James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT
james.madara@ama-assn.org

August 29, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS–3419–P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates, CMS–3419–P

Dear Administrator Brooks-LaSure:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services Conditions of Participation for Rural Emergency Hospitals (REH) and Critical Access Hospital (CoP Updates Proposed Rule.[1] The AMA supports the goals of the Proposed Rule to ensure equitable access to high quality care in rural communities and understands the importance of this proposed rule as rural hospitals continue to close leaving vast care deserts.

In the rule, Centers for Medicare and Medicaid Services (CMS) proposes conditions of participation (CoPs) for REHs, a new facility-type under Medicare created through the passage of the Consolidated Appropriations Act of 2020. Under this new Medicare facility-type, critical access hospitals (CAHs) and other hospitals can convert to REHs to continue offering emergency and outpatient care instead of closing. Consistent with statutory intent, REH's will be granted more flexibility in establishing conditions of participation in an effort to reach as many underserved rural communities as possible. However, as expansion of care is considered under this proposed rule it is equally important to ensure that the quality of care remains high and that safe treatment is provided. As such, the AMA offers the following comments.

Proposed Condition of Participation: Governing Body and Organizational Structure of the REH

Governing Body Requirements

The Administration has proposed that a REH must have an effective governing body, or responsible individual or individuals, that are legally responsible for the conduct of the REH. The commission of the governing body will include, in accordance with state law, determining which categories of practitioners are eligible candidates for appointment to the medical staff. However, though it is encouraged that the medical director be a physician, it is not required. The AMA understands and supports the need to have an effective governing body; however, we believe that it is important that an experienced physician be included in the governing body and serve as the medical director of the REH. Physicians are uniquely

[1] https://www.federalregister.gov/documents/2022/07/06/2022-14153/medicare-and-medicaid-programs-conditions-of-participation-cops-for-rural-emergency-hospitals-reh#sectno-reference-485.520.

positioned and trained to be the head of the care team. With the additional years of education and training that physicians receive, they are prepared to lead other health care professionals, they understand the role that all the health practitioners play, and they are the best equipped to understand the medical implications of decisions that are made quickly in the emergency medicine setting. As such, it should be required that a physician be the medical director of an REH.

Telemedicine Credentialing and Privileging

In the proposed rule the Administration looks to expand the use of telemedicine within REHs. CMS notes the important role that telemedicine plays when providing care in rural communities and proposes a flexible telemedicine and privileging process similar to the telemedicine process requirements established for hospitals and CAHs. This includes enabling the governing body to develop an agreement with the distant site telemedicine provider, which must be a Medicare-participating hospital, specifying that the governing body of the distant site hospital is responsible for providing the telemedicine services to meet the licensing and credentialing requirements per Medicare regulations. Under this alternative approach, the governing body of the REH could grant privileges to distant-site physicians and practitioners based on the recommendations of its medical staff. These flexibilities would allow a practitioner to utilize a variety of methods to provide health care services, including being on-site at a facility or at a distant site furnishing services remotely to a patient located at an originating site which includes a REH.

The AMA supports the increased use of telemedicine and applauds the requirement that the individual distant-site physician or practitioner hold a license issued or recognized by the state in which the REH whose patients are receiving such telemedicine services is located. However, there are a few shortcomings within this proposal. Many physicians have experience and expertise in providing emergency care in rural areas, and typically live in the communities where they work. While telemedicine will be needed in REHs to consult specialists or to fill in when local physicians are unavailable, REHs should not be permitted to use telemedicine to provide all physician services and supervision when a local physician is otherwise available and willing to provide the care in person.

Moreover, the AMA is concerned that the proposal to require distant site hospitals to meet Medicare licensing and credentialing requirements could be interpreted to apply to direct-to-consumer (DTC) telemedicine companies that may enter into agreements with REHs. If a significant amount of an REH's care is provided by or overseen by DTC telehealth companies, this streamlined credentialing process for telemedicine entities could lead to fragmented care. DTC telehealth companies do not typically coordinate with patients' primary care physicians and are often located hundreds of miles away from the patient, without any knowledge of the local community. The clinicians providing care, therefore, are unaware of what community-based resources are available to meet patients' health-related social needs and may be unequipped to refer REH patients to other health care professionals for follow-up care. Thus, we urge CMS to ensure that REH CoPs encourage the employment of local physicians and do not allow REHs to replace local physicians with clinicians who provide care to REH patients exclusively through telemedicine.

