

ACEP's First Take from the 2023 Medicare Outpatient Prospective Payment System (OPPS) Final Rule

On November 1, 2022, the Centers for Medicare & Medicaid Services (CMS) <u>released a Medicare annual payment rule</u> for calendar year (CY) 2023 that impacts payments for outpatient hospital services. The rule includes finalized conditions of participation (CoPs) for a new facility-type in Medicare called rural emergency hospitals (REHs), as well as other REH and hospital outpatient policies that were included in the CY 2023 OPPS proposed rule. ACEP responded to both the <u>REH CoP proposed rule</u> and the <u>CY2023 OPPS proposed rule</u>. Below is a high-level summary of key final policies.

With respect to our major concerns about staffing requirements for REHs, ACEP strongly opposed CMS' proposal to allow a nursing assistant, clinical technician, or an 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 because we believed that the finalization of this proposal poses significant patient safety concerns. Further, it could also increase the chances that REHs violate 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. CMS responded to our comment that they "believe that the intent of the legislation is to ensure that REHs have the flexibility to determine who best meets the needs of their community while ensuring the provision of safe, quality patient care" and "expect REHs to determine who is best to fill this role based on the scope of services provided by the REH and the population served." Despite our objections, CMS is finalizing the requirement that the REH be staffed at all times "by an individual who is competent in the skills needed to address emergency medical care" and "must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient."

Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs)

Proposed Basic Definitions and Requirements

CMS finalized the following proposed definitions for REHs and CoPs.

- CMS defines an REH as "an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services in which the annual per patient average length of stay does not exceed 24 hours. The REH must not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-REH or posthospital extended care services."
- CMS proposes to certify a facility as an REH if the facility was, as of December 27, 2020, a critical access hospital (CAH) or a hospital with no more than 50 beds located in a rural county.
- REHs must be in compliance with applicable Federal, state, and local laws and regulation. REHs also must be licensed in the state as an REH or be approved as meeting standards for licensing by the agency in the state or locality responsible for licensing hospitals.

ACEP supported the finalization of these proposals.

Governing Body and Organizational Structure

- Overall Governing Body Requirements: CMS is finalizing the proposal that REHs must have
 an effective governing body, or responsible individual or individuals, 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.
- **Telemedicine Credentialing and Privileging:** CMS is finalizing the requirements as proposed that the governing body of the REH whose patients are receiving the telemedicine services could grant privileges to distant-site physicians and practitioners based on the recommendations of its medical staff. ACEP supported the finalization of this proposal.

ACEP sought clarification as to whether 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. CMS clarified that in order for REHs to choose the provision laid out in the rule, an REH must "ensure that (1) the distant-site hospital providing the telemedicine services was a Medicare-participating hospital; (2) the individual distant-site physician or practitioner was privileged at the distant-site hospital providing telemedicine services, and that this distant-site hospital provided a current list of the physician's or practitioner's privileges; (3) the individual distant-site physician or practitioner held a license issued or recognized by the state in which the REH, whose patients are receiving the telemedicine services, was located; and (4) with respect to a distant-site physician or practitioner granted privileges by the REH, the REH had evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and send the distant-site hospital this information for use in its periodic appraisal of the individual distant-site physician or practitioner."

Emergency Services

CMS is finalizing the proposal to require REHs to comply with both the CAH and Hospital CoPs for emergency services, including a requirement that they have emergency services that meet the needs of their respective patients presenting at the individual facility; there be emergency services that are organized under the direction of a qualified member of the medical staff and are integrated with other departments of the REH; and adequate medical and nursing personnel qualified in emergency care to meet the needs of the facility. ACEP requested that REHs also be required to possess video laryngoscopes for endotracheal intubation, various trays for venous and arterial vascular access and chest tube placement, and an emergency ultrasound machine, but CMS did not include these in the CoP.

CMS also sought comment on the proposed staffing requirements for the provision of emergency services in an REH to gain insight on the appropriateness of not requiring a practitioner to be on-site at the REH at all times. ACEP continues to believe that, when possible, board-certified emergency physicians should oversee all care delivered in REHs. There is no residency training program that prepares physicians to

provide services in both urban and rural EDs as well as emergency medicine residency programs. However, when a board-certified emergency physician is not available, it is still critical that physicians experienced and/or trained in emergency medicine (such as family physicians) oversee care being delivered by non-physician practitioners in REHs. Despite our comments, CMS "believe[s] that given the workforce challenges faced by healthcare facilities providing care and services in rural communities, it would be overly burdensome to require specific expertise of the practitioners who are providing services to patients presenting to the REH for emergency care."

