

Accreditation Participation Requirements (APR) Chapter

APR.01.01.01

The critical access hospital submits information to The Joint Commission as required.

Element(s) of Performance for APR.01.01.01

1. The critical access hospital meets all requirements for timely submissions of data and information to The Joint Commission.

Note 1: The Joint Commission will impose the following consequence for failure to comply with this APR: If the critical access hospital consistently fails to meet the requirements for the timely submission of data and information to The Joint Commission, the critical access hospital will be required to undergo an Accreditation with Follow-up Survey. Failure to resolve this issue at the time of the Accreditation with Follow-up Survey may result in an accreditation decision change.

Note 2: The proposed consequences address only compliance with the requirement itself. They do not address the content of the critical access hospital's submissions to The Joint Commission. For example, if information in a critical access hospital's electronic application for accreditation (E-App) leads to inaccuracies in the appropriate length of the survey and a longer survey is required, the critical access hospital will incur the additional costs of the longer survey. In addition, if there is evidence that the critical access hospital has intentionally falsified the information submitted to The Joint Commission, the requirement at APR.01.02.01, EP 1 and its consequences will apply. (See also APR.01.02.01, EP 1)

APR.01.02.01

The critical access hospital provides accurate information throughout the accreditation process.

Element(s) of Performance for APR.01.02.01

- 1. The critical access hospital provides accurate information throughout the accreditation process. Note 1: Information may be received in any of the following ways:
 - · Provided verbally
 - Obtained through direct observation by, or in an interview or any other type of communication with, a Joint Commission employee
 - Derived from documents supplied by the critical access hospital to The Joint Commission
 - · Submitted electronically by the critical access hospital to The Joint Commission

Note 2: For the purpose of this requirement, falsification is defined as the fabrication, in whole or in part, and through commission or omission, of any information provided by an applicant or accredited organization to The Joint Commission. This includes redrafting, reformatting, or deleting document content. However, the organization may submit supporting material that explains the original information submitted to The Joint Commission. These additional materials must be properly identified, dated, and accompanied by the original documents.(See also APR.01.01.01, EP 1)

APR.01.03.01

The critical access hospital reports any changes in the information provided in the application for accreditation and any changes made between surveys.

Element(s) of Performance for APR.01.03.01

1. The critical access hospital notifies The Joint Commission in writing within 30 days of a change in ownership, control, location, capacity, services offered, or required licensure.

Note 1: When the critical access hospital changes ownership, control, location, capacity, or services offered, it may be necessary for The Joint Commission to survey the critical access hospital again.

Note 2: If the critical access hospital does not provide written notification to The Joint Commission within 30 days of these changes, the critical access hospital may be denied accreditation.

2. The critical access hospital notifies The Joint Commission immediately upon receiving notice from the Centers for Medicare & Medicaid Services (CMS) that its deemed status has been removed due to Medicare condition-level noncompliance identified during a recent CMS complaint or validation survey.

APR.02.01.01

The critical access hospital permits the performance of a survey at The Joint Commission's discretion.

Element(s) of Performance for APR.02.01.01

1. The critical access hospital permits the performance of a survey at The Joint Commission's discretion.

APR.04.01.01

The critical access hospital selects and uses performance measures from among those available that are relevant to the services it provides and the population(s) it serves to meet specified ORYX® measure reporting requirements for accreditation.

Note: Critical access hospitals are encouraged to keep up-to-date on any changes in the ORYX® requirements by reviewing recent issues of The Joint Commission Perspectives® or by going to the "Measurement" area on The Joint Commission website at http://www.jointcommission.org.

Element(s) of Performance for APR.04.01.01

- 1. The critical access hospital selects and uses measures that reflect the following characteristics: Relevant to the critical access hospital
- 2. The critical access hospital selects and uses measures that reflect the following characteristics: Support strategic measurement goals
- 3. The critical access hospital selects and uses measures that reflect the following characteristics: Target high-volume, high-risk, problem-prone issues
- 4. The critical access hospital selects and uses measures that reflect the following characteristics: Provide opportunities to improve the quality of care
- 5. The critical access hospital selects chart-abstracted measures and/or electronic clinical quality measures (eCQMs) based on its patient population/services offered to meet current ORYX® requirements.
- 6. The critical access hospital selects performance measures within The Joint Commission's data submission application.
- 7. The critical access hospital discusses with the surveyor how the data are used to identify, prioritize, and monitor performance improvement activities.
- 8. The critical access hospital uses each individual measure to identify patterns, trends, or variations for improvement opportunities before replacing it. (For example, chart-abstracted measures should begin the first quarter of the calendar year or first quarter following receipt of an accreditation decision letter and be used for the remainder of the calendar year before replacing any measures.)

- 9. Based on Joint Commission statistical analysis, the critical access hospital continues to use a measure if the data suggest an unstable pattern of performance or otherwise identify an opportunity for improvement.
- 10. The critical access hospital selects a new measure if the data reflect stable and satisfactory performance.
- 12. The critical access hospital's performance measure data are submitted to The Joint Commission in timelines established and technical manner prescribed by The Joint Commission.
- 13. The organization resolves data quality issues for reported performance measures.
- 14. For the most recent 12-month calendar reporting period, the critical access hospital achieves and sustains an acceptable level of performance for each measure, as defined by Joint Commission statistical analysis, before it discontinues a measure's use in performance improvement activities.

APR.05.01.01

The critical access hospital allows The Joint Commission to review the results of external evaluations from publicly recognized bodies.

Element(s) of Performance for APR.05.01.01

1. When requested, the critical access hospital provides The Joint Commission with all official records and reports of licensing, examining, reviewing, or planning bodies.

APR.06.01.01

Applicants and accredited critical access hospitals do not use Joint Commission employees to provide accreditation-related consulting services.

Element(s) of Performance for APR.06.01.01

1. The critical access hospital does not use Joint Commission employees to provide any accreditation-related consulting services.

APR.07.01.01

The critical access hospital accepts the presence of Joint Commission surveyor management staff or a Board of Commissioners member in the role of observer of an on-site survey.

Element(s) of Performance for APR.07.01.01

- 1. The critical access hospital allows Joint Commission surveyor management staff or a member of the Board of Commissioners to observe the on-site survey.
 - Note 1: The observer will not participate in the on-site survey process, including the scoring of standards compliance. Surveyor management staff will only participate in the survey process if they feel it is necessary to bring any potential findings or observations to the attention of the surveyor and the critical access hospital. Note 2: The critical access hospital will not incur any additional survey fees because an observer(s) is present.

APR.08.01.01

The critical access hospital accurately represents its accreditation status and the programs and services to which Joint Commission accreditation applies.

Element(s) of Performance for APR.08.01.01

- 1. The critical access hospital's advertising accurately reflects the scope of programs and services that are accredited by The Joint Commission.
- 2. The critical access hospital does not engage in any false or misleading advertising about its accreditation award.

APR.09.01.01

The critical access hospital notifies the public it serves about how to contact its critical access hospital management and The Joint Commission to report concerns about patient safety and quality of care.

Note: Methods of notice may include, but are not limited to, distribution of information about The Joint Commission, including contact information in published materials such as brochures and/or posting this information on the critical access hospital's website.

Element(s) of Performance for APR.09.01.01

- 1. The critical access hospital informs the public it serves about how to contact its management to report concerns about patient safety and quality of care.
- 2. The critical access hospital informs the public it serves about how to contact The Joint Commission to report concerns about patient safety and quality of care.

APR.09.02.01

Any individual who provides care, treatment, and services can report concerns about safety or the quality of care to The Joint Commission without retaliatory action from the critical access hospital.

Element(s) of Performance for APR.09.02.01

- 1. The critical access hospital educates its staff, medical staff, and other individuals who provide care, treatment, and services that concerns about the safety or quality of care provided in the organization may be reported to The Joint Commission.
- 2. The critical access hospital informs its staff and medical staff that it will take no disciplinary or punitive action because an employee, physician, or other individual who provides care, treatment, and services reports safety or quality-of-care concerns to The Joint Commission.
- 3. The critical access hospital takes no disciplinary or punitive action against employees, physicians, or other individuals who provide care, treatment, and services when they report safety or quality-of-care concerns to The Joint Commission.

APR.09.04.01

The critical access hospital provides care, treatment, services, and an environment that pose no risk of an "Immediate Threat to Health or Safety."

Element(s) of Performance for APR.09.04.01

1. The critical access hospital provides care, treatment, services, and an environment that pose no risk of an "Immediate Threat to Health or Safety."

Emergency Management (EM) Chapter

EM.09.01.01

The critical access hospital has a comprehensive emergency management program that utilizes an all-hazards approach.

Element(s) of Performance for EM.09.01.01

- 1. The critical access hospital has a written comprehensive emergency management program that utilizes an all-hazards approach. The program includes, but is not limited to, the following:
 - Leadership structure and program accountability
 - · Hazard vulnerability analysis
 - · Mitigation and preparedness activities
 - · Emergency operations plan and policies and procedures
 - Education and training
 - · Exercises and testing
 - · Continuity of operations plan
 - · Disaster recovery
 - · Program evaluation

CoP(s): §482.15, §485.625

- 2. If the critical access hospital is part of a health care system that has a unified and integrated emergency management program and it chooses to participate in the program, the following must be demonstrated within the coordinated emergency management program:
 - Each separately certified critical access hospital within the system actively participates in the development of the unified and integrated emergency management program
 - The program is developed and maintained in a manner that takes into account each separately certified critical access hospital's unique circumstances, patient population, and services offered
 - Each separately certified critical access hospital is capable of actively using the unified and integrated emergency management program and is in compliance with the program
 - Documented community-based risk assessment utilizing an all-hazards approach
 - Documented individual, facility-based risk assessment utilizing an all-hazards approach for each separately certified critical access hospital within the health care system
 - · Unified and integrated emergency plan
 - Integrated policies and procedures
 - Coordinated communication plan
 - Training and testing program

CoP(s): $\S482.15(f)(1)$, $\S482.15(f)(2)$, $\S482.15(f)(3)$, $\S482.15(f)(4)$, $\S482.15(f)(4)(i)$, $\S482.15(f)(4)(ii)$, $\S482.15(f)(5)$, $\S485.625(f)(1)$, $\S485.625(f)(2)$, $\S485.625(f)(3)$, $\S485.625(f)(4)$, $\S485.625(f)(4)(ii)$, $\S485.625(f)(4)(ii)$, $\S485.625(f)(5)$

3. The critical access hospital complies with all applicable federal, state, and local emergency preparedness laws and regulations.

CoP(s): §482.15, §482.15(c), §482.15(f)(5), §485.625, §485.625(c), §485.625(f)(5)

- 4. For rehabilitation and psychiatric distinct part units in critical access hospitals: If a critical access hospital has one or more transplant programs (as defined in 42 CFR 482.70) the following must occur:
 - A representative from each transplant program must be included in the development and maintenance of the critical access hospital's emergency preparedness program
 - The critical access hospital must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the critical access hospital, each transplant program, and the organ procurement organization (OPO) for the donation service area where the critical access hospital is situated, unless the critical access hospital has been granted a waiver to work with another OPO, during an emergency

CoP(s): §482.15(g)(1), §482.15(g)(2)

EM.11.01.01

The critical access hospital conducts a hazard vulnerability analysis utilizing an all-hazards approach.

Element(s) of Performance for EM.11.01.01

- 1. The critical access hospital conducts a facility-based hazard vulnerability analysis (HVA) using an all-hazards approach that includes the following:
 - Hazards that are likely to impact the critical access hospital's geographic region, community, facility, and patient population
 - A community-based risk assessment (such as those developed by external emergency management agencies)
 - Separate HVAs for its other accredited facilities if they significantly differ from the main site The findings are documented.

Note: A separate HVA is only required if the accredited facilities are in different geographic locations, experience different hazards or threats, or the patient population and services offered are unique to this facility.

CoP(s): §482.15(a)(1), §485.625(a)(1)

- 2. The critical access hospital's hazard vulnerability analysis includes the following:
 - Natural hazards (such as flooding, wildfires)
 - Human-caused hazards (such as bomb threats or cyber/information technology crimes)
 - Technological hazards (such as utility or information technology outages)
 - Hazardous materials (such as radiological, nuclear, chemical)
 - Emerging infectious diseases (such as the Ebola, Zika, or SARS-CoV-2 viruses)

CoP(s): §482.15(a)(1), §485.625(a)(1)

3. The critical access hospital evaluates and prioritizes the findings of the hazard vulnerability analysis to determine what presents the highest likelihood of occurring and the impacts those hazards will have on the operating status of the critical access hospital and its ability to provide services. The findings are documented.

CoP(s): §482.15(a)(2), §482.15(f)(4), §485.625(a)(2), §485.625(f)(4)

4. The critical access hospital uses its prioritized hazards from the hazard vulnerability analysis to identify and implement mitigation and preparedness actions to increase the resilience of the critical access hospital and helps reduce disruption of essential services or functions.

CoP(s): §482.15(a)(2), §482.15(f)(4), §485.625(a)(2), §485.625(f)(4)

EM.12.01.01

The critical access hospital develops an emergency operations plan based on an all-hazards approach.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazards vulnerability analysis when developing an emergency operations plan.

Element(s) of Performance for EM.12.01.01

- 1. The critical access hospital has a written all-hazards emergency operations plan (EOP) with supporting policies and procedures that provides guidance to staff and volunteers on actions to take during emergency or disaster incidents. The EOP and policies and procedures include, but are not limited to, the following:
 - · Mobilizing incident command
 - Communications plan
 - Maintaining, expanding, curtailing, or closing operations
 - · Protecting critical systems and infrastructure
 - Conserving and/or supplementing resources
 - Surge plans (such as flu or pandemic plans)
 - · Identifying alternate treatment areas or locations
 - Sheltering in place
 - Evacuating (partial or complete) or relocating services
 - Safety and security
 - · Securing information and records

CoP(s): §482.15(a), §482.15(b), §482.15(c), §482.15(f)(5), §485.625(a), §485.625(b), §485.625(c), §485.625(f) (5)

2. The critical access hospital's emergency operations plan identifies the patient population(s) that it will serve, including at-risk populations, and the types of services it would have the ability to provide in an emergency or disaster event.

Note: At-risk populations such as the elderly, dialysis patients, or persons with physical or mental disabilities may have additional needs to be addressed during an emergency or disaster incident such as medical care, communication, transportation, supervision, and maintaining independence.

CoP(s): §482.15(a)(3), §482.15(f)(4), §485.625(a)(3), §485.625(f)(4)

3. The critical access hospital's emergency operations plan includes written procedures for when and how it will shelter in place or evacuate (partial or complete) its staff, volunteers, and patients.
Note 1: Shelter-in-place plans may vary by department and facility and may vary based on the type of emergency or situation.

Note 2: Safe evacuation from the critical access hospital includes consideration of care, treatment, and service needs of evacuees, staff responsibilities, and transportation.

CoP(s): §482.15(b)(3), §482.15(b)(4), §485.625(b)(3), §485.625(b)(4)

- 4. The emergency operations plan includes written procedures for how the critical access hospital will provide essential needs for its staff, volunteers, and patients, whether they shelter in place or evacuate, that includes, but is not limited to, the following:
 - Food and other nutritional supplies
 - · Medications and related supplies
 - · Medical/surgical supplies
 - · Medical oxygen and supplies
 - · Potable or bottled water

CoP(s): §482.15(b)(1)(i), §485.625(b)(1)(i)

6. The critical access hospital's emergency operations plan includes a process for cooperating and collaborating with other health care facilities; health care coalitions; and local, tribal, regional, state, and federal emergency preparedness officials' efforts to leverage support and resources and to provide an integrated response during an emergency or disaster incident.

CoP(s): §482.15(a)(4), §482.15(f)(4), §485.625(a)(4), §485.625(f)(4)

7. The critical access hospital must develop and implement emergency preparedness policies and procedures that address the role of the critical access hospital under a waiver declared by the Secretary, in accordance with section 1135 of the Social Security Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

Note 1: This element of performance is applicable only to critical access hospitals that receive Medicare, Medicaid, or Children's Health Insurance Program reimbursement.

Note 2: For more information on 1135 waivers, visit https://www.cms.gov/about-cms/what-we-do/emergency-response/how-can-we-help/waivers-flexibilities and https://www.cms.gov/about-cms/agency-information/emergency/downloads/consolidated_medicare_ffs_emergency_qsas.pdf.

CoP(s): §482.15(b)(8), §485.625(b)(8)

EM.12.02.01

The critical access hospital has a communications plan that addresses how it will initiate and maintain communications during an emergency.

Note: The critical access hospital considers prioritized hazards identified as part of its hazard vulnerability analysis when developing an emergency response communications plan.

Element(s) of Performance for EM.12.02.01

- 1. The critical access hospital maintains a contact list of individuals and entities that are to be notified in response to an emergency. The list of contacts includes the following:
 - Staff

- Physicians and other licensed practitioners
- Volunteers
- · Other health care organizations
- Entities providing services under arrangement, including suppliers of essential services, equipment, and supplies
- Relevant community partners (such as fire, police, local incident command, public health departments)
- Relevant authorities (federal, state, tribal, regional, and local emergency preparedness staff)
- Other sources of assistance (such as health care coalitions)

Note: The type of emergency will determine what organizations/individuals need to be contacted to assist with the emergency or disaster incident.

 $\label{eq:copsimple} \begin{aligned} &\text{CoP(s): } \S 482.15(\text{c})(1)(\text{i}), \ \S 482.15(\text{c})(1)(\text{ii}), \ \S 482.15(\text{c})(1)(\text{iii}), \ \S 482.15(\text{c})(1)(\text{iv}), \ \S 482.15(\text{c})(1)(\text{v}), \ \S 482.15(\text{c})(1)(\text{v}), \ \S 482.15(\text{c})(1)(\text{ii}), \ \S 485.625(\text{c})(1)(\text{iii}), \ \S 485.625(\text{c})(1)(\text{iii}), \ \S 485.625(\text{c})(1)(\text{iv}), \ \S 485.625(\text{c})(1)(\text{v}), \ \S 485.625(\text{c})(2)(\text{ii}) \end{aligned}$

3. The critical access hospital's communication plan describes how the critical access hospital will communicate with and report information about its organizational needs, available occupancy, and ability to provide assistance to relevant authorities.

Note: Examples of critical access hospital needs include shortages in personal protective equipment, staffing shortages, evacuation or transfer of patients, and temporary loss of part or all organization function.

CoP(s): §482.15(c)(7), §485.625(c)(7)

- 4. In the event of an emergency or evacuation, the critical access hospital's communications plan includes a method for sharing and/or releasing location information and medical documentation for patients under the hospital's care to the following individuals or entities, in accordance with law and regulation:
 - · Patient's family, representative, or others involved in the care of the patient
 - · Disaster relief organizations and relevant authorities
 - · Other health care providers

Note: Sharing and releasing of patient information is consistent with 45 CFR 164.510(b)(1)(ii) and (b)(4).

CoP(s): §482.15(c)(4), §482.15(c)(5), §482.15(c)(6), §485.625(c)(4), §485.625(c)(5), §485.625(c)(6)

- 5. The critical access hospital's communications plan identifies its primary and alternate means for communicating with staff and relevant authorities (such as federal, state, tribal, regional, and local emergency preparedness staff). The plan includes procedures for the following:
 - How and when alternate/backup communication methods are used
 - Verifying that its communications systems are compatible with those of community partners and relevant authorities the critical access hospital plans to communicate with
 - Testing the functionality of the critical access hospital's alternate/backup communication systems or equipment

Note: Examples of alternate/backup communication systems include amateur radios, portable radios, text-based notifications, cell and satellite phones, and reverse 911 notification systems.

CoP(s): §482.15(b)(3), §482.15(c)(3)(i), §482.15(c)(3)(ii), §485.625(b)(3), §485.625(c)(3)(ii), §485.625(c)(3)(iii)

EM.12.02.03

The critical access hospital has a staffing plan for managing all staff and volunteers during an emergency or disaster incident.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a staffing plan.

Element(s) of Performance for EM.12.02.03

- The critical access hospital develops a staffing plan for managing all staff and volunteers to meet patient care
 needs during the duration of an emergency or disaster incident or during a patient surge. The plan includes the
 following:
 - · Methods for contacting off-duty staff
 - · Acquisition of staff from its other health care facilities
 - Use of volunteer staffing, such as staffing agencies, health care coalition support, and those deployed as part of the disaster medical assistance teams

Note: If the critical access hospital determines that it will never use volunteers during disasters, this is documented in its plan.

CoP(s): §482.15(b)(6), §485.625(b)(6)

- 2. The critical access hospital's staffing plan addresses the management of all staff and volunteers as follows:
 - · Reporting processes
 - · Roles and responsibilities for essential functions
 - Integration of staffing agencies, volunteer staffing, or deployed medical assistance teams into assigned roles and responsibilities

CoP(s): §482.15(b)(6), §485.625(b)(6)

EM.12.02.05

The critical access hospital has a plan for providing patient care and clinical support during an emergency or disaster incident.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a plan for patient care and clinical support.

Element(s) of Performance for EM.12.02.05

1. The critical access hospital's plan for providing patient care and clinical support includes written procedures and arrangements with other hospitals and providers for how it will share patient care information and medical documentation and how it will transfer patients to other health care facilities to maintain continuity of care.

CoP(s): §482.15(b)(7), §482.15(c)(4), §485.625(b)(7), §485.625(c)(4)

EM.12.02.07

The critical access hospital has a plan for safety and security measures to take during an emergency or disaster incident.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a plan for safety and security.

Element(s) of Performance for EM.12.02.07

2. The critical access hospital's plan for safety and security measures includes a system to track the location of its on-duty staff and volunteers and patients when sheltered in place, relocated, or evacuated. If on-duty staff and volunteers and patients are relocated during an emergency, the critical access hospital documents the specific name and location of the receiving facility or evacuation location.

Note: Examples of systems used for tracking purposes include the use of established technology or tracking systems or taking head counts at defined intervals.

CoP(s): §482.15(b)(2), §485.625(b)(2)

EM.12.02.09

The critical access hospital has a plan for managing resources and assets during an emergency or disaster incident. Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a plan for resources and assets.

Element(s) of Performance for EM.12.02.09

- 1. The critical access hospital's plan for managing its resources and assets describes in writing how it will document, track, monitor, and locate the following resources (on-site and off-site inventories) and assets during and after an emergency or disaster incident:
 - · Medications and related supplies
 - · Medical/surgical supplies
 - · Medical gases, including oxygen and supplies
 - · Potable or bottled water and nutrition
 - Non-potable water
 - · Laboratory equipment and supplies
 - Personal protective equipment
 - Fuel for operations
 - · Equipment and nonmedical supplies to sustain operations

Note: The critical access hospital should be aware of the resources and assets it has readily available and what resources and assets may be quickly depleted depending on the type of emergency or disaster incident.

CoP(s): §482.15(e)(3), §485.625(e)(3)

- 2. The critical access hospital's plan for managing its resources and assets describes in writing how it will obtain, allocate, mobilize, replenish, and conserve its resources and assets during and after an emergency or disaster incident, including the following:
 - · If part of a health care system, coordinating within the system to request resources
 - · Coordinating with local supply chains or vendors
 - · Coordinating with local, state, or federal agencies for additional resources

- · Coordinating with regional health care coalitions for additional resources
- Managing donations (such as food, water, equipment, materials)

Note: High priority should be given to resources that are known to deplete quickly and are extremely competitive to acquire and replenish (such as fuel, oxygen, personal protective equipment, ventilators, intravenous fluids, antiviral and antibiotic medications).

CoP(s): §482.15(e)(3), §485.625(e)(3)

EM.12.02.11

The critical access hospital has a plan for managing essential or critical utilities during an emergency or disaster incident.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a plan for utilities management.

Element(s) of Performance for EM.12.02.11

1. The critical access hospital's plan for managing utilities describes in writing the utility systems that it considers as essential or critical to provide care, treatment, and services.

Note: Essential or critical utilities to consider may include systems for electrical distribution; emergency power; vertical and horizontal transport; heating, ventilation, and air conditioning; plumbing and steam boilers; medical gas; medical/surgical vacuum; and network or communication systems.

CoP(s): §482.15(e), §485.625(e)

2. The critical access hospital's plan for managing utilities describes in writing how it will continue to maintain essential or critical utility systems if one or more are impacted during an emergency or disaster incident.

CoP(s): §482.15(e), §482.15(e)(3), §485.625(e), §485.625(e)(3)

3. The critical access hospital's plan for managing utilities describes in writing alternative means for providing essential or critical utilities, such as water supply, emergency power supply systems, fuel storage tanks, and emergency generators.

CoP(s): §482.15(e), §482.15(e)(3), §485.625(e), §485.625(e)(3)

- 4. The critical access hospital's plan for managing utilities includes alternate sources for maintaining energy to the following:
 - Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions
 - · Emergency lighting
 - · Fire detection, extinguishing, and alarm systems
 - · Sewage and waste disposal

Note: It is important for critical access hospitals to consider alternative means for maintaining temperatures at a level that protects the health and safety of all persons within the facility. For example, when safe temperature levels cannot be maintained, the critical access hospital considers partial or full evacuation or closure.

EM.13.01.01

The critical access hospital has a continuity of operations plan.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a continuity of operations plan.

Element(s) of Performance for EM.13.01.01

1. The critical access hospital has a written continuity of operations plan (COOP) that is developed with the participation of key executive leaders, business and finance leaders, and other department leaders as determined by the critical access hospital. These key leaders identify and prioritize the services and functions that are considered essential or critical for maintaining operations.

Note: The COOP provides guidance on how the critical access hospital will continue to perform its essential business functions to deliver essential or critical services. Essential business functions to consider include administrative/vital records, information technology, financial services, security systems, communications/ telecommunications, and building operations to support essential and critical services that cannot be deferred during an emergency; these activities must be performed continuously or resumed quickly following a disruption.

CoP(s): §482.15(a)(3), §482.15(f)(4), §485.625(a)(3), §485.625(f)(4)

2. The critical access hospital's continuity of operations plan identifies in writing how and where it will continue to provide its essential business functions when the location of the essential or critical service has been compromised due to an emergency or disaster incident.

Note: Example of options to consider for providing essential services include use of off-site locations, space maintained by another organization, existing facilities or space, telework (remote work), or telehealth.

CoP(s): §482.15(a)(3), §482.15(f)(4), §485.625(a)(3), §485.625(f)(4)

3. The critical access hospital has a written order of succession plan that identifies who is authorized to assume a particular leadership or management role when that person(s) is unable to fulfill their function or perform their duties.

CoP(s): §482.15(a)(3), §482.15(f)(4), §485.625(a)(3), §485.625(f)(4)

4. The critical access hospital has a written delegation of authority plan that provides the individual(s) with the legal authorization to act on behalf of the critical access hospital for specified purposes and to carry out specific duties.

Note: Delegations of authority are an essential part of an organization's continuity program and should be sufficiently detailed to make certain the critical access hospital can perform its essential functions. Delegations of

authority will specify a particular function that an individual is authorized to perform and includes restrictions and limitations associated with that authority.

CoP(s): §482.15(a)(3), §482.15(f)(4), §485.625(a)(3), §485.625(f)(4)

EM.15.01.01

The critical access hospital has an emergency management education and training program.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing education and training.

Element(s) of Performance for EM.15.01.01

The critical access hospital has a written education and training program in emergency management that is based on the critical access hospital's prioritized risks identified as part of its hazard vulnerability analysis, emergency operations plan, communications plan, and policies and procedures.
Note: If the critical access hospital has developed multiple hazard vulnerability analyses based on the location of other services offered, the education and training for those facilities are specific to their needs.

CoP(s): §482.15(d), §482.15(f)(5), §485.625(d), §485.625(f)(5)

- 2. The critical access hospital provides initial education and training in emergency management to all new and existing staff, individuals providing services under arrangement, and volunteers that are consistent with their roles and responsibilities in an emergency. The initial education and training include the following:
 - Activation and deactivation of the emergency operations plan
 - · Communications plan
 - · Emergency response policies and procedures
 - Evacuation, shelter-in-place, lockdown, and surge procedures
 - Where and how to obtain resources and supplies for emergencies (such as procedure manuals or equipment) Documentation is required.

- 3. The critical access hospital provides ongoing education and training to all staff, individuals providing services under arrangement, and volunteers that are consistent with their roles and responsibilities in an emergency. The education and training occur at the following times:
 - At least every two years
 - · When roles or responsibilities change
 - When there are significant revisions to the emergency operations plan, policies, and/or procedures
 - When procedural changes are made during an emergency or disaster incident requiring just-in-time education and training.

Documentation is required.

Note 1: Staff demonstrate knowledge of emergency procedures through participation in drills and exercises, as well as post-training tests, participation in instructor-led feedback (for example, questions and answers), or other methods determined and documented by the organization.

Note 2: Critical access hospitals are not required to retrain staff on the entire emergency operations plan but can choose to provide education and training specific to the new or revised elements of the emergency management program.

CoP(s): §482.15(d)(1)(ii), §482.15(d)(1)(iii), §482.15(d)(1)(iv), §482.15(d)(1)(v), §485.625(d)(1)(ii), §485.625(d)(1)(iv), §485.625(d)(1)(v)

EM.16.01.01

The critical access hospital plans and conducts exercises to test its emergency operations plan and response procedures.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing emergency exercises.

Element(s) of Performance for EM.16.01.01

- 1. The critical access hospital describes in writing a plan for when and how it will conduct annual testing of its emergency operations plan (EOP). The planned exercises are based on the following:
 - · Likely emergencies or disaster scenarios
 - · EOP and policies and procedures
 - After-action reports (AAR) and improvement plans
 - Six critical areas (communications, staffing, patient care and clinical support, safety and security, resources and assets, utilities)

Note 1: The planned exercises should attempt to stress the limits of its emergency response procedures to assess how prepared the critical access hospital may be if a real event or disaster were to occur based on past experiences.

Note 2: An AAR is a detailed critical summary or analysis of an emergency or disaster incident, including both planned and unplanned events. The report summarizes what took place during the event, analyzes the actions taken by participants, and provides areas needing improvement.

CoP(s): §482.15(d), §482.15(f)(5), §485.625(d), §485.625(f)(5)

- 2. The critical access hospital is required to conduct two exercises per year to test the emergency operations plan.
 - One of the annual exercises must consist of an operations-based exercise as follows:
 - Full-scale, community-based exercise; or
 - · Functional, facility-based exercise when a community-based exercise is not possible
 - The other annual exercise must consist of either an operations-based or discussion-based exercise as follows:
 - · Full-scale, community-based exercise; or
 - · Functional, facility-based exercise; or
 - · Mock disaster drill; or
 - Tabletop, seminar, or workshop that is led by a facilitator and includes a group discussion using narrated, clinically relevant emergency scenarios and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

Exercises and actual emergency or disaster incidents are documented (after-action reports).

Note 1: The critical access hospital would be exempt from conducting its next annual operations-based exercise if it experiences an actual emergency or disaster incident (discussion-based exercises are excluded from

exemption). An exemption only applies if the critical access hospital provides documentation that it activated its emergency operations plan.

Note 2: See the Glossary for the definitions of operations-based and discussion-based exercises.

CoP(s): §482.15(d)(2), §482.15(d)(2)(i), §482.15(d)(2)(i)(A), §482.15(d)(2)(i)(B), §482.15(d)(2)(ii)(A), §482.15(d) (2)(ii)(B), §482.15(d)(2)(ii)(C), §485.625(d)(2), §485.625(d)(2)(i), §485.625(d)(2)(i)(A), §485.625(d)(2)(ii)(B), §485.625(d)(2)(ii)(B), §485.625(d)(2)(ii)(B), §485.625(d)(2)(ii)(C)

EM.17.01.01

The critical access hospital evaluates its emergency management program, emergency operations plan, and continuity of operations plans.

Element(s) of Performance for EM.17.01.01

The multidisciplinary committee that oversees the emergency management program reviews and evaluates all exercises and actual emergency or disaster incidents. The committee reviews after-action reports (AARs), identifies opportunities for improvement, and recommends actions to take to improve the emergency management program. The AARs and improvement plans are documented.
Note 1: The review and evaluation address the effectiveness of its emergency response procedure, continuity of operations plans (if activated), training and exercise programs, evacuation procedures, surge response procedures, and activities related to communications, resources and assets, security, staff, utilities, and patients. Note 2: An AAR provides a detailed critical summary or analysis of a planned exercise or an actual emergency

or disaster incident. The report summarizes what took place during the event, analyzes the actions taken by

CoP(s): §482.15(d)(2)(iii), §485.625(d)(2)(iii)

- 3. The critical access hospital reviews and makes necessary updates based on after-action reports or opportunities for improvement to the following items every two years, or more frequently if necessary:
 - · Hazard vulnerability analysis
 - · Emergency management program
 - Emergency operations plan, policies, and procedures

participants, and provides areas needing improvement.

- · Communications plan
- · Continuity of operations plan
- · Education and training program
- · Testing program

CoP(s): §482.15(a), §482.15(b), §482.15(c), §482.15(d), §482.15(d)(2)(iii), §482.15(f)(5), §485.625(a), §485.625(b), §485.625(c), §485.625(d), §485.625(d)(2)(iii), §485.625(f)(5)

Human Resources (HR) Chapter

HR.11.01.01

The critical access hospital has the necessary staff to support the care, treatment, and services it provides.

Element(s) of Performance for HR.11.01.01

1. The critical access hospital's food and dietetic services administrative and technical staff are competent to perform their responsibilities.

CoP(s): §482.28(a)(3)

- 2. A registered nurse with training and experience in emergency care is allowed to conduct specific medical screening examinations only if both of the following conditions are met:
 - The registered nurse is on site and immediately available at the critical access hospital when a patient requests medical care.
 - The patient's request for medical care is within the scope of practice of a registered nurse and consistent with applicable state laws and the critical access hospital's bylaws and rules and regulations.

CoP(s): §485.618(d)(2)(i), §485.618(d)(2)(ii)

HR.11.01.03

The critical access hospital determines how staff function within the organization.

Element(s) of Performance for HR.11.01.03

1. All staff who provide patient care, treatment, and services are qualified and possess a current license, certification, or registration, in accordance with law and regulation.

CoP(s): §482.11(c), §485.608(d)

2. Professional staff supervise ancillary staff.

CoP(s): §485.631(a)(2)

- 3. The critical access hospital develops and implements a procedure to verify and document the following:
 - Credentials of staff using the primary source when licensure, certification, or registration is required by federal, state, or local law and regulation. This is done at the time of hire and at the time credentials are renewed.
 - Credentials of staff (primary source not required) when licensure, certification, or registration is not required by law and regulation. This is done at the time of hire and at the time credentials are renewed.
 - Note 1: It is acceptable to verify current licensure, certification, or registration with the primary source via a secure electronic communication or by telephone, if this verification is documented.
 - Note 2: A primary verification source may designate another agency to communicate credentials information. The designated agency can then be used as a primary source.
 - Note 3: An external organization (for example, a credentials verification organization [CVO]) may be used to verify credentials information. A CVO must meet the CVO guidelines identified in the Glossary.

Note 4: The critical access hospital determines the required qualifications for staff based on job responsibilities.

CoP(s): §482.23(b)(2)

HR.11.02.01

The critical access hospital defines and verifies staff qualifications.

Element(s) of Performance for HR.11.02.01

The critical access hospital defines staff qualifications specific to their job responsibilities. Note 1: Qualifications for infection control may be met through ongoing education, training, experience, and/or certification (such as that offered by the Certification Board for Infection Control). Note 2: For rehabilitation and psychiatric distinct part units in critical access hospitals: Qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speechlanguage pathologists, or audiologists, as defined in 42 CFR 484, provide physical therapy, occupational therapy, speech-language pathology, or audiology services, if these services are provided by the critical access hospital. See Glossary for definitions of physical therapist, physical therapist assistant, occupational therapist, occupational therapy assistant, speech-language pathologist, and audiologist.
Note 3: For rehabilitation and psychiatric distinct part units in critical access hospitals: If respiratory care services are provided, staff qualified to perform specific respiratory care procedures and the amount of supervision

are provided, staff qualified to perform specific respiratory care procedures and the amount of supervision required to carry out the specific procedures is designated in writing.

CoP(s): §482.42(a)(1), §482.56(a)(2), §482.57(b)(1), §482.58(b)(6), §483.65(b), §485.635(e), §485.640(a)(1)

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: The director of rehabilitation services has the knowledge, experience, and capabilities to supervise and administer the services.

CoP(s): §482.56(a)(1)

4. For swing beds in critical access hospitals: The critical access hospital does not employ individuals who have been found guilty by a court of law of abusing, neglecting, exploiting, misappropriating property, or mistreating residents or who have had a finding entered into the state nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents, or misappropriation of residents' property.

CoP(s): §482.58(b)(3), §483.12(a)(3)(i), §483.12(a)(3)(i), §483.12(a)(3)(ii), §483.12(a)(3)(ii), §485.645(d)(3)

HR.11.03.01

The critical access hospital provides orientation, education, and training to their staff.

Element(s) of Performance for HR.11.03.01

1. Staff participate in ongoing education and training to maintain or increase their competency and, as needed, when staff responsibilities change. Staff participation is documented.

CoP(s): §482.42(c)(2)(iv), §485.640(c)(2)(iv)

HR.11.04.01

The critical access hospital evaluates staff competence and performance.

Element(s) of Performance for HR.11.04.01

1. Staff competence is initially assessed and documented as part of orientation and once every three years, or more frequently as required by critical access hospital policy or in accordance with law and regulation.

CoP(s): §482.42(c)(2)(iv), §485.640(c)(2)(iv)

Infection Prevention and Control (IC) Chapter

IC.04.01.01

The critical access hospital has a hospitalwide infection prevention and control program for the surveillance, prevention, and control of health care—associated infections (HAIs) and other infectious diseases.

Element(s) of Performance for IC.04.01.01

- 2. The infection preventionist(s) or infection control professional(s) is responsible for the following:
 - Development and implementation of hospitalwide infection surveillance, prevention, and control policies and procedures that adhere to law and regulation and nationally recognized guidelines
 - Documentation of the infection prevention and control program and its surveillance, prevention, and control activities
 - Competency-based training and education of critical access hospital personnel and staff, including medical staff and, as applicable, personnel providing contracted services in the critical access hospital, on infection prevention and control guidelines, policies and procedures and their application
 - Prevention and control of health care—associated infections and other infectious diseases, including auditing staff adherence to infection prevention and control policies and procedures
 - Communication and collaboration with all components of the critical access hospital involved in infection prevention and control activities, including but not limited to the antibiotic stewardship program, sterile processing department, and water management program
 - Communication and collaboration with the critical access hospital's quality assessment and performance improvement program to address infection prevention and control issues

Note: The outcome of competency-based training is the staff's ability to demonstrate the skills and tasks specific to their roles and responsibilities. Examples of competencies may include donning/doffing of personal protective

equipment and the ability to correctly perform the processes for high-level disinfection. (For more information on competency requirements, refer to HR.11.04.01 EP 1).(See also PE.04.01.05, EP 2)

- 3. The critical access hospital's infection prevention and control program has written policies and procedures to guide its activities and methods for preventing and controlling the transmission of infections within the critical access hospital and between the critical access hospital and other institutions and settings. The policies and procedures are in accordance with the following hierarchy of references:
 - a. Applicable law and regulation.
 - b. Manufacturers' instructions for use.
 - c. Nationally recognized evidence-based guidelines and standards of practice, including the Centers for Disease Control and Prevention's (CDC) Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings or, in the absence of such guidelines, expert consensus or best practices. The guidelines are documented within the policies and procedures.

Note 1: Relevant federal, state, and local law and regulations include but are not limited to the Centers for Medicare & Medicaid Services' Conditions of Participation, Food and Drug Administration's regulations for reprocessing single-use medical devices; Occupational Safety and Health Administration's Bloodborne Pathogens Standard 29 CFR 1910.1030, Personal Protective Equipment Standard 29 CFR 1910.132, and Respiratory Protection Standard 29 CFR 1910.134; health care worker vaccination laws; state and local public health authorities' requirements for reporting of communicable diseases and outbreaks; and state and local regulatory requirements for biohazardous or regulated medical waste generators.

Note 2: For full details on the CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, refer to https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/introduction-methods-definition-of-terms.html.

Note 3: The critical access hospital determines which evidence-based guidelines, expert recommendations, best practices, or a combination thereof it adopts in its policies and procedures.

CoP(s): §482.42, §482.42(a)(2), §485.640, §485.640(a)(2)

- 4. The critical access hospital's policies and procedures for cleaning, disinfection, and sterilization of reusable medical and surgical devices and equipment address the following:
 - Cleaning, disinfection, and sterilization of reusable medical and surgical devices in accordance with the Spaulding classification system and manufacturers' instructions
 - Use of disinfectants registered by the Environmental Protection Agency for noncritical devices and equipment according to the directions on the product labeling, including but not limited to indication, specified use dilution, contact time, and method of application
 - Use of FDA-approved liquid chemical sterilants for the processing of critical devices and high-level disinfectants for the processing of semicritical devices in accordance with FDA-cleared label and device manufacturers' instructions
 - Required documentation for device reprocessing cycles, including but not limited to sterilizer cycle logs, the frequency of chemical and biological testing, and the results of testing for appropriate concentration for chemicals used in high-level disinfection
 - Resolution of conflicts or discrepancies between a medical device manufacturer's instructions and manufacturers' instructions for automated high-level disinfection or sterilization equipment
 - · Criteria and process for the use of immediate-use steam sterilization

• Actions to take in the event of a reprocessing error or failure identified either prior to the release of the reprocessed item(s) or after the reprocessed item(s) was used or stored for later use

Note 1: The Spaulding classification system classifies medical and surgical devices as critical, semicritical, or noncritical based on risk to the patient from contamination on a device and establishes the levels of germicidal activity (sterilization, high-level disinfection, intermediate-level disinfection, and low-level disinfection) to be used for the three classes of devices.

Note 2: Depending on the nature of the incident, examples of actions may include quarantine of the sterilizer, recall of item(s), stakeholder notification, patient notification, surveillance, and follow-up.

CoP(s): §482.42(a)(2), §485.640(a)(2)

5. The infection prevention and control program reflects the scope and complexity of the critical access hospital services provided by addressing all locations, patient populations, and staff. (See also LD.11.01.01, EP 10)

CoP(s): §482.42, §482.42(a)(4), §485.640, §485.640(a)(4)

IC.05.01.01

The critical access hospital's governing body, or responsible individual, is accountable for the implementation, performance, and sustainability of the infection prevention and control program.

Element(s) of Performance for IC.05.01.01

The critical access hospital's governing body, or responsible individual, is responsible for the implementation, performance, and sustainability of the infection prevention and control program and provides resources to support and track the implementation, success, and sustainability of the program's activities. Note: To make certain that systems are in place and operational to support the program, the governing body, or responsible individual, provides access to information technology; laboratory services; equipment and supplies; local, state, and federal public health authorities' advisories and alerts, such as the CDC's Health Alert Network (HAN); FDA alerts; manufacturers' instructions for use; and guidelines used to inform policies.

CoP(s): §482.42, §482.42(c)(1)(i), §485.640, §485.640(c)(1)(i)

2. The critical access hospital's governing body, or responsible individual, ensures that the problems identified by the infection prevention and control program are addressed in collaboration with critical access hospital quality assessment and performance improvement leaders and other leaders (for example, the medical director, nurse executive, and administrative leaders).

CoP(s): §482.42, §482.42(c)(1)(ii), §485.640, §485.640(c)(1)(ii)

IC.06.01.01

The critical access hospital implements its infection prevention and control program through surveillance, prevention, and control activities.

Element(s) of Performance for IC.06.01.01

3. The critical access hospital implements activities for the surveillance, prevention, and control of health care—associated infections and other infectious diseases, including maintaining a clean and sanitary environment

to avoid sources and transmission of infection, and addresses any infection control issues identified by public health authorities that could impact the critical access hospital.(See also NPG.05.03.01, EP 1)

CoP(s): §482.42, §482.42(a)(3), §485.640, §485.640(a)(3)

- 4. The critical access hospital implements its policies and procedures for infectious disease outbreaks, including the following:
 - Implementing infection prevention and control activities when an outbreak is first recognized by internal surveillance or public health authorities
 - · Reporting an outbreak in accordance with state and local public health authorities' requirements
 - Investigating an outbreak
 - Communicating information necessary to prevent further transmission of the infection among patients, visitors, and staff, as appropriate

CoP(s): §482.42(a)(3), §485.640(a)(3)

- 5. The critical access hospital implements policies and procedures to minimize the risk of communicable disease exposure and acquisition among its staff, in accordance with law and regulation. The policies and procedures address the following:
 - · Screening and medical evaluations for infectious diseases
 - Immunizations
 - Staff education and training
 - · Management of staff with potentially infectious exposures or communicable illnesses

CoP(s): §482.42(a)(3), §485.640(a)(3)

Information Management (IM) Chapter

IM.11.01.01

The critical access hospital plans for continuity of its information management processes.

Element(s) of Performance for IM.11.01.01

1. The critical access hospital develops and implements policies and procedures regarding medical documentation and patient information during emergencies and other interruptions to information management systems, including security and availability of patient records to support continuity of care.

Note: These policies and procedures are based on the emergency plan, risk assessment, and emergency communication plan and are reviewed and updated at least every 2 years.

CoP(s): §482.15(b)(5), §485.625(b)(5)

IM.12.01.01

The critical access hospital protects the privacy and confidentiality of health information.

Element(s) of Performance for IM.12.01.01

1. The critical access hospital develops and implements policies and procedures addressing the privacy and confidentiality of health information.

Note: For swing beds in critical access hospitals: Policies and procedures also address the resident's personal records.

CoP(s): §482.13(d)(1), §482.24(b)(3), §482.58(b)(1), §483.10(h), §483.10(h), §483.10(h)(3), §485.614(d)(1), §485.638(b)(1), §485.645(d)(1)

2. The critical access hospital discloses health information only as authorized by the patient with the patient's written consent or as otherwise required by law and regulation.

Note: For swing beds in critical access hospitals: The critical access hospital allows representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with state law.

CoP(s): §482.58(b)(1), §483.10(h)(3)(i), §483.10(h)(3)(i), §483.10(h)(3)(ii), §483.10(h)(3)(ii), §485.638(b)(3), §485.645(d)(1)

3. The critical access hospital develops and implements policies and procedures for the release of medical records. The policies and procedures are in accordance with law and regulation, court orders, or subpoenas. Note: Information from or copies of records may be released only to authorized individuals, and the critical access hospital makes certain that unauthorized individuals cannot gain access to or alter patient records.

CoP(s): §482.24(b)(3), §485.638(b)(2)

IM.12.01.03

The critical access hospital maintains the security and integrity of health information.

Element(s) of Performance for IM.12.01.03

- 1. The critical access hospital develops and implements a written policy that addresses the security of health information, including the following:
 - · Access and use
 - Integrity of health information against loss, damage, unauthorized alteration or use, unintentional change, and accidental destruction
 - Intentional destruction of health information
 - When and by whom the removal of health information is permitted

Note: Removal refers to those actions that place health information outside the critical access hospital's control.

CoP(s): §482.24(b)(3), §485.638(b)(2)

IM.13.01.01

The critical access hospital records health information in standardized formats.

Element(s) of Performance for IM.13.01.01

1. The critical access hospital uses standardized terminology, definitions, abbreviations, acronyms, symbols, and dose designations.

IM.13.01.03

The critical access hospital retrieves, disseminates, and transmits health information in useful formats.

Element(s) of Performance for IM.13.01.03

1. The critical access hospital has a system for coding and indexing medical records to make health information accessible when needed for patient care, treatment, and services.

Note: For rehabilitation and psychiatric distinct part units in critical access hospitals: The medical records system allows for timely retrieval of patient information by diagnosis and procedure.

CoP(s): §482.24(b)(2)

IM.13.01.05

The critical access hospital meets requirements for the electronic exchange of patient health information. Note: This standard only applies to critical access hospitals that utilize an electronic health records system or other electronic administrative system that conforms with the content exchange standard at 45 CFR 170.205(d)(2).

Element(s) of Performance for IM.13.01.05

1. The critical access hospital demonstrates that its electronic health records system's (or other electronic administrative system's) notification capacity is fully operational and is used in accordance with applicable state and federal laws and regulations for the exchange of patient health information.

CoP(s): §482.24(d)(1), §485.638(d)(1)

2. The critical access hospital demonstrates that its electronic health records system (or other electronic administrative system) sends notifications that include, at a minimum, the patient's name, treating licensed practitioner's name, and sending institution's name.

CoP(s): §482.24(d)(2), §485.638(d)(2)

- 3. In accordance with the patient's expressed privacy preferences and applicable laws and regulations, the critical access hospital's electronic health records system (or other electronic administrative system) sends notifications directly, or through an intermediary that facilitates exchange of health information, at the following times, when applicable:
 - The patient's emergency department registration
 - · The patient's inpatient admission

CoP(s): §482.24(d)(3), §482.24(d)(3)(i), §482.24(d)(3)(ii), §485.638(d)(3), §485.638(d)(3)(i), §485.638(d)(3)(ii)

4. In accordance with the patient's expressed privacy preferences and applicable laws and regulations, the critical access hospital's electronic health records system (or other electronic administrative system) sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to or at the time of the patient's discharge or transfer from the critical access hospital's emergency department or inpatient services.

CoP(s): §482.24(d)(4), §482.24(d)(4)(i), §482.24(d)(4)(ii), §485.638(d)(4), §485.638(d)(4)(i), §485.638(d)(4)(ii)

- 5. The critical access hospital makes a reasonable effort to confirm that its electronic health records system (or other electronic administrative system) sends the notifications to all applicable post–acute care service providers and suppliers, as well as any of the following who need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:
 - · Patient's established primary care licensed practitioner
 - Patient's established primary care practice group or entity
 - Other licensed practitioners, or other practice groups or entities, identified by the patient as primarily responsible for the patient's care

Note: The term "reasonable effort" means that the critical access hospital has a process to send patient event notifications while working within the constraints of its technology infrastructure. There may be instances in which the critical access hospital (or its intermediary) cannot identify an applicable recipient for a patient event notification despite establishing processes for identifying recipients. In addition, some recipients may not be able to receive patient event notifications in a manner consistent with the critical access hospital system's capabilities.

CoP(s): §482.24(d)(5), §482.24(d)(5)(i), §482.24(d)(5)(ii), §482.24(d)(5)(iii), §485.638(d)(5), §485.638(d)(5)(iii), §485.638(d)(5)(iii)

Leadership (LD) Chapter

LD.11.01.01

The governing body is ultimately accountable for the safety and quality of care, treatment, and services.

Element(s) of Performance for LD.11.01.01

1. The critical access hospital has a governing body or an individual that assumes full legal responsibility for determining, implementing, and monitoring policies governing the critical access hospital's total operation and for administering those policies to provide quality health care in a safe environment.

CoP(s): §482.12, §485.627(a)

- 2. The governing body does the following:
 - · Approves and is responsible for the effective operation of the grievance process
 - Reviews and resolves grievances, unless it delegates responsibility in writing to a grievance committee
 For rehabilitation and psychiatric distinct part units in critical access hospitals: The governing body also does the following:
 - Determines, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff
 - Appoints members of the medical staff after considering the recommendations of the existing members of the medical staff
 - · Makes certain that the medical staff has bylaws

- · Approves medical staff bylaws and other medical staff rules and regulations
- Makes certain that the medical staff is accountable to the governing body for the quality of care provided to patients
- Makes certain that the criteria for selection to the medical staff are based on individual character, competence, training, experience, and judgment
- Makes certain that under no circumstances is the accordance of staff membership or professional privileges in the critical access hospital dependent solely upon certification, fellowship, or membership in a specialty body or society
- Makes certain that the medical staff develops and implements written policies and procedures for appraisal of emergencies, initial treatment, and referral of patients at the locations without emergency services when emergency services are not provided at the critical access hospital, or are provided at the critical access hospital but not at one or more off-campus locations

CoP(s): $\S482.12(a)(1)$, $\S482.12(a)(2)$, $\S482.12(a)(3)$, $\S482.12(a)(4)$, $\S482.12(a)(5)$, $\S482.12(a)(6)$, $\S482.12(a)(7)$, $\S482.12(f)(2)$, $\S482.12(f)(3)$, $\S482.13(a)(2)$, $\S482.14(a)(2)$

- 3. The governing body provides the organized medical staff with the opportunity to be represented at governing body meetings (through attendance and voice) by one or more of its members, as selected by the organized medical staff.
- 4. Organized medical staff members are eligible for full membership in the critical access hospital's governing body, unless legally prohibited.
- 5. For rehabilitation and psychiatric distinct part units in critical access hospitals: The governing body consults directly with the individual assigned the responsibility for the organization and conduct of the critical access hospital's medical staff or with the individual's designee. At a minimum, this direct consultation occurs periodically throughout the fiscal or calendar year and includes a discussion of matters related to the quality of medical care provided to the critical access hospital's patients. For a multihospital system using a single governing body, the single multihospital system governing body consults directly with the individual responsible for the organized medical staff (or the individual's designee) of each hospital within its system.

CoP(s): §482.12(a)(10)

6. The governing body appoints the chief executive officer responsible for managing the critical access hospital.

CoP(s): §482.12(b)

7. For rehabilitation and psychiatric distinct part units in critical access hospitals: The governing body makes certain that patients are under the care of the appropriate licensed practitioners.

8. The governing body or designated individual is responsible and accountable for the quality assessment and performance improvement program. The governing body makes sure that performance improvement activities reflect the complexity of the critical access hospital's organization and services; are ongoing and comprehensive; involve all departments and services, including those services provided under contract or arrangement; and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors

and objective measures to evaluate its organizational processes, functions, and services. (For more information on contracted services, see Standard LD.14.03.03)

Note: For rehabilitation and psychiatric distinct part units in critical access hospitals: If the hospital does not have a governing body, it identifies the leadership structure that is responsible for these activities.

CoP(s): §482.21, §485.641(b)(1), §485.641(b)(2), §485.641(b)(3), §485.641(b)(4), §485.641(c)

- 9. If a critical access hospital is part of a system consisting of multiple separately accredited hospitals, critical access hospitals, and/or rural emergency hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, critical access hospitals, and/or rural emergency hospitals, the system governing body can elect to have a unified and integrated quality assessment and performance improvement program for all of its member facilities after determining that such decision is in accordance with all applicable state and local laws. Each separately certified critical access hospital subject to the system governing body demonstrates that the unified and integrated quality assessment and performance improvement program does the following:
 - Accounts for each member critical access hospital's unique circumstances and any significant differences in patient populations and services offered
 - Establishes and implements policies and procedures to make certain that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated program has mechanisms in place to ensure that issues localized to particular critical access hospitals are duly considered and addressed

Note: The system governing body is responsible and accountable for making certain that each of its separately certified critical access hospitals meets the requirements for quality assessment and performance improvement at 42 CFR 485.641.

CoP(s): §482.21(f), §482.21(f)(1), §482.21(f)(2), §485.641(f), §485.641(f)(1), §485.641(f)(2)

- 10. If a critical access hospital is part of a multihospital system with separately accredited hospitals, critical access hospitals, and/or rural emergency hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, critical access hospitals, and/or rural emergency hospitals, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities after determining that such a decision is in accordance with applicable law and regulation.
 - Each separately certified critical access hospital subject to the system governing body demonstrates that the unified and integrated infection prevention and control program and the antibiotic stewardship program do the following:
 - Account for each member critical access hospital's unique circumstances and any significant differences in patient populations and services offered
 - Establish and implement policies and procedures to make certain that the needs and concerns of each separately certified critical access hospital, regardless of practice or location, are given due consideration
 - Have mechanisms in place to ensure that issues localized to particular critical access hospitals are duly considered and addressed
 - Designate a qualified individual(s) at the critical access hospital with expertise in infection prevention and control and in antibiotic stewardship as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship (as directed by the unified infection prevention and control and antibiotic stewardship programs), and providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to critical access hospital staff

Note: The system governing body is responsible and accountable for making certain that each of its separately certified critical access hospitals meet all of the requirements at 42 CFR 485.640(g).(See also IC.04.01.01, EP 5)

CoP(s): §482.42(d), §482.42(d)(1), §482.42(d)(2), §482.42(d)(3), §482.42(d)(4), §485.640(g), §485.640(g)(1), §485.640(g)(2), §485.640(g)(3), §485.640(g)(4)

11. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home evaluates the effectiveness of how the primary care clinician and the interdisciplinary team partner with the patient to support continuity of care and comprehensive, coordinated care.

LD.11.01.03

The critical access hospital identifies the responsibilities of its leaders.

Element(s) of Performance for LD.11.01.03

- 1. The person responsible for the operation of the critical access hospital under 42 CFR 485.627(b)(2) is also responsible for the following:
 - Services provided in the critical access hospital whether or not they are furnished under arrangements or agreements
 - Ensuring that contractors of services (including contractors for shared services and joint ventures) provide services that enable the critical access hospital to comply with all applicable Centers for Medicare & Medicaid (CMS) Conditions of Participation and standards for the contracted services

CoP(s): §485.616(c)(3), §485.635(c)(4)(i), §485.635(c)(4)(ii)

LD.11.02.01

The critical access hospital has an organized medical staff that is accountable to the governing body.

Element(s) of Performance for LD.11.02.01

1. The critical access hospital has an organized medical staff that is accountable to the governing body for the quality of care provided to patients.

CoP(s): §482.22(b)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The governing body approves the structure of the organized medical staff.

CoP(s): §482.22(b)(1)

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: A doctor of medicine or osteopathy or, if permitted by state law, a doctor of dental surgery or dental medicine, or a doctor of podiatric medicine is responsible for the organization and conduct of the medical staff.

CoP(s): §482.22(b)(3)(i), §482.22(b)(3)(ii), §482.22(b)(3)(iii)

LD.12.01.01

Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" [PI] chapter.)

Element(s) of Performance for LD.12.01.01

The critical access hospital develops, implements, maintains, and documents an effective, ongoing, data-driven, hospitalwide quality assessment and performance improvement program.
 Note: For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital maintains and demonstrates evidence of its QAPI program for review by CMS.

CoP(s): §482.21, §485.641

- 2. As part of performance improvement, leaders (including the governing body) do the following:
 - Set priorities for performance improvement activities related to improved health outcomes that are shown to be predictive of desired patient outcomes, patient safety, and quality of care
 - Give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities and consider the incidence, prevalence, and severity of problems in those areas
 - · Identify the frequency and detail of data collection for performance improvement activities
 - Use measures to analyze and track performance

CoP(s): §482.21(b)(3), §482.21(c)(1)(i), §482.21(c)(1)(ii), §482.21(c)(1)(iii), §485.641(d)(1), §485.641(d)(2), §485.641(d)(3)

- 3. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the critical access hospital), medical staff, and administrative officials are responsible and accountable for the following:
 - An ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained
 - The hospitalwide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and all improvement actions are evaluated
 - Clear expectations for safety are established
 - Adequate resources are allocated for measuring, assessing, improving, and sustaining the critical access hospital's performance and reducing risk to patients
 - The determination of the number of distinct improvement projects is conducted annually

CoP(s): §482.21(e)(1), §482.21(e)(2), §482.21(e)(3), §482.21(e)(4), §482.21(e)(5)

- 4. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The interdisciplinary team actively participates in performance improvement activities.
- 5. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: Leaders use qualitative data collection methods to involve patients in performance improvement activities.

Note: Qualitative data collection methods are used to provide insight into patients' opinions, along with underlying reasons and motivations. Examples of qualitative methods include focus groups, telephonic or inperson patient interviews or patient rounding, and patient participation on performance improvement committees.

LD.13.01.01

The critical access hospital complies with law and regulation.

Element(s) of Performance for LD.13.01.01

1. The critical access hospital provides care, treatment, and services in accordance with licensure requirements and federal, state, and local laws, rules, and regulations.

CoP(s): §482.1(a)(1)(i), §482.1(a)(1)(ii), §482.1(b), §482.11(a), §485.608, §485.608(a), §485.608(b)

2. The critical access hospital is licensed in accordance with law and regulation to provide the care, treatment, or services for which the critical access hospital is seeking accreditation from The Joint Commission.
Note: For rehabilitation or psychiatric distinct part units in critical access hospitals: The critical access hospital is licensed or approved as meeting the standards for licensing established by the state or responsible locality.

CoP(s): §412.25(a)(5), §482.11(b)(1), §482.11(b)(2), §485.608(c)

3. Except as permitted for critical access hospitals having distinct part units under 42 CFR 485.647, the critical access hospital maintains no more than 25 inpatient beds that can be used for either inpatient or swing bed services.

Note: Any bed in a unit of the facility that is licensed as a distinct part skilled nursing facility at the time the facility applies to the state for designation as a critical access hospital is not counted in this 25-bed count.

CoP(s): §485.620(a), §485.645(a)(2)

4. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital provides no more than 10 beds in a distinct part unit. The beds are physically separate from the critical access hospital's other beds.

Note 1: Beds in the rehabilitation and psychiatric distinct part units are excluded from the 25 inpatient-bed count limits specified in 42 CFR 485.620(a).

Note 2: The average annual 96-hour length of stay requirement specified under 42 CFR 485.620(b) does not apply to the 10 beds in the distinct part units specified in 42 CFR 485.647(b)(1). Admissions and days of inpatient care in the distinct part units are not taken into account in determining the critical access hospital's compliance with the limits on the number of beds and length of stay in 42 CFR 485.620.

CoP(s): §412.25(a)(7), §485.647(b)(1), §485.647(b)(2), §485.647(b)(3)

5. The critical access hospital provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

CoP(s): §485.620(b)

6. If the critical access hospital is a member of a rural health network, the network meets the criteria required by the Centers for Medicare & Medicaid Services' (CMS) regulations at 42 CFR 485.603.

Note: See the Glossary for a definition of rural health network.

CoP(s): §485.603, §485.603(a), §485.603(a)(1), §485.603(a)(2), §485.603(b), §485.603(b)(1), §485.603(b)(2), §485.603(b)(3), §485.603(c), §485.603(c)(1), §485.603(c)(2), §485.603(c)(3)

- 7. For rehabilitation and psychiatric distinct part units: The critical access hospital maintains the following:
 - Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval
 - A fully funded plan to transfer these records to another hospital or other entity if the critical access hospital ceases operation for any reason

CoP(s): §482.27(b)(5)(i), §482.27(b)(5)(ii)

LD.13.01.03

The critical access hospital reviews services for medical necessity.

Element(s) of Performance for LD.13.01.03

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has a utilization review plan that provides for review of services provided by the critical access hospital and the medical staff to patients entitled to benefits under the Medicare and Medicaid programs. Note: The critical access hospital does not need to have a utilization review plan if either a quality improvement organization (QIO) has assumed binding review for the critical access hospital or the Centers for Medicare & Medicaid Services (CMS) has determined that the utilization review procedures established by the state under title XIX of the Social Security Act are superior to the procedures required in this section, and has required critical access hospitals in that state to meet the utilization review plan requirements under 42 CFR 456.50 through 42 CFR 456.245.

CoP(s): §482.30, §482.30(a)(1), §482.30(a)(2)

- 2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital's utilization review plan provides for the review of Medicare and Medicaid patients with respect to the medical necessity of the following:
 - · Admissions to the critical access hospital
 - Duration of stays
 - · Professional services provided, including drugs and biologicals

Note 1: The critical access hospital may perform reviews of admissions before, during, or after hospital admission.

Note 2: The critical access hospital may perform reviews on a sample basis, except for reviews of extended stay cases.

CoP(s): §482.30(c)(1), §482.30(c)(1)(i), §482.30(c)(1)(ii), §482.30(c)(1)(iii), §482.30(c)(2), §482.30(c)(3)

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has a utilization review committee that is either a staff committee or a group outside the critical access hospital established by the local medical society and some or all the hospitals in the locality or in a manner approved by the Centers for Medicare & Medicaid Services.

Note: If, because of the small size of the critical access hospital, it is impracticable to have a properly functioning staff committee, the utilization review committee is established by a group outside the critical access hospital, as specified in 42 CFR 482.30(b)(1)(ii).

CoP(s): §482.30(b)(1)(i), §482.30(b)(1)(ii), §482.30(b)(1)(ii)(A), §482.30(b)(1)(ii)(B), §482.30(b)(2)

4. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital's utilization review committee consists of two or more licensed practitioners, and at least two of the members of the committee are doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in 42 CFR 482.12(c)(1).

Note: The committee or group's reviews are not conducted by any individual who has a direct financial interest (for example, an ownership interest) in that critical access hospital or who was professionally involved in the care of the patient whose case is being reviewed. (See also MS.16.01.03, EP 5)

CoP(s): §482.30(b), §482.30(b)(3), §482.30(b)(3)(i), §482.30(b)(3)(ii)

5. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital's utilization review committee reviews professional services provided to determine medical necessity and to promote the most efficient use of available health facilities and services.

CoP(s): §482.30(f)

- 6. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital develops and implements a process to determine if an admission or continued stay is not medically necessary. This determination is made by one of the following:
 - One member of the utilization review committee if the licensed practitioner(s) responsible for the patient's care, as specified in 42 CFR 482.12(c), concurs with the determination or fails to present their views when afforded the opportunity
 - At least two members of the utilization review committee in all other cases

Note: Before determining that an admission or continued stay is not medically necessary, the utilization review committee consults the licensed practitioner(s) responsible for the patient's care and affords the practitioner(s) the opportunity to present their views.

CoP(s): §482.30(d)(1)(i), §482.30(d)(1)(ii), §482.30(d)(2)

- 7. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital is paid for inpatient hospital services under the prospective payment system set forth in 42 CFR Part 412, it conducts a review of duration of stays and a review of professional services as follows:
 - For duration of stays, the critical access hospital reviews only cases that it determines to be outlier cases based on extended length of stay, as described in 42 CFR 412.80(a)(1)(i).
 - For professional services, the critical access hospital reviews only cases that it determines to be outlier cases based on extraordinarily high costs, as described in 42 CFR 412.80(a)(1)(ii).

CoP(s): §482.30(c)(4), §482.30(c)(4)(i), §482.30(c)(4)(ii)

8. For rehabilitation and psychiatric distinct part units in critical access hospitals: In critical access hospitals that are not paid under the prospective payment system, the utilization review (UR) committee periodically reviews, as specified in the UR plan, each current inpatient during a continuous period of extended duration. The scheduling of the periodic reviews may be the same for all cases or differ for different classes of cases.

Note: The UR committee conducts its review no later than 7 days after the day required in the UR plan.

CoP(s): §482.30(e)(1), §482.30(e)(1)(i), §482.30(e)(1)(ii)

9. For rehabilitation and psychiatric distinct part units: In critical access hospitals paid under the prospective payment system, the utilization review (UR) committee reviews all cases where the extended length of stay exceeds the threshold criteria for the diagnosis, as described in 42 CFR 412.80 (a)(1)(i). The critical access hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis. Note: The UR committee conducts its review no later than 7 days after the day required in the UR plan.

CoP(s): §482.30(e)(2), §482.30(e)(3)

10. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the utilization review committee determines that admission to or continued stay in the critical access hospital is not medically necessary, the committee gives written notification to the critical access hospital, the patient, and the licensed practitioner(s) responsible for the patient's care, as specified in 42 CFR 482.12(c), no later than 2 days after the determination.

CoP(s): §482.30(d)(3)

11. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has utilization review standards appropriate to the services offered in the unit(s).

CoP(s): §412.25(a)(6)

LD.13.01.05

For rehabilitation and psychiatric distinct part units in critical access hospitals: The leaders develop an annual operating budget and, when needed, a long-term capital expenditure plan.

Element(s) of Performance for LD.13.01.05

- 1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has an overall institutional plan that meets the following conditions:
 - The plan includes an annual operating budget that is prepared according to generally accepted accounting principles and that has all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.
 - The plan provides for capital expenditures for at least a 3-year period, including the year in which the operating budget is applicable.

CoP(s): §482.12(d)(1), §482.12(d)(2), §482.12(d)(3)

- 2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The institutional plan includes and identifies in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of \$600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Social Security Act [42 U.S.C. 1320a–1], by the state in which the critical access hospital is located) that relates to any of the following:
 - · Acquisition of land
 - · Improvement of land, buildings, and equipment
 - · Replacement, modernization, and expansion of buildings and equipment

CoP(s): §482.12(d)(4), §482.12(d)(4)(i), §482.12(d)(4)(ii), §482.12(d)(4)(iii)

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: The institutional plan is prepared by representatives of the critical access hospital's governing body, the administrative staff, and the medical staff under the direction of the governing body. The institutional plan is reviewed and updated annually.

CoP(s): §482.12(d)(6), §482.12(d)(7)(i), §482.12(d)(7)(ii)

- 4. For rehabilitation and psychiatric distinct part units in critical access hospitals: The institutional plan is submitted for review to the planning agency designated in accordance with section 1122(b) of the Social Security Act (42 U.S.C. 1320a–1(b)), or if an agency is not designated, to the appropriate health planning agency in the state. A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Social Security Act (42 U.S.C. 1395mm(b)), and if the US Department of Health and Human Services determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because of one of the following:
 - The facilities do not provide common services at the same site.
 - The facilities are not available under a contract of reasonable duration.
 - Full and equal medical staff privileges in the facilities are not available.
 - Arrangements with these facilities are not administratively feasible.
 - The purchase of these services is more costly than if the HMO or CMP provided the services directly.

CoP(s): §482.12(d)(5), §482.12(d)(5)(i), §482.12(d)(5)(ii), §482.12(d)(5)(iii), §482.12(d)(5)(iv), §482.12(d)(5)(v)

LD.13.01.07

The critical access hospital effectively manages its programs, services, sites, or departments.

Element(s) of Performance for LD.13.01.07

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital's emergency services are supervised by a qualified member of the medical staff.

CoP(s): §482.55(b)(1)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital assigns one or more individuals who are responsible for outpatient services.

CoP(s): §482.54(b)(1)

- 3. For rehabilitation and psychiatric distinct part units in critical access hospitals: A qualified doctor of medicine or osteopathy directs the following services, when provided:
 - Anesthesia
 - · Nuclear medicine
 - · Respiratory care

Note 1: The anesthesia service is responsible for all anesthesia administered in the critical access hospital.

Note 2: For respiratory care services, the director may serve on either a full-time or part-time basis.

CoP(s): §482.52, §482.53(a)(1), §482.57(a)(1)

LD.13.01.09

The critical access hospital has policies and procedures that guide and support patient care, treatment, and services.

Element(s) of Performance for LD.13.01.09

- 1. The critical access hospital develops and implements written policies and procedures that guide health care services. The policies and procedures are consistent with state law and include the following:
 - Description of the services furnished by the critical access hospital, including those provided through agreement or arrangement
 - · Emergency medical services
 - Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services provided by the critical access hospital
 - · Rules for the storage, handling, dispensation, and administration of drugs and biologicals
 - Guidelines for addressing post–acute care needs of the patients receiving critical access hospital services Note: If patients are transferred or discharged to a provider for which there is no agreement or arrangement, the critical access hospital verifies that the patient has been accepted and treated.

2. The doctor of medicine or osteopathy, in conjunction with the physician assistant, nurse practitioner, or clinical nurse specialist, participates in developing, executing, and periodically reviewing the critical access hospital's written policies governing the services provided.

CoP(s): §485.631(b)(1)(ii), §485.631(c)(1)(i)

3. The critical access hospital develops health care service policies and procedures with the advice of members of its professional health care staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists if they are on staff.

CoP(s): §485.635(a)(2)

4. The critical access hospital's policies are reviewed at least every two years by the group of professional personnel required under LD.13.01.09, EP 3, and updated as necessary.

CoP(s): §485.635(a)(4)

5. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital develops and implements policies and procedures that minimizes drug errors. The medical staff develops these policies and procedures unless delegated to the pharmaceutical service.

CoP(s): §482.25

6. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital develops and implements surgical care policies and procedures that maintain high standards for medical practice and patient care.

CoP(s): §482.51(b)

7. For rehabilitation and psychiatric distinct part units in critical access hospitals: If respiratory care services are provided, services are delivered in accordance with policies and procedures approved by the medical staff.

CoP(s): §482.57(b)

8. In coordination with area emergency response systems, the critical access hospital establishes procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact 24 hours a day, 7 days a week, to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the critical access hospital or other appropriate locations for treatment.

CoP(s): §485.618(e)

LD.13.02.01

Ethical principles guide the critical access hospital's business practices.

Element(s) of Performance for LD.13.02.01

- 1. The critical access hospital discloses the names and addresses of the following:
 - Person principally responsible for the operation of the critical access hospital
 - · Person responsible for medical direction of the critical access hospital

CoP(s): §485.627(b)(1), §485.627(b)(2)

- 2. For swing beds in critical access hospitals: Each Medicaid-eligible resident is informed in writing, either at the time of admission or when the resident becomes eligible for Medicaid, of the following:
 - Items and services included in the state plan for which the resident may not be charged
 - Items and services that the critical access hospital offers, those for which the resident may be charged, and the amount of charges for those services

Note: The critical access hospital informs the resident when changes are made to the items and services.

CoP(s): §482.58(b)(1), §483.10(g)(17)(i)(A), §483.10(g)(17)(i)(A), §483.10(g)(17)(i)(B), §483.10(g)(17)(ii), §483.10(g)(17)(ii), §483.10(g)(17)(ii),

 For swing beds in critical access hospitals: The critical access hospital informs residents before or at the time of admission, and periodically during the resident's stay, of services available in the critical access hospital and of charges for those services not covered under Medicare, Medicaid, or by the critical access hospital's per diem rate.

CoP(s): §482.58(b)(1), §483.10(g)(18), §483.10(g)(18), §485.645(d)(1)

LD.13.03.01

The critical access hospital provides services that meet patient needs.

Element(s) of Performance for LD.13.03.01

- 1. The critical access hospital provides services directly or through referral, consultation, contractual arrangements, or other agreements that meet the needs of the population(s) served, are organized appropriate to the scope and complexity of services offered, and are in accordance with accepted standards of practice. Services may include but are not limited to the following:
 - Outpatient
 - Emergency
 - · Medical records
 - · Diagnostic and therapeutic radiology
 - · Nuclear medicine
 - Surgical
 - Anesthesia
 - Laboratory
 - · Respiratory
 - Dietetic

CoP(s): §482.24, §482.24(a), §482.26, §482.26(a), §482.27, §482.27(a), §482.28, §482.51, §482.51(a), §482.51(b), §482.52, §482.52(a), §482.52(b), §482.53, §482.53(a), §482.54, §482.55, §482.55(a)(1), §482.55(a) (2), §482.57, §482.57(a), §485.635(b)(3), §485.639

2. The critical access hospital has an organized nursing service, with a plan of administrative authority and delineation of responsibility for patient care, that provides nursing services to meet the needs of its patients. Note: For rehabilitation and psychiatric distinct part units in critical access hospitals: Rural hospitals with a 24-hour nursing waiver granted under 42 CFR 488.54(c) are not required to have 24-hour nursing services.

CoP(s): §482.23, §482.23(a), §482.23(b)(1), §485.635(d)

3. The critical access hospital provides acute care inpatient services.

CoP(s): §485.635(b)(1)(ii)

4. The critical access hospital provides basic outpatient services (diagnostic and therapeutic services and supplies that are commonly provided in a physician's office or at another entry point into the health care delivery system, such as low intensity hospital outpatient department or emergency department). These services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

CoP(s): §485.635(b)(1)(i)

5. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital provides outpatient services, the services are integrated with inpatient services.

CoP(s): §482.54(a)

6. The critical access hospital provides emergency medical services that meet the needs of its inpatients and outpatients as a first response to common life-threatening injuries and acute illnesses.

Note: Emergency services are available 24-hours a day, 7 days a week.

CoP(s): §485.618, §485.618(a), §485.635(b)(4)

7. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital provides emergency services, the services are under the direction of a qualified member of the medical staff and are integrated with other departments of the critical access hospital.

CoP(s): §482.55, §482.55(a)(1), §482.55(a)(2)

8. For rehabilitation and psychiatric distinct part units in critical access hospitals: If emergency services are provided at the critical access hospital, the critical access hospital complies with the requirements of 42 CFR 482.55.

CoP(s): §482.12(f)(1)

9. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital provides nuclear medicine services, and nuclear medicine staff perform laboratory tests, the services meet the applicable requirements for laboratory services specified in 42 CRF 482.27.

CoP(s): §482.53(b)(3)

10. If the critical access hospital provides outpatient surgical services, the services are consistent with the quality of inpatient surgical care.

CoP(s): §482.51, §485.639

11. For rehabilitation and psychiatric distinct part units in critical access hospitals: The surgical services are consistent with the resources available.

CoP(s): §482.51(a), §482.51(b)

- 12. The critical access hospital provides the following basic laboratory services essential to the immediate diagnosis and treatment of the patient:
 - · Chemical examination of urine by the stick method, the tablet method, or both (including urine ketones)
 - · Hemoglobin or hematocrit tests
 - Blood glucose tests
 - · Examination of stool specimens for occult blood
 - · Pregnancy tests
 - · Primary culturing for transmittal to a certified laboratory

Note 1: The laboratory meets the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 263a). (Refer to the laboratory requirements specified in 42 CFR 493)

Note 2: For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has laboratory services available, either directly or through a contractual agreement with a Clinical Laboratory Improvement Amendments (CLIA)—certified laboratory that meets the requirements of 42 CFR 493.

13. For rehabilitation and psychiatric distinct part units in critical access hospitals: Emergency laboratory services are available 24 hours a day, 7 days a week.

CoP(s): §482.27(a)(1)

14. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital maintains a written description of the scope of laboratory services provided that is available to the medical staff.

CoP(s): §482.27(a)(2)

15. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital provides respiratory care services, and respiratory care staff perform blood gasses or other clinical laboratory tests, the applicable requirements for laboratory services specified in 42 CFR 482.27 are met.

CoP(s): §482.57(b)(2)

16. The critical access hospital provides services, directly or by arrangement, for the procurement, safekeeping, and transfusion of blood and provides services for making blood products available for emergencies on a 24-hour basis.

CoP(s): §485.618(c)(1)

17. The critical access hospital provides blood storage facilities, either directly or by arrangement, that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy.

Note: If blood banking services are provided under an arrangement, the arrangement is approved by the critical access hospital's medical staff and by the persons directly responsible for the operation of the critical access hospitals.

CoP(s): §485.618(c)(2)

- 18. For psychiatric distinct part units in critical access hospitals: The critical access hospital provides psychological services, social work services, psychiatric nursing, and therapeutic activities provided by qualified staff to meet the needs of its patients.
 - Note 1: The therapeutic activities program is appropriate to the needs and interests of patients and is directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.
 - Note 2: The psychological services are provided in accordance with accepted standards of practice, service objectives, and established policies and procedures.

CoP(s): §412.27(b), §412.27(d)(4), §412.27(d)(6), §412.27(d)(6)(i)

19. For swing beds in critical access hospitals: The critical access hospital provides or arranges for culturally competent and trauma-informed services, as outlined by the comprehensive care plan, that meet professional standards of quality and are provided by qualified staff in accordance with each resident's written plan of care.

CoP(s): §483.21(b)(3)(i), §483.21(b)(3)(ii), §483.21(b)(3)(iii)

LD.13.03.03

Care, treatment, and services provided through contractual agreement are provided safely and effectively.

Element(s) of Performance for LD.13.03.03

1. The critical access hospital maintains a current list of all patient care services provided under contract, arrangement, or agreement. The list describes nature and scope of services provided.

CoP(s): §482.12(e), §482.12(e)(2), §485.635(c)(3)

- 2. The governing body is responsible for all services provided in the critical access hospital, including contracted services. The governing body assesses that services are provided in a safe and effective manner and takes action to address issues pertaining to quality and performance.
 - Note: For rehabilitation and psychiatric distinct part units in critical access hospitals: The governing body makes certain that a contractor of services (including one for shared services and joint ventures) provides services that permit the critical access hospital to that comply with applicable Centers for Medicare & Medicaid Services (CMS) Conditions of Participation and standards for contract services.

CoP(s): §482.12(e), §482.12(e)(1)

- 3. When telemedicine services are furnished to the critical access hospital's patients, the originating site has a written agreement with the distant site that specifies the following:
 - The distant site is a contractor of services to the critical access hospital.

- The distant site furnishes services in a manner that permits the originating site to be in compliance with all applicable Medicare Conditions of Participation for the contracted services, in accordance with 42 CFR 485.635(c)(4)(ii).
- The originating site makes certain through the written agreement that all distant-site telemedicine providers' credentialing and privileging processes meet, at a minimum, the Medicare Conditions of Participation at 42 CFR 485.616(c)(1)(i) through (c)(1)(vii).

Note: For the language of the Medicare Conditions of Participation pertaining to telemedicine, refer to https://www.ecfr.gov.

If the originating site chooses to use the credentialing and privileging decision of the distant-site telemedicine provider, then the following requirements apply:

- The governing body of the distant site is responsible for having a process that is consistent with the credentialing and privileging requirements in the "Medical Staff" (MS) chapter (Standards MS.17.01.01 through MS.17.04.01).
- The governing body of the originating site grants privileges to a distant-site physician or other licensed practitioner based on the originating site's medical staff recommendations, which rely on information provided by the distant site.

The written agreement includes that it is the responsibility of the governing body of the distant-site hospital to meet the requirements of this element of performance.

CoP(s): §482.12(a)(9), §485.616(c)(3)

- 4. When telemedicine services are provided to the critical access hospital's patients through an agreement with a distant-site hospital, the critical access hospital's governing body makes certain that the written agreement specifies that it is the responsibility of the governing body of the distant-site hospital to do the following with regard to its physicians or other licensed practitioners providing telemedicine services:
 - Determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff
 - Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff
 - · Assure that the medical staff has bylaws
 - Approve medical staff bylaws and other medical staff rules and regulations
 - Make certain that the medical staff is accountable to the governing body for the quality of care provided to patients
 - Make certain that the criteria for selection for appointment to the medical staff are individual character, competence, training, experience, and judgment
 - Make certain that under no circumstances is the accordance of staff membership or professional privileges in the critical access hospital dependent solely upon certification, fellowship or membership in a specialty body or society

CoP(s): §485.616(c)(1), §485.616(c)(1)(i), §485.616(c)(1)(ii), §485.616(c)(1)(iii), §485.616(c)(1)(iv), §485.616(c)(1)(vi), §485.616(c)(1)(vii)

- 5. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital routinely uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement includes that the blood collecting establishment notify the critical access hospital within the specified timeframes under the following circumstances:
 - Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of human

immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection

- Within 45 days of the test for the results of the supplemental (additional, more specific) test for HIV or HCV or other follow-up testing required by the US Food and Drug Administration
- -Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available

CoP(s): §482.27(b)(3), §482.27(b)(3)(i), §482.27(b)(3)(ii), §482.27(b)(3)(iii)

- 7. The critical access hospital has agreements or arrangements, as appropriate, with one or more providers or suppliers participating under Medicare to furnish services not directly provided by the critical access hospital to its patients, including but not limited to the following:
 - · Services of doctors of medicine or osteopathy
 - · Additional or specialized diagnostic and clinical laboratory services not available at the critical access hospital
 - Food and other services to meet inpatient nutritional needs to the extent they are not provided directly by the critical access hospital

CoP(s): §485.635(c)(1)(i), §485.635(c)(1)(ii), §485.635(c)(1)(iii)

- 8. If the critical access hospital is a member of a rural health network, it has an agreement with at least one hospital that is a member of the network to address the following:
 - · Patient referral and transfer
 - Development and use of network communications systems, including electronic sharing of patient data, telemetry, and medical records, if the network has in operation such a system
 - Provision of emergency and nonemergency transportation between the facility and the hospital

CoP(s): §485.616(a)(1), §485.616(a)(2), §485.616(a)(3)

- 9. If the critical access hospital is a member of a rural health network, it has an agreement with respect to credentialing and quality assurance with at least one of the following organizations:
 - · Hospital that is a member of the network
 - · Quality improvement organization (QIO) or equivalent entity
 - · Other appropriate and qualified entity in the state rural health care plan

CoP(s): §485.616(b)(1), §485.616(b)(2), §485.616(b)(3)

LD.13.03.03

Care, treatment, and services provided through contractual agreement are provided safely and effectively.

Element(s) of Performance for LD.13.03.03

1. The critical access hospital maintains a current list of all patient care services provided under contract, arrangement, or agreement. The list describes nature and scope of services provided.

CoP(s): §482.12(e), §482.12(e)(2), §485.635(c)(3)

2. The governing body is responsible for all services provided in the critical access hospital, including contracted services. The governing body assesses that services are provided in a safe and effective manner and takes action to address issues pertaining to quality and performance.

Note: For rehabilitation and psychiatric distinct part units in critical access hospitals: The governing body makes certain that a contractor of services (including one for shared services and joint ventures) provides services that permit the critical access hospital to that comply with applicable Centers for Medicare & Medicaid Services (CMS) Conditions of Participation and standards for contract services.

CoP(s): §482.12(e), §482.12(e)(1)

- 3. When telemedicine services are furnished to the critical access hospital's patients, the originating site has a written agreement with the distant site that specifies the following:
 - The distant site is a contractor of services to the critical access hospital.
 - The distant site furnishes services in a manner that permits the originating site to be in compliance with all applicable Medicare Conditions of Participation for the contracted services, in accordance with 42 CFR 485.635(c)(4)(ii).
 - The originating site makes certain through the written agreement that all distant-site telemedicine providers' credentialing and privileging processes meet, at a minimum, the Medicare Conditions of Participation at 42 CFR 485.616(c)(1)(i) through (c)(1)(vii).

Note: For the language of the Medicare Conditions of Participation pertaining to telemedicine, refer to https://www.ecfr.gov.

If the originating site chooses to use the credentialing and privileging decision of the distant-site telemedicine provider, then the following requirements apply:

- The governing body of the distant site is responsible for having a process that is consistent with the credentialing and privileging requirements in the "Medical Staff" (MS) chapter (Standards MS.17.01.01 through MS.17.04.01).
- The governing body of the originating site grants privileges to a distant-site physician or other licensed practitioner based on the originating site's medical staff recommendations, which rely on information provided by the distant site.

The written agreement includes that it is the responsibility of the governing body of the distant-site hospital to meet the requirements of this element of performance.

CoP(s): §482.12(a)(9), §485.616(c)(3)

- 4. When telemedicine services are provided to the critical access hospital's patients through an agreement with a distant-site hospital, the critical access hospital's governing body makes certain that the written agreement specifies that it is the responsibility of the governing body of the distant-site hospital to do the following with regard to its physicians or other licensed practitioners providing telemedicine services:
 - Determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff
 - Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff
 - · Assure that the medical staff has bylaws
 - · Approve medical staff bylaws and other medical staff rules and regulations
 - Make certain that the medical staff is accountable to the governing body for the quality of care provided to patients
 - Make certain that the criteria for selection for appointment to the medical staff are individual character, competence, training, experience, and judgment

 Make certain that under no circumstances is the accordance of staff membership or professional privileges in the critical access hospital dependent solely upon certification, fellowship or membership in a specialty body or society

CoP(s): §485.616(c)(1), §485.616(c)(1)(i), §485.616(c)(1)(ii), §485.616(c)(1)(iii), §485.616(c)(1)(iv), §485.616(c)(1)(vi), §485.616(c)(1)(vii)

- 5. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital routinely uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement includes that the blood collecting establishment notify the critical access hospital within the specified timeframes under the following circumstances:
 - Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection
 - Within 45 days of the test for the results of the supplemental (additional, more specific) test for HIV or HCV or other follow-up testing required by the US Food and Drug Administration
 - -Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available

CoP(s): §482.27(b)(3), §482.27(b)(3)(i), §482.27(b)(3)(ii), §482.27(b)(3)(iii)

- 7. The critical access hospital has agreements or arrangements, as appropriate, with one or more providers or suppliers participating under Medicare to furnish services not directly provided by the critical access hospital to its patients, including but not limited to the following:
 - · Services of doctors of medicine or osteopathy
 - · Additional or specialized diagnostic and clinical laboratory services not available at the critical access hospital
 - Food and other services to meet inpatient nutritional needs to the extent they are not provided directly by the critical access hospital

CoP(s): §485.635(c)(1)(i), §485.635(c)(1)(ii), §485.635(c)(1)(iii)

- 8. If the critical access hospital is a member of a rural health network, it has an agreement with at least one hospital that is a member of the network to address the following:
 - · Patient referral and transfer
 - Development and use of network communications systems, including electronic sharing of patient data, telemetry, and medical records, if the network has in operation such a system
 - Provision of emergency and nonemergency transportation between the facility and the hospital

CoP(s): §485.616(a)(1), §485.616(a)(2), §485.616(a)(3)

- 9. If the critical access hospital is a member of a rural health network, it has an agreement with respect to credentialing and quality assurance with at least one of the following organizations:
 - · Hospital that is a member of the network
 - · Quality improvement organization (QIO) or equivalent entity

Other appropriate and qualified entity in the state rural health care plan

CoP(s): §485.616(b)(1), §485.616(b)(2), §485.616(b)(3)

Medication Management (MM) Chapter

MM.11.01.01

The critical access hospital safely manages pharmaceutical services.

Element(s) of Performance for MM.11.01.01

1. Drugs and biologicals are procured, stored, controlled, and distributed, in accordance with federal and state laws and accepted standards of practice.

CoP(s): §482.25(a), §482.25(b), §485.635(d)(3)

MM.11.01.03

The pharmacy is a resource for medication related information.

Element(s) of Performance for MM.11.01.03

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: Information relating to drug interactions, drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration is available to the professional staff.

CoP(s): §482.25(b)(8)

MM.12.01.01

The critical access hospital selects and procures medications.

Element(s) of Performance for MM.12.01.01

1. The critical access hospital maintains a formulary that includes medication strength and dosage. The formulary is readily available to those involved in medication management.

Note 1: Sample medications are not required to be on the formulary.

Note 2: In some settings, the term "list of medications available for use" is used instead of "formulary." The terms are synonymous.

CoP(s): §482.25(b)(9)

MM.13.01.01

The critical access hospital safely stores medications.

Element(s) of Performance for MM.13.01.01

 The critical access hospital maintains current and accurate records of the receipt and disposition of all scheduled drugs.

CoP(s): §482.25(a)(3), §485.635(a)(3)(iv)

The critical access hospital stores all medications and biologicals, including controlled (scheduled) medications, in a secured area and locked when necessary to prevent diversion in accordance with law and regulation.
 Note 1: Scheduled medications include those listed in Schedules II–V of the Comprehensive Drug Abuse

Prevention and Control Act of 1970.

Note 2: This element of performance is also applicable to sample medications.

Note 3: Only authorized staff have access to locked areas.

CoP(s): §482.25(b)(2)(i), §482.25(b)(2)(ii), §482.25(b)(2)(iii), §485.623(b)(3)

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital reports abuses and losses of controlled substances, in accordance with federal and state law and regulation, to the individual responsible for the pharmacy department or service and, as appropriate, to the chief executive officer. Note: This element of performance is also applicable to sample medications.

CoP(s): §482.25(b)(7)

4. The critical access hospital removes all expired, damaged, mislabeled, contaminated, or otherwise unusable medications and stores them separately from medications available for patient use. Note: This element of performance is also applicable to sample medications.

CoP(s): §482.25(b)(3), §485.635(a)(3)(iv)

5. For rehabilitation and psychiatric distinct part units in critical access hospitals: When a pharmacist is not available, only designated staff obtain drugs and biologicals from the pharmacy or storage area in accordance with policies and procedures of medical staff and pharmaceutical service, and applicable federal and state law and regulation.

CoP(s): §482.25(b)(4)

6. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital maintains records of the receipt and distribution of radiopharmaceuticals.

CoP(s): §482.53(d)(3)

MM.14.01.01

Medication orders are clear and accurate.

Element(s) of Performance for MM.14.01.01

 Orders for drugs and biologicals are documented and signed by any practitioner who is authorized to write orders in accordance with state law, hospital policy, and medical staff bylaws, rules, and regulations.
 Note: Influenza and pneumococcal vaccines may be administered per physician-approved hospital policy after an assessment of contraindications.

CoP(s): §482.23(c)(3), §482.23(c)(3)(iii)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital minimizes the use of verbal and telephone medication orders.

CoP(s): §482.23(c)(3)(i)

- 3. The critical access hospital develops and implements a written policy that defines the following:
 - · Specific types of medication orders that it deems acceptable for use
 - Minimum required elements of a complete medication order, which includes medication name, medication dose, medication route, and medication frequency
 - · When indication for use is required on a medication order
 - Precautions for ordering medications with look-alike or sound-alike names
 - · Actions to take when medication orders are incomplete, illegible, or unclear
 - Required elements for medication titration orders, including the medication name, medication route, initial rate of infusion (dose/unit of time), incremental units to which the rate or dose can be increased or decreased, how often the rate or dose can be changed, the maximum rate or dose of infusion, and the objective clinical measure to be used to guide changes

Note 1: Examples of objective clinical measures to be used to guide titration changes include blood pressure, Richmond Agitation—Sedation Scale (RASS), and the Confusion Assessment Method (CAM).

Note 2: Drugs and biologicals not specifically prescribed as to time or number of doses are automatically stopped after a reasonable time that is predetermined by the medical staff.

CoP(s): §482.25(a), §482.25(b)(5)

4. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home has an electronic prescribing process.

MM.15.01.01

The critical access hospital safely prepares medications.

Element(s) of Performance for MM.15.01.01

1. A pharmacist or other staff authorized in accordance with state and federal law and regulation compounds, labels, and dispenses drugs and biologicals, regardless of whether the services are provided by critical access hospital staff or under arrangement.

Note 1: When an on-site licensed pharmacist is available, a pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations.

Note 2: For rehabilitation and psychiatric distinct part units in critical access hospitals: A pharmacist supervises all compounding, packaging, and dispensing of drugs and biologicals except in urgent situations in which a delay could harm the patient or when the product's stability is short.

CoP(s): §482.25(b)(1)

2. The critical access hospital develops and implements policies and procedures for sterile medication compounding of nonhazardous and hazardous medications in accordance with state and federal law and regulation.

Note: All compounded medications are prepared in accordance with the orders of a physician or other licensed practitioner.

CoP(s): §482.25(b)(1)

3. The critical access hospital assesses competency of staff who conduct sterile medication compounding of nonhazardous and hazardous medications in accordance with state and federal law and regulation and critical access hospital policies.

CoP(s): §482.25(b)(1)

4. The critical access hospital conducts sterile medication compounding of nonhazardous and hazardous medications within a proper environment in accordance with state and federal law and regulation and critical access hospital policies.

Note: Aspects of a proper environment include but are not limited to air exchanges and pressures, ISO designations, viable testing, and cleaning/disinfecting.

CoP(s): §482.25(b)(1)

5. The critical access hospital properly stores compounded sterile preparations of nonhazardous and hazardous medications and labels them with beyond-use dates in accordance with state and federal law and regulation and critical access hospital policies.

CoP(s): §482.25(b)(1)

6. The critical access hospital conducts quality assurance of compounded sterile preparations of nonhazardous and hazardous medications in accordance with state and federal law and regulation and critical access hospital policies.

CoP(s): §482.25(b)(1)

7. For rehabilitation and psychiatric distinct part units in critical access hospitals: An appropriately trained registered pharmacist or doctor of medicine or osteopathy performs or supervises in-house preparation of radiopharmaceuticals.

CoP(s): §482.25(b)(1), §482.53(b)(1)

MM.15.01.03

Medications are labeled.

Element(s) of Performance for MM.15.01.03

Medication containers are labeled whenever medications are prepared but not immediately administered.
 Note 1: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.

 Note 2: This element of performance is also applicable to sample medications.

CoP(s): §485.635(a)(3)(iv)

MM.16.01.01

The critical access hospital safely administers medications.

Element(s) of Performance for MM.16.01.01

- Drugs and biologicals are prepared and administered in accordance with federal and state laws, the orders of
 the licensed practitioner or practitioners responsible for the patient's care, and accepted standards of practice.
 For rehabilitation and psychiatric distinct part units in critical access hospitals: Drugs and biologicals may be
 prepared and administered as follows:
 - On the orders of other practitioners not specified under 42 CFR 482.12(c) only if such practitioners are acting in accordance with state law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.
 - On the orders contained within preprinted and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of 42 CFR 482.24(c)(3).

CoP(s): §482.23(c)(1), §482.23(c)(1)(i), §482.23(c)(1)(ii)

2. Drugs, biologicals, and intravenous medications are administered by, or under the supervision of, a registered nurse, a doctor of medicine or osteopathy, or, where permitted by state law, a physician assistant. Note: For rehabilitation and psychiatric distinct part units in critical access hospitals: Drugs and biologicals are administered by, or under supervision of, nursing or other staff in accordance with federal and state laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

CoP(s): §482.23(c)(2), §485.635(d)(3)

- 3. The critical access hospital develops and implements policies and procedures that guide the safe and accurate self-administration of medications by the patient or their caregiver or support person, where appropriate.
 - Note 1: This applies to critical access hospital—issued medications and the patient's own medications brought into the critical access hospital.
 - Note 2: The term "self-administered medication(s)" may refer to medications administered by a family member.

CoP(s): §482.23(c)(6)

- 4. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital allows a patient to self-administer specific hospital-issued medications, the critical access hospital has policies and procedures in place that address the following:
 - Making certain that an order is issued by a licensed practitioner responsible for the patient's care and that it is consistent with the critical access hospital's self-administration policy
 - Determining that the patient or the patient's caregiver or support person is capable of administering the specified medication(s)
 - Instructing the patient or the patient's caregiver or support person, where appropriate, in the safe and accurate administration of the specified medication(s)
 - · Addressing the security of the medications for each patient

Note: The term "self-administered medication(s)" may refer to medications administered by a family member.

CoP(s): §482.23(c)(6)(i)(A), §482.23(c)(6)(i)(B), §482.23(c)(6)(i)(C), §482.23(c)(6)(i)(D)

- 5. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital allows a patient to self-administer their own specific medications brought into the hospital, the critical access hospital has policies and procedures in place that address the following:
 - Making certain that an order is issued by a practitioner responsible for the patient's care and that it is consistent with the critical access hospital's self-administration policy
 - Determining that the patient or the patient's caregiver or support person is capable of administering the specified medication(s)
 - Instructing the patient or the patient's caregiver or support person, where appropriate, in the safe and accurate administration of the specified medication(s)
 - · Addressing the security of the medications for each patient
 - Identifying the specified medication(s) and visually evaluating the medication(s) for integrity

Note: The term "self-administered medication(s)" may refer to medications administered by a family member.

CoP(s): §482.23(c)(6)(ii)(A), §482.23(c)(6)(ii)(B), §482.23(c)(6)(ii)(C), §482.23(c)(6)(ii)(D)

MM.17.01.01

The critical access hospital responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

Element(s) of Performance for MM.17.01.01

 The critical access hospital develops and implements policies and procedures for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.
 Note: This element of performance is also applicable to sample medications.

CoP(s): §482.23(c)(5), §485.635(a)(3)(v)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: Medication administration errors, adverse drug reactions, and medication incompatibilities, as defined by the critical access hospital, are immediately reported to the attending physician or licensed practitioner and, as appropriate, to the hospitalwide quality assessment and performance improvement program.

CoP(s): §482.25(b)(6)

3. The critical access hospital has a method (such as using established benchmarks for the size and scope of services provided by the critical access hospital or studies on reporting rates published in peer-reviewed journals) by which to measure the effectiveness of its process for identifying and reporting medication errors and adverse drug reactions to the quality assessment and performance improvement program.

CoP(s): §482.25(b)(6)

MM.18.01.01

The critical access hospital establishes antibiotic stewardship as an organizational priority through support of its antibiotic stewardship program.

Element(s) of Performance for MM.18.01.01

1. The antibiotic stewardship program reflects the scope and complexity of the critical access hospital services provided.

CoP(s): §482.42, §482.42(b)(4), §485.640, §485.640(b)(4)

2. The critical access hospital demonstrates that an individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership.

CoP(s): §482.42(b)(1), §485.640(b)(1)

- 3. The leader(s) of the antibiotic stewardship program is responsible for the following:
 - Development and implementation a critical access hospitalwide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.
 - · All documentation, written or electronic, of antibiotic stewardship program activities.
 - Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as with the critical access hospital's infection prevention and control and QAPI programs, on antibiotic use issues.
 - Competency-based training and education of critical access hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the critical access hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

CoP(s): §482.42, §482.42(c)(3)(i), §482.42(c)(3)(ii), §482.42(c)(3)(iii), §482.42(c)(3)(iv), §485.640, §485.640(c) (3)(i), §485.640(c)(3)(ii), §485.640(c)(3)(iii), §485.640(c)(3)(iv)

4. The governing body, or responsible individual, ensures all antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the critical access hospital's QAPI leadership.

CoP(s): §482.42(c)(1)(ii), §485.640(c)(1)(ii)

- 5. The critical access hospitalwide antibiotic stewardship program:
 - Demonstrates coordination among all components of the critical access hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services.

- Documents the evidence-based use of antibiotics in all departments and services of the critical access hospital.
- · Documents any improvements, including sustained improvements, in proper antibiotic use.

6. The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use.

CoP(s): §482.42(b)(3), §485.640(b)(3)

7. The governing body, or responsible individual, ensures that systems are in place and operational for the tracking of all antibiotic use activities in order to demonstrate the implementation, success, and sustainability of such activities.

CoP(s): §482.42(c)(1)(i), §485.640(c)(1)(i)

Medical Staff (MS) Chapter

MS.14.01.01

Medical staff bylaws address self-governance and accountability to the governing body.

Element(s) of Performance for MS.14.01.01

- 1. The medical staff adopts and enforces bylaws to carry out its responsibilities. The bylaws are approved by the governing body and include the following:
 - Description of the organization of the medical staff, including criteria for medical staff membership
 - Description of the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body
 - Criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges
 - For rehabilitation or psychiatric distinct part units in critical access hospitals: Statement of the duties and privileges of each category of medical staff (for example, active, courtesy)

Note: Distant-site physicians and practitioners requesting privileges to provide telemedicine services under an agreement with the critical access hospital are also subject to the requirements in 42 CFR 482.12(a)(8) and (a) (9), and 42 CFR 482.22(a)(3) and (a)(4).

CoP(s): §482.22(c)(1), §482.22(c)(2), §482.22(c)(3), §482.22(c)(4), §482.22(c)(6)

2. The medical staff bylaws include the qualifications for appointment and reappointment to the medical staff. Note: For rehabilitation and psychiatric distinct part units in critical access hospitals: The medical staff is composed of doctors of medicine or osteopathy. In accordance with state law, including scope of practice laws, the medical staff may also include other categories of physicians, as listed at 42 CFR 482.12(c)(1), and other licensed practitioners who the governing body determines are eligible for appointment. (See also MS.20.01.01, EP 1)

CoP(s): §482.22(a)

- 3. For rehabilitation and psychiatric distinct part units in critical access hospitals: The medical staff bylaws include requirements for the following:
 - Medical history and physical examination for each patient as described in PC.10.01.01, EP 1
 - Updated patient examinations as described in PC.10.01.01, EP 2
 - Assessments in lieu of medical history and physical examinations for patients as described in PC.10.01.01, EP 3

CoP(s): §482.22(c)(5)(i), §482.22(c)(5)(ii), §482.22(c)(5)(iii)

- 9. The medical staff bylaws include the following requirements:
 - · Description of those members of the medical staff who are eligible to vote
 - · Process for credentialing and recredentialing physicians and other licensed practitioners
 - Process for fair hearings and appeals, which at a minimum, includes the process for scheduling and conducting hearings and appeals.

MS.14.03.01

Multihospital systems can choose to establish a unified and integrated medical staff in accordance with state and local laws.

Element(s) of Performance for MS.14.03.01

1. If a critical access hospital is part of a multihospital system with separately accredited hospitals, critical access hospitals, and/or rural emergency hospitals, and the system chooses to establish a unified and integrated medical staff, in accordance with state and local laws, the following occurs: Each separately accredited critical access hospital demonstrates that its medical staff members (that is, all medical staff members who hold privileges to practice at that specific hospital) have voted by majority, in accordance with medical staff bylaws, either to accept the unified and integrated medical staff structure or to opt out of such a structure and maintain a separate and distinct medical staff for their critical access hospital.

CoP(s): §482.22(b)(4)(i), §485.631(e)(1)

2. If a critical access hospital is part of a multihospital system with separately accredited hospitals, critical access hospitals, and/or rural emergency hospitals, and the system chooses to establish a unified and integrated medical staff, the following occurs: The unified and integrated medical staff takes into account each member critical access hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital, critical access hospital, and rural emergency hospital.

CoP(s): §482.22(b)(4)(iii), §485.631(e)(3)

3. If a critical access hospital is part of a multihospital system with separately accredited hospitals, critical access hospitals, and/or rural emergency hospitals, and the system chooses to establish a unified and integrated medical staff, the following occurs: The unified and integrated medical staff develops and implements policies and procedures and mechanisms to make certain that the needs and concerns expressed by members of the medical staff at each of its separately accredited hospitals, critical access hospitals, and/or rural emergency hospitals, regardless of practice or location, are duly considered and addressed.

CoP(s): §482.22(b)(4)(iv), §485.631(e)(4)

- 4. If a critical access hospital is part of a multihospital system with separately accredited hospitals, critical access hospitals, and/or rural emergency hospitals, and the system chooses to establish a unified and integrated medical staff, the unified and integrated medical staff bylaws, rules, and requirements include the following:
 - Process for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees
 - Description of the process by which medical staff members at each separately accredited hospital (that is, all medical staff members who hold privileges to practice at that specific hospital) are advised of their right to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their respective critical access hospital

CoP(s): §482.22(b)(4)(ii), §485.631(e)(2)

MS.15.01.01

For rehabilitation and psychiatric distinct part units in critical access hospitals: There is a medical staff executive committee.

Note: The medical staff as a whole may serve as the executive committee. In smaller, less complex critical access hospitals where the entire medical staff functions as the executive committee, it is often designated as a committee of the whole.

Element(s) of Performance for MS.15.01.01

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: The majority of voting medical staff executive committee members are fully licensed doctors of medicine or osteopathy actively practicing in the critical access hospital.

CoP(s): §482.22(b)(2)

MS.16.01.01

The organized medical staff oversees the quality of patient care, treatment, and services provided by physicians and other licensed practitioners privileged through the medical staff process.

Element(s) of Performance for MS.16.01.01

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has an organized medical staff that operates under bylaws approved by the governing body and that is responsible for the quality of medical care provided by the critical access hospital.

CoP(s): §482.22

2. Physician members of the organized medical staff are designated to perform the oversight activities of the organized medical staff.

- 3. Physicians and other licensed practitioners practice only within the scope of their privileges as determined through mechanisms defined by the organized medical staff.
- 6. The medical staff requires that a physician or other licensed practitioner who has been granted privileges by the critical access hospital to do so performs a patient's medical history and physical examination and required updates.

Note: As permitted by state law and critical access hospital policy, the organized medical staff may choose to allow practitioners who are not licensed to practice independently to perform part or all of a patient's medical history and physical examination under the supervision of, or through appropriate delegation by, a specific qualified doctor of medicine or osteopathy who is accountable for the patient's medical history and physical examination.

- 7. The organized medical staff does the following:
 - Defines when a medical history and physical examination must be validated and countersigned by a physician with appropriate privileges
 - Specifies the minimal content of medical histories and physical examinations, which may vary by setting or level of care, treatment, and services
- 8. For psychiatric distinct part units in critical access hospitals: The clinical director, service chief, or equivalent for inpatient psychiatric services monitors and evaluates the medical staff's treatment and services for quality and appropriateness.

CoP(s): §412.27(d)(2)(ii)

9. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital provides emergency services, the policies and procedures governing emergency medical care are established by and are a continuing responsibility of the medical staff.

CoP(s): §482.55(a)(3)

- 10. If the medical staff chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements would apply in lieu of a comprehensive medical history and physical examination, the policy is based on the following:
 - Patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure
 - Nationally recognized guidelines and standards of practice for assessment of particular types of patients prior to specific outpatient surgeries and procedures
 - · Applicable state and local health and safety laws

The critical access hospital demonstrates evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services.

Note: For rehabilitation and psychiatric distinct part units in critical access hospitals: For law and regulation guidance pertaining to the medical history and physical examination at 42 CFR 482.22(c)(5)(iii), refer to https://www.ecfr.gov/.

CoP(s): §482.22(c)(5)(iv), §482.22(c)(5)(v), §482.22(c)(5)(v)(A), §482.22(c)(5)(v)(B), §482.22(c)(5)(v)(C)

11. For rehabilitation and psychiatric distinct part units in critical access hospitals: The medical staff determines the qualifications of the radiology staff who use equipment and administer procedures.

Note: Technologists who perform diagnostic computed tomography exams will, at a minimum, meet the requirements specified at NPG.13.01.01, EP 1.

CoP(s): §482.26(c)(2)

12. For rehabilitation and psychiatric distinct part units in critical access hospitals: The medical staff approves the nuclear services director's specifications for the qualifications, training, functions, and responsibilities of the nuclear medicine staff.

CoP(s): §482.53(a)(2)

13. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: Through the privileging process, the organized medical staff determines which licensed practitioners are qualified to serve in the role of primary care clinician.

MS.16.01.03

The management and coordination of each patient's care, treatment, and services is the responsibility of a physician or other licensed practitioner with appropriate privileges.

Element(s) of Performance for MS.16.01.03

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: Patients are admitted to the critical access hospital only on the recommendation of a licensed practitioner permitted by the state to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in MS.16.01.03, EP 4, that patient is under the care of a doctor of medicine or osteopathy.

CoP(s): §482.12(c)(2)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: A doctor of medicine or osteopathy is on duty or on call at all times.

CoP(s): §482.12(c)(3)

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and is not specifically within the scope of practice, as defined by the medical staff and in accordance with state law, of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor, as limited under 42 CFR 12(c)(1)(v); or clinical psychologist.

CoP(s): §482.12(c)(4), §482.12(c)(4)(i), §482.12(c)(4)(ii), §482.12(c)(4)(ii)(A), §482.12(c)(4)(ii)(B), §482.12(c)(4)(ii)(C)

- 4. For rehabilitation and psychiatric distinct part units in critical access hospitals: Every Medicare patient is under the care of at least one of the following:
 - A doctor of medicine or osteopathy (This requirement does not limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care staff to the extent recognized under state law or a state's regulatory mechanism.)

- A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the state and who is acting within the scope of their license
- A doctor of podiatric medicine, but only with respect to functions which they are legally authorized by the state to perform
- A doctor of optometry who is legally authorized to practice optometry by the state in which they practice
- A chiropractor who is licensed by the state or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist
- A clinical psychologist as defined in 42 CFR 410.71, but only with respect to clinical psychologist services as defined in 42 CFR 410.71 and only to the extent permitted by state law(See also LD.14.01.03, EP 5)

CoP(s): §482.12(c)(1)(i), §482.12(c)(1)(ii), §482.12(c)(1)(iii), §482.12(c)(1)(iv), §482.12(c)(1)(v), §482.12(c)(1)(vi)

6. The doctor of medicine or osteopathy provides medical direction for the critical access hospital's health care activities and consultation for, and medical staff supervision of, the health care staff.

CoP(s): §485.631(b)(1)(i)

7. Whenever a patient is admitted to the critical access hospital by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff is notified of the admission.

CoP(s): §485.631(c)(3)

8. The doctor of medicine or osteopathy, in conjunction with the physician assistant and/or nurse practitioner members of the critical access hospital staff, provides medical orders and medical care services to the critical access hospital's patients.

CoP(s): §485.631(b)(1)(iii)

- 9. If not being performed by a doctor of medicine or osteopathy, the physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions:
 - Provides services in accordance with the critical access hospital's policies
 - · Arranges for, or refers patients to, needed services that cannot be furnished at the critical access hospital
 - · Maintains and transfers patient records when patients are referred

CoP(s): §485.631(c)(2)(i), §485.631(c)(2)(ii)

10. The doctor of medicine or osteopathy, in conjunction with the physician assistant, the nurse practitioner, and/or clinical nurse specialist members of the critical access hospital staff, periodically review the patients' records.

CoP(s): §485.631(b)(1)(iii), §485.631(c)(1)(ii)

11. The doctor of medicine or osteopathy periodically reviews and signs the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants.

CoP(s): §485.631(b)(1)(iv)

12. The doctor of medicine or osteopathy periodically reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants.

Note: Outpatient records are reviewed to the extent required by state law where state law requires outpatient record reviews, cosignatures, or both by a collaborating physician.

CoP(s): §485.631(b)(1)(v)

13. A doctor of medicine or osteopathy is present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the critical access hospital, and is available through direct radio, telephone, or electronic communication for consultation, assistance with medical emergencies, or patient referral.

CoP(s): §485.631(b)(2)

MS.16.03.01

The organized medical staff has a leadership role in organizationwide performance improvement activities to improve patient safety and the quality of care, treatment, and services.

Element(s) of Performance for MS.16.03.01

- 3. The medical staff is actively involved in pain assessment, pain management, and safe opioid prescribing through the following:
 - Participating in the establishment of protocols and quality metrics
 - · Reviewing performance improvement data
- 6. The medical staff is actively involved in the measurement, assessment, and improvement of the appropriateness of clinical practice patterns.
- 7. The critical access hospital takes appropriate remedial action to address deficiencies found through the quality assurance program.
- 8. The critical access hospital documents the outcome of all remedial action.

MS.17.01.01

Prior to granting a privilege, the critical access hospital determines if the resources necessary to support the requested privilege are currently available or available within a specified time frame.

Element(s) of Performance for MS.17.01.01

- 1. The critical access hospital has a process to determine whether sufficient space, equipment, staffing, and financial resources are in place or available within a specified time frame to support each requested privilege.
- 2. The critical access hospital consistently determines the resources needed for each requested privilege.

MS.17.01.03

The critical access hospital collects information regarding each physician's or other licensed practitioner's current license status, training, experience, competence, and ability to perform the requested privilege.

Element(s) of Performance for MS.17.01.03

- 1. The governing body approves the credentialing process.
- 2. The critical access hospital verifies that the physician or other licensed practitioner requesting approval is the same person identified in the credentialing documents by viewing one of the following:
 - · Current picture hospital ID card
 - Valid picture ID issued by a state or federal agency (for example, a driver's license or passport)
- 3. The credentialing process requires that the critical access hospital verifies in writing and from the primary source whenever feasible, or from a credentials verification organization (CVO), the following information for the applicant:
 - Current licensure at the time of initial granting, renewal, and revision of privileges and at the time of license expiration
 - · Relevant training
 - · Current competence

CoP(s): §482.11(c), §485.608(d)

4. For rehabilitation and psychiatric distinct part units in critical access hospitals: The medical staff examines the credentials of all candidates eligible for medical staff membership and makes recommendations to the governing body on the appointment of these candidates, in accordance with state law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations.

Note: A candidate who has been recommended by the medical staff and who has been appointed by the governing body is also subject to 42 CFR 482.22(a).

CoP(s): §482.22(a)(2)

5. For rehabilitation and psychiatric distinct part units in critical access hospitals: A full-time, part-time, or consulting radiologist, who is a doctor of medicine or osteopathy qualified by education and experience in radiology, supervises ionizing radiology services and interprets radiologic tests that the medical staff determine to require a radiologist's specialized knowledge.

CoP(s): §482.26(c)(1)

6. For psychiatric distinct part units in critical access hospitals: Inpatient psychiatric services are under the direction and supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program and who meets the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

CoP(s): §412.27(d)(2), §412.27(d)(2)(i)

- 7. For rehabilitation distinct part units in critical access hospitals: The critical access hospital has a director of the rehabilitation unit who fulfills all of the following requirements:
 - Provides services to the unit and to its inpatients for at least 20 hours per week
 - · Is a doctor of medicine or osteopathy
 - Is licensed under state law to practice medicine or surgery
 - Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services

CoP(s): §412.29(g)(1), §412.29(g)(2), §412.29(g)(3), §412.29(g)(4)

8. The quality and appropriateness of the diagnosis and treatment provided by nurse practitioners, clinical nurse specialists, and physician assistants are evaluated by a member of the critical access hospital's medical staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the organization.

CoP(s): §485.631(d)(1)

- 9. The quality and appropriateness of the diagnosis and treatment provided by doctors of medicine or osteopathy at the critical access hospital are evaluated by one of the following:
 - A hospital that is a member of the network, when applicable
 - · A quality improvement organization or equivalent entity
 - Another appropriate and qualified entity identified in the state's rural health care plan

Note: In the case of distant-site physicians and practitioners providing telemedicine services to the critical access hospital's patients under an agreement between the critical access hospital and a distant hospital or between the critical access hospital and a distant-site telemedicine entity, the quality and appropriateness of the diagnosis and treatment provided is evaluated by one of the entities listed in this element of performance.

CoP(s): §412.27(d)(2)(ii), §485.631(d)(2)(i), §485.631(d)(2)(ii), §485.631(d)(2)(iii), §485.631(d)(2)(iv), §485.631(d)(2)(v)

10. The critical access hospital's medical staff reviews the findings from the evaluations of doctors of medicine or osteopathy, including any findings or recommendations of the quality improvement organization, and makes the necessary changes as specified in 42 CFR 485.631 paragraphs (b) through (d).

CoP(s): §485.631(d)(3)

MS.17.02.01

The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.

Element(s) of Performance for MS.17.02.01

- 1. The critical access hospital, based on recommendations by the organized medical staff and approval by the governing body, develops and implements criteria that determine if a physician or other licensed practitioner is allowed to provide patient care, treatment, and services within the scope of the privilege(s) requested. Evaluation of all of the following are included in the criteria:
 - · Current licensure and/or certification, as appropriate, verified with the primary source
 - · Specific relevant training, verified with the primary source

- Evidence of physical ability to perform the requested privilege
- Data from professional practice review by an organization(s) that currently privileges the applicant (if available)
- · Peer and/or faculty recommendation
- When renewing privileges, review of the physician's or other licensed practitioner's performance within the critical access hospital

CoP(s): §485.639(c)

- 3. An applicant submits a statement that no health problems exist that could affect their ability to perform the privileges requested.
- 4. The critical access hospital queries the National Practitioner Data Bank (NPDB) in accordance with applicable law and regulation.
- 5. Completed applications for privileges are acted on within the time period specified in the medical staff bylaws, rules, and regulations, or in policies and procedures.
- 6. The critical access hospital designates the practitioners who are allowed to perform surgery, in accordance with appropriate policies and procedures, and with scope of practice laws and regulations. Surgery is performed only by the following:
 - A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Social Security Act
 - · A doctor of dental surgery or dental medicine
 - · A doctor of podiatric medicine

CoP(s): §482.51(a)(4), §485.639, §485.639(a), §485.639(a)(1), §485.639(a)(2), §485.639(a)(3)

7. For rehabilitation and psychiatric distinct part units in critical access hospitals: The surgical service maintains a current roster listing each practitioner's surgical privileges.

Note: The roster may be in paper or electronic format.

CoP(s): §482.51(a)(4)

- 8. The critical access hospital uses participation in continuing education in decisions about reappointment to medical staff membership, or renewal or revision of individual clinical privileges.
- 9. All physicians and other licensed practitioners that provide care, treatment, and services possess a current license, certification, or registration, as required by law and regulation.

CoP(s): §482.11(c), §485.608(d)

MS.17.02.03

The organized medical staff reviews and analyzes all relevant information regarding each requesting physician's or other licensed practitioner's current licensure status, training, experience, current competence, and ability to perform the requested privilege.

Element(s) of Performance for MS.17.02.03

1. Decisions on membership and granting of privileges include criteria that are directly related to the quality of health care, treatment, and services.

CoP(s): §482.51(a)(4)

3. The critical access hospital completes the credentialing and privileging decision process in a timely manner.

MS.17.04.01

Under certain circumstances, temporary clinical privileges may be granted for a limited period of time.

Element(s) of Performance for MS.17.04.01

- 1. Temporary privileges are granted to meet an important patient care need for a time period defined in the medical staff bylaws.
- 2. When temporary privileges are granted to meet an important care need, the organized medical staff verifies current licensure and current competence.
- 3. Temporary privileges may be granted to applicants for new privileges while awaiting review and approval by the organized medical staff upon verification of the following:
 - · Current licensure
 - · Relevant training or experience
 - · Current competence
 - · Ability to perform the privileges requested
 - · Other criteria required by the medical staff bylaws
 - A query and evaluation of the National Practitioner Data Bank (NPDB) information
 - · A complete application
 - · No current or previously successful challenge to licensure or registration
 - · No subjection to involuntary termination of medical staff membership at another organization
 - · No subjection to involuntary limitation, reduction, denial, or loss of clinical privileges
- 4. All temporary privileges are granted by the chief executive officer or authorized designee.
- 5. All temporary privileges are granted on the recommendation of the medical staff president or authorized designee.
- 6. Temporary privileges for applicants for new privileges are granted for no more than 120 days.

MS.18.02.01

The organized medical staff defines the circumstances requiring monitoring and evaluation of a physician's or other licensed practitioner's professional performance.

Element(s) of Performance for MS.18.02.01

- 1. The organized medical staff develops and consistently implements criteria to be used for evaluating the performance of physicians or other licensed practitioners when issues affecting the provision of safe, high quality patient care are identified.
- 3. The performance monitoring process is clearly defined and includes each of the following elements:
 - · Criteria for conducting performance monitoring
 - · Method for establishing a monitoring plan specific to the requested privilege
 - · Method for determining the duration of performance monitoring
 - · Circumstances under which monitoring by an external source is required
- 4. The triggers that indicate the need for performance monitoring are clearly defined. Note: Triggers can be single incidents or evidence of a clinical practice trend.
- 5. Criteria are developed that determine the type of monitoring to be conducted.
- 6. The measures employed to resolve performance issues are clearly defined.
- 7. The measures employed to resolve performance issues are consistently implemented.

MS.18.02.03

Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privilege(s), or to revoke an existing privilege prior to or at the time of renewal.

Element(s) of Performance for MS.18.02.03

- The medical staff's ongoing professional practice evaluation includes a clearly defined process that facilitates the
 periodic evaluation of each physician's or other licensed practitioner's professional practice.
 Note: For rehabilitation or psychiatric distinct part units in critical access hospitals: Privileges are granted for a
 period not to exceed three years or for the period required by law and regulation if shorter.
 - CoP(s): §482.22(a)(1)
- 2. The process for the ongoing professional practice evaluation includes the type of data to be collected, which is determined by individual departments and approved by the organized medical staff.
- 3. The process for the ongoing professional practice evaluation includes the use of information resulting from the ongoing professional practice evaluation to determine whether to continue, limit, or revoke any existing privilege(s).

MS.18.03.01

The organized medical staff, pursuant to the medical staff bylaws, evaluates and acts on reported concerns regarding a privileged physician's or other licensed practitioner's clinical practice and/or competence.

Element(s) of Performance for MS.18.03.01

1. The critical access hospital, based on recommendations by the organized medical staff and approval by the governing body, has a clearly defined process for collecting, investigating, and addressing clinical practice concerns.

Note: Reported concerns regarding a privileged physician's or other licensed practitioner's professional practice are uniformly investigated and addressed, as defined by the critical access hospital and applicable law.

MS.20.01.01

Physicians or other licensed practitioners who are responsible for the care, treatment, and services of the patient via telemedicine link are subject to the credentialing and privileging processes of the originating site.

Element(s) of Performance for MS.20.01.01

- 1. When telemedicine services are furnished to the critical access hospital's patients through an agreement with a distant-site hospital or telemedicine entity, the governing body of the originating critical access hospital may choose to rely upon the credentialing and privileging decisions made by the distant-site hospital or telemedicine entity for the individual distant-site physicians and other licensed practitioners providing such services if the critical access hospital's governing body includes all of the following provisions in its written agreement with the distant-site hospital or telemedicine entity:
 - The distant site telemedicine entity provides services in accordance with contract service requirements.
 - The distant-site telemedicine entity's medical staff credentialing and privileging process and standards is consistent with the critical access hospital's process and standards, at a minimum.
 - The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.
 - The individual distant-site physician or other licensed practitioner is privileged at the distant-site hospital or telemedicine entity providing the telemedicine services, and the distant-site hospital or telemedicine entity provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital or telemedicine entity.
 - The individual distant-site physician or other licensed practitioner holds a license issued or recognized by the state in which the critical access hospital whose patients are receiving the telemedicine services is located.
 - For distant-site physicians or other licensed practitioners privileged by the originating critical access hospital, the originating critical access hospital internally reviews services provided by the distant-site physician or other licensed practitioner and sends the distant-site hospital or telemedicine entity information for use in the periodic evaluation of the practitioner. At a minimum, this information includes adverse events that result from the telemedicine services provided by the distant-site physician or other licensed practitioner to the critical access hospital's patients and complaints the critical access hospital has received about the distant-site physician or other licensed practitioner.

Note 1: In the case of distant-site physicians and licensed practitioners providing telemedicine services to the critical access hospital's patients under a written agreement between the critical access hospital and a distant-site telemedicine entity, the distant-site telemedicine entity is not required to be a Medicare participating provider or supplier.

Note 2: For rehabilitation and psychiatric distinct part units in critical access hospitals: The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at 42 CFR 482.12(a)(1) through (a)(7) and 482.22(a)(1) through (a)(2).(See also MS.14.01.01, EP 2)

National Performance Goals (NPG) Chapter

NPG.01.01.01

The critical access hospital has a process in place to correctly identify patients when providing care, treatment, and services.

Element(s) of Performance for NPG.01.01.01

1. The critical access hospital has a process in place to correctly identify patients when providing care treatment, and services. This includes using at least two patient identifiers. The critical access hospital does not use the patient's room number or physical location is not used as an identifier.

Note: Examples of patient identifiers may include but are not limited to the following:

- Assigned identification number (for example, medical record number)
- · Telephone number or another person-specific identifier
- Electronic identification technology coding, such as bar coding or RFID, that includes two or more personspecific identifiers
- 2. The critical access hospital labels containers used for blood and other specimens in the presence of the patient.
- 3. The critical access hospital uses distinct methods of identification for newborn patients.
 - Note: Examples of methods to prevent misidentification may include the following:
 - Distinct naming systems could include using the mother's first and last names and the newborn's gender (for example: "Smith, Judy Girl" or "Smith, Judy Girl A" and "Smith, Judy Girl B" for multiples).
 - Standardized practices for identification banding (for example, using two body sites and/or bar coding for identification).
 - Establish communication tools among staff (for example, visually alerting staff with signage noting newborns with similar names).

NPG.01.02.01

The critical access hospital reports critical results of tests and diagnostic procedures on a timely basis.

Element(s) of Performance for NPG.01.02.01

- 1. The critical access hospital develops and implements written procedures for managing the critical results of tests and diagnostic procedures that address the following:
 - · The definition of critical results of tests and diagnostic procedures
 - · By whom and to whom critical results of tests and diagnostic procedures are reported
 - The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures
- The critical access hospital evaluates the timeliness of reporting the critical results of tests and diagnostic procedures.

NPG.01.04.01

The critical access hospital has a process for hand-off communication.

Element(s) of Performance for NPG.01.04.01

2. The critical access hospital's process for hand-off communication provides for the opportunity for discussion between the giver and receiver of patient information.

Note: Such information may include the patient's condition, care, treatment, medications, services, and any recent or anticipated changes to any of these.

NPG.01.05.01

The critical access hospital improves the safety of clinical alarm systems.

Element(s) of Performance for NPG.01.05.01

- 1. Identify the most important alarm signals to manage based on the following:
 - · Input from the medical staff and clinical departments
 - Risk to patients if the alarm signal is not attended to or if it malfunctions
 - · Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue
 - · Potential for patient harm based on internal incident history
 - · Published best practices and guidelines
- 2. Establish policies and procedures for managing the alarms identified in NPG.01.05.01, EP 1 that, at a minimum, address the following:
 - · Clinically appropriate settings for alarm signals
 - · When alarm signals can be disabled
 - · When alarm parameters can be changed
 - · Who in the organization has the authority to set alarm parameters
 - Who in the organization has the authority to change alarm parameters
 - Who in the organization has the authority to set alarm parameters to "off"
 - · Monitoring and responding to alarm signals
 - Checking individual alarm signals for accurate settings, proper operation, and detectability.

NPG.01.05.02

The critical access hospital recognizes and responds to changes in a patient's condition.

Note: Hospitals are not required to create rapid response teams or medical emergency teams in order to meet this standard. The existence of these types of teams does not mean that all of the elements of performance are automatically achieved.

Element(s) of Performance for NPG.01.05.02

1. The critical access hospital develops and implements written criteria describing early warning signs of a change or deterioration in a patient's condition and the appropriate action to take.

NPG.01.05.03

Resuscitative services are available throughout the critical access hospital.

Element(s) of Performance for NPG.01.05.03

1. The critical access hospital provides resuscitative services based on national standards of care, guidelines, and the critical access hospital's policies, procedures, or protocols.

- 2. Resuscitation equipment is available for use based on the needs of the population served.

 Note: For example, if the critical access hospital has a pediatric population, pediatric resuscitation equipment should be available.
- 3. The critical access hospital provides education and training to staff involved in the provision of resuscitative services. The critical access hospital determines which staff complete this education and training based on their job responsibilities and critical access hospital policies and procedures. The education and training are provided at the following intervals:
 - At orientation
 - · A periodic basis thereafter, as determined by the critical access hospital
 - · When staff responsibilities change

Note 1: Topics may cover resuscitation procedures or protocols; use of cardiopulmonary resuscitation techniques, devices, or equipment; and roles and responsibilities during resuscitation events.

Note 2: The critical access hospital determines the format and content of education and training (for example, a skills day, a mock code).

NPG.01.05.04

The critical access hospital develops and implements processes for post-resuscitation care.

Element(s) of Performance for NPG.01.05.04

- 1. The critical access hospital develops and implements policies, procedures, or protocols based on current scientific literature for interdisciplinary post–cardiac arrest care.
 - Note 1: Post–cardiac arrest care is aimed at identifying, treating, and mitigating acute pathophysiological processes after cardiac arrest and includes evaluation for targeted temperature management and other aspects of critical care management.
 - Note 2: This requirement does not apply to critical access hospitals that do not provide post-cardiac arrest care.
- 2. The critical access hospital develops and implements policies, procedures, or protocols based on current scientific literature to determine the neurological prognosis for patients who remain comatose after cardiac arrest.
 - Note 1: Because any single method of neuroprognostication has an intrinsic error rate, current guidelines recommend that multiple testing modalities be incorporated into the critical access hospital's routine procedures and protocols to improve decision-making accuracy.
 - Note 2: This requirement does not apply to critical access hospitals that do not provide post-cardiac arrest care.

NPG.01.05.05

The critical access hospital reviews resuscitation cases to identify opportunities for improvement.

Element(s) of Performance for NPG.01.05.05

1. An interdisciplinary committee reviews cases and data to identify and suggest practice and system improvements in resuscitation performance.

Note 1: Review examples could include the following:

- How often early warning signs of clinical deterioration were present prior to in-hospital cardiac arrest in patients in nonmonitored or non-critical care units
- Timeliness of staff's response to a cardiac arrest
- Quality of cardiopulmonary resuscitation (CPR)
- · Post-cardiac arrest care processes
- Outcomes following cardiac arrest

Note 2: The review functions may be designated to an existing interdisciplinary committee.

NPG.01.06.01

The critical access hospital conducts a preprocedure verification process.

Element(s) of Performance for NPG.01.06.01

- 1. The critical access hospital implements a preprocedure process to verify the correct procedure, for the correct patient, at the correct site.
 - Note: The patient is involved in the verification process when possible.
- 2. The critical access hospital identifies the items that must be available for the procedure and uses a standardized list to verify their availability. At a minimum, these items include the following:
 - Relevant documentation (for example, history and physical, signed procedure consent form, nursing assessment, and preanesthesia assessment)
 - Labeled diagnostic and radiology test results (for example, radiology images and scans, or pathology and biopsy reports) that are properly displayed
 - Any required blood products, implants, devices, and/or special equipment for the procedure Note: The expectation of this element of performance is that the standardized list is available and is used consistently during the preprocedure verification. It is not necessary to document that the standardized list was used for each patient.

NPG.01.06.01

The critical access hospital conducts a preprocedure verification process.

Element(s) of Performance for NPG.01.06.01

- 1. The critical access hospital implements a preprocedure process to verify the correct procedure, for the correct patient, at the correct site.
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 - Any required blood products, implants, devices, and/or special equipment for the procedure Note: The expectation of this element of performance is that the standardized list is available and is used consistently during the preprocedure verification. It is not necessary to document that the standardized list was used for each patient.

NPG.01.06.02

The critical access hospital marks the procedure site.

Element(s) of Performance for NPG.01.06.02

- 1. The critical access hospital identifies those procedures that require marking of the incision or insertion site. At a minimum, sites are marked when there is more than one possible location for the procedure and when performing the procedure in a different location would negatively affect quality or safety. Note: For spinal procedures, in addition to preoperative skin marking of the general spinal region, special intraoperative imaging techniques may be used for locating and marking the exact vertebral level.
- 2. The procedure site is marked before the procedure is performed and, if possible, with the patient involved.

- 3. The procedure site is marked by a licensed practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed. In limited circumstances, the licensed practitioner may delegate site marking to an individual who is permitted by the organization to participate in the procedure and has the following qualifications:
 - An individual in a medical postgraduate education program who is being supervised by the licensed practitioner performing the procedure; who is familiar with the patient; and who will be present when the procedure is performed
 - A licensed individual who performs duties requiring a collaborative agreement or supervisory agreement with the licensed practitioner performing the procedure (that is, an advanced practice registered nurse [APRN] or physician assistant [PA]); who is familiar with the patient; and who will be present when the procedure is performed.

Note: The critical access hospital's leaders define the limited circumstances (if any) in which site marking may be delegated to an individual meeting these qualifications.

- 4. The method of marking the site and the type of mark is unambiguous and is used consistently throughout the critical access hospital.
 - Note: The mark is made at or near the procedure site and is sufficiently permanent to be visible after skin preparation and draping. Adhesive markers are not the sole means of marking the site.
- 5. A written, alternative process is in place for patients who refuse site marking or when it is technically or anatomically impossible or impractical to mark the site (for example, mucosal surfaces or perineum). Note: Examples of other situations that involve alternative processes include the following:
 - Minimal access procedures treating a lateralized internal organ, whether percutaneous or through a natural orifice
 - Teeth
 - · Premature infants, for whom the mark may cause a permanent tattoo

NPG.01.06.03

The critical access hospital performs a time-out before the procedure.

Element(s) of Performance for NPG.01.06.03

- 1. The critical access hospital conducts a time-out immediately before starting the invasive procedure or making the incision.
- 2. The time-out has the following characteristics:
 - It is standardized, as defined by the critical access hospital.
 - It is initiated by a designated member of the team.
 - It involves the immediate members of the procedure team, including the individual performing the procedure, the anesthesia providers, the circulating nurse, the operating room technician, and other active participants who will be participating in the procedure from the beginning.
- 3. When two or more procedures are being performed on the same patient, and the person performing the procedure changes, the critical access hospital performs a time-out before each procedure is initiated.
- 4. During the time-out, the team members agree, at a minimum, on the following:
 - · Correct patient identity
 - · The correct site
 - The procedure to be done
- 5. The critical access hospital documents the completion of the time-out.

 Note: The critical access hospital determines the amount and type of documentation.

NPG.02.01.01

The mission, vision, and goals guide the critical access hospital's actions.

Element(s) of Performance for NPG.02.01.01

1. The governing body, senior managers, and leaders of the organized medical staff work together to create the critical access hospital's mission, vision, and goals, which guide the leaders' actions. The mission, vision, and goals are communicated to staff and the population(s) served.

NPG.02.02.01

The critical access hospital addresses conflicts of interest and ethics.

Element(s) of Performance for NPG.02.02.01

- 1. The governing body, senior managers, and leaders of the organized medical staff work together to define in writing conflicts of interest that could affect safety and quality of care, treatment, and services.
- 2. The governing body, senior managers, and leaders of the organized medical staff work together to develop a written policy that defines how conflicts of interest will be addressed.
- 3. Conflicts of interest are disclosed as defined by the critical access hospital.
- 4. Senior managers and leaders of the organized medical staff work with the governing body to develop and implement an ongoing process for managing conflict among leadership groups that has the potential to adversely affect patient safety or quality of care.
- 5. The critical access hospital develops and implements a process that allows staff, patients, and families to address ethical issues or issues prone to conflict.

NPG.02.03.01

The critical access hospital's leaders design work processes to focus individuals on safety and quality issues.

Element(s) of Performance for NPG.02.03.01

- 1. The leaders implement a critical access hospitalwide patient safety program as follows:
 - One or more qualified individuals or an interdisciplinary group manage the safety program.
 - All departments, programs, and services within the critical access hospital participate in the safety program.
 - The scope of the safety program includes the full range of safety issues, from potential or no-harm errors (sometimes referred to as close calls ["near misses"] or good catches) to hazardous conditions and sentinel events.
- 2. The leaders encourage external reporting of significant adverse events, including voluntary reporting programs in addition to mandatory programs.
 - Note: Examples of voluntary programs include The Joint Commission Sentinel Event Database and the US Food and Drug Administration (FDA) MedWatch.
- As part of the safety program, the leaders create procedures for responding to system or process failures.
 Note: Responses might include continuing to provide care, treatment, and services to those affected, containing the risk to others, and preserving factual information for subsequent analysis.
- 4. The leaders provide and encourage the use of systems for internal reporting of a system or process failure, or the results of a proactive risk assessment, without the risk of retaliation.

Note: This EP is intended to minimize staff reluctance to report errors in order to help an organization understand the source and results of system and process failures. The EP does not conflict with holding individuals accountable for errors due to negligence.

- 5. The critical access hospital conducts thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events as described in the "Sentinel Event Policy" (SE) chapter of this manual.
- 6. The leaders make support systems available for staff who have been involved in an adverse or sentinel event. Note: Support systems recognize that health care workers who are involved in sentinel events may be negatively affected by the event and require support. Support systems provide staff with help and support as well as additional resources through the human resources function or an employee assistance program. Support systems also focus on the process rather than blaming the involved individuals.
- 7. At least every 18 months, the critical access hospital selects one high-risk process and conducts a proactive risk assessment.
 - Note: For suggested components, refer to the Proactive Risk Assessment section at the beginning of this chapter.
- 8. To improve safety and to reduce the risk of medical errors, the critical access hospital analyzes and uses information about system or process failures and the results of proactive risk assessments.
- 9. Communication processes are effective in doing the following:
 - · Fostering the safety of the patient and their quality of care
 - · Supporting a culture of safety and quality
 - · Meeting the needs of internal and external users
 - Informing those who work in the critical access hospital of changes in the environment
 - Disseminating lessons learned from comprehensive systematic analyses (for example, root cause analyses), system or process failures, and proactive risk assessments to all affected staff
- 10. Leaders evaluate the effectiveness of communication methods.
- 11. Leaders regularly evaluate the culture of safety and quality using valid and reliable tools. Possible issues are identified by the culture of safety evaluation. Proposed improvements are prioritized and implemented.
- 12. Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.
- 13. Leaders create and implement a process for managing behaviors that undermine a culture of safety.

NPG.02.04.01

The critical access hospital has a workplace violence prevention program.

Element(s) of Performance for NPG.02.04.01

- 1. The critical access hospital has a workplace violence prevention program led by a designated individual and developed by a multidisciplinary team that includes the following:
 - · Policies and procedures to prevent and respond to workplace violence
 - A process to report incidents in order to analyze incidents and trends
 - A process for follow up and support to victims and witnesses affected by workplace violence, including trauma and psychological counseling, if necessary
 - Reporting of workplace violence incidents to the governing body

- 2. As part of its workplace violence prevention program, the critical access hospital provides training, education, and resources (at time of hire, annually, and whenever changes occur regarding the workplace violence prevention program) to leaders, staff, and licensed practitioners. The critical access hospital determines what aspects of training are appropriate for individuals based on their roles and responsibilities. The training, education, and resources address prevention, recognition, response, and reporting of workplace violence as follows:
 - · What constitutes workplace violence
 - Education on the roles and responsibilities of leaders, clinical staff, security personnel, and external law enforcement
 - Training in de-escalation, nonphysical intervention skills, physical intervention techniques, and response to emergency incidents
 - The reporting process for workplace violence incidents
- 3. The critical access hospital conducts an annual worksite analysis related to its workplace violence prevention program. The critical access hospital takes actions to mitigate or resolve the workplace violence safety and security risks based on findings from the analysis.
 - Note: A worksite analysis includes a proactive analysis of the worksite, an investigation of the critical access hospital's workplace violence incidents, and an analysis of how the program's policies and procedures, training, education, and environmental design reflect best practices and conform to applicable laws and regulations.

NPG.03.01.01

Critical access hospital leadership provides oversight and support of the emergency management program.

Element(s) of Performance for NPG.03.01.01

- 1. The critical access hospital's senior leaders provide oversight and support for the following emergency management program activities:
 - · Allocation of resources for the emergency management program
 - Review of the emergency management program documents
 - Review of the emergency operations plan, policies and procedures, and training and education that support the emergency management program
 - Review of after-action reports (AAR) and improvement plans
 - Note 1: The critical access hospital defines who the members of the senior leadership group are as well as their roles and responsibilities for emergency management–related activities.
 - Note 2: An AAR provides a detailed critical summary or analysis of a planned exercise or actual emergency or disaster incident. The report summarizes what took place during the event, analyzes the actions taken by participants, and identifies areas needing improvement.
- 2. The critical access hospital's senior leaders identify a qualified individual to lead the emergency management program who has defined responsibilities that include, but are not limited to, the following:
 - · Developing and maintaining the emergency operations plan and policies and procedures
 - Implementing the four phases of emergency management (mitigation, preparedness, response, and recovery)
 - Implementing emergency management activities across the six critical areas (communications, staffing, patient clinical and support services, safety and security, resources and assets, and utilities)
 - Coordinating the emergency management exercises and developing after-action reports
 - · Collaborating across clinical and operational areas to implement organizationwide emergency management
 - Identifying and collaborating with community response partners

Note: Education, training, and experience in emergency management should be taken into account when considering the qualifications of the individual(s) who lead the program.

- 3. The critical access hospital has a multidisciplinary committee that oversees the emergency management program. The committee includes the emergency program lead and other participants identified by the critical access hospital; meeting frequency, goals, and responsibilities are defined by the committee.
 - Note 1: Other multidisciplinary committee participants may include representatives from senior leadership, nursing services, medical staff, pharmacy services, infection prevention and control, facilities engineering, security, and information technology.
 - Note 2: The multidisciplinary committee that oversees the emergency management program may be incorporated into an existing committee.
- 4. The multidisciplinary committee provides input and assists in the coordination of the preparation, development, implementation, evaluation, and maintenance of the critical access hospital's emergency management program. The activities include, but are not limited to, the following:
 - · Hazard vulnerability analysis
 - Emergency operations plan, policies, and procedures
 - · Continuity of operations plan
 - Training and education
 - Planning and coordinating incident response exercises (seminars; workshops; tabletop exercises; functional exercises; full-scale, community-based exercises)
 - · After-action reports and improvement plans

Note: An after-action report (AAR) provides a detailed critical summary or analysis of a planned exercise or actual emergency or disaster incident. The report summarizes what took place during the event, analyzes the actions taken by participants, and specifies areas needing improvement.

NPG.03.02.01

The critical access hospital develops an emergency operations plan based on an all-hazards approach.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazards vulnerability analysis when developing an emergency operations plan.

Element(s) of Performance for NPG.03.02.01

- The critical access hospital's incident command structure describes the overall incident command operations, including specific incident command roles and responsibilities. The incident command structure is flexible and scalable to respond to varying types and degrees of emergencies or disaster incidents.
 Note: The incident command structure may include facilities, equipment, staff, procedures, and communications within a defined organizational structure.
- 2. The critical access hospital identifies the individual(s) who has the authority to activate the critical access hospital's emergency operations plan and/or the critical access hospital's incident command.
- 3. The critical access hospital identifies its primary and alternate sites for incident command operations and determines how it will maintain and support operations at these sites.
 - Note 1: Alternate command center sites may include the use of virtual command centers.
 - Note 2: Maintaining and supporting operations at alternate sites include having appropriate supplies, resources, communications, and information technology capabilities.

NPG.03.02.02

The critical access hospital has a communications plan that addresses how it will initiate and maintain communications during an emergency.

Note: The critical access hospital considers prioritized hazards identified as part of its hazard vulnerability analysis when developing an emergency response communications plan.

Element(s) of Performance for NPG.03.02.02

- 1. The critical access hospital's communications plan describes how it will establish and maintain communications in order to deliver coordinated messages and information during an emergency or disaster incident to the following individuals:
 - Staff and volunteers (including individuals providing care at alternate sites)
 - · Patients and family members, including people with disabilities and other access and functional needs
 - Community partners (such as fire department, emergency medical services, police, public health department)
 - Relevant authorities (federal, state, tribal, regional, and local emergency preparedness staff)
 - · Media and other stakeholders

Note: Examples of means of communication include text messaging, phone system alerts, email, social media, and augmentative and alternative communication (AAC) for those with difficulties communicating using speech.

2. The emergency response communications plan identifies the critical access hospital's warning and notification alerts specific to emergency and disaster events and the procedures to follow when an emergency or disaster incident occurs.

NPG.03.02.03

The critical access hospital has a staffing plan for managing all staff and volunteers during an emergency or disaster incident.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a staffing plan.

Element(s) of Performance for NPG.03.02.03

- 1. The critical access hospital's staffing plan describes in writing how it will manage volunteer licensed practitioners when the emergency operations plan has been activated and the critical access hospital is unable to meet its patient needs. The critical access hospital does the following:
 - · Verifies and documents the identity of all volunteer licensed practitioners
 - Completes primary source verification of licensure as soon as the immediate situation is under control or within 72 hours from the time the volunteer licensed practitioner presents to the organization
 - Provides oversight of the care, treatment, and services provided by volunteer licensed practitioners Note: If primary source verification of licensure cannot be completed within 72 hours, the critical access hospital documents the reason(s) it could not be performed.
- 2. The critical access hospital identifies the individual(s) responsible for granting disaster privileges to volunteer physicians and other licensed practitioners and has a process for granting these privileges. This is documented in the medical staff bylaws, rules and regulations, or policies and procedures.
- 3. The emergency response staffing plan describes how it will provide employee assistance and support, which includes the following:
 - Staff support needs (for example, housing, transportation)
 - Family support needs of staff (for example, child care, elder care)
 - · Mental health and wellness needs

NPG.03.02.04

The critical access hospital has a plan for providing patient care and clinical support during an emergency or disaster incident.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a plan for patient care and clinical support.

Element(s) of Performance for NPG.03.02.04

- 1. The critical access hospital's plan for providing patient care and clinical support includes written procedures for managing individuals that may present during a disaster or emergency that are not in need of medical care (such as visitors).
- 2. The critical access hospital coordinates with the local medical examiner's office, local mortuary services, and other local, regional, or state services when there is a surge of unidentified or deceased patients.

NPG.03.02.05

The critical access hospital has a plan for safety and security measures to take during an emergency or disaster incident

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a plan for safety and security.

Element(s) of Performance for NPG.03.02.05

1. The critical access hospital has a plan for safety and security measures. The plan describes the roles that community security agencies (for example, police, sheriff, National Guard) will have in the event of an emergency and how the critical access hospital will coordinate security activities with these agencies.

NPG.03.02.06

The critical access hospital has a plan for managing resources and assets during an emergency or disaster incident. Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a plan for resources and assets.

Element(s) of Performance for NPG.03.02.06

- 1. The critical access hospital's plan for managing its resources and assets describes in writing the actions the critical access hospital will take to sustain the needs of the critical access hospital for up to 96 hours based on calculations of current resource consumptions.
 - Note 1: Critical access hospitals are not required to remain fully functional for 96 hours or stockpile 96 hours' worth of supplies.
 - Note 2: The 96-hour time frame provides a framework for critical access hospitals to evaluate their capability to be self-sufficient for at least 96 hours. For example, if a critical access hospital loses electricity and has backup generators, the emergency response plan for resources and assets establishes how much fuel is on hand and how long those generators can be operated before determining next steps. The plan may also address conservation of resources and assets, such as rationing existing resources, canceling noncritical procedures, or redirecting resources.

NPG.03.03.01

The critical access hospital has a disaster recovery plan.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing a disaster recovery plan.

Element(s) of Performance for NPG.03.03.01

- 1. The critical access hospital has a disaster recovery plan that describes in writing its strategies for when and how it will do the following:
 - · Conduct critical access hospitalwide damage assessments
 - · Restore critical systems and essential services
 - · Return to full operations
- The critical access hospital's disaster recovery plan describes in writing how the critical access hospital will
 address family reunification and coordinate with its local community partners to help locate and assist with the
 identification of adults and unaccompanied children.

NPG.03.04.01

The critical access hospital has an emergency management education and training program.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing education and training.

Element(s) of Performance for NPG.03.04.01

1. The critical access hospital requires that incident command staff participate in education and training specific to their duties and responsibilities in the incident command structure.

Note: The critical access hospital may choose to develop its own training, or it may require incident command staff to take an incident command–related course(s) such as those offered by the Federal Emergency Management Agency.

NPG.03.05.01

The critical access hospital plans and conducts exercises to test its emergency operations plan and response procedures.

Note: The critical access hospital considers its prioritized hazards identified as part of its hazard vulnerability analysis when developing emergency exercises.

Element(s) of Performance for NPG.03.05.01

 Each accredited freestanding outpatient care building that provides patient care, treatment, and services is required to conduct at least one operations-based or discussion-based exercise per year to test its emergency response procedures, if not conducted in conjunction with the critical access hospital's emergency exercises. Exercises and actual emergency or disaster incidents are documented.

NPG.03.06.01

The critical access hospital evaluates its emergency management program, emergency operations plan, and continuity of operations plans.

Element(s) of Performance for NPG.03.06.01

1. The after-action reports, identified opportunities for improvement, and recommended actions to improve the emergency management program are forwarded to senior critical access hospital leaders for review.

NPG.04.01.01

Improving health care equity for the critical access hospital's patients is a quality and safety priority.

Element(s) of Performance for NPG.04.01.01

- 1. The critical access hospital designates an individual(s) to lead activities to improve health care equity for the critical access hospital's patients.
 - Note: Leading the critical access hospital's activities to improve health care equity may be an individual's primary role or part of a broader set of responsibilities.
- 2. The critical access hospital assesses the patient's health-related social needs (HRSNs) and provides information about community resources and support services.
 - Note 1: Critical access hospitals determine which HRSNs to include in the patient assessment. Examples of a patient's HRSNs may include the following:
 - · Access to transportation
 - · Difficulty paying for prescriptions or medical bills
 - · Education and literacy
 - · Food insecurity
 - · Housing insecurity

Note 2: HRSNs may be identified for a representative sample of the critical access hospital's patients or for all the critical access hospital's patients.

- 3. The critical access hospital identifies health care disparities in its patient population by stratifying quality and safety data using the sociodemographic characteristics of the critical access hospital's patients.
 - Note 1: Critical access hospitals may focus on areas with known health care disparities identified in the scientific literature (for example, organ transplantation, maternal care, diabetes management) or select measures that affect all patients (for example, experience of care and communication).
 - Note 2: Critical access hospitals determine which sociodemographic characteristics to use for stratification analyses. Examples of sociodemographic characteristics may include the following:
 - Age
 - Gender
 - · Preferred language
 - Race and ethnicity
 - Veterans
 - · Patients in rural communities
 - · Physical, mental, and cognitive disabilities
- 4. The critical access hospital develops a written action plan that describes how it will improve health care equity by addressing at least one of the health care disparities identified in its patient population.
- 5. The critical access hospital acts when it does not achieve or sustain the goal(s) in its action plan to improve health care equity.
- 6. At least annually, the critical access hospital informs key stakeholders, including leaders, licensed practitioners, and staff, about its progress to improve health care equity.

NPG.05.01.01

The critical access hospital implements its infection prevention and control program through surveillance, prevention, and control activities.

Element(s) of Performance for NPG.05.01.01

- 1. To prioritize the program's activities, the critical access hospital identifies risks for infection, contamination, and exposure that pose a risk to patients and staff based on the following:
 - · Its geographic location, community, and population served
 - · The care, treatment, and services it provides
 - · The analysis of surveillance activities and other infection control data
 - Relevant infection control issues identified by the local, state, or federal public health authorities that could impact the critical access hospital

Note: Risks may include organisms with a propensity for transmission within health care facilities based on published reports and the occurrence of clusters of patients (for example, norovirus, respiratory syncytial virus, influenza, measles, organisms with antimicrobial resistance such as Carbapenem-resistant Enterobacterales [CRE] and Candida auris).

2. The critical access hospital reviews identified risks at least annually or whenever significant changes in risk occur.

NPG.05.02.01

The critical access hospital implements processes to support preparedness for high-consequence infectious diseases or special pathogens.

Element(s) of Performance for NPG.05.02.01

- 1. The critical access hospital develops and implements protocols for high-consequence infectious diseases or special pathogens. The protocols are readily available for use at the point of care and address the following:
 - Identify: Procedures for screening at the points of entry to the critical access hospital for respiratory symptoms, fever, rash, and travel history to identify or initiate evaluation for high-consequence infectious diseases or special pathogens
 - Isolate: Procedures for transmission-based precautions
 - · Inform: Procedures for informing public health authorities and key critical access hospital staff
 - · Required personal protective equipment and proper donning and doffing techniques
 - Infection control procedures to support continued and safe provision of care while the patient is in isolation and to reduce exposure among staff, patients, and visitors using the hierarchy of controls
 - Procedures for managing waste and cleaning and disinfecting patient care spaces, surfaces, and equipment Note 1: Points of entry may include the emergency department, urgent care, and ambulatory clinics. Note 2: See the Glossary for a definition of hierarchy of controls.
- 2. The critical access hospital develops and implements education and training and assesses competencies for staff who will implement protocols for high-consequence infectious diseases or special pathogens.

NPG.05.03.01

The critical access hospital complies with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines and/or the current World Health Organization (WHO) hand hygiene guidelines.

Element(s) of Performance for NPG.05.03.01

1. The critical access hospital implements a program that follows categories IA, IB, and IC of either the current Centers for Disease Control and Prevention (CDC) and/or the current World Health Organization (WHO) hand hygiene guidelines. The program sets goals for improving compliance with hand hygiene based on established goals.(See also IC.06.01.01, EP 3)

NPG.06.01.01

Pain assessment and pain management, including safe opioid prescribing, are identified as an organizational priority.

Element(s) of Performance for NPG.06.01.01

- 1. The critical access hospital has a leader or leadership team that is responsible for pain management and safe opioid prescribing, as well as developing and monitoring performance improvement activities.
- 2. The critical access hospital provides nonpharmacologic pain treatment modalities.
- 3. The critical access hospital provides staff with educational resources and programs to improve pain assessment, pain management, and the safe use of opioid medications based on the identified needs of its patient population.
- 4. The critical access hospital provides information to staff on available services for consultation and referral of patients with complex pain management needs.
- 5. The critical access hospital identifies opioid treatment programs that can be used for patient referrals.
- The critical access hospital facilitates licensed practitioner and pharmacist access to the Prescription Drug
 Monitoring Program databases.
 Note: This element of performance is applicable in any state that has a Prescription Drug Monitoring Program
 database, whether querying is voluntary or is mandated by state regulations for all patients prescribed opioids.
- 7. Critical access hospital leadership works with its clinical staff to identify and acquire the equipment needed to monitor patients who are at high risk for adverse outcomes from opioid treatment.

NPG.06.02.01

The critical access hospital assesses and manages the patient's pain and minimizes the risks associated with treatment.

Element(s) of Performance for NPG.06.02.01

- 1. The critical access hospital has defined criteria to screen, assess, and reassess pain that are consistent with the patient's age, condition, and ability to understand.
- 2. The critical access hospital screens patients for pain during emergency department visits and at the time of admission.
- The critical access hospital treats the patient's pain or refers the patient for treatment.
 Note: Treatment strategies for pain may include nonpharmacologic, pharmacologic, or a combination of approaches.

- 4. The critical access hospital develops a pain treatment plan based on evidence-based practices and the patient's clinical condition, past medical history, and pain management goals.
- 5. The critical access hospital involves the patient in the pain management treatment planning process through the following:
 - Developing realistic expectations and measurable goals that the patient understands for the degree, duration, and reduction of pain
 - Discussing the objectives used to evaluate treatment progress (for example, relief of pain and improved physical and psychosocial function)
 - Providing education on pain management, treatment options, and safe use of opioid and nonopioid medications when prescribed
- 6. The critical access hospital monitors patients identified as being high risk for adverse outcomes related to opioid treatment.
- 7. The critical access hospital reassesses and responds to the patient's pain through the following:
 - Evaluation and documentation of response(s) to pain intervention(s)
 - Progress toward pain management goals, including functional ability (for example, ability to take a deep breath, turn in bed, walk with improved pain control)
 - · Side effects of treatment
 - · Risk factors for adverse events caused by the treatment
- 8. The critical access hospital educates the patient and family on discharge plans related to pain management, including the following:
 - · Pain management plan of care
 - Side effects of pain management treatment
 - Daily living activities, including the home environment, that might exacerbate pain or reduce effectiveness of the pain management plan of care and strategies to address these issues
 - · Safe use, storage, and disposal of opioids when prescribed

NPG.06.03.01

The critical access hospital collects data on pain assessment and management.

Element(s) of Performance for NPG.06.03.01

1. The critical access hospital analyzes data collected on pain assessment and pain management to identify areas that need change to increase safety and quality for patients.

NPG.07.01.01

The critical access hospital respects the patient's right to receive information in a manner the patient understands.

Element(s) of Performance for NPG.07.01.01

- 1. The critical access hospital respects the patient's right to and need for effective communication.
- 2. The critical access hospital provides interpreting and translation services, as necessary.

 Note: For critical access hospitals that elect The Joint Commission Primary Care Medical Home option:

 Language interpreting options may include trained bilingual staff, contract interpreting services, or employed language interpreters. These options may be provided in person or via telephone or video. The documents translated, and the languages into which they are translated, are dependent on the primary care medical home's patient population.

3. The critical access hospital communicates with the patient who has vision, speech, hearing, or cognitive impairments in a manner that meets the patient's needs.

NPG.07.02.01

The critical access hospital honors the patient's right to give or withhold informed consent.

Element(s) of Performance for NPG.07.02.01

- 1. The critical access hospital develops and implements a written policy on informed consent that describes the following:
 - Specific care, treatment, and services that require informed consent
 - · Circumstances that would allow for exceptions to obtaining informed consent
 - · Process used to obtain informed consent
 - Physicians or other licensed practitioners permitted to conduct the informed consent discussion in accordance with law and regulation
 - · How informed consent is documented in the patient record

Note: Documentation may be recorded in a form, in progress notes, or elsewhere in the record.

- When a surrogate decision-maker may give informed consent
- 2. The informed consent process includes a discussion about the following:
 - · Patient's proposed care, treatment, and services.
 - Potential benefits, risks, and side effects of the patient's proposed care, treatment, and services; the likelihood of the patient achieving their goals; and any potential problems that might occur during recuperation.
 - Reasonable alternatives to the patient's proposed care, treatment, and services. The discussion encompasses risks, benefits, and side effects related to the alternatives and the risks related to not receiving the proposed care, treatment, and services.

NPG.07.03.01

The critical access hospital assesses the patient who may be a victim of possible abuse, neglect, and exploitation.

Element(s) of Performance for NPG.07.03.01

- The critical access hospital uses written criteria to identify those patients who may be victims of physical assault, sexual assault, sexual molestation, domestic abuse, elder or child abuse, neglect, and exploitation. Patients are evaluated upon entry into the critical access hospital and on an ongoing basis.
 Note: Criteria can be based on age, sex, and circumstance.
- 2. To assist with referrals of possible victims of abuse, neglect, and exploitation, the critical access hospital maintains a list of private and public community agencies that can provide or arrange for assessment and care.
- 3. The critical access hospital educates staff about how to recognize signs of possible abuse, neglect, and exploitation and about their roles in follow-up.
- 4. The critical access hospital internally reports cases of possible abuse, neglect, and exploitation.

NPG.07.04.01

The critical access hospital treats the patient in a dignified and respectful manner.

Element(s) of Performance for NPG.07.04.01

1. The critical access hospital respects the patient's cultural and personal values, beliefs, and preferences.

2. The critical access hospital accommodates the patient's right to religious and other spiritual services.

NPG.08.01.01

The critical access hospital reduces the risk for suicide.

Note: EPs 2–7 apply to patients in psychiatric distinct part units in critical access hospitals or patients being evaluated or treated for behavioral health conditions as their primary reason for care in critical access hospitals. In addition, EPs 3–7 apply to all patients who express suicidal ideation during the course of care.

Element(s) of Performance for NPG.08.01.01

1. For psychiatric distinct part units in critical access hospitals: The critical access hospital conducts an environmental risk assessment that identifies features in the physical environment that could be used to attempt suicide; the critical access hospital takes necessary action to minimize the risk(s) (for example, removal of anchor points, door hinges, and hooks that can be used for hanging).

For nonpsychiatric units in critical access hospitals: The organization implements procedures to mitigate the risk of suicide for patients at high risk for suicide, such as one-to-one monitoring, removing objects that pose a risk for self-harm if they can be removed without adversely affecting the patient's medical care, assessing objects brought into a room by visitors, and using safe transportation procedures when moving patients to other parts of the critical access hospital.

Note: Nonpsychiatric units in critical access hospitals do not need to be ligature resistant. Nevertheless, these facilities should routinely assess clinical areas to identify objects that could be used for self-harm and remove those objects, when possible, from the area around a patient who has been identified as high risk for suicide. This information can be used for training staff who monitor high-risk patients (for example, developing checklists to help staff remember which equipment should be removed when possible).

CoP(s): §482.13(c)(2)

 The critical access hospital screens all patients for suicidal ideation who are being evaluated or treated for behavioral health conditions as their primary reason for care using a validated screening tool.
 Note: The Joint Commission requires screening for suicidal ideation using a validated tool starting at age 12 and above.

CoP(s): §482.13(c)(2)

3. The critical access hospital uses an evidence-based process to conduct a suicide assessment of patients who have screened positive for suicidal ideation. The assessment directly asks about suicidal ideation, plan, intent, suicidal or self-harm behaviors, risk factors, and protective factors.

Note: EPs 2 and 3 can be satisfied through the use of a single process or instrument that simultaneously screens patients for suicidal ideation and assesses the severity of suicidal ideation.

CoP(s): §482.13(c)(2)

4. The critical access hospital documents patients' overall level of risk for suicide and the plan to mitigate the risk for suicide.

CoP(s): §482.13(c)(2)

- 5. The critical access hospital follows written policies and procedures addressing the care of patients identified as at risk for suicide. At a minimum, these should include the following:
 - · Training and competence assessment of staff who care for patients at risk for suicide
 - · Guidelines for reassessment
 - Monitoring patients who are at high risk for suicide

CoP(s): §482.13(c)(2)

- 6. The critical access hospital follows written policies and procedures for counseling and follow-up care at discharge for patients identified as at risk for suicide.
- 7. The critical access hospital monitors implementation and effectiveness of policies and procedures for screening, assessment, and management of patients at risk for suicide and takes action as needed to improve compliance.

CoP(s): §482.13(c)(2)

NPG.09.01.01

The critical access hospital uses standardized procedures for managing tissues.

Element(s) of Performance for NPG.09.01.01

- 1. The critical access hospital develops and implements standardized written procedures for the acquisition, receipt, storage, and issuance of tissues.
- 2. The critical access hospital confirms that tissue suppliers are registered with the US Food and Drug Administration (FDA) as a tissue establishment and maintain a state license when required.
 - Note 1: This element of performance does not apply to autologous tissue- or cellular-based products considered tissue for the purposes of these standards but classified as medical devices by the FDA.
 - Note 2: The supplier's FDA registration status may also be checked annually by using the FDA's online database: https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/find-tissue-establishment.
- 3. The critical access hospital follows the tissue suppliers' or manufacturers' written directions for transporting, handling, storing, and using tissue.
- 4. The critical access hospital maintains daily records to demonstrate that tissues requiring a controlled environment are stored at the required temperatures.
 - Note 1: Types of tissue storage include room temperature, refrigerated, frozen (for example, deep freezing colder than -40°C), and liquid nitrogen storage.
 - Note 2: Tissues requiring no greater control than "ambient temperature" (defined as the temperature of the immediate environment) for storage would not require temperature monitoring.
- 5. The critical access hospital continuously monitors the temperature of refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues.
 - Note 1: Continuous temperature recording is not required but may be available with some continuous temperature monitoring systems.
 - Note 2: For tissue stored at room temperature, continuous temperature monitoring is not required.
- 6. Refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues at a controlled temperature have functional alarms and an emergency backup plan.
 - Note: For tissue stored at room temperature, alarm systems are not required.

NPG.09.02.01

The critical access hospital traces all tissues bi-directionally.

Element(s) of Performance for NPG.09.02.01

- 1. The critical access hospital's records allow any tissue to be traced from the donor or tissue supplier to the recipient(s) or other final disposition, including discard, and from the recipient(s) or other final disposition back to the donor or tissue supplier.
- 2. The critical access hospital identifies, in writing, the materials and related instructions used to prepare or process tissues.

NPG.09.03.01

The critical access hospital investigates adverse events related to tissue use or donor infections.

Element(s) of Performance for NPG.09.03.01

- 1. The critical access hospital has a written procedure to investigate tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue. The procedure includes the following at a minimum:
 - Investigating disease transmission or other complications that are suspected of being directly related to the use of tissue
 - Reporting of a post-transplant infection or adverse event related to the use of tissue to the tissue supplier as soon as the critical access hospital becomes aware
 - Sequestering of tissue whose integrity may have been compromised or that is reported by the tissue supplier as a suspected cause of infection
 - Identifying and informing tissue recipients of infection risk when donors are subsequently found to have human immunodeficiency virus (HIV), human T-lymphotropic virus-I/II (HTLV-I/II), viral hepatitis, or other infectious agents known to be transmitted through tissue

NPG.10.01.01

Policies and procedures for waived tests are established, current, approved, and readily available.

Element(s) of Performance for NPG.10.01.01

- 1. The person from the critical access hospital whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, establishes written policies and procedures for waived testing that address the following:
 - · Clinical usage and limitations of the test methodology
 - Need for confirmatory testing (for example, recommendations made by the manufacturer for rapid tests) and result follow-up recommendations (for example, a recommendation to repeat the test when results are higher or lower than the reportable range of the test)
 - · Specimen type, collection, and identification, and required labeling
 - · Specimen preservation, if applicable
 - Instrument maintenance and function checks, such as calibration
 - Storage conditions for test components
 - · Reagent use, including not using a reagent after its expiration date
 - · Quality control (including frequency and type) and corrective action when quality control is unacceptable
 - · Test performance
 - · Result reporting, including not reporting individual patient results unless quality control is acceptable
 - Equipment performance evaluation

- Note 1: Policies and procedures for waived testing are made available to testing personnel.
- Note 2: The designee should be knowledgeable by virtue of training, experience, and competence about the waived testing performed.
- 2. Policies or procedures for each waived test are consistent with manufacturers' instructions for use and include specific operational policies (that is, detailed quality control protocols and any other institution-specific procedures regarding the test or instrument).

NPG.10.02.01

Staff performing waived tests are competent.

Element(s) of Performance for NPG.10.02.01

- 1. Staff who perform waived testing have been trained for each test that they are authorized to perform. The training for each waived test is documented.
 - Note: This includes training on the use and maintenance of instruments.
- 2. Competence for waived testing is assessed according to critical access hospital policy at defined intervals, but at least at the time of orientation and annually thereafter. Competency is assessed using at least two of the following methods per person per test:
 - Performance of a test on a blind specimen
 - · Periodic observation of routine work by the supervisor or qualified designee
 - · Monitoring of each user's quality control performance
 - · Use of a written test specific to the test assessed

This competency is documented.

Note 1: When a licensed practitioner performs waived testing that does not involve an instrument and the test falls within their specialty, the critical access hospital may use the medical staff credentialing and privileging process to document evidence of training and competency in lieu of annual competency assessment. In this circumstance, individual privileges include the specific waived tests appropriate to the scope of practice that they are authorized to perform. At the discretion of the person from the critical access hospital whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate or according to critical access hospital policy, more stringent competency requirements may be implemented.

Note 2: Provider-performed microscopy (PPM) procedures are not waived tests.

NPG.11.01.01

The critical access hospital manages security risks.

Element(s) of Performance for NPG.11.01.01

- 1. The critical access hospital controls access to and from areas it identifies as security sensitive.
- 2. The critical access hospital develops and implements written policies and procedures to follow in the event of a security incident, including an infant or pediatric abduction.
- 3. The critical access hospital develops and implements a process(es) for continually monitoring, internally reporting, and investigating the following:
 - · Injuries to patients or others within the critical access hospital's facilities and grounds
 - · Occupational illnesses and staff injuries
 - Incidents of damage to its property or the property of others
 - Safety and security incidents involving patients, staff, or others within its facilities, including those related to workplace violence
 - · Hazardous materials and waste spills and exposures

- · Fire safety management problems, deficiencies, and failures
- · Medical or laboratory equipment management problems, failures, and use errors
- Utility systems management problems, failures, or use errors

Note 1: All the incidents and issues listed above may be reported to staff in quality assessment, improvement, or other functions. A summary of such incidents may also be shared with the person designated to coordinate safety management activities.

Note 2: Review of incident reports often requires that legal processes be followed to preserve confidentiality. Opportunities to improve care, treatment, and services, or to prevent similar incidents, are not lost as a result of following the legal process.

- 4. The critical access hospital coordinates administrative and clinical decisions for patients under legal or correctional restrictions on the following:
 - · Use of seclusion and restraint for nonclinical purposes
 - · Imposition of disciplinary restrictions
 - · Restriction of rights
 - · Plan for discharge and continuing care, treatment, and services
 - Length of stay

NPG.11.02.01

The critical access critical access hospital assesses and manages the patient's risks for falls.

Element(s) of Performance for NPG.11.02.01

1. The critical access hospital implements fall risk reduction interventions based on the patient population, setting, and individual patient's assessed risks.

NPG.11.03.01

The critical access hospital manages utility systems.

Element(s) of Performance for NPG.11.03.01

- The critical access hospital develops and implements written procedures for responding to utility system disruptions. The procedures include but are not limited to shutting off a malfunctioning system and notifying staff in the affected areas.
- 2. The critical access hospital develops and implements a policy to provide emergency backup for essential medication dispensing equipment identified by the critical access hospital, such as automatic dispensing cabinets, medication carousels, and central medication robots.
 - Note: Examples of emergency backup can include emergency power, battery-based indoor generators, or other actions describing how dispensing and administration of medications will continue when emergency backup is needed.
- 3. The critical access hospital develops and implements a policy to provide emergency backup for essential refrigeration for medications identified by the critical access hospital, such as designated refrigerators and freezers.
 - Note: Examples of emergency backup can include emergency power, battery-based indoor generators, or other actions describing how refrigeration of medications will continue when emergency backup is needed.

NPG.11.04.01

The critical access hospital safely prepares and stores food and nutrition products.

Element(s) of Performance for NPG.11.04.01

1. The critical access hospital prepares and stores food and nutrition products (including those brought in by patients or their families) using proper sanitation.

NPG.12.01.01

The critical access hospital's leadership team ensures that there is qualified ancillary staff required to meet the needs of the population served and determine how they function within the organization.

Element(s) of Performance for NPG.12.01.01

1. Leaders provide for an adequate number and mix of qualified individuals to support safe, quality care, treatment, and services.

Note 1: The number and mix of individuals is appropriate to the scope and complexity of the services offered. Services may include but are not limited to the following:

- · Rehabilitation services
- · Emergency services
- · Outpatient services
- Respiratory services
- · Pharmaceutical services, including emergency pharmaceutical services
- Diagnostic and therapeutic radiology services

Note 2: Emergency services staff are qualified in emergency care.

Note 3: For rehabilitation and psychiatric distinct part units in critical access hospitals: As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date.

CoP(s): §412.25(a)(13), §412.27(d)(6)(ii), §482.25(a)(2), §482.26, §482.26(a), §482.54(b)(2), §482.55(b)(2), §482.57(a)(2), §485.631(a)(3), §485.635(b)(3)

2. Staff that provide care, treatment, and services meet the personnel qualifications required by the Centers for Medicare & Medicaid Services' (CMS) regulations at 42 CFR 485.604.

Note: The following terms are defined in the Glossary: clinical nurse specialist, nurse practitioner, physician assistant.

3. The critical access hospital has a professional health care staff that includes one or more doctors of medicine or osteopathy and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

CoP(s): §485.631(a)(1)

4. A doctor of medicine or osteopathy, physician's assistant, nurse practitioner, or clinical nurse specialist is available to provide patient care at all times when the critical access hospital is in operation.

CoP(s): §485.631(a)(4)

5. A doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist with training or experience in emergency care is on call and immediately available by telephone or radio contact, and they are available on site within 30 minutes, 24 hours a day, 7 days a week.

Note: If all of the following criteria are met, these practitioners are available on site within 60 minutes:

- The critical access hospital is located in an area designated as a frontier (that is, an area with fewer than six residents per square mile based on the latest population data published by the US Census Bureau) or in an area that meets the criteria for a remote location adopted by the state in its rural health care plan and approved by the Centers for Medicare & Medicaid Services (CMS) under section 1820(b) of the Social Security Act.
- The state has determined under criteria in its rural health plan that allowing an emergency response time longer than 30 minutes is the only feasible method for providing emergency care to residents of the area served by the critical access hospital.
- The state maintains documentation showing that the response time of up to 60 minutes at a particular designated critical access hospital is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

CoP(s): §485.618(d)(1), §485.618(d)(1)(i), §485.618(d)(1)(ii)(A), §485.618(d)(1)(ii)(B), §485.618(d)(1)(ii)(C)

6. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has a medical record service that has administrative responsibility for medical records. The critical access hospital employs adequate staff to support the prompt completion, filing, and retrieval of records.

CoP(s): §482.24(a)

7. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has dietetic services that are directed and adequately staffed by qualified personnel. Note: For critical access hospitals that provide dietetic services through contracted services, the contracted service has a dietician who serves the critical access hospital full-time, part-time, or on a consultant basis and acts as a liaison to critical access hospital medical staff for recommendations on dietetic policies that affect

patient care, treatment, and services.

CoP(s): §482.28

8. The critical access hospital has a full-time employee, qualified through education, training, or experience, who serves as director to oversee the daily management of food and dietetic services.

CoP(s): §482.28(a)(1)(i), §482.28(a)(1)(ii), §482.28(a)(1)(iii)

9. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has a qualified dietitian on a full-time, part-time, or consultative basis.

CoP(s): §482.28(a)(2)

10. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has a pharmacy that is directed by a registered pharmacist. If the critical access hospital does not have a pharmacy, it has a drug storage area under competent supervision, as defined by the critical access hospital.
Note: The pharmacy or drug storage area is administered in accordance with accepted professional principles.

CoP(s): §482.25

11. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has a full-time, part-time, or consulting pharmacist who is responsible for developing, supervising, and coordinating all pharmacy services activities.

CoP(s): §482.25(a)(1)

12. The critical access hospital's governing body, or responsible individual, based on the recommendation of the medical staff and nursing leaders, appoints an infection preventionist(s) or infection control professional(s) qualified through education, training, experience, or certification in infection prevention to be responsible for the infection prevention and control program.

CoP(s): §482.42(a)(1), §485.640(a)(1)

- 13. For rehabilitation and psychiatric distinct part units in critical access hospitals: The surgical services include but are not limited to the following staff:
 - An experienced registered nurse or doctor of medicine or osteopathy who supervises the operating rooms
 - Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) who serve as scrub nurses, if under the supervision of a registered nurse
 - · Qualified registered nurses who perform circulating duties in the operating room

Note: In accordance with applicable state laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

CoP(s): §482.51(a)(1), §482.51(a)(2), §482.51(a)(3)

NPG.12.02.01

The nurse executive directs the implementation of a nurse staffing plan(s).

Element(s) of Performance for NPG.12.02.01

- 1. The nurse executive, who is a licensed registered nurse, is responsible for the operation of nursing services, including determining the following:
 - · Nursing policies and procedure
 - · Types and numbers of nursing and other staff necessary to provide nursing care for all areas of the hospital

CoP(s): §482.23(a)

- 2. The nurse executive assumes an active leadership role with the critical access hospital's governing body, senior leadership, medical staff, management, and other clinical leaders in the critical access hospital's decision-making structure and process.
 - Note 1: The nurse executive possesses a postgraduate degree in nursing or a related field, the knowledge and skills associated with an advanced degree, or a written plan to obtain these qualifications.
 - Note 2: A related field may include health care administration or business administration.
- 3. A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the critical access hospital has one or more inpatients.

CoP(s): §485.631(a)(5)

4. A registered nurse provides (or assign to other staff) the nursing care of each patient, including patients at a skilled nursing facility level of care in a swing-bed critical access hospital. The care is provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available. Note 1: For rehabilitation and psychiatric distinct part units in critical access hospitals: A registered nurse directly provides or supervises the nursing services provided by other staff to patients 24 hours a day, 7 days a week. The critical access hospital has a licensed practical nurse or registered nurse on duty at all times. Note 2: For rehabilitation and psychiatric distinct part units in critical access hospitals: Rural hospitals with a 24-hour nursing waiver granted under 42 CFR 488.54(c) are not required to have 24-hour nursing services.

CoP(s): §482.23, §482.23(b)(1), §485.635(d)(1)

5. For rehabilitation and psychiatric distinct part units in critical access hospitals: There is an adequate number of licensed registered nurses, licensed practical (vocational) nurses, and other staff to provide nursing care to all patients.

Note: To make certain the immediate availability of a registered nurse for the care of any patient, there are supervisors and staff for each department or nursing unit.

CoP(s): §482.23(b)

6. For psychiatric distinct part units in critical access hospitals: The director of psychiatric nursing is a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing or is qualified by education and experience in the care of the mentally ill. The director of psychiatric nursing demonstrates competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care provided.

CoP(s): §412.27(d)(3), §412.27(d)(3)(i)

- 7. For rehabilitation and psychiatric distinct part units in critical access hospitals: The hospital has policies and procedures that establish which outpatient departments, if any, are not required to have a registered nurse present. The policies and procedures meet the following requirements:
 - Establish criteria that such outpatient departments need to meet, taking into account the types of services provided, the general level of acuity of patients served by the department, and established standards of practice for the services provided
 - · Describe alternative staffing plans
 - · Are approved by the nurse executive

Are reviewed at least once every three years

CoP(s): §482.23(b)(7), §482.23(b)(7)(i), §482.23(b)(7)(ii), §482.23(b)(7)(iii), §482.23(b)(7)(iv)

- 8. A registered nurse satisfies the personnel availability requirements in 42 CFR 485.618(d)(1) for a temporary period if all of the following conditions are met:
 - The critical access hospital has no more than 10 beds.
 - The critical access hospital is located in an area designated as a frontier area or remote location as described in 42 CFR 485.618(d)(1)(ii)(A).
 - The state in which the critical access hospital is located submits a letter to the Centers for Medicare & Medicaid Services (CMS) signed by the governor, following consultation on the issue of using registered nurses on a temporary basis as part of its state rural health care plan with the state boards of medicine and nursing and in accordance with state law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in 42 CFR 485.618(d)(1). The letter from the governor attests that they have consulted with the state boards of medicine and nursing about issues related to access to and the quality of emergency services in the state. The letter from the governor also describes the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in 42 CFR 485.618(d)(1).
 - Once the governor submits a letter, the critical access hospital submits documentation to the state survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in 42 CFR 485.618(d).

Note: The critical access hospital's request for using registered nurses on a temporary basis or its withdrawal of this request can be submitted to CMS at any time and is effective upon submission.

CoP(s): §485.618(d)(3)(i), §485.618(d)(3)(ii), §485.618(d)(3)(iii), §485.618(d)(3)(iv), §485.618(d)(4)

9. The nurse executive is responsible for monitoring the effectiveness of the nurse staffing plan.

NPG.12.03.01

For psychiatric distinct part units in critical access hospitals: The critical access hospital develops and implements staffing plans according to law and regulation.

Element(s) of Performance for NPG.12.03.01

2. For psychiatric distinct part units in critical access hospitals: The critical access hospital makes certain a registered professional nurse is available 24 hours a day.

CoP(s): §412.27(d)(3)(ii)

3. For psychiatric distinct part units in critical access hospitals: The number of qualified therapists, support personnel, and consultants is adequate to provide therapeutic activities consistent with each patient's active treatment program.

CoP(s): §412.27(d)(6)(ii)

4. For psychiatric distinct part units in critical access hospitals: There is an adequate number of qualified professional, technical, and consultative staff (including but not limited to doctors of medicine and/or osteopathy, registered nurses, licensed practical nurses, and mental health workers) to do the following:

- · Evaluate patients
- Formulate written individualized, comprehensive treatment plans
- · Provide active treatment measures
- · Engage in discharge planning
- · Provide the nursing care necessary under each patient's active treatment program
- · Maintain progress notes on each patient
- · Provide essential psychiatric services

CoP(s): $\S412.27(d)$, $\S412.27(d)(1)(i)$, $\S412.27(d)(1)(ii)$, $\S412.27(d)(1)(iii)$, $\S412.27(d)(1)(iii)$, $\S412.27(d)(1)(iv)$, $\S412.27(d)(3)$, $\S412.27(d)(3)(ii)$

- 6. For psychiatric distinct part units in critical access hospitals: The critical access hospital has a director of social services who monitors and evaluates the quality and appropriateness of social services provided. Social services staff responsibilities include but are not limited to the following:
 - · Participating in discharge planning
 - · Arranging for follow-up care
 - Developing mechanisms for the exchange of appropriate information with sources outside the critical access hospital

Note: Social services are provided in accordance with accepted standards of practice and established policies and procedures.

CoP(s): §412.27(d)(5)

NPG.12.04.01

The critical access hospital verifies that staff complete all requirements for employment and practice within their scope of practice.

Element(s) of Performance for NPG.12.04.01

- 1. The critical access hospital obtains a criminal background check on the applicant as required by law and regulation or critical access hospital policy. Criminal background checks are documented.
- 2. Staff comply with applicable health screening as required by law and regulation or critical access hospital policy. Health screening compliance is documented.
- 3. Staff who provide patient care, treatment, and services practice within the scope of their license, certification, or registration, in accordance with law and regulation.

NPG.12.05.01

The critical access hospital provide education and training and evaluates staff competence.

Element(s) of Performance for NPG.12.05.01

- 1. The critical access hospital orients staff on the following:
 - · Relevant hospitalwide and unit-specific policies and procedures

- Their specific job duties, including those related to infection prevention and control and assessing and managing pain
- · Sensitivity to cultural diversity based on their job duties and responsibilities
- Patient rights, including ethical aspects of care, treatment, or services and the process used to address ethical issues based on their job duties and responsibilities

 Completion of this orientation is documented.
- 2. The critical access hospital evaluates staff performance once every three years, or more frequently as required by critical access hospital policy or in accordance with law and regulation. Staff are evaluated based on performance expectations that reflect their job responsibilities. This evaluation is documented.

NPG.13.01.01

The critical access hospital defines and verifies qualifications and education requirements for imaging services staff.

Element(s) of Performance for NPG.13.01.01

- 1. Technologists who perform diagnostic computed tomography (CT) exams have advanced-level certification by the American Registry of Radiologic Technologists (ARRT) or the Nuclear Medicine Technology Certification Board (NMTCB) in computed tomography or have one of the following qualifications:
 - State licensure that permits them to perform diagnostic CT exams and documented training on the provision of diagnostic CT exams
 - Registration and certification in radiography by ARRT and documented training on the provision of diagnostic CT exams
 - Certification in nuclear medicine technology by ARRT or NMTCB and documented training on the provision of diagnostic CT exams
 - Note 1: This element of performance does not apply to CT exams performed for therapeutic radiation treatment planning or delivery or for calculating attenuation coefficients for nuclear medicine studies.
 - Note 2: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.
- 2. The critical access hospital verifies and documents that diagnostic medical physicists who support computed tomography (CT) services have board certification in diagnostic radiologic physics or radiologic physics by the American Board of Radiology, or in diagnostic imaging physics by the American Board of Medical Physics, or in diagnostic radiological physics by the Canadian College of Physicists in Medicine, or meet all of the following requirements:
 - A graduate degree in physics, medical physics, biophysics, radiologic physics, medical health physics, or a closely related science or engineering discipline from an accredited college or university
 - College coursework in the biological sciences with at least one course in biology or radiation biology and one course in anatomy, physiology, or a similar topic related to the practice of medical physics
 - Documented experience in a clinical CT environment conducting at least 10 CT performance evaluations under the direct supervision of a board-certified medical physicist
 - Note: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.
- 3. The critical access hospital verifies and documents that individuals who perform diagnostic computed tomography (CT) examinations participate in ongoing education that includes annual training on the following:
 - Radiation dose optimization techniques and tools for pediatric and adult patients addressed in the Image Gently® and Image Wisely® campaigns
 - · Safe procedures for operation of the types of CT equipment they will use

Note 1: Information on the Image Gently and Image Wisely initiatives can be found online at https://www.imagegently.org and https://www.imagewisely.org, respectively.

Note 2: This element of performance does not apply to CT systems used for therapeutic radiation treatment planning or delivery or for calculating attenuation coefficients for nuclear medicine studies.

Note 3: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

- 4. The critical access hospital verifies and documents that technologists who perform magnetic resonance imaging (MRI) examinations participate in ongoing education, including annual training on safe MRI practices in the MRI environment that addresses the following:
 - Patient screening criteria that address ferromagnetic items, electrically conductive items, medical implants and devices, and risk for nephrogenic systemic fibrosis (NSF)
 - Proper patient and equipment positioning activities to avoid thermal injuries
 - Equipment and supplies that have been determined to be acceptable for use in the MRI environment (MR safe or MR conditional)
 - · MRI safety response procedures for patients who require urgent or emergent medical care
 - MRI system emergency shutdown procedures, such as MRI system quench and cryogen safety procedures
 - Patient hearing protection
 - · Management of patients with claustrophobia, anxiety, or emotional distress

Note: Terminology for defining the safety of items in the magnetic resonance environment is provided in ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (http://www.astm.org).

NPG.13.02.01

The critical access hospital's imaging services have a designated leader and follow current safe imaging practices.

Element(s) of Performance for NPG.13.02.01

- 1. The critical access hospital designates an individual to serve as the radiation safety officer who is responsible for making certain that radiologic services are provided in accordance with law, regulation, and critical access hospital policy. This individual has the necessary authority and leadership support to do the following:
 - Monitor and verify compliance with established radiation safety practices (including oversight of dosimetry monitoring)
 - · Provide recommendations for improved radiation safety
 - · Intervene as needed to stop unsafe practices
 - Implement corrective action
- 2. The critical access hospital provides radiology services that meet safety standards approved by nationally recognized professional organizations. At a minimum, diagnostic radiology services are maintained and available at all times the critical access hospital provides services, including emergency services.
 Note: If the critical access hospital also provides other radiology services, such as therapeutic radiology, the requirements of this element of performance also apply to those services.
- 3. The critical access hospital establishes or adopts diagnostic computed tomography (CT) imaging protocols based on current standards of practice, which address key criteria including the following:
 - Clinical indication
 - · Contrast administration
 - Age (to indicate whether the patient is pediatric or an adult)
 - · Patient size and body habitus
 - · Expected radiation dose index range

Note: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

4. Diagnostic computed tomography (CT) imaging protocols are reviewed and kept current with input from an interpreting physician, medical physicist, and lead imaging technologist to make certain that they adhere to current standards of practice and account for changes in CT imaging equipment. These reviews are conducted at time frames identified by the critical access hospital. (For rehabilitation and psychiatric distinct part units in critical access hospitals, refer to MS.17.01.03, EP 5 for supervision of radiologic services)
Note: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

NPG.13.03.01

The critical access hospital manages imaging safety risks.

Element(s) of Performance for NPG.13.03.01

- 1. The critical access hospital manages magnetic resonance imaging (MRI) safety risks associated with the following:
 - · Patients who may experience claustrophobia, anxiety, or emotional distress
 - Patients who may require urgent or emergent medical care
 - Patients with medical implants, devices, or imbedded metallic foreign objects (such as shrapnel)
 - Ferromagnetic objects entering the MRI environment
 - · Acoustic noise
- 2. The critical access hospital manages magnetic resonance imaging (MRI) safety risks by doing the following:
 - Restricting access of everyone not trained in MRI safety or screened by staff trained in MRI safety from the scanner room and the area that immediately precedes the entrance to the MRI scanner room.
 - Making sure that these restricted areas are controlled by and under the direct supervision of staff trained in MRI safety.
 - Posting signage at the entrance to the MRI scanner room that conveys that potentially dangerous magnetic fields are present in the room. Signage should also indicate that the magnet is always on except in cases where the MRI system, by its design, can have its magnetic field routinely turned on and off by the operator.
- 3. For critical access hospitals that provide computed tomography (CT), positron emission tomography (PET), nuclear medicine (NM), or fluoroscopy services: The radiation safety officer, diagnostic medical physicist, or health physicist reviews the results of dosimetry monitoring at least quarterly to assess whether staff radiation exposure levels are "as low as reasonably achievable" (ALARA) and below regulatory limits.
 Note 1: For the definition of ALARA, please refer to US Nuclear Regulatory Commission federal regulation 10 CFR 20.1003.
 - Note 2: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.
- 4. For diagnostic computed tomography (CT) services: At least annually, a diagnostic medical physicist does the following:
 - Measures the radiation dose (in the form of volume computed tomography dose index [CTDIvol]) produced by each diagnostic CT imaging system for the following four CT protocols: adult brain, adult abdomen, pediatric brain, and pediatric abdomen. If one or more of these protocols is not used by the critical access hospital, other commonly used CT protocols may be substituted.

 Verifies that the radiation dose (in the form of CTDIvol) produced and measured for each protocol tested is within 20 percent of the CTDIvol displayed on the CT console. The dates, results, and verifications of these measurements are documented.

Note 1: This element of performance is only applicable for systems capable of calculating and displaying radiation doses.

Note 2: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

Note 3: Medical physicists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the physicist. (For more information, refer to HR.11.01.03, EP 1; HR.11.02.01, EP 2; NPG.12.04.01, EP 3)

- 5. For diagnostic computed tomography (CT) services: At least annually, a diagnostic medical physicist conducts a performance evaluation of all CT imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes the use of phantoms to assess the following imaging metrics:
 - · Image uniformity
 - · Scout prescription accuracy
 - · Alignment light accuracy
 - · Table travel accuracy
 - · Radiation beam width
 - · High-contrast resolution
 - · Low-contrast detectability
 - · Geometric or distance accuracy
 - · CT number accuracy and uniformity
 - Artifact evaluation

Note 1: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

Note 2: Medical physicists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the physicist. (For more information, refer to HR.11.01.03, EP 1; HR.11.02.01, EP 2; NPG.12.04.01, EP 3)

- 6. At least annually, a diagnostic medical physicist or magnetic resonance imaging (MRI) scientist conducts a performance evaluation of all MRI imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes the use of phantoms to assess the following imaging metrics:
 - · Image uniformity for all radiofrequency (RF) coils used clinically
 - · Signal-to-noise ratio (SNR) for all coils used clinically
 - · Slice thickness accuracy
 - · Slice position accuracy
 - Alignment light accuracy
 - · High-contrast resolution
 - Low-contrast resolution (or contrast-to-noise ratio)
 - · Geometric or distance accuracy
 - · Magnetic field homogeneity
 - Artifact evaluation

Note: Medical physicists or MRI scientists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the medical physicist or MRI scientist. (For more information, refer to HR.11.01.03, EP 1; HR.11.02.01, EP 2; NPG.12.04.01, EP 3)

NPG.13.04.01

The critical access hospital monitors quality improvement projects related to imaging safety.

Element(s) of Performance for NPG.13.04.01

- 1. The critical access hospital collects data on the following:
 - · Patient perception of the safety and quality of care, treatment, or services
 - · Patient thermal injuries that occur during magnetic resonance imaging (MRI) exams
 - · Incidents where ferromagnetic object unintentionally entered the MRI scanner room
 - · Injuries resulting from the presence of ferromagnetic objects in the MRI scanner room
 - Data on pain assessment and pain management, including types of interventions and effectiveness
 - Surgeries in which the postoperative diagnosis (clinical or pathological) was unexpected and could indicate that a clinically significant diagnostic error occurred

Note: The critical access hospital's medical staff determine which unexpected postoperative diagnoses are clinically significant. Examples may include but are not limited to the following:

- A preoperative pathology or cytology report was interpreted as a malignancy, but no malignancy was found in the surgical specimen.
- A patient underwent surgery for acute appendicitis, but the appendix was normal on the postsurgical pathology exam.
- An operation was performed because of a presumed malignancy based on a radiology report, but no malignancy was found.
- 2. The critical access hospital reviews and analyzes incidents where the radiation dose index (computed tomography dose index [CTDIvol], dose length product [DLP], or size-specific dose estimate [SSDE]) from diagnostic CT examinations exceeded expected dose index ranges identified in imaging protocols. These incidents are then compared to external benchmarks.
 - Note 1: While the CTDIvol, DLP, and SSDE are useful indicators for monitoring radiation dose indices from the CT machine, they do not represent the patient's radiation dose.
 - Note 2: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

NPG.14.01.01

The critical access hospital safely manages pharmaceutical services.

Element(s) of Performance for NPG.14.01.01

- 1. When an on-site pharmacy is not open 24 hours a day, 7 days a week, the following occurs:
 - A health care professional, who the critical access hospital determines is qualified , reviews the medication order in the pharmacist's absence
 - A pharmacist conducts a retrospective review of all medication orders during this period as soon as a pharmacist is available or the pharmacy opens
- 2. When automatic dispensing cabinets (ADCs) are used, the critical access hospital develops and implements a policy that describes the types of medication overrides that will be reviewed for appropriateness and the frequency of the reviews. A 100% review of overrides is not required.

NPG.14.02.01

The critical access hospital selects and procures medications.

Element(s) of Performance for NPG.14.02.01

- 1. The critical access hospital standardizes and limits the number of drug concentrations available to meet patient care needs.
- 2. The critical access hospital follows a process to communicate medication shortages and outages to staff who participate in medication management.
- 3. The critical access hospital follows written medication substitution protocols to be used in the event of a medication shortage or outage and communicates the medication substitution protocols for shortages or outages to all affected staff.

NPG.14.03.01

The critical access hospital labels all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings.

Note: Medication containers include syringes, medicine cups, and basins.

Element(s) of Performance for NPG.14.03.01

- 1. In perioperative and other procedural settings both on and off the sterile field, the critical access hospital labels medications and solutions that are not immediately administered. This applies even if there is only one medication being used.
 - Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.
- 2. In perioperative and other procedural settings both on and off the sterile field, labeling occurs when any medication or solution is transferred from the original packaging to another container.
- 3. In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the following:
 - · Medication or solution name
 - Strength
 - Amount of medication or solution containing medication (if not apparent from the container)
 - Diluent name and volume (if not apparent from the container)
 - Expiration date and time

Note: The date and time are not necessary for short procedures, as defined by the critical access hospital.

- 4. The critical access hospital verifies all medication or solution labels both verbally and visually. Verification is done by two individuals qualified to participate in the procedure whenever the person preparing the medication or solution is not the person who will be administering it.
- 5. The critical access hospital labels each medication or solution as soon as it is prepared, unless it is immediately administered.
 - Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.

NPG.14.04.01

The hospital reduces the likelihood of patient harm associated with the use of anticoagulant therapy.

Note: This requirement does not apply to routine situations in which short-term prophylactic anticoagulation is used for preventing venous thromboembolism (for example, related to procedures or hospitalization).

Element(s) of Performance for NPG.14.04.01

- 1. The critical access hospital uses approved protocols and evidence-based practice guidelines for reversal of anticoagulation and management of bleeding events related to each anticoagulant medication.
- The critical access hospital uses approved protocols and evidence-based practice guidelines for perioperative management of all patients on oral anticoagulants.
 Note: Perioperative management may address the use of bridging medications, timing for stopping an anticoagulant, and timing and dosing for restarting an anticoagulant.
- 3. The critical access hospital uses only oral unit-dose products, prefilled syringes, or premixed infusion bags when these types of products are available.

 Note: For pediatric patients, prefilled syringe products should be used only if specifically designed for children.

NPG.14.05.01

The critical access hospital maintains and communicates accurate patient medication information.

Element(s) of Performance for NPG.14.05.01

- 1. The critical access hospital obtains information on the medications the patient is currently taking when they are admitted to the critical access hospital or are seen in an outpatient setting. This information is documented in a list or other format that is useful to those who manage medications.
 - Note 1: Current medications include those taken at scheduled times and those taken on an as-needed basis. See the Glossary for a definition of medications.
 - Note 2: It is often difficult to obtain complete information on current medications from a patient. A good faith effort to obtain this information from the patient and/or other sources will be considered as meeting the intent of the EP.
- 2. Define the types of medication information (for example, name, dose, route, frequency, purpose) to be collected in non-24-hour settings.
 - Note: Examples of non-24-hour settings include the emergency department, primary care, outpatient radiology, ambulatory surgery, and diagnostic settings.
- Compare the medication information the patient brought to the critical access hospital with the medications ordered for the patient by the critical access hospital in order to identify and resolve discrepancies.
 Note: Discrepancies include omissions, duplications, contraindications, unclear information, and changes. A qualified individual, identified by the critical access hospital, does the comparison.
- 4. Provide the patient (or family, caregiver, or support person as needed) with written information on the medications the patient should be taking when they are discharged from the critical access hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose).
- 5. Explain the importance of managing medication information to the patient when they are discharged from the critical access hospital or at the end of an outpatient encounter.
 - Note: Examples include instructing the patient to give a list to their primary care provider; to update the information when medications are discontinued, doses are changed, or new medications (including over-

the-counter products) are added; and to carry medication information at all times in the event of emergency situations. (For information on patient education on medications, refer to Standards MM.16.01.01, PC.12.02.01, and PC.14.01.01.)

NPG.14.06.01

The critical access hospital has an active antibiotic stewardship program.

Element(s) of Performance for NPG.14.06.01

- 1. The critical access hospital has a multidisciplinary committee that oversees the antibiotic stewardship program. Note 1: The committee may be composed of representatives from the medical staff, pharmaceutical services, the infection prevention and control program, nursing services, microbiology, information technology, and the quality assessment and performance improvement program.
 - Note 2: The committee may include part-time or consultant staff. Participation may occur on site or remotely.
- 2. The antibiotic stewardship program monitors the critical access hospital's antibiotic use by analyzing data on days of therapy per 1,000 days present or 1,000 patient days or by reporting antibiotic use data to the National Healthcare Safety Network's Antimicrobial Use Option of the Antimicrobial Use and Resistance Module.

Nursing (NR) Chapter

NR.11.01.01

The nurse executive directs the implementation of nursing policies and procedures, nursing standards, and a nurse staffing plan(s).

Element(s) of Performance for NR.11.01.01

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: A registered nurse assigns the nursing care for each patient to other nursing staff in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

CoP(s): §482.23(b)(5)

 For rehabilitation and psychiatric distinct part units in critical access hospitals: All licensed nurses who provide services in the critical access hospital adhere to its policies and procedures.
 Note: This applies to all nursing staff providing services (that is, hospital employee, contract, lease, other

inote: This applies to all nursing staff providing services (that is, nospital employee, contract, lease, other agreement, or volunteer).

CoP(s): §482.23(b)(6)

3. The nurse executive provides for the supervision and evaluation of the clinical activities of all nursing staff in accordance with nursing policies and procedures.

Note: This applies to all nursing staff who are providing services (that is, hospital employee, contract, lease, other agreement, or volunteer).

CoP(s): §482.23(b)(6)

4. A registered nurse (or physician assistant, when permitted by state law) supervises and evaluates the nursing care for each patient, including patients at a skilled nursing facility-level of care in a swing-bed critical access hospital.

CoP(s): §482.23(b)(3), §485.635(d)(2)

Provision of Care, Treatment, and Services (PC) Chapter

PC.11.01.01

The critical access hospital accepts the patient for care, treatment, and services based on its ability to meet the patient's needs.

Element(s) of Performance for PC.11.01.01

1. The critical access hospital develops and implements a written process for accepting a patient that addresses admission criteria and procedures for accepting referrals.

Note: Admission criteria is applied uniformly to all patients (both Medicare and non-Medicare patients).

CoP(s): §412.25(a)(2)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program.

Note: This procedure makes certain that the preadmission screening for each Medicare Part A fee-for-service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the inpatient rehabilitation facility.

CoP(s): §412.29(d)

3. For psychiatric distinct part units in critical access hospitals: Patients with a psychiatric principal diagnosis (listed in the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR) or in Chapter 5 of the International Classification of Diseases, 9th Revision (ICD-9-CM)) are admitted only when the intensity of the active treatment can be provided only in an inpatient hospital setting.

CoP(s): §412.27(a)

PC.11.02.01

The critical access hospital assesses and reassesses the patient and the patient's condition according to defined time frames.

Element(s) of Performance for PC.11.02.01

1. The critical access hospital conducts the patient's initial assessment within the written time frames it defines and in accordance with law and regulation.

2. A medical history and physical examination is completed and documented no more than 30 days prior to, or within 24 hours after, registration or inpatient admission but prior to surgery or a procedure requiring anesthesia services.

Note 1: For rehabilitation and psychiatric distinct part units in critical access hospitals: Medical histories and physical examinations are performed as required in this element of performance, except prior to any specific outpatient surgical or procedural services for which an assessment is performed instead as provided under 42 CFR 482.24(c)(4)(i)(C).

Note 2: For law and regulation guidance pertaining to the medical history and physical examination at 42 CFR 482.22(c)(5)(iii) and 482.51(b)(1)(iii), refer to https://www.ecfr.gov/.

CoP(s): §482.24(c)(4)(i)(A), §482.51(b)(1)(i)

3. For a medical history and physical examination that was completed within 30 days prior to registration or inpatient admission, an update documenting any changes in the patient's condition is completed within 24 hours after registration or inpatient admission, but prior to surgery or a procedure requiring anesthesia services. Note 1: For rehabilitation and psychiatric distinct part units in critical access hospitals: Medical histories and physical examinations are performed as required in this element of performance, except prior to any specific outpatient surgical or procedural services for which an assessment is performed instead as provided under 42 CFR 482.24(c)(4)(i)(C).

Note 2: For law and regulation guidance pertaining to the medical history and physical examination at 42 CFR 482.22(c)(5)(iii), refer to https://www.ecfr.gov/.

CoP(s): §482.24(c)(4)(i)(B), §482.51(b)(1)(ii)

4. For rehabilitation and psychiatric distinct part units in critical access hospitals: When the medical staff allows an assessment (in lieu of a comprehensive medical history and physical examination) for patients receiving specific outpatient surgical or procedural services, the patient assessment is completed and documented after registration but prior to the surgery or procedure requiring anesthesia services.

Note: For further regulatory guidance at 42 CFR 482.24(c)(4)(i)(A) and (B), 482.51(b)(1)(i) and (ii), and 482.22(c) (5)(v), refer to https://www.ecfr.gov/.

CoP(s): §482.51(b)(1)(iii)

5. For rehabilitation distinct part units in critical access hospitals: The critical access hospital develops and implements a process to make certain that patients receive close medical supervision, as evidenced by at least three face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation, to assess the patient both medically and functionally and to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.

Note: Beginning with the second week, as defined in 42 CFR 412.622, after admission to the inpatient rehabilitation unit, a non-physician practitioner who is determined by the inpatient rehabilitation unit to have specialized training and experience in inpatient rehabilitation may conduct one of the three required face-to-face patient visits per week, provided that such duties are within the nonphysician practitioner's scope of practice under applicable state law.

CoP(s): §412.29(e)

6. For swing beds in critical access hospitals: The critical access hospital completes the resident's comprehensive assessment within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition.

Note: For this element of performance, the term "readmission" means a return to the critical access hospital following a temporary absence for hospitalization or for therapeutic leave.

CoP(s): §483.20(b)(2), §483.20(b)(2)(i), §485.645(d)(5)

7. For swing beds in critical access hospitals: The critical access hospital conducts a comprehensive assessment within 14 calendar days after it determines that there has been a significant change in the resident's physical or mental condition.

Note: For this element of performance, the term "significant change" means a major decline or improvement in the resident's status that will not resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and that requires interdisciplinary review or revision of the care plan, or both.

CoP(s): §483.20(b)(2), §483.20(b)(2)(ii), §485.645(d)(5)

8. For swing beds in critical access hospitals: Each resident receives a comprehensive assessment no less often than every 12 months.

CoP(s): §483.20(b)(2), §483.20(b)(2)(iii), §485.645(d)(5)

- 11. For swing beds in critical access hospitals: The comprehensive assessment of the resident includes the following:
 - · Identifying and demographic information
 - · Customary routines
 - · Cognitive patterns
 - · Communication needs
 - · Vision needs
 - · Psychosocial well-being
 - · Mood and behavior patterns
 - · Physical functioning and structural problems
 - Continence
 - · Disease(s), diagnoses, and health conditions
 - · Dental status
 - Nutritional status (such as usual body weight or desirable body weight range, electrolyte balance)
 - Skin
 - Pursuit of activity
 - · Medications
 - · Need for special treatment(s) and procedure(s)
 - · Discharge planning

Note: The critical access hospital maintains the resident's acceptable nutritional status parameters unless the resident's clinical condition demonstrates that this is not possible or the resident's preferences indicate otherwise.

§483.20(b)(1)(xii), §483.20(b)(1)(xiii), §483.20(b)(1)(xiv), §483.20(b)(1)(xv), §483.20(b)(1)(xvi), §483.25(g)(1), §485.645(d)(5), §485.645(d)(8)

12. For swing beds in critical access hospitals: The comprehensive assessment of the resident includes documentation of summary information about the additional assessment(s) performed through the resident assessment protocols.

CoP(s): §483.20(b)(1)(xvii), §485.645(d)(5)

13. For swing beds in critical access hospitals: The comprehensive assessment includes direct observation and communication with the resident and communication with staff members on all shifts.

CoP(s): §483.20(b)(1)(xviii), §485.645(d)(5)

PC.11.02.03

For psychiatric distinct part units in critical access hospitals: The critical access hospital assesses the needs of patients who receive treatment for emotional and behavioral disorders.

Element(s) of Performance for PC.11.02.03

1. For psychiatric distinct part units in critical access hospitals: Patients who receive treatment for emotional and behavioral disorders receive an assessment that includes a history of mental, emotional, behavioral, and substance use problems, their co-occurrence, and their treatment.

CoP(s): §412.27(c)(1)(v)

- 2. For psychiatric distinct part units in critical access hospitals: Each patient receives a psychiatric evaluation completed within 60 hours of admission. The psychiatric evaluation includes the following:
 - Medical history
 - · Record of mental status
 - · Description of the onset of illness and the circumstances leading to admission
 - · Description of attitudes and behavior
 - Estimation of intellectual functioning, memory functioning, and orientation
 - Inventory of the patient's assets in descriptive, not interpretative, fashion

 $\label{eq:copsimple} \text{CoP(s): } \S412.27(c)(2)(i), \\ \S412.27(c)(2)(ii), \\ \S412.27(c)(2)(iii), \\ \S412.27(c)(2)(iv), \\ \S412.27(c)(2)(v), \\ \S412.$

PC.11.02.07

For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home effectively communicates with patients when providing care, treatment, or services.

Element(s) of Performance for PC.11.02.07

1. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care clinician and the interdisciplinary team identify the patient's oral and written communication needs, including the patient's preferred language for discussing health care.

Note: Examples of communication needs include the need for personal devices such as hearing aids or glasses, language interpreters, communication boards, and translated or plain language materials. (Refer to RC.12.01.01, EP 1)

PC.11.03.01

The critical access hospital plans the patient's care.

Element(s) of Performance for PC.11.03.01

- 1. The critical access hospital develops, implements, and revises a written individualized plan of care based on the following:
 - · Needs identified by the patient's assessment, reassessment, and results of diagnostic testing
 - The patient's goals and the time frames, settings, and services required to meet those goals

Note 1: Nursing staff develops and keeps current a nursing plan of care, which may be a part of an interdisciplinary plan of care, for each inpatient.

Note 2: The hospital evaluates the patient's progress and revises the plan of care based on the patient's progress.

Note 3: For rehabilitation distinct part units in critical access hospitals: The plan is reviewed and revised as needed by a physician in consultation with other professional staff who provide services to the patient.

CoP(s): §412.29(h), §482.23(b)(4), §485.635(d)(4), §485.645(d)(5), §485.645(d)(6)

2. The critical access hospital involves the patient in the development and implementation of their plan of care. Note: For swing beds in critical access hospitals: The resident has the right to be informed, in advance, of changes to their plan of care.

CoP(s): §482.13(b)(1), §482.58(b)(1), §483.10(c)(2)(iii), §483.10(c)(2)(iii), §485.614(b)(1), §485.645(d)(1)

- 3. For psychiatric distinct part units in critical access hospitals: Each patient has an individual comprehensive treatment plan that is based on an inventory of the patient's strengths and disabilities. The written plan includes the following:
 - · Substantiated diagnosis
 - Short-term and long-term goals
 - · Specific treatment modalities utilized
 - · Responsibilities of each member of the treatment team
 - · Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out

CoP(s): §412.27(c)(3)(i)

- 4. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: Patient self-management goals are developed in partnership with patients, based on criteria established by the organization, and incorporated into the patient's treatment plan.
 - Note: Examples of criteria include the patient's disease process or condition and specific patient populations, such as those with multiple comorbidities or a chronic disease. It is not expected that self-management goals be developed for every patient.
- 5. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home uses clinical decision support tools to guide decision making.
- 6. For swing beds in critical access hospitals: The interdisciplinary team involves the resident and the resident's representative in developing the person-centered, comprehensive treatment plan.

Note 1: The treatment plan includes documentation of the following:

- Any specialized or rehabilitation services the critical access hospital will provide as a result of preadmission screening and resident review (PASARR) recommendations and any disagreement with PASARR recommendations
- Resident's goals for admission and desired outcomes
- Resident's preferences and potential for future discharge, including whether the resident's desire to return to
 the community was assessed and any referrals to local contact agencies and/or other appropriate entities for
 this purpose
- · Discharge plans
- Measurable objectives and time frames to meet a resident's medical, nursing, and mental and psychosocial needs

Note 2: If not feasible for the resident and the resident's representative to participate in the development of the treatment plan, an explanation is included in the resident's medical record.

 $CoP(s): \S 483.21(b)(1), \S 483.21(b)(1)(iii), \S 483.21(b)(1)(iv), \S 483.21(b)(1)(iv)(A), \S 483.21(b)(1)(iv)(B), \S 483.21(b)(1)(iv)(C), \S 483.21(b)(2)(ii)(E), \S 485.645(d)(5)$

7. For swing beds in critical access hospitals: The resident's comprehensive treatment plan includes the services to be provided to attain or maintain the resident's optimal physical, mental, and psychosocial well-being.

Note: The comprehensive treatment plan includes any services that would otherwise be required under 42 CFR 483.24, 483.25, or 483.40 but are not provided due to the resident's exercise of rights, including the right to refuse treatment.

CoP(s): §483.21(b)(1)(i), §483.21(b)(1)(ii)

8. For swing beds in critical access hospitals: The critical access hospital develops the resident's written comprehensive plan of care as soon as possible after admission, but no later than seven calendar days after the resident's comprehensive assessments are completed.

CoP(s): §483.21(b)(2)(i), §485.645(d)(5)

9. For swing beds in critical access hospitals: The resident's written plan of care is developed by an interdisciplinary team comprised of health care professionals involved in the resident's care, treatment, and services. At a minimum, the team includes the attending physician, registered nurse with responsibility for the resident, nurse

aide with responsibility for the resident, a member of the food and nutrition services staff, and other appropriate staff as determined by the resident's needs or as requested by the resident.

Note: The plan of care is reviewed and revised by the interdisciplinary team after each assessment.

CoP(s): §483.21(b)(2)(ii)(A), §483.21(b)(2)(ii)(B), §483.21(b)(2)(ii)(C), §483.21(b)(2)(ii)(D), §483.21(b)(2)(ii)(F), §483.21(b)(2)(iii), §485.645(d)(5)

PC.12.01.01

The critical access hospital provides care, treatment, and services as ordered or prescribed and in accordance with law and regulation.

Element(s) of Performance for PC.12.01.01

1. Prior to providing care, treatment, and services, the critical access hospital obtains or renews orders (verbal or written) from a physician or other licensed practitioner in accordance with professional standards of practice; law and regulation; critical access hospital policies; and medical staff bylaws, rules, and regulations.

Note 1: This includes but is not limited to respiratory services, radiology services, rehabilitation services, nuclear medicine services, and dietetic services, if provided.

Note 2: Patient diets, including therapeutic diets, are ordered by the physician or other licensed practitioner responsible for the patient's care or by a qualified dietitian or qualified nutrition professional who is authorized by the medical staff and acting in accordance with state law governing dietitians and nutrition professionals. The requirement of 42 CFR 483.25(i) is met for inpatients receiving care at a skilled nursing facility subsequent to critical access hospital care.

CoP(s): §482.26(b)(4), §482.28(b)(2), §482.53(d)(4), §482.56(b), §482.57(b)(3), §482.58(b)(6), §483.65(b), §485.635(a)(3)(vi), §485.645(d)(6)

- 2. For rehabilitation and psychiatric distinct part units in critical access hospitals: Any physician or other licensed practitioner who orders outpatient services meets the following conditions:
 - · Responsible for the care of the patient
 - Licensed in the state where they provide care to the patient
 - · Acting within their scope of practice under state law
 - Authorized in accordance with state law and policies adopted by the medical staff and approved by the governing body to order the applicable outpatient services

Note: This applies to physicians or other licensed practitioners who are appointed to the critical access hospital's medical staff or have been granted privileges, as well as practitioners not appointed to the medical staff who satisfy the above criteria.

CoP(s): §482.54(c)(1), §482.54(c)(2), §482.54(c)(3), §482.54(c)(4), §482.54(c)(4)(i), §482.54(c)(4)(ii)

3. The critical access hospital administers blood transfusions and intravenous medications in accordance with state law and approved medical staff policies and procedures.

CoP(s): §482.23(c)(4)

4. If the critical access hospital provides rehabilitation, physical therapy, occupational therapy, speech-language pathology, or audiology services, the services are organized and provided in accordance with national accepted standards of practice.

Note: For rehabilitation distinct part units in critical access hospitals: The critical access hospital provides rehabilitation nursing, physical therapy, and occupational therapy, and, as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services by qualified staff in accordance with national accepted standards of practice.

CoP(s): §412.29(f), §482.56, §482.56(a), §482.56(b)(2)

5. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: Each patient has a designated primary care clinician.

PC.12.01.03

The critical access hospital provides interdisciplinary, collaborative care, treatment, and services.

Element(s) of Performance for PC.12.01.03

1. The critical access hospital provides care, treatment, and services to the patient in an interdisciplinary, collaborative manner.

Note: For rehabilitation distinct part units in critical access hospitals: The critical access hospital uses a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status related to goal attainment and discharge plans, and team conferences that are held at least once per week to determine the appropriateness of treatment.

CoP(s): §412.29(i)

PC.12.01.05

Resuscitative services are available throughout the critical access hospital.

Element(s) of Performance for PC.12.01.05

- 1. For rehabilitation and psychiatric distinct part units in critical access hospitals: At a minimum, operating room suites have the following equipment available:
 - Call-in system (process to communicate with or summon staff outside of the operating room when needed)
 - Cardiac monitor
 - Resuscitator (hand-held or mechanical device that provides positive airway pressure)
 - Defibrillator
 - · Aspirator (hand-held or mechanical device used to suction out fluids or secretions)
 - Tracheotomy set

CoP(s): §482.51(b)(3)

PC.12.01.07

The critical access hospital recognizes and responds to changes in a patient's condition.

Note: Critical access hospitals are not required to create rapid response teams or medical emergency teams in order to meet this standard. The existence of these types of teams does not mean that all of the elements of performance are automatically achieved.

Element(s) of Performance for PC.12.01.07

 The critical access hospital maintains equipment, supplies, and drugs and biologicals commonly used in lifesaving procedures. These items are kept at the critical access hospital and are available for treating emergency cases.

Note 1: The drugs and biologicals commonly used in life-saving procedures include but are not limited to analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions. Note 2: Equipment and supplies commonly used life-saving procedures include but are not limited to airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

CoP(s): §485.618(b), §485.618(b)(1), §485.618(b)(2)

PC.12.01.09

The critical access hospital makes food and nutrition products available to its patients.

Element(s) of Performance for PC.12.01.09

- 1. The nutritional needs of the individual patient are met in accordance with clinical practice guidelines and recognized dietary practices.
 - Note 1: Diet menus meet the needs of the patients.
 - Note 2: For swing beds in critical access hospitals: The critical access hospital meets the assisted nutrition and hydration requirement at 42 CFR 483.25(g) with respect to inpatients receiving posthospital skilled nursing facility care.
 - CoP(s): §482.28(b), §482.28(b)(1), §485.635(a)(3)(vi)
- 2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The dietician and medical staff approve a therapeutic diet manual that is current and available to all medical, nursing, and food service staff. Note: For the purposes of this element of performance, current is defined as having a publication or revision date no more than five years old.

CoP(s): §482.28(b)(3)

3. For swing beds in critical access hospitals: The critical access hospital offers the resident sufficient fluid intake to maintain proper hydration and health.

CoP(s): §483.25(g)(2), §485.645(d)(8)

PC.12.02.01

The critical access hospital provides patient education and training based on each patient's needs and abilities.

Element(s) of Performance for PC.12.02.01

- 1. The critical access hospital performs a learning needs assessment for each patient, which includes the following:
 - Cultural and religious beliefs
 - Emotional barriers
 - Desire and motivation to learn
 - · Physical or cognitive limitations
 - · Barriers to communication
- 3. Based on the patient's condition and assessed needs, the education and training provided to the patient by the critical access hospital include the following:
 - · An explanation of the plan for care, treatment, and services
 - · Basic health practices and safety
 - Information on the safe and effective use of medications
 - · Nutrition interventions (for example, supplements) and modified diets
 - Discussion of pain, the risk for pain, the importance of effective pain management, the pain assessment process, and methods for pain management
 - Information on oral health
 - Information on the safe and effective use of medical equipment or supplies provided by the critical access hospital
 - · Habilitation or rehabilitation techniques to help the patient reach maximum independence
 - · Fall reduction strategies
- 5. The critical access hospital provides the patient education on how to communicate concerns about patient safety issues that occur before, during, and after care is received.
- 6. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care clinician and the interdisciplinary team educate the patient on self-management tools and techniques based on the patient's individual needs. (Refer to PC.11.03.01, EP 7)
- 7. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The interdisciplinary team identifies the patient's health literacy needs.
 Note: Typically this is an interactive process. For example, patients may be asked to demonstrate their understanding of information provided by explaining it in their own words.
- 8. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care clinician and the interdisciplinary team incorporate the patient's health literacy needs into the patient's education.

PC.12.03.01

For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The patient has access to the primary care medical home 24 hours a day, 7 days a week.

Note: Access may be provided through a number of methods, including telephone, e-mail, websites, portals, and flexible hours.

Element(s) of Performance for PC.12.03.01

- 1. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides patients with access to the following 24 hours a day, 7 days a week:
 - · Appointment availability/scheduling
 - · Requests for prescription renewal
 - · Test results
 - · Clinical advice for urgent health needs
- For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home offers flexible scheduling to accommodate patient care needs.
 Note: This may include open scheduling, same-day appointments, group visits, expanded hours, and arrangements with other organizations.
- 3. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home has a process to address patient urgent care needs 24 hours a day, 7 days a week.

PC.12.03.03

For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home is accountable for providing patient care. (Refer to Standard PC.12.03.05)

Element(s) of Performance for PC.12.03.03

- 1. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home manages transitions in care and provides or facilitates patient access to care, treatment, or services, including the following:
 - · Acute care
 - · Management of chronic care
 - · Preventive services that are age- and gender-specific
 - · Behavioral health needs
 - · Oral health care
 - Urgent and emergent care
 - Substance abuse treatment

Note: Some of these services may be obtained through the use of community resources, as available, or in collaboration with other organizations.

- 2. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides care that addresses various phases of a patient's lifespan, including end-of-life care.
- 3. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides disease and chronic care management services to its patients.

- 4. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides population-based care.
- 5. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home uses health information technology to do the following:
 - Support the continuity of care and the provision of comprehensive and coordinated care, treatment, or services
 - · Document and track care, treatment, or services
 - Support disease management, including providing patient education
 - · Support preventive care, treatment, or services
 - · Create reports for internal use and external reporting
 - · Facilitate electronic exchange of information among providers
 - Support performance improvement

PC.12.03.05

For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care clinician and the interdisciplinary team work in partnership with the patient to support the continuity of care and the provision of comprehensive and coordinated care, treatment, or services.

Element(s) of Performance for PC.12.03.05

- 1. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home identifies the composition of the interdisciplinary team, based on individual patient needs.
- 2. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The members of the interdisciplinary team provide comprehensive and coordinated care, treatment, or services and maintain the continuity of care.
 - Note: The provision of care may include making internal and external referrals.
- 3. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care clinician and the interdisciplinary team provide care for a designated group of patients.
- 4. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care clinician is responsible for making certain that the interdisciplinary team provides comprehensive and coordinated care, treatment, or services and maintains the continuity of care as described in EPs 6–10. Note: Coordination of care may include making internal and external referrals, developing and evaluating treatment plans, and resolving conflicts in the provision of care.
- 5. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: When a patient is referred internally or externally, the interdisciplinary team reviews and tracks the care provided to the patient and, as needed, acts on recommendations for additional care, treatment, and services.
 Note: Internal referrals include orders for laboratory tests and imaging.
- 6. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The interdisciplinary team participates in the development of the patient's treatment plan.
- 7. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The interdisciplinary team works in partnership with the patient to achieve planned outcomes.

- 8. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The interdisciplinary team monitors the patient's progress toward achieving treatment goals.
- 9. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The interdisciplinary team involves the patient in the development of the patient's treatment plan.
- 10. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The interdisciplinary team assesses patients for health risk behaviors.

PC.13.01.01

The critical access hospital plans operative or other high-risk procedures.

Note: Equipment identified in the elements of performance is available to the operating room suites.

Element(s) of Performance for PC.13.01.01

- 1. Anesthesia is administered only by the following individuals:
 - · A qualified anesthesiologist
 - A doctor of medicine or osteopathy other than an anesthesiologist, including an osteopathic practitioner recognized under section 1101(a)(7) of the Social Security Act
 - · A doctor of dental surgery or dental medicine, who is qualified to administer anesthesia under state law
 - · A doctor of podiatric medicine, who is qualified to administer anesthesia under state law
 - A certified registered nurse anesthetist (CRNA), as defined in 42 CFR 410.69(b) of this chapter, supervised by the operating practitioner, except as provided in 42 CFR 485.639(e) regarding the state exemption for this supervision
 - An anesthesiologist's assistant, as defined in 42 CFR 410.69(b), supervised by an anesthesiologist
 - A supervised trainee in an approved educational program

Note 1: In accordance with 42 CFR 413.85(e), an approved nursing and allied health education program is a planned program of study that is licensed by state law, or if licensing is not required, is accredited by a recognized national professional organization. Such national accrediting bodies include, but are not limited to, the Commission on Accreditation of Allied Health Education Programs and the National League of Nursing Accrediting Commission.

Note 2: See Glossary for the definition of certified registered nurse anesthetist (CRNA) and anesthesiologist assistant.

Note 3: The CoP at 42 CFR 485.639(e) for state exemption states: A critical access hospital may be exempted from the requirement for doctor of medicine or osteopathy supervision of CRNAs if the state in which the critical access hospital is located submits a letter to the Centers for Medicare & Medicaid Services (CMS) signed by the governor, following consultation with the state's boards of medicine and nursing, requesting exemption from doctor of medicine or osteopathy supervision for CRNAs. The letter from the governor must attest that they have consulted with the state boards of medicine and nursing about issues related to access to and the quality of anesthesia services in the state and has concluded that it is in the best interests of the state's citizens to opt out of the current doctor of medicine or osteopathy supervision requirement and that the opt-out is consistent with state law. The request for exemption and recognition of state laws and the withdrawal of the request may be submitted at any time and are effective upon submission.

Note 4: Only the above individuals can administer deep sedation/analgesia.

 $\begin{aligned} &\text{CoP(s): } \S 482.52(a)(1), \ \S 482.52(a)(2), \ \S 482.52(a)(3), \ \S 482.52(a)(4), \ \S 482.52(a)(5), \ \S 482.52(c)(1), \ \S 482.52(c)(2), \\ &\S 485.639(c)(1)(i), \ \S 485.639(c)(1)(ii), \ \S 485.639(c)(1)(iii), \ \S 485.639(c)(1)(iv), \ \S 485.639(c)(1)(vi), \\ &\S 485.639(c)(1)(vii), \ \S 485.639(c)(2), \ \S 485.639(e)(1), \ \S 485.639(e)(2) \end{aligned}$

PC.13.01.03

The critical access hospital provides the patient with care before and after operative or other high-risk procedures.

Element(s) of Performance for PC.13.01.03

1. A qualified physician or other licensed practitioner, in accordance with 42 CFR 485.639(c), conducts a preanesthesia patient assessment to evaluate the risk of anesthesia.

CoP(s): §485.639(b)(2)

- 2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital develops and implements policies and procedures for anesthesia that include the delineation of preanesthesia and postanesthesia responsibilities. The policies require the following for each patient:
 - A preanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in 42 CFR 482.52(a), within 48 hours prior to surgery or a procedure requiring anesthesia services.
 - · An intraoperative anesthesia record.
 - A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in 42 CFR 482.52(a), no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery is completed in accordance with state law and critical access hospital policies and procedures that have been approved by the medical staff and reflect current standards of anesthesia care.

CoP(s): §482.52(b), §482.52(b)(1), §482.52(b)(2), §482.52(b)(3)

3. A qualified physician or other licensed practitioner, in accordance with 42 CFR 485.639(a), reevaluates the patient immediately before surgery, to evaluate the risk of the procedure to be performed.

CoP(s): §485.639(b)(1)

5. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has adequate provisions for immediate postoperative care.

CoP(s): §482.51(b)(4)

6. A qualified physician or other licensed practitioner evaluates the patient for proper anesthesia recovery, as specified in 42 CFR 485.639(c), before discharging the patient from the recovery area or from the critical access hospital.

CoP(s): §485.639(b)(3)

7. The critical access hospital discharges patients following the surgical procedure in the company of a responsible adult, except in situations where the practitioner who performed the surgical procedure determines the patient may leave unaccompanied.

CoP(s): §485.639(d)

PC.13.01.05

For rehabilitation and psychiatric distinct part units in critical access hospitals: The laboratory has written policies and procedures for the handling of tissue specimens removed during a surgical procedure.

Element(s) of Performance for PC.13.01.05

 For rehabilitation and psychiatric distinct part units in critical access hospitals: The laboratory develops and implements written policies and procedures for collecting, preserving, transporting, receiving, and reporting examination results for tissue specimens.

CoP(s): §482.27(a)(3)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The laboratory develops and implements a written policy, approved by the medical staff and a pathologist, that establishes which tissue specimens require only a macroscopic examination and which require both a macroscopic and microscopic examination.

CoP(s): §482.27(a)(4)

PC.13.02.01

The critical access hospital uses restraint or seclusion only when it can be clinically justified or when warranted by patient behavior that threatens the physical safety of the patient, staff, or others.

Note: See Glossary for the definitions of restraint and seclusion.

Element(s) of Performance for PC.13.02.01

1. The critical access hospital does not use restraint or seclusion of any form as a means of coercion, discipline, convenience, or staff retaliation. Restraint or seclusion is only used to protect the immediate physical safety of the patient, staff, or others when less restrictive interventions have been ineffective and is discontinued at the earliest possible time, regardless of the length of time specified in the order.

CoP(s): §482.13(e), §482.13(e)(2), §482.13(e)(9), §482.58(b)(3), §485.614(e), §485.614(e)(2), §485.645(d)(3)

2. The critical access hospital uses the least restrictive form of restraint or seclusion that will be effective to protect the patient, a staff member, or others from harm.

CoP(s): §482.13(e)(3), §482.58(b)(3), §485.614(e)(3), §485.645(d)(3)

3. For swing beds in critical access hospitals: The critical access hospital does not use physical or chemical restraints that are imposed for purposes of discipline or convenience and are not required to treat the resident's

medical symptoms. When the use of restraints is indicated, the critical access hospital uses the least restrictive alternative for the least amount of time and documents ongoing reevaluation of the need for restraints.

CoP(s): §483.12(a)(2), §483.12(a)(2)

4. The critical access hospital restraint policies are followed when any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or when a drug or medication is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. Note: A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

CoP(s): §482.13(e)(1)(i)(A), §482.13(e)(1)(i)(B), §482.13(e)(1)(i)(C), §485.614(e)(1)(i)(A), §485.614(e)(1)(i)(B), §485.614(e)(1)(i)(C)

 The critical access hospital seclusion policies are followed when a patient is involuntarily confined alone in a room or area from which the patient is physically prevented from leaving.
 Note: Seclusion is only used for the management of violent or self-destructive behavior.

CoP(s): §482.13(e)(1)(ii), §485.614(e)(1)(ii)

PC.13.02.03

The critical access hospital uses restraint or seclusion safely.

Element(s) of Performance for PC.13.02.03

- 1. The critical access hospital's use of restraint or seclusion meets the following requirements:
 - · In accordance with a written modification to the patient's plan of care
 - Implemented by trained staff using safe techniques identified by the critical access hospital's policies and procedures in accordance with law and regulation

CoP(s): §482.13(e)(4)(i), §482.13(e)(4)(ii), §482.13(f), §485.614(f)

PC.13.02.05

For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital initiates restraint or seclusion based on an individual order.

Element(s) of Performance for PC.13.02.05

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital uses restraint or seclusion as ordered by a physician or other authorized licensed practitioner responsible for the patient's care in accordance with critical access hospital policy and state law and regulation.

CoP(s): §482.13(e)(5)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital does not use standing orders or PRN (also known as "as needed") orders for restraint or seclusion.

CoP(s): §482.13(e)(6)

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: The attending physician or clinical psychologist is consulted as soon as possible, in accordance with critical access hospital policy, if they did not order the restraint or seclusion.

Note: The definition of "physician" is the same as that used by the Centers for Medicare & Medicaid Services (CMS) (refer to the Glossary).

CoP(s): §482.13(e)(7)

- 4. For rehabilitation and psychiatric distinct part units in critical access hospitals: Unless state law is more restrictive, orders for the use of restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, staff, or others may be renewed within the following time limits:
 - · 4 hours for adults 18 years of age or older
 - · 2 hours for children and adolescents 9 to 17 years of age
 - 1 hour for children under 9 years of age

Orders may be renewed according to the time limits for a maximum of 24 consecutive hours.

CoP(s): §482.13(e)(8)(i), §482.13(e)(8)(i)(A), §482.13(e)(8)(i)(B), §482.13(e)(8)(i)(C)

5. For rehabilitation and psychiatric distinct part units in critical access hospitals: Unless state law is more restrictive, every 24 hours, a physician or other authorized licensed practitioner responsible for the patient's care sees and evaluates the patient before writing a new order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, staff, or others, in accordance with critical access hospital policy and state law and regulation.

CoP(s): §482.13(e)(8)(ii)

6. For rehabilitation and psychiatric distinct part units in critical access hospitals: Orders for restraint used to protect the physical safety of a nonviolent or non-self-destructive patient are renewed in accordance with critical access hospital policy.

CoP(s): §482.13(e)(8)(iii)

PC.13.02.07

For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital monitors patients who are restrained or secluded.

Element(s) of Performance for PC.13.02.07

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: Physicians, other licensed practitioners, or staff who have been trained in accordance with 42 CFR 482.13(f) monitor the condition of patients in restraint or seclusion at an interval determined by the critical access hospital.

CoP(s): §482.13(e)(10)

PC.13.02.09

The critical access hospital has written policies and procedures that guide the use of restraint or seclusion.

Element(s) of Performance for PC.13.02.09

1. The critical access hospital's policies and procedures regarding the use of restraint or seclusion that are consistent with current standards of practice.

For rehabilitation and psychiatric distinct part units in critical access hospitals: The policies and procedures include the following:

- · Definitions for restraint and seclusion that are consistent with state and federal law and regulation
- · Physician and other licensed practitioner training requirements
- Staff training requirements
- · Who has authority to order restraint or seclusion
- · Who has authority to discontinue the use of restraint or seclusion
- · Who can initiate the use of restraint or seclusion
- · Circumstances under which restraint or seclusion is discontinued
- · Requirement that restraint or seclusion is discontinued as soon as is safely possible
- Who can assess and monitor patients in restraint or seclusion
- Time frames for assessing and monitoring patients in restraint or seclusion

CoP(s): §482.13(e)(11), §485.614(e)(4)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: Physicians and other licensed practitioners authorized to order restraint or seclusion (through critical access hospital policy in accordance with law and regulation) have a working knowledge of the critical access hospital policy regarding the use of restraint or seclusion.

CoP(s): §482.13(e)(11)

PC.13.02.11

For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital evaluates and reevaluates the patient who is restrained or secluded.

Element(s) of Performance for PC.13.02.11

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: A physician or other licensed practitioner responsible for the patient's care evaluates the patient in person within one hour of the initiation

of restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the physical safety of the patient, staff, or others. A registered nurse may conduct the in-person evaluation within one hour of the initiation of restraint or seclusion if they are trained in accordance with the requirements in PC.13.02.17, EP 3.

Note: The critical access hospital also follows any state statute or regulation that may be more stringent than the requirements in this element of performance.

CoP(s): §482.13(e)(12)(i)(A), §482.13(e)(12)(i)(B), §482.13(e)(13)

- 2. For rehabilitation and psychiatric distinct part units in critical access hospitals: The in-person evaluation is conducted within one hour of the initiation of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the physical safety of the patient, staff, or others. The evaluation includes the following:
 - · An evaluation of the patient's immediate situation
 - · The patient's reaction to the intervention
 - The patient's medical and behavioral condition
 - The need to continue or terminate the restraint or seclusion

CoP(s): §482.13(e)(12)(ii)(A), §482.13(e)(12)(ii)(B), §482.13(e)(12)(ii)(C), §482.13(e)(12)(ii)(D)

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: When the in-person evaluation (performed within one hour of the initiation of restraint or seclusion) is done by a trained registered nurse, they consult with the attending physician or other licensed practitioner responsible for the care of the patient as soon as possible after the evaluation, as determined by critical access hospital policy.

CoP(s): §482.13(e)(14)

PC.13.02.13

For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital continually monitors patients who are simultaneously restrained and secluded.

Element(s) of Performance for PC.13.02.13

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The patient who is simultaneously restrained and secluded is continually monitored by trained staff, either in person or through the use of both video and audio equipment that is in close proximity to the patient.

Note: In this element of performance, continually means ongoing without interruption.

CoP(s): §482.13(e)(15)(i), §482.13(e)(15)(ii)

PC.13.02.15

For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital documents the use of restraint or seclusion.

Element(s) of Performance for PC.13.02.15

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: Documentation of restraint or seclusion in the medical record includes the following:

- The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior
- · Description of the patient's behavior and the intervention used
- Alternatives or other less restrictive interventions attempted (as applicable)
- Patient's condition or symptom(s) that warranted the use of the restraint or seclusion
- Patient's response to the intervention(s) used, including the rationale for continued use of the intervention

CoP(s): §482.13(e)(16)(i), §482.13(e)(16)(ii), §482.13(e)(16)(iii), §482.13(e)(16)(iv), §482.13(e)(16)(v)

PC.13.02.17

The critical access hospital trains staff to safely implement the use of restraint or seclusion.

Element(s) of Performance for PC.13.02.17

- 1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital trains staff on the use of restraint and seclusion and assesses their competence at the following intervals:
 - · At orientation
 - Before participating in the use of restraint or seclusion
 - · On a periodic basis thereafter, as determined by critical access hospital policy

CoP(s): §482.13(f)(1)(i), §482.13(f)(1)(ii), §482.13(f)(1)(iii)

- 2. Staff education and training include the following:
 - Patient-centered, trauma-informed, competency-based training and education on the use of restraint and seclusion for staff, including medical staff and, as applicable, staff providing contract services
 - · Alternatives to the use of restraint or seclusion

CoP(s): §485.614(f)(1), §485.614(f)(2)

- 3. For rehabilitation and psychiatric distinct part units in critical access hospitals: Based on the population served, staff education, training, and demonstrated knowledge focus on the following:
 - Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of restraint or seclusion
 - · Use of nonphysical intervention skills
 - Methods for choosing the least restrictive intervention based on an assessment of the patient's medical or behavioral status or condition
 - Safe application and use of all types of restraint or seclusion used in the critical access hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia)
 - Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary
 - Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by critical access hospital policy associated with the in-person evaluation conducted within one hour of initiation of restraint or seclusion

• Use of first aid techniques and certification in the use of cardiopulmonary resuscitation (CPR), including required periodic recertification

CoP(s): §482.13(f)(2)(i), §482.13(f)(2)(ii), §482.13(f)(2)(iii), §482.13(f)(2)(iv), §482.13(f)(2)(v), §482.13(f)(2)(vi), §482.13(f)(2)(vii)

4. For rehabilitation and psychiatric distinct part units in critical access hospitals: Individuals providing staff training in restraint or seclusion are qualified as evidenced by education, training, and experience in the techniques used to address patient behaviors that necessitate the use of restraint or seclusion.

CoP(s): §482.13(f)(3)

5. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital documents in staff records that they have completed restraint and seclusion training and demonstrated competence.

CoP(s): §482.13(f)(4)

PC.13.02.19

The critical access hospital reports deaths associated with the use of restraint or seclusion.

Element(s) of Performance for PC.13.02.19

- 1. The critical access hospital reports the following information to the Centers for Medicare & Medicaid Services regarding deaths related to restraint or seclusion:
 - Each death that occurs while a patient is in restraint or seclusion
 - Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion
 - Each death known to the critical access hospital that occurs within one week after restraint or seclusion was used when it is reasonable to assume that the use of the restraint or seclusion contributed directly or indirectly to the patient's death

Note 1: This reporting requirement includes all restraints except soft wrist restraints. For more information on deaths related to the use of soft wrist restraints, refer to EP 3 in this standard.

Note 2: In this element of performance "reasonable to assume" includes but is not limited to deaths related to restrictions of movement for prolonged periods of time or deaths related to chest compression, restriction of breathing, or asphyxiation.

CoP(s): §482.13(g), §482.13(g)(1)(i), §482.13(g)(1)(ii), §482.13(g)(1)(iii), §485.614(g), §485.614(g)(1)(i), §485.614(g)(1)(iii)

2. The deaths addressed in PC.13.02.19, EP 1, are reported to the Centers for Medicare & Medicaid Services by telephone, by facsimile, or electronically no later than the close of the next business day following knowledge of the patient's death. The date and time that the patient's death was reported is documented in the patient's medical record.

CoP(s): §482.13(g)(1), §482.13(g)(3)(i), §485.614(g)(1), §485.614(g)(3)(i)

- 3. When no seclusion has been used and when the only restraints used on the patient are wrist restraints composed solely of soft, nonrigid, cloth-like material, the critical access hospital does the following:
 - Records in a log or other system any death that occurs while a patient is in restraint. The information is recorded within seven days of the date of death of the patient.
 - Records in a log or other system any death that occurs within 24 hours after a patient has been removed from such restraints. The information is recorded within seven days of the date of death of the patient.
 - Documents in the patient record the date and time that the death was recorded in the log or other system.
 - Documents in the log or other system the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner responsible for the patient's care, medical record number, and primary diagnosis(es).
 - Makes the information in the log or other system available to the Centers for Medicare & Medicaid Services, either electronically or in writing, immediately upon request.

CoP(s): $\S482.13(g)(2)(i)$, $\S482.13(g)(2)(ii)$, $\S482.13(g)(3)(ii)$, $\S482.13(g)(4)(i)$, $\S482.13(g)(4)(ii)$, $\S482.13(g)(4)(iii)$, $\S485.614(g)(2)(ii)$, $\S485.614(g)(2)(ii)$, $\S485.614(g)(2)(ii)$, $\S485.614(g)(4)(iii)$

PC.14.01.01

The critical access hospital follows its process for discharging or transferring patients.

Element(s) of Performance for PC.14.01.01

- The critical access hospital has an effective discharge planning process that focuses on, and is consistent with, the patient's goals and treatment preferences; makes certain there is an effective transition of the patient from the critical access hospital to postdischarge care; and reduces the factors leading to preventable critical access hospital and hospital readmissions.
 - Note: The critical access hospital's discharge planning process requires regular reevaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan is updated as needed to reflect these changes.

CoP(s): §482.43, §482.43(a)(6), §485.642, §485.642(a)(6)

2. The critical access hospital begins the discharge planning process early in the patient's episode of care, treatment, and services.

CoP(s): §482.43(a), §485.642(a)

3. As part of the discharge planning evaluation, the critical access hospital evaluates the patient's need for appropriate post–critical access hospital services, including but not limited to hospice care services, extended care services, home health services, and non–health care services and community-based care providers. The critical access hospital also evaluates the availability of the appropriate services and the patient's access to those services as part of the discharge planning evaluation.

CoP(s): §482.43(a)(2), §485.642(a)(2)

4. The patient, the patient's caregiver(s) or support person(s), physicians, other licensed practitioners, clinical psychologists, and staff who are involved in the patient's care, treatment, and services participate in planning the patient's discharge or transfer. The patient and their caregiver(s) or support person(s) are included as active partners when planning for postdischarge care.

Note 1: For rehabilitation and psychiatric distinct part units in critical access hospitals: The definition of "physician" is the same as that used by the Centers for Medicare & Medicaid Services (refer to the Glossary). Note 2: For psychiatric distinct part units in critical access hospitals: Social service staff responsibilities include but are not limited to participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of information with sources outside the critical access hospital.

Note 3: For swing beds in critical access hospitals: The critical access hospital notifies the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and reasons for the move. The notice is in writing, in a language and manner they understand, and includes the items described in 42 CFR 483.15(c)(5). The critical access hospital also provides sufficient preparation and orientation to residents to make sure that transfer or discharge from the critical access hospital is safe and orderly. The critical access hospital sends a copy of the notice to a representative of the office of the state's long-term care ombudsman.

CoP(s): §482.43, §482.58(b)(2), §483.15(c)(3)(i), §483.15(c)(3)(i), §483.15(c)(3)(iii), §483.15(c)(3)(iii), §483.15(c)(7), §483.15(c)(7), §485.642, §485.642(a)(5), §485.645(d)(2)

5. The critical access hospital performs a discharge planning evaluation and creates a discharge plan for those patients it identifies at an early stage of hospitalization are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning or at the request of the patient, patient's representative, or the patient's physician.

Note 1: The discharge planning evaluation is completed in a timely manner so that appropriate arrangements for post–hospital care are made before discharge and unnecessary delays in discharge are avoided.

Note 2: The discharge planning evaluation is performed and subsequent discharge plan is created by, or under the supervision of, a registered nurse, social worker, or other qualified person.

CoP(s): §482.43(a), §482.43(a)(1), §482.43(a)(4), §482.43(a)(5), §485.642(a), §485.642(a)(1), §485.642(a)(4)

6. The critical access hospital discusses the results of the discharge planning evaluation with the patient or their representative, including any reevaluations performed and any arrangements made.

CoP(s): §482.43(a)(3), §485.642(a)(3)

7. The critical access hospital assists the patient, their family, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes but is not limited to home health agency, skilled nursing facility, inpatient rehabilitation facility, and long-term care hospital data on quality measures and resource-use measures. The critical access hospital makes certain that the post–acute care data on quality measures and resource-use measures is relevant and applicable to the patient's goals of care and treatment preferences.

CoP(s): §482.43(a)(8), §485.642(a)(8)

8. For rehabilitation and psychiatric distinct part units in critical access hospitals: The patient's discharge plan includes a list of home health agencies, skilled nursing facilities, inpatient rehabilitation facilities, or long-term care hospitals that are available to the patient, participating in the Medicare program, and serving the geographic area in which the patient resides (as defined by the home health agency or, in the case of a skilled nursing

facility, inpatient rehabilitation facility, or long-term care hospital, in the geographic area requested by the patient). The critical access hospital documents in the medical record that this list was presented to the patient or the patient's representative.

Note 1: Home health agencies must request to be listed by the critical access hospital.

Note 2: This list is only presented to patients for whom home health care, posthospital extended care services, skilled nursing, inpatient rehabilitation, or long-term care hospital services are identified as needed.

CoP(s): §482.43(c)(1), §482.43(c)(1)(i), §482.43(c)(1)(iii)

9. For rehabilitation and psychiatric distinct part units in critical access hospitals: For patients enrolled in managed care organizations, the critical access hospital makes patients aware of the need to verify with their managed care organization which practitioners, providers, or certified suppliers are in the managed care organization's network. If the critical access hospital has information on which practitioners, providers, or certified suppliers are in the network of the patient's managed care organization, it shares this information with the patient or the patient's representative.

CoP(s): §482.43(c)(1)(ii)

10. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital informs the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of postdischarge services and, when possible, respects the patient's or their representative's goals of care and treatment preferences, as well as other preferences when they are expressed. The critical access hospital does not limit the qualified providers or suppliers that are available to the patient.

CoP(s): §482.43(c)(2)

11. For rehabilitation and psychiatric distinct part units in critical access hospitals: The discharge plan identifies any home health agency or skilled nursing facility in which the critical access hospital has a disclosable financial interest and any home health agency or skilled nursing facility that has a disclosable financial interest in a critical access hospital.

Note: Disclosure of financial interest is determined in accordance with the provisions in 42 CFR 420, subpart C, and section 1861 of the Social Security Act (42 U.S.C. 1395x).

CoP(s): §482.43(c)(3)

12. For swing beds in critical access hospitals: The critical access hospital provides the written notice of transfer or discharge at least 30 days before the resident is transferred or discharged.

Note: Notice may be made as soon as is practical before transfer or discharge when the safety of the individuals in the facility would be endangered, the health of the individuals in the facility would be endangered, the resident's health improves sufficiently to allow a more immediate transfer or discharge, immediate transfer or

discharge is required by the resident's urgent medical needs, or a resident has not resided in the facility for 30 days.

- 13. For swing beds in critical access hospitals: The written notice before transfer or discharge specified in 42 CFR 483.15(c)(3) includes the following:
 - · Reason for transfer or discharge
 - · Effective date of transfer or discharge
 - · Location to which the resident is transferred or discharged
 - Statement of the resident's appeal rights, including the name, address (mailing and e-mail), and telephone number of the entity which receives appeal requests; information on how to obtain an appeal form; where to find assistance in completing the form; and how to submit the appeal hearing request
 - Name, address (mailing and e-mail), and telephone number of the office of the state's long-term care ombudsman
 - For a resident with intellectual and developmental disabilities, the mailing and e-mail address and telephone number of the agency responsible for the protection and advocacy of these individuals, established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000
 - For a resident with a mental disorder or related disabilities, the mailing and e-mail address and telephone number of the agency responsible for the protection and advocacy of these individuals, established under the Protection and Advocacy for Mentally III Individuals Act

14. The critical access hospital assesses its discharge planning process on a regular basis, as defined by the critical access hospital. The assessment includes an ongoing, periodic review of a representative sample of discharge plans, including plans for patients who were readmitted within 30 days of a previous admission, to make certain that the plans are responsive to patient postdischarge needs.

CoP(s): §482.43(a)(7), §485.642(a)(7)

PC.14.01.03

For swing beds in critical access hospitals: Residents are not transferred or discharged from the critical access hospital unless they meet specific criteria, in accordance with law and regulation.

Element(s) of Performance for PC.14.01.03

- 1. For swing beds in critical access hospitals: The critical access hospital transfers or discharges residents only under at least one of the following conditions:
 - The resident's health has improved to the point where they no longer need the critical access hospital's services.
 - The transfer or discharge is necessary for the resident's welfare, and the critical access hospital cannot meet the resident's needs.
 - The safety of the individuals in the critical access hospital is endangered due to the resident's clinical or behavioral status.

- The health of individuals in the critical access hospital would otherwise be endangered.
- The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the critical access hospital. Nonpayment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for their stay. For a resident who becomes eligible for Medicaid after admission to a critical access hospital, the critical access hospital may charge a resident only the allowable charges under Medicaid.
- · The critical access hospital ceases operation.

Note: The critical access hospital cannot transfer or discharge a resident while an appeal is pending pursuant to 42 CFR 431.230, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the critical access hospital. The critical access hospital documents the danger that failure to transfer or discharge would pose.

CoP(s): §482.58(b)(2), §483.15(c)(1)(i)(A), §483.15(c)(1)(i)(A), §483.15(c)(1)(i)(B), §483.15(c)(1)(i)(C), §483.15(c)(1)(i)(C), §483.15(c)(1)(i)(C), §483.15(c)(1)(i)(D), §483.15(c)(1)(i)(D), §483.15(c)(1)(i)(E), §483.15(c)(1)(i)(F), §483.15(c)(1)(ii), §483.15(

2. For critical access hospitals with swing beds: In the case of critical access hospital closure, the administrator of the critical access hospital provides written notification prior to the impending closure to the state survey agency, the office of the state's long-term care ombudsman, residents of the critical access hospital, and the residents' representatives, as well as the plan for the transfer and adequate relocation of the residents.

CoP(s): §483.15(c)(8), §485.645(d)(2)

PC.14.02.01

The critical access hospital coordinates the patient's care, treatment, and services based on the patient's needs.

Element(s) of Performance for PC.14.02.01

- 1. The critical access hospital develops and implements a process to receive or share patient information when the patient is referred to internal providers of care, treatment, and services.
 - Note: For rehabilitation distinct part units in critical access hospitals: The process includes how it will transmit necessary clinical patient information to the distinct part unit when a critical access hospital patient is transferred to the unit.

CoP(s): §412.25(a)(4)

2. For swing beds in critical access hospitals: The critical access hospital provides medically related social services to attain or maintain the optimal physical, mental, and psychosocial well-being of each resident.

CoP(s): §482.58(b)(4), §483.40(d), §483.40(d), §485.645(d)(4)

3. For swing beds in critical access hospitals: The critical access hospital assists residents who are eligible and wish to apply for reimbursement of dental services as an incurred medical expense under the state plan. The critical access hospital may charge a Medicare resident an additional amount for routine and emergency dental services.

CoP(s): §482.58(b)(7), §483.55(a)(2), §483.55(a)(2), §483.55(b)(5), §483.55(b)(5), §485.645(d)(7)

4. For swing beds in critical access hospitals: The critical access hospital develops and implements a policy identifying circumstances when loss of or damage to a resident's dentures is the critical access hospital's responsibility, and it may not charge a resident for the loss or damage of dentures.

CoP(s): §482.58(b)(7), §483.55(a)(3), §483.55(a)(3), §483.55(b)(4), §483.55(b)(4), §485.645(d)(7)

5. For swing beds in critical access hospitals: If necessary or requested, the critical access hospital assists residents in making dental appointments and arranging for transportation to and from the dental services location.

6. For critical access hospitals with swing beds: The critical access hospital refers residents with lost or damaged dentures for dental services within three days. If referral does not occur within three days, the critical access hospital documents what was done to make sure that the resident could adequately eat and drink and any extenuating circumstances that led to the delay.

CoP(s): §482.58(b)(7), §483.55(a)(5), §483.55(a)(5), §483.55(b)(3), §483.55(b)(3), §485.645(d)(7)

7. For swing beds in critical access hospitals: The critical access hospital provides or obtains from an outside resource routine (to the extent covered under the state plan) and emergency dental services.

CoP(s): §482.58(b)(7), §483.55(b)(1)(i), §483.55(b)(1)(i), §485.645(d)(7)

8. For swing beds in critical access hospitals: If a resident's comprehensive plan of care requires specialized rehabilitative services, including but not limited to physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for a mental disorder and intellectual disability or services of a lesser intensity, the critical access hospital provides or obtains the required services from a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Social Security Act.

CoP(s): §482.58(b)(6), §483.65(a)(1), §483.65(a)(1), §483.65(a)(2), §483.65(a)(2), §485.645(d)(6)

PC.14.02.03

When a patient is discharged or transferred, the critical access hospital gives information about the care, treatment, and services provided to the patient to other service providers who will provide the patient with care, treatment, or services.

Element(s) of Performance for PC.14.02.03

- 1. The critical access hospital provides or transmits necessary medical information when discharging, transferring, or referring the patient to post–acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners who are responsible for the patient's follow-up or ancillary care. Necessary medical information includes, at a minimum, the following:
 - · Current course of illness and treatment
 - · Postdischarge goals of care
 - · Treatment preferences at the time of discharge

Note: For swing beds in critical access hospitals: The information sent to the receiving provider also includes the following:

- · Contact information of the physician or other licensed practitioner responsible for the care of the resident
- · