Illinois Health and Hospital Association

MEDICARE PAYMENT FACT SHEET

NOVEMBER 2022

RURAL EMERGENCY HOSPITALS – COPS

On Nov. 3, the Centers for Medicare & Medicaid Services (CMS) released its calendar year (CY) 2023 outpatient prospective payment system (OPPS) final rule. Within this final rule, CMS finalized policies and procedures specific to rural emergency hospitals (REHs), including CMS-3419-F which finalizes Conditions of Participation (CoPs) for REHs. This fact sheet summarizes the REH CoPs. For a summary of the REH policies and procedures from the CY 2023 OPPS final rule, see IHA's Rural Emergency Hospital fact sheet.

Definition of REH: An entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary, and in which the annual per patient average length of stay does not exceed 24 hours.

If an REH exceeds the 24 hour average annual per patient length of stay, CMS expects the REH to have documentation demonstrating its attempt(s) to transfer a patient or reasons for an extended length of stay. This information will be reviewed and considered by CMS when making determinations regarding the REH's compliance with the length of stay requirement. A patient's length of stay begins with the registration, check-in or triage of the patient (whichever occurs first) and ends with the discharge of the patient from the REH.

Designation and Certification of REHs: CMS will certify a facility as an REH if the facility was, as of Dec. 27, 2020, a CAH, or a subsection d hospital with not more than 50 beds located in a county (or equivalent unit of local government) considered rural, or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Social Security Act (SSA). Hospitals that were eligible for REH status on Dec. 27, 2020 and have subsequently closed, are eligible to seek REH designation after the closure of the facility. Bed count is determined by calculating the number of available bed days during the most recent cost reporting period divided by the number of days in the most recent cost reporting period.

Compliance with Federal, State, and Local Laws and Regulations: REHs must be in compliance with applicable Federal, state, and local laws and regulations. Specifically, REHs must be located in a state that provides for the licensing of such a hospital under state or applicable local law. REHs must also ensure that personnel are licensed or meet other applicable standards required by state or local laws to provide services within their respective applicable scope of practice. If a state or locality has more stringent laws or regulations than the federal government, the REH must comply with the more stringent state and local laws.

Governing Body and Organizational Structure of the REH: REHs must have a governing body or individual(s) that are legally responsible for the conduct of the REH. The governing body must determine which categories of practitioners are eligible to serve as medical staff in accordance with state law, and must ensure said medical staff is accountable to the governing body for the quality of patient care provided by the REH.

REHs are on the list of permissible telehealth originating sites for telehealth services, and the REH's governing body must ensure that when telemedicine services are furnished to the REH's patients through an agreement with a Medicare-participating distant-site hospital, there must be an agreement with the distant-site hospital specifying that the governing body of the distant-site hospital providing telehealth services meets the requirements in §485.510(a)(1) through (7) with regard to its physicians or practitioners providing telehealth services.

The REH must also ensure that:

- The distant-site hospital providing the telemedicine services was a Medicare-participating hospital;
- 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;
- 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
- 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. The REH must send the distant-site hospital this information for use in its periodic appraisal of the individual distant-site physician or practitioner.

Provision of Services: REHs must furnish healthcare services in accordance with appropriate written policies and consistent with applicable state law. Written policies must include a description of the services the REH furnishes (including those furnished through agreement or arrangement), policies and procedures for emergency medical services, guidelines for the medical management of health problems, and policies and procedures that address the post-acute care needs of all patients receiving services furnished by an REH. Policies must be reviewed at least biennially and updated as necessary.

REHs must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice. Emergency services must be organized under the direction of a qualified member of the medical staff, and emergency services must be integrated with other departments of the REH. There must be adequate medical and nursing personnel qualified in emergency care to meet the needs of the REH.

Laboratory Services: REHs must provide basic laboratory services essential to the immediate diagnosis and treatment of the patient and consistent with nationally recognized standards of care for emergency services. In addition to laboratory services required for CAHs, REHs are encouraged to provide laboratory services that include a complete blood count, basic metabolic panel, magnesium, phosphorus, liver function tests, amylase, lipase, cardiopulmonary tests, lactate, coagulation studies, arterial blood gas, venous blood gas, quantitative human chorionic gonadotropin, and urine toxicology.

All laboratory services must be provided in a facility certified in accordance with Clinical Laboratory Improvement Amendments (CLIA) requirements at 42 CFR part 493, and emergency

laboratory services essential to the immediate diagnosis of a patient must be available 24 hours per day.

Radiologic Services: REHs must provide diagnostic radiologic services, and all other radiologic services that meet the needs of their patients (e.g., ultrasounds to evaluate the growth of a fetus; x-ray services if the REH is in a mining community). All radiologic services must be furnished by qualified personnel in accordance with state law, and REHs must institute proper safety precautions, perform periodic inspections of equipment, periodically check radiation works for exposure, and only provide radiologic services based on the order of practitioners with clinical privileges or authorization by the medical staff and governing body.

