions. The most evidence-based resolution is a separate definition for dissociative sedation.

THE JOINT COMMISSION

- Like CMS, the Joint Commission should acknowledge the unique qualifications of emergency physicians to provide all levels of procedural sedation.
- The Joint Commission should acknowledge that the most appropriate and patient-centric oversight for the multidisciplinary practice of procedural sedation is a collaborative, multidisciplinary sedation committee.
- The current Joint Commission standards that address scheduled, elective sedation encounters should be amended to recognize the unique issues and needs of unscheduled, urgent and emergent sedation.
- To address and resolve the existing high variance in hospital classification of ketamine, the Joint Commission should acknowledge that the clinical effects of this dissociative agent are incompatible with their existing sedation state definitions. The most evidence-based resolution is a separate definition for dissociative sedation.

DET NORSKE VERITAS HEALTHCARE

- See recommendations for CMS

HEALTH CARE FACILITIES ACCREDITATION PROGRAM

- See recommendations for CMS

STATE NURSING BOARDS

- Emergency nurses are critical care nurses and, while working in direct collaboration with the ordering physician, should be permitted to administer any and all medications ordered for procedural sedation.

UNITED STATES FOOD AND DRUG ADMINISTRATION

- Clinicians, administrators, and policy-makers must recognize that modern procedural sedation practice is commonly off-label, as FDA product labeling does not include applications in widespread use that are supported by well-established evidence.
- Clinicians, administrators, and policy-makers should not rely on FDA product labeling to establish procedural sedation policy or practice. Instead, high quality evidence in medical literature should be referenced.

Figure. Recommendations to regulatory agencies and organizations regarding modifications of and enhancements to their guidance that would improve the access of ED patients to modern, safe, and effective procedural sedation care. Should any of these organizations request it, ACEP is willing to provide specific text proposals that would address these concerns.

Procedural Sedation Is Not Anesthesia

The language used in CMS regulations depicts procedural sedation as a subset of anesthesia, despite clear differences in definitions between the various sedation states and general anesthesia. Emergency physicians administer procedural sedation for short, focused procedures: targeting drugs, doses, and techniques that are likely to preserve independent airway control and effective, spontaneous ventilation. In contrast, operative general anesthesia usually involves lengthy procedures and active airway control. TJC and all major specialty society guidelines clearly distinguish procedural sedation from general anesthesia. When discussing procedural sedation, the CMS guidelines use inapplicable operating room nomenclature (eg, "anesthesia administration," "postanesthesia evaluation," "postoperative hydration"). CMS uses the nonstandard phrase "anesthesia continuum" to refer to the "sedation continuum,"[31] whereas TJC and all major specialty society guidelines recognize general anesthesia as simply the terminus of this sedation continuum.

This erroneous merging of procedural sedation with general anesthesia is confusing and misleading, and projects an anesthesiacentric CMS paradigm on the multidisciplinary practice of procedural sedation. CMS further conflates the differing concepts of sedation and analgesia by arbitrarily classifying minimal and moderate sedation as "analgesia." Sedation is not analgesia, and analgesia is not sedation. Given such a context, readers of CMS regulations are thus prone to misjudge the nature and evidence supporting procedural sedation outside of the operating room. Examples follow.

Multidisciplinary Procedural Sedation Leadership Versus an "Anesthesia Service"

A first example of the aforementioned paradigm is the CMS stipulation that procedural sedation be organized under an "anesthesia service" directed by a single physician—in practice almost always an anesthesiologist—in contrast to TJC, which supports oversight by a multidisciplinary, hospitalwide sedation committee. CMS encourages "collaborative" development of the policies within the anesthesia service; however, such multidisciplinary input is "not required."[31]