Additionally, it is important for the Administration to ensure that the staffing standards of the distant-site telemedicine entities are equivalent to that of the REH—including ensuring access to a board-certified emergency physician or other physician with significant training and/or experience in emergency medicine. As this proposed rule moves forward it will be important to clarify if the distant-site hospital and physicians and practitioners that are credentialed and privileged to provide telemedicine services within that hospital must be enrolled in Medicare. Although CMS first states that the REH must ensure that "the distant-site hospital providing the telemedicine services is a Medicare-participating hospital,"

CMS later concludes "that it is important that the medical staff of a distant-site telemedicine entity, **which may not be a Medicare-participating hospital**, be included in an optional and streamlined credentialing and privileging process for those REHs electing to enter into agreements for telemedicine services with such entities" (emphasis added). CMS must clarify that all distant-site hospitals, as well as the physicians and practitioners providing services in that distant-site hospital (even if they are contractors), must be enrolled in Medicare and appropriately qualified to provide services to Medicare beneficiaries. CMS should also clearly articulate the existing Medicare regulations regarding the supervision of non-physician practitioners and how telehealth can be a platform by which physicians can supervise care being delivered by non-physician practitioners.

Overall, it is most important to ensure that if telemedicine is being utilized it is not at the expense of inpatient care, especially in emergency hospitals, and to ensure that when telemedicine is offered it is provided by a physician, or someone on a physician lead team, who is familiar with the location and lifestyle of the patient to ensure that the quality of care provided to patients is not compromised.

Proposed Condition of Participation: Emergency Services

The proposed rule states that REHs must comply with both the CAH and Hospital CoPs for emergency services, including the requirement that they possess the necessary equipment and personnel to properly and safely administer emergency services to patients presenting at the facility. This includes requiring that REHs provide emergency services that are organized under the direction of a qualified member of the medical staff and integrated with other departments of the REH.

The requirement that REHs comply with the CAH and Hospital CoPs for emergency services is a necessary first step; however, in order to have a functioning emergency department that can truly meet the needs of the rural population the REH intends to serve, the CoPs for REHs and rural emergency departments (EDs) should include video laryngoscopes for endotracheal intubation, various trays for venous and arterial vascular access and chest tube placement, and an emergency ultrasound machine.

CMS also proposed that there be adequate emergency medical and nursing personnel available to safely run the facility. However, the rule also proposed that there should not be a requirement that a practitioner to be on-site at an REH at all times. The AMA believes that effective emergency care cannot be provided without a physician on-site at all times,and, therefore, there should always be at least one board-certified physician on site to oversee all care delivered in REHs. Emergency patients represent some of the most complex and critically ill patients and their condition can deteriorate rapidly. As such, successful management of these patients requires years of specialized training which nurse practitioners (NPs) and physician assistants (PAs) do not possess.

The AMA remains steadfast in its commitment to patients who have said repeatedly that they want and expect physicians to lead their health care team and participate in their health care determinations. In a recent survey of U.S. voters, 95 percent said it is important for a physician to be involved in their diagnosis and treatment decisions.[2] However, by not requiring that a physician always be present at an RHE, this rule could remove physicians from the care team during the most critical moments of care, when patients with potentially life-threatening conditions are first brought to the emergency department.

[2] https://www.ama-assn.org/system/files/scope-of-practice-protect-access-physician-led-care.pdf.

While all health care professionals play a critical role in providing care to patients, and NPs, PAs, and other non-physician practitioners (NPPs) are important members of the care team, their skill sets are not interchangeable with those of fully educated and trained physicians. This is fundamentally evident based on the difference in education and training between the distinct professions. Physicians complete four years of medical school plus three to seven years of residency, including 10,000-16,000 hours of clinical training.[3] By contrast, NPs, complete only two to three years of education, have no residency requirement, and have only 500-720 hours of clinical training.[4] Moreover, the current PA education model is two years in length with only 2,000 hours of clinical care and no residency requirement.[5] Patients expect the most qualified person—physician experts with unmatched training, education, and experience—to be diagnosing and treating injured or sick individuals and making often complex clinical determinations quickly and accurately. NPPs do not have the education and training to make these types of decisions alone and need the in-person supervision of a physician, especially during emergency situations.

All emergency patients deserve access to a physician and, preferably, a specialist in emergency or family medicine. As such, CMS should require that at least one physician is always physically present at a REH to ensure that proper care is administered during life threatening emergencies.

Proposed Condition of Participation: Additional Outpatient Medical and Health Services

CMS proposed to allow REHs to provide outpatient medical and health services in addition to providing emergency services and observation care. These include services that are commonly furnished in a physician's office such as radiology, laboratory work, outpatient rehabilitation, surgical intervention, maternal health, and behavioral health services. CMS further proposed to require that these outpatient services meet the needs of the community in which they are located and be based on nationally recognized standards of practice. Per the proposed rule, REHs must also have a system in place for referral from the REH to different levels of care, have effective communication systems in place to ensure the REH meets a patient's needs, and have established relationships with hospitals that have the resources and capacity to deliver care beyond the level of care delivered at the REH.

The AMA supports the expansion of providing outpatient medical and health services. Many patients in rural areas lack the ability to easily access outpatient services, which results in reliance on emergency departments for outpatient care. As such, enabling REHs to fill gaps in rural communities' access to outpatient services could prevent high utilization of emergency department care and improve care continuity and quality. Moreover, integrating a primary care physician into more individual's routine care will increase the health of individuals and the community overall. This increased standard of care could include helping to ensure that individuals have access to family physicians so that patients can receive ongoing and comprehensive outpatient services, such as primary care, maternity care, behavioral health care, and other services.

CMS further requested comments on other outpatient services that a REH should deliver in order to participate in Medicare. CMS mentions maternal health services, mental health services, and surgical services as examples of outpatient services that REHs could deliver in underserved rural communities. While strong arguments can be made for CoPs that address maternal health care and mental health care in rural communities, we urge CMS to afford REHs maximum flexibility in designing outpatient programs

[3] https://www.ama-assn.org/system/files/scope-of-practice-physician-training.pdf.
[4] *Id*.
[5] https://college.mayo.edu/academics/explore-health-care-careers/careers-a-z/physician-assistant/.

that meet the needs of their communities. A CoP mandates a one-size fits all approach that may not work well in rural communities with limited resources.

REHs that serve rural communities and communities with high rates of infant mortality should have the flexibility to offer outpatient maternal health services. The United States has the highest maternal mortality rate among developed countries, and according to the Centers for Disease Control and Prevention (CDC), 60 percent or more of these maternal deaths are preventable.[6] Furthermore, CDC data show that Black and Indigenous women are three to four times more likely to die from pregnancy-related causes than White women.[7] Additional data from the American Hospital Association (AHA) discovered that more than 10 million women of color live in rural communities in the United States.[8] Supplementary research has indicated that rural counties with large populations of Black women have higher rates of obstetric unit closures.[9] As such, the AMA understands the importance of increasing access to maternal care and supports CMS' efforts to address inequity and decrease maternal morbidity and mortality and believes, at a minimum, that a CoP for REHs should require emergency physicians to be able to provide adequate prenatal, delivery, and postnatal care including, but not limited to, recognizing and initiating treatment of preeclampsia, miscarriage, and postpartum depression, as well as precipitous deliveries and common delivery complications such as shoulder dystocia and postpartum hemorrhage.

Over the last decade, we have seen a substantial reduction in maternity care services within rural communities, causing maternal care deserts to develop and expand. Concurrent with the increased focus on maternal care delivery, hospitals with smaller maternity units have been closing. According to a policy brief by the University of Minnesota Rural Health Research Center, the percent of rural counties without obstetric services rose from 45 to 54 percent between 2004 and 2014. Moreover, only 30 percent of the rural noncore counties (areas with less than 10,000 residents) had continual access to obstetrics services.[10] As a result, women in rural areas of the United States must travel greater distances for prenatal, obstetrical, and postpartum care which significantly increases the risk of preterm delivery, poorer outcomes, and delivery in non-ideal settings. Therefore, comprehensive maternal health care is imperative as a condition of participation for REHs.