A qualified radiologist or other personnel qualified under state law either full-time, part-time, or on a consulting basis must be on staff to interpret radiologic tests that require specialized knowledge (this may be fulfilled via telehealth), and the radiologist in an REH must sign reports only of their interpretations.

Radiological reports and films must be preserved for five years. This is consistent with the REH requirement for maintenance and retention of REH medical records.

Pharmaceutical Services: REHs must be able to meet the pharmaceutical needs of its patients. REHs must have a pharmacy or drug storage area administered in accordance with accepted professional principles and state/Federal laws.

A registered pharmacist or other qualified individual in accordance with state scope of practice laws must direct pharmaceutical services or, when appropriate, have a drug storage area that is supervised by an individual who is competent to do so. This individual does not have to be full-time, but must be available for sufficient time to provide oversight based on the scope and complexity of services offered at the REH.

All compounding, packaging, and dispensing of drugs must be done by a licensed pharmacist or a licensed physician, or under the supervision of a pharmacist or other qualified individual acting in accordance with state scope of practice laws and be performed consistent with state/Federal laws.

All drugs biological must be kept in secure areas and locked when appropriate. Drugs listed in Schedules II, III, IV, and V must be locked within a secure area and only authorized personnel may have access to that locked area.

REHs must administer blood transfusions, blood products and intravenous medications in accordance with state law and approved medical staff policies and procedures. Orders given orally for drugs and biological must be followed by a written order, signed by the prescribing physician or other authorized prescriber.

Any adverse reactions must be reported to the physician responsible for the patient and documented in the record. REHs must also have a procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Additional Outpatient Medical and Health Services: If an REH chooses to provide additional outpatient medical and health services, those services must be appropriately organized and meet the needs of patients in accordance with acceptable standards of practice. Provision of

additional services must be based on nationally recognized guidelines and standards of practice, aligning with hospital CoPs for outpatient services.

Patients requiring a higher level of care must be transferred to an acute care hospital or CAH, requiring REHs to have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate. REHs must also have an effective communication system in place between the REH and patients (or responsible individuals) and their families, ensuring the REH is responsive to their needs and preferences.

Personnel requirements for REHs that choose to provide additional outpatient medical and health services include requirements that ensure the additional services are overseen by at least one responsible individual, have appropriate professional and nonprofessional personnel available at each location where services are offered, and are provided by a physician or other clinician with experience and training in the specialty service area.

Outpatient medical and health services may only be ordered by a practitioner who: is responsible for the care of the patient; is licensed in the state where they provide care to the patient; is acting within their scope of practice under state law; and is authorized to order the applicable outpatient services in accordance with state law and policies adopted by the medical staff, and approved by the governing body.

Standards for an REH performing outpatient surgical services are consistent with the CAH requirements. The standards ensure that the services are conducted in a safe manner by qualified practitioners with specific protocols for administering anesthesia. CMS expects REHs to provide surgical services to patients not requiring hospitalization, and when the expected duration of services would not exceed 24 hours following an admission.

Infection Prevention and Control and Antibiotic Stewardship: Each REH must have facility-wide infection prevention and control and antibiotic stewardship programs. These programs must be coordinated with the REH quality assessment and performance improvement (QAPI) program, for the surveillance, prevention, and control of Healthcare-Associated Infections (HAIs) and other infectious diseases, and for the optimization of antibiotic use through stewardship. The individual(s) overseeing these programs must be qualified via education or other training.

The infection prevention and control program must include surveillance, prevention, and control of HAIs, and must address any infection control issues identified by public health authorities.

The antibiotic stewardship program must meet certain goals, including: demonstrated coordination among all components of the REH responsible for antibiotic use and resistance; documentation of the evidence-based use of antibiotics in all departments and services of the REH; and documentation of improvements, including sustained improvements, in proper antibiotic use.

If the REH is part of a system consisting of multiple, separately certified hospitals, CAHs, and/or REHs under a single system governing body, that governing body may elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities, if such a decision is in accordance with all applicable state and local laws. Each separately certified REH subject to the system's single governing body would need to

demonstrate that the unified and integrated infection prevention and control and antibiotic stewardship programs:

- Were established in a manner that takes into account each REH's unique circumstances and any significant differences in patient populations and services offered;
- Established and implemented policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration; and
- Had mechanisms in place to ensure that issues localized to particular REHs were duly considered and addressed.

Each REH would also need to demonstrate that it had designated a qualified individual(s) with expertise in infection prevention and control and in antibiotic stewardship at the REH to be responsible for communicating with the system's unified infection prevention and control and antibiotic stewardship programs. This individual would also be responsible for implementing and maintaining the policies and procedures governing those programs and providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to REH staff.

In compliance with COVID-19 related interim final rules, REHs must also:

- Electronically report data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential when the Secretary of Health and Human Services has declared a Public Health Emergency (PHE) directly related to such specific pathogens and infectious diseases;
- Electronically report information about COVID-19 and seasonal influenza, including the REH's current inventory and use of any COVID-19-related therapeutics beginning at the conclusion of the COVID-19 PHE and continuing until April 30, 2024; and
- Develop and implement policies and procedures to ensure that all staff, with the exception of those with valid exemptions, are fully vaccinated for COVID-19 until Nov. 4, 2024.

Staffing and Staff Responsibilities: The emergency department (ED) of the REH must be staffed 24 hours per day, 7 days per week. While there is staffing flexibility, REHs are expected to staff the ED with individuals competent to receive patients and activate the appropriate medical resources for the treatment of the patient. Such staff may include a nurse, nursing assistant, clinical technician, or an emergency medicine technician (EMT).

REHs must also perform periodic review of clinical privileges and performance, similar to the CAH standards at 485.631.

There must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist with training or experience in emergency care on call and immediately available by telephone or radio contact, and available on site within specified timeframes (30 or 60 minutes depending on location of the REH). REHs are encouraged to have a board-certified emergency physician serving as the medical director if possible.

Nursing Services: REHs must have a director of nursing who is a licensed registered nurse and is responsible for the operation of the nursing services. REHs must have an organized nursing service available to provide 24-hour nursing services for the provision of patient care. REHs should have a sufficient number of nurses based on the number of patients receiving services in the REH and the level of care required by those patients. Patient care responsibilities must be delineated for all nursing service personnel and nursing services must be provided in accordance with recognized standards of practice.

Discharge Planning: REHs must implement a discharge planning process to begin identifying, early in the provision of services, the anticipated post-discharge goals, preferences, and needs of the patient. They must begin to develop an appropriate discharge plan for patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning. This includes a discharge planning evaluation that assesses a patient's likely need for appropriate services following REH care that includes, but is not limited to, hospice care services, post-REH extended care services, home health services, and non-healthcare services and community-based care providers. It must also include a determination of the availability of the appropriate services, as well as identify the patient's access to those services.

A patient's discharge needs evaluation and discharge plan must be documented and completed on a timely basis. The discharge needs evaluation and discharge plan should be coordinated by a registered nurse, social worker, or other qualified personnel.

The discharge planning process should be assessed on a regular basis, including an ongoing review of a representative sample of discharge plans. CMS expects this would include patients who were ED revisits or presented to the ED within 30 days of a previous visit to ensure that the REH is responsive to the discharge needs of the patient.

REHs are required to share data with patients on quality and resource use measures of local post-acute care providers to assist them in selecting a post-acute care provider. REHs must discharge the patient, and also transfer or refer the patient where applicable. They must also transfer all necessary medical information pertaining to the patient's course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

Patient's Rights: All patients have the right to receive care in a safe setting, and the facility must protect the patient's emotional and physical health and safety. REHs must inform patients of and permit them to exercise their rights; address privacy and safety; adhere to the confidentiality of patient records; abide by restrictions on the use of restraint and seclusion; and adhere to patient visitation rights.

The final rule outlines Patient Right CoPs specific to the patient notice of rights, including exercising those rights; the use of restraints and seclusion; staff training requirements for the use of restraints or seclusion; death reporting requirements; and patient visitation rights.

Quality Assessment and Performance Improvement (QAPI) Program: REHs must develop, implement, and maintain an effective, ongoing, REH-wide, data-driven QAPI program. This QAPI

program ensures that REHs systematically review their operating systems and processes of care to identify and implement opportunities to deliver effective care to their patients, with a focus on improving health outcomes and preventing and reducing medical errors.

An REH QAPI program must contain five parts: (a) program and scope; (b) program data collection and analysis; (c) program activities; (d) executive responsibilities; and (e) unified and integrated QAPI program for an REH in a multi-hospital system.

Agreements: REHs must have a transfer agreement with at least one level I or level II trauma center that is Medicare-certified, state licensed or verified by the American College of Surgeons. It is acceptable for the level I or II trauma center to be located in a state other than the state where the REH is located.

This requirement does not preclude an REH from also having transfer agreements with hospitals that are not designated as a level I or II trauma center.

Medical Records: REHs must maintain a medical records system in accordance with written policies and procedures. The medical record must be legible, complete, accurately documented, readily accessible, and systematically organized. REHs must designate a member of the professional staff as responsible for maintaining the records.

For each patient receiving healthcare services, the REH must maintain a record that includes, as applicable, identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and healthcare needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient. These include reports of physical examinations; diagnostic and laboratory test results, including clinical laboratory services; consultative findings and all orders of doctors of medicine or osteopathy or other practitioners; reports of treatments and medications; nursing notes and documentation of complications; and other pertinent information necessary to monitor the patient's progress, such as temperature graphics or progress notes describing the patient's response to treatment. The record must also include dated signatures of the doctor of medicine or osteopathy or other healthcare professional overseeing the patient.

REHs must maintain the confidentiality of patients' medical record information. REHs must ensure such records would be retained for at least 5 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

If the REH uses an electronic medical record system, the REH must conform with the content exchange standard at 45 CFR 170.205(d)(2). REHs must demonstrate that the system's notification capacity was fully operational and sends notifications with at least specified patient information, as appropriate, and facilitates the exchange of health information when the patient is registered, discharged, or transferred from the REH's ED. Finally, the REH must make a reasonable effort to ensure that the system can send notifications to specific recipients, including the patient's applicable post-acute care and primary care services providers.

Emergency Preparedness: REHs must establish a comprehensive, consistent, flexible, and dynamic regulatory approach to emergency preparedness for REHs that aligns with the existing emergency preparedness standards for other Medicare and Medicaid participating providers

and suppliers. In addition to complying with all applicable Federal, state, and local emergency preparedness requirements, the REH must establish and maintain an emergency preparedness program that addressed four core elements, including: (1) risk assessment and planning; (2) policies and procedures; (3) communication; and (4) training and testing.

REHs must develop and maintain an emergency preparedness plan that is reviewed and updated at least every 2 years. The emergency plan must be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. It must also include strategies for addressing emergency events identified by the risk assessment; address the patient population, including, but not limited to, the type of services the REH has the ability to provide in an emergency; and outline continuity of operations, including delegations of authority and succession plans. It must include a process for cooperation and collaboration with local, tribal, regional, state, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

REHs must develop and maintain an emergency preparedness training and testing program based on the emergency plan, policies and procedures and communication plan, and review and update it at least every two years. The training program must include initial training in the emergency preparedness policies and procedures for new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles. REHs must provide emergency preparedness training at least every two years, maintain documentation of all emergency preparedness training, demonstrate staff knowledge of emergency procedures, and if the emergency preparedness policies and procedures are significantly updated, conduct training on the updated policies and procedures.

REHs must conduct two testing exercises to test the emergency program, including a full-scale or functional community-based exercise and an additional exercise of its choice, every two years. If a community-based exercise was not accessible, the REH should conduct a facility-based functional exercise. If the REH experienced an actual natural or man-made emergency that required activation of the emergency plan, the REH would be exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

The second, additional exercise should be conducted opposite the year the full-scale or functional exercise was conducted. It could include a second full-scale community-based exercise or an individual, facility-based functional exercise, a mock disaster drill, or a tabletop exercise or workshop led by a facilitator. This could include a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. REHs should revise their emergency plans as needed based on the results of these exercises.

REHs must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the NFPA®. CMS also outlined system inspection and testing requirements in compliance with NFPA® 99, NFPA® 110 and NFPA® 101 standards.

Finally, if an REH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elected to have a unified and integrated emergency preparedness

program, the REH could choose to participate in the system's coordinated emergency preparedness program.

Physical Environment: REHs must be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. This includes emergency power and lighting in at least all areas serviced by the emergency supply source, including but not limited to, the operating, recovery, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, the REH must have battery lamps and flashlights available. The REH must also have facilities for emergency gas and water supply, and a safe and sanitary environment that is properly constructed, equipped and maintained to protect the health and safety of all patients.

Skilled Nursing Facility Distinct Part Unit: REHs are allowed to establish a unit that is a distinct part licensed as a SNF to furnish post-REH or post-hospital extended care services. This unit must be separately licensed and certified to provide SNF services at all times. A distinct part SNF must be physically distinguishable from the REH, must be fiscally separate for cost reporting purposes, and the beds in the certified distinct part SNF unit of an REH must meet the requirements applicable to distinct part SNFs at 42 CFR part 483, subpart B.

Medicare payment for SNF services furnished in these distinct part SNFs of an REH would be under the SNF prospective payment system. A distinct part SNF of an REH is not subject to the REH's length of stay limits of less than an annual per patient average of 24 hours.

Contact:

Cassie Yarbrough, Senior Director, Medicare Policy
630-276-5516 | cyarbrough@team-iha.org

Sources:
Centers for Medicare & Medicaid Services. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; etc. Filed on Nov. 3, 2022. Available from: https://www.federalregister.gov/public-inspection/2022-23918/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment. Accessed Nov. 3, 2022.