

August 17, 2022

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services PO Box 8016 Baltimore, MD 21244

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

Dear Administrator Brooks-LaSure:

On behalf of the American Academy of Family Physicians (AAFP), representing 127,600 family physicians and medical students across the country, I write in response to the proposed rule to establish Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) as published in the July 6, 2022 version of the Federal Register.

The Consolidation Appropriations Act of 2021 (CAA) established a new REH Medicare facilitytype to ensure access to care in rural communities amid rural hospital closures. Many rural hospitals do not have the patient volume to continue offering traditional, acute inpatient hospital services. However, demand for emergency and other outpatient services still exists in these rural communities. 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 altogether. In this rule, CMS proposes to establish CoPs for REHs, which will be eligible to be paid for services beginning January 1, 2023.

The AAFP has long advocated to improve access to high-quality care in rural communities. Family physicians are uniquely trained to provide a broad scope of health care services to patients across the lifespan. This enables them to tailor their practice location and individual scope of practice to the needs of their communities. As a result, family physicians are an essential source of emergency services, maternity care, hospital outpatient services, and primary care in rural areas. 22 percent of family physicians practice in rural areas while 20 percent of the U.S. population lives in such areas. 1 Many family physicians choose to practice in rural areas because it enables them to practice full scope family medicine.

Family physicians are an essential source of emergency care in rural areas. Multiple studies have demonstrated that, while many family physicians provide emergency care in urban and suburban communities, rural family physicians are more likely to work in emergency departments. A 2019 study found that more than 15 percent of family physicians in small rural areas and more than 10 percent in frontier areas practice primarily in emergency department settings.<sup>2</sup> About 13 percent of family physicians in small rural areas and 29 percent of family

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physicians in frontier areas provide emergency department coverage in addition to their primary ambulatory practice.<sup>3</sup> These results reflected an increase in the proportion of family physicians primarily practicing in emergency department settings compared to data from 2008-2012.<sup>4</sup>

An analysis of 2017 Medicare claims data found 30 percent of family physicians and half of all rural family physicians provide some care outside the clinic or ambulatory setting, such as in an emergency room, hospital, or nursing home.<sup>5</sup> The researchers found that 7.9 percent of rural family physicians, which is equal to 635 physicians, practice solely in an emergency department, with another 879 rural family physicians (or 45.6 percent of rural family physicians) practicing in emergency departments in addition to other settings.<sup>6</sup> These findings suggest that family medicine training is producing a workforce that can provide care in a variety of settings, allowing family physicians to meet the varied needs of the population, especially when facilities, specialties, or workforce are limited.

In 2006, the then-Institute of Medicine (IOM) (now known as the National Academies) published a report on the state and future of emergency medicine in the US. The report highlighted workforce challenges in rural areas, acknowledged that family physicians are an essential source of emergency care in rural areas, and called for more collaboration between emergency medicine and family medicine specialties.<sup>7</sup>

Emergency medicine is an integral part of family medicine training. The Accreditation Council for Graduate Medical Education (ACGME) requirements for family medicine residents reflect values that are complementary to the importance of providing emergency care. For example, family medicine residents must demonstrate competence to independently manage patients of all ages in various outpatient settings; evaluate patients of all ages with undiagnosed and undifferentiated presentations; recognize and provide initial management of emergency medical problems; and perform medical, diagnostic, and surgical procedures essential for the area of practice. The current ACGME program requirements for family medicine include a greater level of specificity for experiences with acutely ill adults and children in emergency settings.

Many family physicians have sought out additional specialized training in emergency medicine, in addition to their family medicine training. AAFP policy <u>encourages</u> family physicians who provide emergency care to utilize elective months of residency training for additional experience. A small number of combined family medicine-emergency medicine programs currently exist, though they are unlikely to meaningfully address rural workforce shortages. However, many family physicians have undergone additional training through emergency medicine fellowships.<sup>10</sup>

The Minnesota chapter of the AAFP created an innovative Comprehensive Advanced Life Support (CALS) course in 1996.<sup>11</sup> The CALS curriculum includes material from all the major advanced life support programs. A team-based approach involving emergency medical services (EMS) providers is integral to the program, and life-saving procedural skills and a core body of knowledge in emergency medicine are basic components of the curriculum. This course is supported by both AAFP and ACEP in efforts to improve rural emergency care.<sup>12</sup> The 2006 IOM report also noted support for the CALS program.<sup>13</sup>

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Despite the overlap in family medicine and emergency medicine training, family physicians are not permitted to take the American Board of Medical Specialties emergency medicine specialty board exam.<sup>14</sup> Therefore, **CMS must ensure federal regulations do not exclude or discount the contributions of family physicians providing emergency care by encouraging, emphasizing, or requiring board certification in emergency medicine.** 

Many rural emergency departments do not have sufficient volume to support a residency-trained emergency physician. Family physicians can provide continuous primary care, maternity care, and acute outpatient care in addition to emergency services, and therefore do not require the same patient volume. Emergency department staffing in small community hospitals by family physicians allows more efficient use of resources in the hospital and in the community.