REHs will undoubtably see patients who require maternity care, including those with obstetrical emergencies. If CMS finalizes insufficient staffing supervision requirements for REHs, it could negatively impact the ability to respond to an obstetrical crisis. As such, it is imperative that there is always a physician on staff in the REH that can adequately handle obstetrical emergencies and that can competently provide general maternity care.

Certified Registered Nurse Anesthetists (CRNAs) Supervision Requirements

The AMA strongly opposes the proposal that would allow a governor, after consulting with the state board of medicine and nursing, to exempt Certified Registered Nurse Anesthetists (CRNAs) from physician supervision requirements. The CoPs are effectively a federal accreditation standard. These health and safety standards are the nationally accepted foundation for improving quality and protecting the health and safety of patients in America's acute care hospitals, critical access hospitals, and

[6] https://www.cdcfoundation.org/sites/default/files/upload/pdf/MMRIAReport.pdf.
[7] https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6835a3-H.pdf.
[8] https://www.aha.org/system/files/media/file/2020/05/cms-rfi-on-maternal-health-in-rural-areas-letter-5-28-2020.pdf.
[9] https://www.ajmc.com/view/role-of-racial-and-geographical-bias-in-rural-maternity-care.
[10] http://rhrc.umn.edu/wp-content/files_mf/1491501904UMRHRCOBclosuresPolicyBrief.pdf.

ambulatory surgery centers. They are intended to ensure that these facilities are providing Medicare and Medicaid beneficiaries an appropriate level of care. Since the inception of the Medicare program, hospitals seeking to participate in the Medicare program must meet the patient safety and quality requirements delineated within the CoP. Consistent with numerous other quality and patient safety standards, the CoPs require physician supervision of CRNAs administering anesthesia. As such, this proposed rule should not deviate from this standard that is upheld for most of the other acute care and critical access hospitals. Moreover, state licensing boards play an important role in ensuring that medical care is properly administered and that providers are disciplined when malpractice is committed. As currently written, the proposed rule would allow a complete disregard for state licensure laws with nothing more than a phone call to meet the consultation requirement.

The AMA strongly supports the team approach to patient care, with each member of the team playing a clearly defined role as determined by his or her education and training. While we greatly value the contribution of CRNAs to the physician-led care team, their training is not equivalent to the four years of medical school, three years of residency training, and 10,000-16,000 hours of clinical training that is required of physician anesthesiologists. CRNAs must complete only a master's degree and possess one year of full-time work experience. This means that CRNAs have only about half of the education and one-fifth the hours of clinical training that physicians possess.

Moreover, patient preparation, administration of anesthesia, and management of potential complications is a complex and technically demanding medical process that requires physician supervision. To ensure the best interests of the patient, in much of the United States, anesthesiologists practice in the model known as the Anesthesia Care Team,[11] which includes the delegation of appropriate medical tasks to non-physicians. This means that the overall health of the patient is ultimately the responsibility of the supervising physician. Though CRNAs are integral members of the care team, the skills and acumen obtained by physicians throughout their extensive education and training make them uniquely qualified to oversee and supervise patients' anesthesiology care.

Furthermore, limited opt-out of CRNA's from federal supervision requirements in critical access hospitals and rural hospitals has failed to improve access to care or reductions in costs. For example, in 2010, former Colorado Governor Bill Ritter, Jr. issued a limited opt-out and though there was no noticeable benefits there was clear evidence that the limited opt-out caused a reduction in the number of anesthesiologists in those rural facilities, especially the critical access hospitals. Since 2016, five studies have been published in peer reviewed journals examining the relationship between opt-out and anesthesia access. All five published studies found that opt-out was not associated with an increase in access to anesthesia care.[12,13, 14,15] The 2019 Graduate Nurse Demonstration Project which was mandated as part of the Affordable Care Act of 2010, found "ninety-six percent of alumni who are [nurse anesthetists…]

[11] ASA Standards, Guidelines and Statements: Statement on the Anesthesia Care Team available at https://www.asahq.org/standards-and-guidelines/statement-on-the-anesthesia-care-team

[12] Sun EC, Miller TR, Halzack NM. In the United States, "Opt-Out" States Show No Increase in Access to Anesthesia Services for Medicare Beneficiaries Compared with Non-"Opt-Out" States. A&A Case Reports. 2016; 6(9):283-5

[13] Sun EC, Dexter F, Miller TR. The Effect of "Opt-Out" Regulation on Access to Surgical Care for Urgent Cases in the United States: Evidence from the National Inpatient Sample. Anesthesia & Analgesia. 2016; 122(6):1983-91.

[14] Sun EC, Dexter F, Miller TR, Baker LC. "Opt Out" and Access to Anesthesia Care for Elective and Urgent Surgeries among U.S. Medicare Beneficiaries. Anesthesiology. 2017; 126(3):461-71.

[15] Schneider JE, Ohsfeldt R, Li P, Miller TR, Scheibling C. Assessing the impact of state "opt-out" policy on access to and costs of surgeries and other procedures requiring anesthesia services. Health Econ Rev. 2017; 7(1):10.

reported working in urban settings. This is not surprising, as [nurse anesthetists] may be more likely to work in urban settings with larger anesthesia departments.[16] Most recently, a 2021 *Journal of Rural Health* article provided in part, "Given that we found no evidence that being in an opt-out state increases the odds of using CRNAs in hospitals, we contribute to the growing literature suggesting that states adopting the opt-out policy have not realized increased health care access or reduced health care costs."[17]

An opt-out similarly fails to save patients 'or taxpayers 'money. Medicare pays the same for anesthesia care whether the service is provided by an anesthesiologist, an anesthesiologist medically directing a nurse anesthetist or certified anesthesiologist assistant, a nurse anesthetist supervised by the operating surgeon, or in those rare circumstances where it takes place, a nurse anesthetist practicing without physician supervision. The amount of the Medicare payment, no matter how it is allocated, is the same regardless of who provides the anesthesia care. Since physician anesthesiologists can perform services that are included in the anesthesia fee that would have to be performed and billed by other physicians, if the hospital chose to utilize nurse anesthetists rather than physician anesthesiologists, it may be more costly to use nurse anesthetists in certain situations. For example, because nurse anesthetists are not qualified to make medical evaluations and judgments, the need for additional consultations by physician specialists and laboratory testing could be greater when a physician anesthesiologist is not involved.

Moreover, this proposed change has immense patient safety implications. An independent outcomes study published in the peer-reviewed journal *Anesthesiology* found that the presence of a physician anesthesiologist prevented 6.9 excess deaths per 1,000 cases when an anesthesia or surgical complication occurred.[18] Moreover, independent studies have shown that the odds of an adverse outcome are 80 percent higher when anesthesia is provided only by a nurse anesthetist as opposed to a physician anesthesiologist.[19] As such, the World Health Organization's International Standards for a Safe Practice of Anesthesia highly recommended that an anesthesiologist lead or oversee anesthesia when administered.[20] Furthermore, "[s]ubstance abuse is the principal cause of professional impairment for CRNAs, with 1 of 10 experiencing addiction to drugs or alcohol. Despite this problem, there is no standardized screening protocol for the identification of substance abuse or misuse for CRNAs."[21] As such, it is extremely important that CRNA's work as part of a physician-lead team so that additional oversight of these providers is given, and an assurance of safe care is provided. Therefore, since physicians have additional training, better patient outcomes, and changing supervision requirements does not decrease cost or increase access, there should not be an opt-out option for CRNA's in REHs.

Condition of Participation: Staffing and Staff Responsibilities

CMS proposed that REHs be staffed full time to ensure that there is always someone available to receive patients and begin medical care. Under the proposed standards, CMS would allow a nursing assistant,