Although the anesthesiologist assigned to manage the anesthesia service can be presumed expert in operative general anesthesia, such skills do not confirm expertise in procedural sedation as commonly performed outside of the operating room, nor effective understanding of its extensive supporting literature. In many hospitals, emergency physicians and others perform more procedural sedation than do anesthesiologists, and their inclusion in procedural sedation leadership not only broadens the expertise but also ensures that its leadership focus is realistic and patientcentric.[8,32] The CMS stipulation of a single anesthesia leader grants that individual wide latitude to create policies based on personal biases that may be at variance with literature evidence, accepted standards of care (such as ACEP procedural sedation guidelines[5-8]), and the appropriate needs of patients outside of the operating room.[1,4,6-8] As noted in the "Introduction," a recent California statewide survey noted that 43% of responding California ED medical directors reported conditional or total limitations on their ability to offer their patients specific levels of procedural sedation or core sedatives; indeed, the practice of deep sedation was specifically and completely prohibited in 18% of responding EDs.[5] These actual clinical situations may deprive patients of humane procedural comfort by the emergency physicians who CMS itself recognizes "are uniquely qualified to provide all levels" of sedation.[19]

Because of the reimbursement for providing procedural sedation, oversight by anesthesia is fraught with potential conflicts of interest.[4,6-8,33] The model of a single service having authority over all procedural sedation does nothing to mitigate and in fact enhances these conflicts of interest. The ASA has asserted its vision of unilateral control over the procedural sedation privileging and practice of all others,[14,15] including its own proprietary educational courses.[34] The ASA has voiced long-standing[15,35] and current[6,13,36] opposition to deep sedation by others, a position at odds with the enormous weight of the scientific evidence. The goal must be patient-centered sedation care, not individual-service, special-interest-centered care.

The most appropriate and patientcentric oversight for the multidisciplinary practice of procedural sedation is a collaborative, multidisciplinary sedation committee. A single physician can chair such a committee; however, the breadth of procedural sedation practitioners should have sufficient representation in this process such that sound, evidence-based procedural sedation advances receive full and appropriate consideration. When unmet procedural sedation needs are identified, the collaborative multidisciplinary leadership should assist with forming solution strategies.[7,8,32]

Unscheduled Procedural Sedation

CMS regulatory guidance is focused on issues and practices germane to scheduled, elective sedation encounters, with such guidance extrapolated to regulate

unscheduled procedural sedation (ie, the provision of sedation on short notice to facilitate urgent or emergency procedures). Despite the specific CMS guidance that "[a] hospital could use multiple guidelines, for example, ACEP for sedation in the emergency department…,"[19] many hospital and anesthesia leaders do not permit emergency physicians to provide care in accordance with ACEP guidelines.[5-8] CMS should acknowledge the widespread practice of unscheduled sedation and its unique issues, needs, and patient benefits as outlined in ACEP policies.[1,3,4]

Sedation Continuum Condensed to "Anesthesia Versus Analgesia"

It is well established that nondissociative sedation exists as a continuum. This continuum is ill suited to subdivision, given its wide span and even, smooth progression. TJC and all major specialty society guidelines advocate graded and nuanced expectations and precautions based on the anticipated sedation depth along this continuum. In contrast, CMS has, in nonstandard fashion, dichotomized this continuum into "anesthesia versus analgesia."[19] CMS defines the continuum levels ranging from deep sedation through general anesthesia as "anesthesia" and those ranging from analgesia through moderate sedation as simply "analgesia."[19,31] CMS regulatory guidance applies uniformly to all continuum levels thus categorized as anesthesia and largely exempts all continuum levels considered analgesia.

Procedural sedation is not anesthesia, as emphasized earlier, and for frequent sedation practitioners this binary, anesthesiacentric paradigm of the sedation continuum is unhelpful and confusing. No specialty societies have subsequently adopted this dichotomy. CMS has recognized this problem, acknowledging "a great deal of feedback from a variety of practitioners suggesting that some of the examples provided in the guidance did not clearly fall on one side or the other of the anesthesia/analgesia spectrum."[19] However, their response was to remove the examples rather than to correct the underlying oversimplification. The anesthesia versus analgesia CMS duality remains problematic for multiple reasons.

First, the act of dichotomizing the sedation continuum is at variance with decades of procedural sedation guidelines and sedation state definitions. By contradicting the core construct of sedation as a continuum, even if just for regulatory convenience, CMS discourages clinical recognition and appreciation of this fundamental tenet of procedural sedation training and safe practice. Anesthesiologists (focused on the provision of general anesthesia) and hospital administrators (focused on regulatory compliance) may experience no discomfort with this anesthesiacentric paradigm; however, effectively managing this sedation continuum is a daily reality for emergency physicians and other practitioners who provide procedural sedation.

Second, the CMS characterization of moderate sedation as analgesia exempts it from traditional, widely accepted safeguards (eg, presedation evaluation, intrasedation monitoring and documentation, postsedation evaluation). Such omissions are at unacceptable variance with all major specialty society guidelines and with TJC standards. This leads to the erroneous designation of deep sedation as "anesthesia" despite their mutually exclusive definitions. This inappropriately equates the risk of brief ED deep sedation, performed with spontaneous respirations, to that of an extended operating room surgery using general anesthesia and active airway manipulation. Such mischaracterization encourages hospitals and anesthesia chiefs to restrict appropriate ED deep sedation care.

Third, CMS has arbitrarily dichotomized the sedation continuum in the territory between moderate and deep sedation, a choice that is the most problematic for emergency physicians, given that we frequently target our sedation depth within this specific zone. By definition, the difference between moderate and deep sedation is a purposeful response to voice or light tactile stimulation versus a purposeful response to repeated or painful stimulation.[31] This distinction is inherently subjective and has long fostered irreconcilable semantic and political disputes.[1,6,27] A consequence of this CMS paradigm of analgesia versus anesthesia is that sedation practitioners are compelled to repeatedly stimulate their patients to reverify their targeted sedation level. Such noxious prodding is fundamentally counterproductive to the intended state of tranquility, and adversely affects patient comfort. Responsiveness is an imperfect surrogate marker for the preferred gauge of sedation safety: ventilatory stability.[1,27,37]

Omission of Ketamine/Dissociative Sedation

Ketamine has been one of the most widely administered ED sedative agents for decades[1,3,10,38,39] and has a level A safety rating from ACEP.[3] In 1999, the ED use of ketamine was reviewed by TJC, found to be consistent with their standards, and highlighted in their publication *Care of Patients: Examples of Compliance*.[40] Despite this, no specific reference to ketamine is made in the CMS regulations. This is problematic in that hospital procedural sedation policies exhibit substantial variability in their treatment of the unique ketamine dissociative state. Some have chosen to classify it as general anesthesia, whereas others designate it

as deep sedation or moderate sedation, with ED restrictions more frequent in the earlier categories.

Ketamine works by an entirely different mechanism than the other sedative and anesthetic agents—by dissociation rather than cortical depression—and this fundamentally separate action challenges its reconciliation with the traditional stages of the sedation continuum.[1,10,25,41] Patients receiving typical dissociative doses are unable to respond to external stimuli (including repeated or painful stimulation), in violation of established definitions of moderate or deep sedation.[13,31,40] However, general anesthesia cannot reasonably apply either in that this definition specifies that "the ability to independently maintain ventilatory function is *often* impaired" and that "patients *often* require assistance in maintaining a patent airway" (emphasis added).[13,31,40] Ketamine uniquely preserves normal, spontaneous ventilation in essentially all cases, and respiratory adverse events are rare and readily managed.[1,10,25,41]

Any labeling of ketamine's effects as "general anesthesia" is not just incorrect according to the definitions mentioned earlier but is also misleading in that it suggests an exaggerated level of risk.[1,10,25,41] The simple resolution to this irreconcilable semantic debate is to separately consider this unique drug on its own terms. ACEP and others endorse a separate category of dissociative sedation with its own definition: "A trancelike cataleptic state characterized by profound analgesia and amnesia, with retention of protective airway reflexes, spontaneous respirations, and cardiopulmonary stability."[2,6,10,25]

TJC

Standards from TJC that address procedural sedation are PC.03.01.01 through PC.03.01.07, PI.01.01.01, and RC.02.01.03.[42]

TJC appropriately classifies procedural sedation levels as distinct from general anesthesia and uses clear and unambiguous terminology that acknowledges these differences (eg, "presedation assessment" versus "preanesthesia assessment"). TJC appropriately does not dichotomize the sedation continuum and requires sedation precautions for moderate sedation. These differences place TJC in greater alignment than CMS with various specialty society procedural sedation guidelines.

We discuss TJC standards relevant to ED procedural sedation next, and provide recommendations in the Figure.

Emergency Physician Skills

Although CMS acknowledges the unique qualifications of emergency physicians to provide all levels of procedural sedation, TJC does not. Such absence permits hospitals and anesthesia leaders to unduly restrict safe and effective sedation practice, depriving ED patients the benefits of humane procedural comfort and anxiolysis.[5-8]

Procedural Sedation Leadership

Unlike the CMS stipulation of an anesthesia service led by a single anesthesiologist, TJC permits oversight of procedural sedation practice either by a single physician or by a collaborative, multidisciplinary committee. It would be preferable for TJC to acknowledge the latter committee format as the most appropriate and patientcentric for reasons discussed in the CMS section. When safe and effective sedation care in accordance with literature evidence, standards of care, and ACEP guidelines is not permitted by single-disciplinary sedation leadership, emergency physicians must have recourse to advocate for their patients.

Unscheduled Procedural Sedation

As with our earlier discussion regarding CMS, TJC's standards are limited to the issues and practices germane to scheduled, elective sedation encounters. TJC standards should acknowledge the widespread practice of unscheduled sedation and its unique issues and needs as outlined in ACEP policy.[1,3,4]

Omission of Ketamine/Dissociative Sedation

As in our earlier discussion regarding CMS, TJC standards make no specific reference to ketamine. The result is substantial variability in how hospital procedural sedation policies address the unique dissociative state, with frequent misclassification as moderate sedation.

TJC highlighted ED ketamine administration to facilitate pediatric procedures in 1999 as an "example of compliance"[40]; however, such language has not been repeated in later TJC documentation, and as a result many hospitals unduly restrict such safe and effective dissociative sedation.

DNV

DNV is an alternative accreditation to TJC. Procedural sedation is addressed under their National Integrated Accreditation for Healthcare "Anesthesia Services" accreditation requirements.[43]

The DNV interpretive guidelines are largely taken verbatim from CMS, with some areas paraphrased. As such, the same issues apply to DNV as to CMS, as discussed earlier.

HFAP

HFAP is an alternative accreditation to TJC. Procedural sedation is addressed under their "Anesthesia Services" accreditation requirements.[44]

The HFAP interpretive guidelines are largely taken verbatim from CMS, with some areas paraphrased. As such, the same issues apply to HFAP as to CMS, as discussed earlier.

STATE NURSING BOARDS

Emergency nursing is a discipline of critical care nursing, and it is within the licensed scope of practice for such nurses to administer intravenous drugs for critical conditions, including cardiac arrest, shock, rapid sequence intubation, anaphylaxis, myocardial infarction, and stroke. Indeed, most emergency nurses do so daily, working in direct, side-by-side collaboration with emergency physicians to facilitate patient management.

Some state nursing boards prohibit ED nurses from administering specific drugs, such as propofol or ketamine for procedural sedation. Nurses can administer these same drugs for other common ED indications (eg, rapid sequence intubation, postintubation sedation, analgesia). CMS has supported nurse administration of sedatives, reporting the following statement in their January 2011 update: "The Emergency Nurses Association (ENA) and the American College of Emergency Physicians (ACEP) support the delivery of medications used for procedural sedation and analgesia by credentialed emergency nurses working under the direct supervision of an emergency physician. These agents include but are not limited to etomidate, propofol, ketamine, fentanyl, and midazolam."[19] In some jurisdictions the laws are unclear, and hospitals may as a result conservatively prohibit nurse administration of sedative agents for fear of a regulatory audit.

When emergency nurses are not permitted to administer procedural sedation agents, this duty then falls to the emergency physician. This is problematic in that it adds complexity, and may result in delays in care, as well as decreased quality in the care provided. The emergency physician should attend to oversight of essential aspects of procedural sedation, including choosing the appropriate medication(s), assessing adequacy of sedation, and ongoing assessment of the airway, respiratory, and hemodynamic status. Requiring the physician to personally administer the drugs may distract him or her from these critical tasks. The emergency nurse is educated, trained, and qualified to prepare and administer all sedative medications. Nursing care includes verification of medications through a double-check process and ensuring that the correct drugs are given in the manner ordered by the physician. Last, most physicians are not granted access to drug-dispensing-control devices (eg, Pyxis). Adding an additional step requiring involvement of the nurses, pharmacist, or both to obtain and hand off the drugs necessary for the procedure increases the number and times that information must be verified, and lengthens the entire procedure. Fragmentation of care and limiting the practice of nurses educated and trained in the administration of these medications increases the risk for error.

FDA

The FDA-approved indications for the 6 most common ED procedural sedation agents are shown in Table 2. Just one (midazolam) has labeling consistent with modern procedural sedation practice, with a second (dexmedetomidine) partially compatible (adults but not children). Propofol is approved not for procedural sedation, but for "monitored anesthesia care." FDA labeling does not reflect the reality that drugs used for sedation are often safely used for anesthesia, and drugs used for anesthesia are often safely used for sedation. Fundamental inconsistencies between labeling and widely accepted standards of care in procedural sedation and operative anesthesia are shown in Table 3.

The wide gap between FDA labeling and routine clinical practice is well known throughout medicine, with off-label indications commonly used in routine practice.[45-52] This disparity is the result of the FDA drug approval process, which relies on drug manufacturers to fund the required, supporting research. The motivations supporting these financial investments are lost once the drug patent expires. Thus, as clinical researchers identify and establish new applications for generic drugs, the corresponding FDA labeling reflects only the original indications. The FDA requires "adequate and well controlled studies,"[53] which are often the most expensive part of bringing a drug to market. For generics, there is no remaining incentive, as summarized by one pharmaceutical executive: "Generic drugs found to work for a new disease are in a state of purgatory."[54] The FDA also typically requires placebo-controlled trials,[47] and it would be unethical to administer placebo in place of a sedative to facilitate a painful procedure.

As a result, off-label drug administration does not mean inappropriate use, and such unapproved indications are widely entrenched in the clinical practice of all major specialties, and are often supported by substantial,

Table 2. FDA-approved indications for sedative agents, sorted by generally decreasing frequency of ED application.

Drug	Anesthesia Indications	Adult Sedation Indications	Pediatric Sedation
Propofol	Adults and children ≥3 y: Induction of general anesthesia Adults and children ≥2 mo: Maintenance of general anesthesia	Initiation and maintenance of monitored anesthesia care sedation Combined sedation and regional anesthesia ICU sedation of patients who are intubated and receiving mechanical ventilation	Not approved
Ketamine	Adults and children ≥16 y: Ketamine is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation. It is best suited for short procedures but it can be used, with additional doses, for longer ones. Ketamine is indicated for the induction of anesthesia before the administration of other general anesthetic agents. Ketamine is indicated to supplement low-potency agents, such as nitrous oxide.	Not approved	Not approved
Midazolam	Adults and children: Intravenously for induction of general anesthesia, before administration of other anesthetic agents. With the use of narcotic premedication, induction of anesthesia can be attained within a relatively narrow dose range and in a short period. Intravenous midazolam can also be used as a component of intravenous supplementation of nitrous oxide and oxygen (balanced anesthesia).	Adults and children: Intramuscularly or intravenously for preoperative sedation/anxiolysis/amnesia Intravenously as an agent for sedation/anxiolysis/amnesia before or during diagnostic, therapeutic, or endoscopic procedures, such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography, cardiac catheterization, oncology procedures, radiologic procedures, suture of lacerations, and other procedures either alone or in combination with other CNS depressants Continuous intravenous infusion for sedation of patients with intubation and mechanical ventilation as a component of anesthesia or during treatment in a critical care setting	
Fentanyl	Adults and children ≥2 y: Analgesic action of short duration during the anesthetic periods, premedication, induction, and maintenance, and in the immediate postoperative period (recovery room) as the need arises Used as a narcotic analgesic supplement in general or regional anesthesia Administration with a neuroleptic as an anesthetic premedication, for the induction of anesthesia, and as an adjunct in the maintenance of general and regional anesthesia Used as an anesthetic agent with oxygen in select high-risk patients, such as those undergoing open heart surgery or certain complicated neurologic or orthopedic procedures	Not approved	Not approved
Dexmedetomidine	Not approved	Dexmedetomidine hydrochloride injection is indicated for sedation of nonintubated patients before and during surgical and other procedures.	Not approved
Etomidate	Adults and children ≥10 y: Etomidate is indicated by intravenous injection for the induction of general anesthesia.	Not approved	Not approved

Table 3. Inconsistencies between FDA product labeling and modern clinical practice.

FDA Drug Labeling	Modern Clinical Practice
Ketamine is not approved for procedural sedation.	For decades, ketamine has been one of the most widely used ED procedural sedation agents. The evidence for this practice is supported by extensive literature and an ACEP level A rating.
Propofol and ketamine are not approved for children for either anesthesia or sedation.	Propofol and ketamine are widely used in children for both operative surgery and procedural sedation, with extensive supporting literature evidence.
Intravenous fentanyl is not approved for use as an analgesic outside of the anesthesia/operating room setting.	Intravenous fentanyl is widely used for analgesia in the ED and in other settings outside of the operating room.
Fentanyl and etomidate are not approved for procedural sedation.	Fentanyl and etomidate have had widespread use for procedural sedation, with ample supporting literature evidence.
Dexmedetomidine is not approved for children.	Dexmedetomidine is widely used in children, with extensive supporting literature evidence.
Propofol "should be administered only by persons trained in the administration of general anesthesia." Ketamine "should be used by or under the direction of physicians experienced in administering general anesthetics." Intravenous fentanyl "should be administered only by persons specifically trained in the use of intravenous anesthetics." Etomidate "should be administered only by persons trained in the administration of general anesthetics."	Propofol, ketamine, intravenous fentanyl, and etomidate are widely administered by emergency physicians and other specialists who are not anesthetists, with extensive supporting literature evidence.

convincing literature evidence.[45,48-52] In many cases, off-label uses predominate for specific clinical conditions, as they do for procedural sedation. Unapproved indications are clinically appropriate when the benefits outweigh the potential risks and suitable clinical alternatives are lacking.[45,47-52] Because children are often excluded from clinical drug studies, off-label indications are particularly prevalent in pediatrics.[45,46,51,52,55] As summarized by the American Academy of Pediatrics, "Off-label use is neither incorrect nor investigational if based on sound scientific evidence, expert medical judgment, or published literature."[46] The American Academy of Pediatrics also states that "[e]vidence, not label indication, remains the gold standard from which practitioners should draw when making therapeutic decisions for their patients."[46]

Accordingly, we must all recognize and accept that modern procedural sedation practice is of necessity primarily off label.[47] Hospitals and clinicians should not rely on FDA product labeling to establish procedural sedation policy or practice when contrary to medical literature evidence.[46,47]

CONCLUSION

As currently written, national regulatory body guidance on procedural sedation has elements that are contradictory, confusing, and out of date. As a result, hospital procedural sedation policies are often widely inconsistent between institutions despite similar settings and resources, putting ED patients at risk by denying them uniform access to safe, effective, and appropriate procedural sedation care. Many hospitals have chosen to take overly conservative stances with respect to regulatory compliance to minimize their perceived risk. Such hospital procedural sedation policies are often written and updated without input from local emergency physicians and are in many cases implemented despite emergency physician objections. We have reviewed and critiqued standards and policies from CMS, TJC, and other primary regulatory organizations with respect to their influence on ED procedural sedation. We recommend modifications of and enhancements to their guidance that would facilitate consistent, evidence-based hospital sedation policies and improve the access of ED patients to modern, safe, and effective procedural sedation care.

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