In many communities, hospital emergency departments are required to provide an enormous amount of primary care services that would ideally be provided in other settings. Family physicians are trained to care for patients with both acute and chronic conditions and are well suited to provide ongoing care to stabilized patients who are awaiting transfer from an REH, in addition to emergency care. <sup>15</sup> Family physicians are also well positioned to track a patient's progress following care provided at an REH and ensure follow-up. Family physicians live and work in the communities where REHs will be located, providing them with a unique understanding of the needs of their communities and enabling them to establish long-term trusting relationships with their patients.

Given the significant value family physicians can and will bring to REHs, the AAFP strongly urges CMS to acknowledge the vital role family physicians currently play in ensuring access to emergency care in rural areas and ensure the final rule enables family physicians to continue practicing in REHs, including serving in REH leadership roles.

## Governing Body and Organizational Structure

#### Governing Body Requirements

CMS is proposing that REHs must have an effective governing body that is legally responsible for the conduct of the REH. This governing body will have the responsibility, in accordance with state law, to determine which categories of practitioners are eligible candidates for appointment to the medical staff of an REH. The AAFP supports these proposals, but as stated below, we believe that a physician with experience in emergency medicine, such as a board-certified family physician with experience in emergency medicine, should be included in the governing body and should serve as the medical director of the REH.

## Telemedicine Credentialing and Privileging

CMS proposes a streamlined credentialing and privileging process for REHs which would enable the governing body to develop an agreement with the distant site telemedicine provider, which must be a Medicare-participating hospital, to specify that it is the responsibility of the governing body of the distant site hospital providing the telemedicine services to meet the licensing and credentialing requirements in Medicare regulations. The goal of this proposal is to

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reduce the burden on REHs of credentialing and privileging telehealth providers while also ensuring REH patients can access the care they need via telemedicine.

The AAFP supports this proposal and agrees that REHs will not have robust administrative staff to conduct credentialing and privileging for all the clinicians who will provide telemedicine services to REH patients.

We note, however, that many family physicians currently provide emergency services in rural communities across the country. These 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.

CMS notes that they have "concluded 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." CMS proposes to require the governing body of the REH to ensure that the distant-site telemedicine entity, acting as a contractor of services, furnishes its services in a manner that enables the REH to comply with all applicable CoPs and standards. The AAFP interprets this proposal to apply to direct-to-consumer (DTC) telehealth companies that may enter into agreements with REHs.

The AAFP is concerned that, if a significant amount of REHs 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 again 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.

We are also concerned that this proposal does not provide CMS with adequate oversight to ensure high-quality care for beneficiaries receiving care in REHs. The AAFP urges CMS not to finalize this proposal for streamlined credentialing of telemedicine entities that are not participating in Medicare.

## **Emergency Services**

The CAA requires REHs to comply with CAH and hospital emergency requirements as currently specified in federal regulation. CMS proposes to require REHs to provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice. CMS also proposes that the REH must have emergency services that are organized under the direction of a qualified member of the medical staff and are integrated with other departments of

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the REH. CMS proposes there be adequate medical and nursing personnel qualified in emergency care to meet the needs of the facility and seeks comments on the proposed staffing requirements to gain insight on the appropriateness of not requiring a practitioner to be on-site at an REH at all times.

The AAFP supports the proposals to require that care must meet the needs of REH patients, must be organized under the direction of the medical staff, and must be integrated with other departments of the REH. The AAFP urges CMS to clarify that REHs must comply with existing Medicare outpatient supervisory requirements in order to deliver care that meets the needs of its patients and comply with this CoP. We provide additional comments regarding the staffing CoP below.

# Laboratory, Radiologic, and Pharmaceutical Services

CMS proposes to require that REHs provide basic laboratory services essential to the immediate diagnosis and treatment of the patient consistent with nationally recognized standards of care for emergency services. The REH must ensure these services are available 24 hours a day. The AAFP supports these proposals.

CMS proposes to require that REHs maintain, or have available, diagnostic radiologic services. REHs are permitted to provide therapeutic radiologic services. All radiologic services provided must be furnished by the REH and provided by personnel qualified under state law. CMS proposes to require radiologic services meet several standards that are consistent with existing CAH CoPs. The AAFP supports this proposal.

CMS proposes to require REHs to have pharmaceutical services that meet the needs of its patients, including a pharmacy or drug storage area that is directed by a registered pharmacist or other qualified individual in accordance with state scope of practice laws. The medical staff is responsible for developing policies and procedures to minimize drug errors. The AAFP supports this proposal.

### Additional Outpatient Medical and Health Services

CMS proposes 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, outpatient rehabilitation, surgical, maternal health, and behavioral health services. CMS further proposes that these outpatient services must meet the needs of the community and be based on nationally recognized standards of practice. REHs must also have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate, and have effective communication systems in place to ensure the REH meets patient's needs, and have established relationships with hospitals that have the resources and capacity to deliver care that is beyond the scope of care delivered at the REH.

The AAFP strongly supports these proposals. Family physicians working in CAH and rural emergency departments continually observe that patients in rural areas lack timely access to outpatient services, which results in reliance on emergency departments for outpatient care. As

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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. Family physicians are the ideal clinicians to provide other comprehensive outpatient services, such as primary care, maternity care, behavioral health care, and other services.

CMS emphasizes the importance of improving access to maternity care in rural areas. Family physician residency training includes a requirement for trainees to gain experience providing maternity care services, including low-risk deliveries. A new analysis from the Robert Graham Center confirms that **family physicians are an essential source of comprehensive maternity care in rural communities.** The researchers found that family physicians are delivering babies in more than 4 in 10 of all US counties (40.7%) and greater than 5 in 10 (52.4%) of these counties are located in non-metropolitan areas. Family physicians are the sole maternity care provider delivering babies in 181 maternity care deserts (MCDs) (about 1 in 5 [16.2%] of all MCDs), serving more than 400,000 women (ages 18-44).

Many family physicians have obtained additional training in cesarean deliveries and other more specialized maternity services in order to fill gaps in their communities. A recent study found that more than half of family physicians providing cesarean deliveries as the primary surgeon did so in rural communities, and about 39 percent did so in a county without any obstetriciangynecologists. <sup>16</sup> Evidence also confirms family physicians can perform cesarean deliveries safely. <sup>1718</sup>

Women from rural communities who stay within their community to deliver have better outcomes than women who travel from rural communities to metropolitan areas to deliver. <sup>19</sup> For all of these reasons, family physicians are ideal clinicians to work in REHs and provide maternity care.

Family physicians regularly provide substance use disorder treatment and other behavioral health services. Family physicians practicing in rural areas report that patients struggle to access behavioral health services within their communities and are often forced to rely on the emergency department for behavioral health services. Family physicians also face challenges referring patients to mental health professionals when they decide additional expertise would benefit their patients. Many family physicians are stepping in to fill the unmet need by seeking additional training, and/or integrating behavioral health into the primary care setting. Family medicine residency training now requires behavioral health to be integrated into residents' training.<sup>20</sup>

The AAFP is strongly supportive of improving access to medication assisted treatment (MAT) for substance use disorders, including by removing regulatory and administrative barriers to providing buprenorphine and other treatments. A recent analysis of 2020 Medicare claims found that family medicine had the highest volume of buprenorphine prescribers compared to other specialties. An many family physicians have extensive experience initiating buprenorphine and other types of MAT, as well as providing maintenance therapy, and are well positioned to provide this care in their local REH. Therefore, family physicians in REHs could help improve access to comprehensive behavioral health services, including MAT.

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CMS proposes personnel requirements for REHs who choose to provide additional outpatient medical and health services. The AAFP urges CMS to clarify that all care delivered in REHs be overseen by physicians who have appropriate expertise in providing those services. In most cases, family physicians will have the requisite expertise to provide this supervision.

#### **COVID Vaccination of REH Staff**

CMS proposes to require REHs to develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. The AAFP has <u>supported</u> CMS' COVID-19 vaccination mandate for health care workers. We support this proposal and urge CMS to finalize it.

## Staffing and Staff Responsibilities

CMS proposes that REHs be staffed 24 hours, 7 days a week to receive patients and activate the appropriate medical resources. Under the proposed standards, CMS would allow a nursing assistant, clinical technician, or emergency medical technician (EMT) to intake a patient who arrives at the REH and then contact an off-site practitioner of the patient's arrival. CMS notes 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.

The AAFP is concerned that this proposal will lead to care delays and poor outcomes for patients arriving at REHs. 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 result in a violation of the Emergency Medical Treatment and Labor Act (EMTALA). The AAFP is concerned that, if finalized, this proposal will worsen rural health disparities.

CMS further proposes to require that 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 proposes to require 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."

Family physicians experience firsthand the health workforce challenges that exist in rural areas. However, these proposals will not sufficiently ensure high-quality care for patients in REHs.

To ensure quality emergency care, it is critical that a physician with training and/or experience in emergency medicine provide the care or oversee the care delivered by non-physician practitioners. Emergency patients represent some of the most complex and critically ill patients in medicine, and effective management of these patients requires years of specialized training. However, the training programs for physician assistants (PAs), clinical

nurse specialists (CNSs), and nurse practitioners (NPs), are extremely abbreviated compared to medical training for physicians, and there is an even greater level of training required for these clinicians to meet a level of care that is safe for patients. The table below compares the training requirements between NPs, PAs, and physicians.

Comparison of Training Requirements			
	Physicians	Nurse Practitioners	Physician Assistants
Clinical education	4 years	2-3 years	2 years
Residency training	3 – 7 years	None	None
Clinical care training (including during medical school for physicians)	10,000-16,000 hours	500-720 hours	2,000 hours
Examinations	21 hours, 820 questions:  - USMLE/COMLEX I: 8 hours, 280 questions  - USMLE/COMLEX II: 9 hours, 315 questions  - USMLE/COMLEX III: 16 hours, 412 questions, 13 case simulations  - Family medicine specialty board: 6 hours, 300 questions	3 hours, 150- 200 questions	5 hours, 300 questions

The highest quality, most efficient patient care is provided by physician-led teams of health professionals. An American Medical Association <u>survey</u> found that more than 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. 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 AAFP is therefore 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

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available to furnish assistance and direction through the duration of the service. Immediate availability requires the immediate physical presence of the supervisory physician or non-physician practitioner such that they are able to intervene right away. 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.

We also note that the AAFP has previously <u>advocated</u> for CMS to allow physicians to meet the requirements for direct supervision by being immediately available through a virtual presence using real-time audio/video technology instead of their physical presence. Family physicians have reported this flexibility has improved access to care in rural areas during the COVID-19 public health emergency.

CMS does not propose to require a board-certified emergency physician serve as the medical director of an REH. However, in the preamble of the proposed rule, CMS encourages REHs to have emergency physicians serve as medical directors, if possible. The AAFP supports the proposal to not require that a board-certified emergency physician serve as the medical director of an REH. We oppose the language encouraging REHs to have an emergency physician serve as medical director and strongly urge CMS to modify this language in the final rule to include family physicians. The language in the proposed rule fails to acknowledge that many family physicians already provide emergency care in rural areas, including areas without a board-certified emergency physician. These family physicians would be excellent REH medical directors, particularly given their experience providing rural emergency medicine, existing relationships in rural communities, and training and expertise in providing other outpatient services, as detailed above. CMS should note in the final rule that having a family physician with experience in emergency medicine serve as medical director would benefit REH patients and further encourage REHs to have family physicians serve as medical directors if possible.

## Medical records

CMS proposes to require that REHs must maintain a medical records system in accordance with a number of standards, including that the REH must maintain the confidentiality of patient information. CMS proposes to require REHs using electronic medical records that conform with existing regulatory standards must also be able to demonstrate that the system's notification capacity is fully operation and the REH uses it in accordance with state and federal laws and regulations.

The AAFP strongly supports these proposals. The AAFP has long advocated to improve health information sharing between acute care facilities, like hospitals and now REHs, with primary care physicians. Electronic notifications regarding patient admission to an REH will enable primary care physicians to help coordinate patients' care and share relevant medical history with the REH clinicians.

### Skilled Nursing Facility Distinct Part Unit

CMS proposes to allow REHs to furnish skilled nursing facility services as a distinct unit in compliance with existing CoPs for long-term care facilities. The AAFP supports this proposal.

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Many family physicians serve as medical directors for skilled nursing facilities and other longterm care facilities. Family physicians in rural communities are uniquely positioned to serve as the medical director for both the REH and its distinct skilled nursing facility.

### CAH Status: Definition of Primary Roads

The AAFP has heard from family physicians practicing in small, rural hospitals that do not currently have CAH status due to the existing distance requirements. One such hospital is located over 30 miles from another hospital, but it can only be reached through a combination of primary and secondary roads. We recommend CMS clarify what the distance requirements are to achieve CAH status when a combination of primary and secondary roads is required.

We appreciate the opportunity to provide input on the proposed rule. Should you have any questions, please contact Meredith Yinger, Manager, Regulatory Affairs at <a href="mailto:myinger@aafp.org">myinger@aafp.org</a>.

Sincerely,

Ada D. Stewart, MD, FAAFP

Board Chair, American Academy of Family Physicians

https://www.ahrq.gov/sites/default/files/publications/files/pcwork3.pdf

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