[16] The Graduate Nurse Education Demonstration Project: Final Evaluation Report, Centers for Medicare and Medicaid Services. August 2019. https://innovation.cms.gov/files/reports/gne-final-eval-rpt.pdf (p.95).
[17] Feyereisen SL, Puro N, McConnell, W. Addressing provider shortages in rural America: The role of state opt-out policy adoptions in promoting hospital anesthesia provision. J Rural Health. 2021; 37(4):684-691.
[18] Silber JH, Kennedy SK, Even-Shoshan O, Chen W, Koziol LFL, Showan AM, Longnecker DE: Anesthesiologist direction and patient outcomes. Anesthesiology 2000; 93: 152-a63.
[19] Memtsoudis SG, Ma Y, Swmidoss CP, Edwards AM, Mazumdar M, Liguori GA: Factors influencing unexpected disposition after orthopedic ambulatory surgery. J Clin Anesth 2012; 24(2):89-95
[20] Gelb AW, Morriss WW, Johnson W, Merry AF, International Standards for a Safe Practice of Anesthesia Workgroup. World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) International Standards for a Safe Practice of Anesthesia. Can J Anaesth 2018; 65:698-708.
[21] https://pubmed.ncbi.nlm.nih.gov/32442099/.

clinical technician, or emergency medical technician (EMT) to intake a patient who arrives at the REH and then contact an off-site practitioner after the patient's arrival. CMS noted in the preamble that they believe "REHs should have the flexibility to determine how to staff the emergency department at the REH" and does not believe it is necessary to have a physician, nurse practitioner, clinical nurse specialist, or physician assistant available to furnish patient care services at all times. CMS further proposed to require a registered nurse, clinical nurse specialist, or licensed practical nurse be on duty whenever the REH has one or more patients receiving emergency services or observation care. Regarding physicians, CMS proposed that a doctor of medicine or osteopathy "must be present for sufficient periods of time" and be "available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral."

Many patients seeking care in REHs will have immediate, acute medical emergencies requiring immediate attention and medical treatment. Under this proposal, the available REH staff may be unable to perform a medical screening examination or stabilize the patient. This could result in poor patient outcomes and be a violation of the Emergency Medical Treatment and Labor Act (EMTALA) if a trained clinician is unable to arrive in time to perform a medical screening examination and stabilize the patient if the patient has an emergency medical condition. As such, if finalized, this proposal could worsen rural health disparities.

The highest quality, most efficient patient care is provided by physician-led teams. Moreover, one of our surveys found that four out of five patients prefer a physician-led health care team. Additionally, nine out of ten respondents said that a physician's additional years of education and training are vital to optimal patient care, especially for complex or emergency conditions.[22] Depending on the specific health setting needs, a team-based approach can include various combinations of physicians, nurses, nurse practitioners, physician assistants, pharmacists, social workers, case managers and other health care professionals. Members of the team share information and assist in decision making based on their unique skills—all with the common goal of providing the safest, best possible care to patients. However, these teams require leadership, and physician expertise is widely recognized as integral to quality medical care. With postgraduate education and extensive clinical training, physicians are the natural leaders in the overall delivery of health care.

The AMA is concerned that CMS does not require REHs to comply with existing Medicare supervision requirements. The current Medicare outpatient supervision policy requires direct supervision of services furnished in a hospital or CAH. Direct supervision is defined as a physician being present on the campus where services are being furnished and immediately available to furnish assistance and direction through the duration of the service. Immediate availability requires the immediate physical presence of the supervisory physician so that instantaneous medical intervention can be provided. We urge CMS to clarify in the final rule that REHs must be in compliance with existing Medicare supervision requirements in order to comply with the CoPs.

While the AMA supports a more flexible approach for REH, all services in an REH should be supervised by a physician medical director either in person or via telehealth. Also, at least one physician should always be physically present in an REH in case situations arise, as they often do in hospital emergency departments, where patients need medical attention that is beyond the expertise of mid-level providers. We do not believe it is sufficient to say that REHs must comply with state law is sufficient as we have seen a slow erosion of laws protecting the physician/patient relationship both at the state level and more recently at the federal level as the VA moves forward with the Federal Supremacy Project. All patients

[22] https://www.ama-assn.org/system/files/2020-10/truth-in-advertising-campaign-booklet.pdf.

deserve care from a physician led team and failure to require a physician to be physically present at the REH could further exacerbate inequities. A rural Medicare patient who needs emergency medical care at an REH should be afforded the same level of care as their urban counterparts in the emergency department of their community hospital.

Proposed Condition of Participation: Discharge Planning

As proposed, this CoP would allow virtually anyone with little to no health care expertise to develop and supervise the discharge process as long as it was initiated (or requested) by a physician. CMS specifically states "any discharge planning evaluation or discharge plan required under this paragraph (a) must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel." We urge CMS to establish a more robust discharge process that not only requires a physician requestor but also requires, at a minimum, a physician to sign off on the discharge plan and to supervise the overall discharge process.

Proposed Conditions of Participation: Patient Rights and Privacy

Given the challenges of operationalizing REHs in rural communities with limited resources, we urge CMS to allow for maximum flexibility in complying with the Health Insurance Portability and Accountability Act (HIPAA) without creating a new set of requirements for REHs. An appropriate balance needs to be struck between informing patients of their rights—which the HIPAA Privacy Rule already requires—and overburdening REHs with new administrative requirements. REHs function with limited resources, funding, and are often short staffed. Even well-intentioned policies can ultimately detract from direct patient care if REH staff are tasked with implementing new or unfamiliar administrative policies and procedures.

We urge CMS to provide maximum flexibility to REH in operationalizing CMS policies in accordance with requirements already outlined within HIPAA regulations. Said another way, REHs are already covered entities under HIPAA and likely already have policies and procedures in place to inform patients of their rights, including how to exercise their rights, and have methods to ensure the privacy, safety, and confidentiality of patient records. We stress that CMS should refrain from creating new policies and procedures that are different, diverge, or expand on what HIPAA-covered entities are already required to comply with. Rather than requiring REHs to reinvent methods to inform patients of their rights, CMS should consider working with the Office for Civil Rights to develop tools or resources that support REH-patient communication. We recognize CMS' desire to inform patients of their rights, but at the same time, CMS needs to ensure its policies considers the unique needs of REHs, the scope of services they provide, and patient populations that they serve.

Use of Restraints and Seclusion

The AMA and its *Code of Medical Ethics* strongly support the principle that all individuals have a fundamental right to be free from unreasonable bodily restraint. While the AMA supports the standard, we recommend that the rule clarify that except in emergencies, patients should be restrained only on a physician's explicit order. The AMA also appreciates the inclusion of training staff on appropriate use of restraints. We recommend, however, including the following principle in the final rule:

> "When a physician is not physically present, a properly trained and authorized health care professional may institute seclusion and restraints when this is clinically appropriate. In such cases the physician shall be contacted immediately."

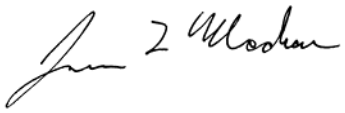
The AMA further supports where the rule makes clear that patients should never be restrained punitively, for convenience, or as an alternative to reasonable staffing. The AMA, therefore, recommends additions to the final rule stating that "the patient has the right to be free of restraints and seclusion unless medically necessary," and that "the use of restraints and seclusion is a medical decision and should not be dictated by government agencies." As further guidance, the AMA also recognizes that there are times when health conditions may result in behavior that puts patients at risk of harming themselves. In such situations, it may be ethically justifiable for physicians to order the use of chemical or physical restraint to protect the patient. The AMA *Code of Medical Ethics* provides that physicians who order chemical or physical restraints should:

- Use best professional judgment to determine whether restraint is clinically indicated for the individual patient.
- Obtain the patient's informed consent to the use of restraint, or the consent of the patient's surrogate when the patient lacks decision-making capacity. Physicians should explain to the patient or surrogate: why restraint is recommended; what type of restraint will be used; and the length of time for which restraint is intended to be used.
- Regularly review the need for restraint and document the review and resulting decision in the patient's medical record.

In certain limited situations, when a patient poses a significant danger to self or others, it may be appropriate to restrain the patient involuntarily. In such situations, the least restrictive restraint reasonable should be implemented and the restraint should be removed promptly when no longer needed.

The AMA is supportive of efforts to expand access to high quality health care in underserved rural communities. However, we encourage CMS to ensure that physicians remain at the center of the care team and are physically present at the REH so that optimal care can be provided in the complex emergency cases that will arise. Should you have any questions, please contact Margaret Garikes, Vice President for Federal Affairs, at margaret.garikes@ama-assn.org, or by calling 202-789-7409.

Sincerely,



James L. Madara, MD