Laboratory Services

CMS proposed that REHs provide basic laboratory services that are essential to the immediate diagnosis and treatment of the patient. ACEP supported this proposal, but requested that blood, urine, Cerebrospinal fluid (CSF), and other body fluid cultures; CSF analysis and synovial fluid analysis; serum and urine pregnancy tests; and ammonia level tests also be included in required laboratory services. In light of our comments, CMS is finalizing the proposal with a modification by incorporating language into the requirement that specifically notes that the laboratory services must be consistent with the patient population and services offered.

Radiologic Services

CMS finalized the proposal for REH radiologic services to mirror that of requirements for critical access hospitals (CAHs). ACEP supported this proposal and supports the finalization of the CoP.

Additional Outpatient Medical and Health Services

CMS finalized the proposal that REHs be allowed to provide additional medical and health outpatient services that include, but are not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. Further, CMS finalized the proposal that the REH have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate. ACEP supported the proposals but emphasized that if there are services that an REH cannot provide, these patients will need to be transferred to larger and/or urban hospitals or other facilities that can provide the needed care.

ACEP commented that at a minimum, a CoP for REHs should require emergency clinicians to be able to recognize and initiate treatment of preeclampsia, miscarriage, and postpartum depression, as well as precipitous deliveries and common delivery complications such as shoulder dystocia and postpartum hemorrhage. We also supported CMS's proposal that REHs have the option to be opioid treatment providers as long as the treatment remains an outpatient service. While CMS recognized the benefit of our comments, they finalized the proposal as written, with expectations that "REHs will provide various outpatient services suggested by commenters including, but not limited to services such as, low-risk labor and delivery supported by any emergency surgical procedures necessary and substance use disorder treatment, if identified by a health needs assessment of their community and in accordance with the CoPs for additional outpatient medical and health services finalized in this rule."

Infection Prevention and Control and Antibiotic Stewardship Programs

CMS is finalizing the proposed CoP for infection prevention and control and antibiotic stewardship programs for REHs that mirrors similar infection prevention and control requirements for hospitals and CAHs. ACEP supports these finalizations, as we appreciate that these requirements match those already instituted for CAHs.

Staff and Staffing Responsibilities

Staffing the REH

ACEP strongly opposed CMS' proposal to allow a nursing assistant, clinical technician, or an 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. The physician, NP, CNS, or PA with training or experience in emergency care must be on call and immediately available by telephone or radio contact and available on site within specified timeframes. We believe that the finalization of this proposal poses significant patient safety concerns. It could also increase the chances that REHs violate 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. While it may not be possible to have a board-certified emergency physician or other physician experienced and/or trained in emergency medicine (such as a family physician) staffing some REHs at all times, it is imperative that any time a patient comes to an REH with an immediate medical emergency, there will be clinician onsite to treat them IMMEDIATELY.

CMS responded to our comment that they "believe that the intent of the legislation is to ensure that REHs have the flexibility to determine who best meets the needs of their community while ensuring the provision of safe, quality patient care" and "expect REHs to determine who is best to fill this role based on the scope of services provided by the REH and the population served." **Despite our objections, CMS is finalizing** the requirement that the REH be staffed at all times "by an individual who is competent in the skills needed to address emergency medical care" and "must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient."

Supervision Requirements

ACEP requested clarification on whether REHs must comply with existing Medicare supervision requirements, given the current requirements that a physician or non-physician practitioner. present on the same campus where services are being furnished, must be "immediately available" to furnish assistance and direction through the duration of the service.

ACEP sought clarification on the rationale of requiring a practitioner to only be "on duty" when the REH has one or more patients receiving emergency services when the nature of EDs, open 24 hours a day, 7 days a week, necessitates constant availability of practitioners to deliver those services in case of

immediate emergency. We also sought clarification on the specific definition of "sufficient periods of time" and being "present" in regard to physical presence or proximity to the campus in which emergency services are being furnished. CMS referred to the Emergency Services CoP, which requires REHs to have a "physician or other practitioner on-call at all times and available on-site within 30 or 60 min (depending on if the facility is located in a frontier area)."

ACEP requested that that CMS modify the CoP to make it a requirement that a physician with experience in emergency medicine serve as the medical director of a REH. While they "encourage" REHs to have such a physician serve in the capacity of medical director if possible, they will not be requiring it.

Training and Education Requirements

CMS is finalizing the proposal that allows care in REHs to be delivered by physicians and non-physician practitioners certified only in Advanced Cardiac Life Support (ACLS), Advanced Trauma Life Support (ATLS), and Pediatric Advanced Life Support (PALS). ACEP requested that this CoP require a much more robust education, training, and onboarding process than what currently exists. CMS did not respond to our request.

Discharge Planning

CMS is finalizing their proposed series of discharge planning requirements that align with those required for CAHs. ACEP supports these requirements.

Patient's Rights

CMS is finalizing the proposal for patient's rights that will set forth the rights of all patients to receive care in a safe setting and provide protection for a patient's emotional health and safety as well as their physical safety. ACEP supports these finalized rules as protections for patients' rights are essential to ensure that patients receive safe and high-quality care in REHs.

Quality Assessment and Performance Improvement (QAPI) Program

CMS is finalizing the proposal to require that every REH develop, implement, and maintain an effective, ongoing, REH-wide, data-driven QAPI program. ACEP strongly believes that there is a need to improve the quality of care delivered in rural areas; however, a potential barrier to quality reporting that REHs may encounter is having access to the data they need to improve their quality performance and having the staff available to analyze the data. REHs may not have the capital to invest in a registry or other mechanism for receiving and analyzing data. Thus, ACEP suggested that CMS should consider contributing additional resources to REHs to specifically help them with their quality reporting and data analytic capabilities. CMS acknowledged our suggestion, but stated that due to the consistency of the QAPI program with current CAH QAPI standards, the hospitals who convert to an REH currently adhere to these standards, and the finalized QAPI requirements will not overburden REH staff.

To further address the staff and staffing responsibilities concerns, CMS is also finalizing a revision to the REH QAPI program to specifically require the REH to measure, analyze, and track staffing as a quality

indicator to assesses processes of care, REH service and operations.

Emergency Preparedness

CMS proposed emergency preparedness requirements that align with the existing emergency preparedness standards for Medicare and Medicaid providers. As part of that approach, REHs must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. REHs must also develop and maintain an emergency preparedness training and testing program that is reviewed and updated at least every 2 years. REHs must conduct exercises to test the emergency plan at least annually. ACEP supported this approach and recommended comprehensive "boots on the ground" drills for an emergency preparedness response plan. While CMS did not acknowledge our comments, they are finalizing the provisions as proposed.

REH Payment Policy

CMS finalized the proposal to consider all covered outpatient department services that would otherwise be paid under the OPPS as REH services in these facilities. REHs will be paid for furnishing REH services at a rate that is equal to the OPPS payment rate for the equivalent covered outpatient department service, increased by five percent. REHs may also provide outpatient services that are not otherwise paid under the OPPS as well as post-hospital extended care services furnished in a unit of the facility that is a distinct part of the facility licensed as a skilled nursing facility; however, these services will not be considered REH services and therefore will be paid under the applicable fee schedule and would not receive the additional five percent payment increase that CMS proposes to apply to REH services. Finally, CMS ruled that REHs will also receive a monthly facility payment.

ACEP supports this payment approach as it aligns with the methodology outlined in the Consolidated Appropriations Act. However, we also noted that the statute only addresses additional facility payments to REHs under the OPPS—not added reimbursement for physicians and other clinicians under the Physician Fee Schedule (PFS) who actually deliver the services in REHs. In order to incentivize physicians and other clinicians to work in rural areas and appropriately staff REHs, ACEP strongly recommended that CMS consider creating an add-on code or modifier that clinicians could append to claims for services delivered in REHs. CMS did not address our recommendation.

REH Provider Enrollment

CMS finalized several provisions that identify the enrollment requirements with which REHs must comply as part of the enrollment process. One of the most important REH enrollment provisions finalized is that the facility may submit a Form CMS-855A change of information application (rather than an initial enrollment application) in order to convert from a CAH to an REH. ACEP supported the finalization of these provisions.

Use of the Medicare Outpatient Observation Notice by REHs

CMS finalized the inapplicability of the Medicare Outpatient Observation Notice (MOON) to require REHs to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours. ACEP suggested that beneficiaries should only be provided information about their status as outpatients after they are stabilized and the REHs have fulfilled their EMTALA obligation. Given the inapplicability of the NOTICE Act requirements to REHs, CMS is not requiring that the MOON be used by REHs.

Rural Emergency Hospitals (REH) Physician Self-Referral Law Update

CMS proposed two updates to the physician self-referral law for the new REH provider type: (1) a new exception for ownership or investment interests in an REH; and (2) revisions to certain existing exceptions to make them applicable to compensation arrangements to which an REH is a party. ACEP supported both these updates. CMS is finalizing revisions to certain existing exceptions to make them applicable to compensation arrangements to which an REH is a party. They are not finalizing the proposed exception for ownership or investment interests in an REH.

Proposed Services that Will Be Paid Only as Inpatient Services

CMS proposed the removal of 10 services from the IPO list. ACEP appreciated CMS' rationale for removing these specific services, as we have opposed previous proposals to eliminate the entire IPO list due to a potential increase in audit burden across the board as two-midnight case reviews increase.

Given public comments, CMS is finalizing their proposal to remove CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, and 21422 from the IPO list and reassign them to status indicator "J1" and APC 5165 beginning in CY 2023. They are also finalizing our proposal to remove CPT code 22632 from the IPO list and

reassign the service to status indicator "N". We are not finalizing our proposal to remove CPT code 16036 from the IPO list and will continue to assign CPT code 16036 to status indicator "C". Finally, they are removing CPT code 47550 and reassigning it to status indicator "N" and removing CPT code 21255 and reassigning it to status indicator "J1" and APC 5165 - Level 5 ENT Procedures.

<u>Supervision by Non-physician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients</u>

CMS proposed a revision to supervision requirements to clarify that nurse practitioners, clinical nurse specialists, physician assistants, certified registered nurse anesthetists, and certified nurse midwives may provide general, direct, and personal supervision of outpatient diagnostic services to the extent that they are authorized to do so under their scope of practice and applicable State law. While this issue does not directly affect emergency physicians, it is indicative of CMS' inclination to support expanded scope.

ACEP commented that we are concerned about CMS' overall position regarding care delivered by non-

physician practitioners. When making any policy choices, we stated that CMS should rely on fact-based resources, including a thorough review of the education and training of nonphysician health care professionals and the impact on the overall cost and quality of care, and that CMS should review the true impact of state scope of practice laws on access to care across the country. We referenced surveys indicating that patients prefer physicians to lead their health care team and that more patients trust a physician to deliver their medical care in an emergency as compared to a nurse, nurse practitioner or physician assistant. We also commented that expanding the scope of practice of nurse practitioners will not increase patient access to care because the actual practice locations of nurse practitioners reveal that they tend to work in the same large urban areas as physicians. We noted that overall, while all health care professionals play a critical role in providing care to patients, their skillsets are not interchangeable with that of fully trained physicians.

CMS acknowledges that physician skill sets are not fully interchangeable with the skill sets of nonphysician practitioners and that the education and training requirements of physicians differ from nonphysician practitioners. However, they disagree that that the skill sets, education and training of physicians do render them solely qualified to supervise diagnostic services. With respect to our concerns about nonphysician practitioners' abilities to safely and accurately perform diagnostic tests, CMS notes that the proposed regulation explicitly limits nonphysician supervision to that which is permitted under the nonphysician practitioner's scope of practice and state law. Furthermore, they note that nothing in the proposed regulation prohibits or limits physicians from continuing to supervise any and all diagnostic tests. As to the studies and surveys cited by commenters related to the functioning of nonphysician practitioners with independent patient panels in the primary care setting and patient preferences regarding who leads their care team and provides their emergency care, CMS questions the relevancy of these findings to allowing nonphysician practitioners to supervise diagnostic tests.

Finally, CMS did not agree with our assertion that the practice locations of nurse practitioners demonstrate that patient access to care will not increase by allowing nonphysician practitioners to supervise diagnostic tests. They did not find the evidence submitted by the commenters sufficient to support the commenters' conclusion that most nurse practitioners tend to live in the same urban areas as physicians, and argued that it fails to account for those rural areas in which nurse practitioners do reside, where it could be expected that allowing nonphysician practitioners to supervise diagnostic tests would increase patient access to care; and it fails to account for medically underserved urban areas where it could also be expected that allowing nonphysician practitioners to supervise diagnostic tests would increase patient access to care.

Despite our comments, they are finalizing the provisions as proposed.

<u>Proposed Payment Adjustments under the IPPS and OPPS for Domestic NIOSH-Approved Surgical N95 Respirators</u>

CMS finalized the proposal to provide payment adjustments to hospitals under the Inpatient Prospective Payment System (IPPS) and OPPS for the additional resource costs they incur to acquire domestic NIOSH-approved surgical N95 respirators, which faced severe shortage at the onset of the COVID-19 pandemic and are essential for the protection of beneficiaries and hospital personnel that interface with

patients. Given the insufficient level of PPE provided to physicians by hospitals, the lack of choice of personal preference for PPE, and the variability in fit of PPE within hospital PPE programs, ACEP commented that we do not think that providing an IPPS adjustment to account for the increased cost of domestically made NIOSH-approved surgical N95 respirators will entirely solve the problem. We encouraged CMS to work with OSHA to ensure that health care workers have the flexibility they need to feel properly protected during future pandemics or COVID-19-driven surges. In response to our suggestion, CMS notes that this policy would not be adopted in isolation. For complementary efforts related to strengthening the U.S. public health and medical supply chain and industrial base, they refer the public to the "Public Health Supply Chain and Industrial Base One-Year Report.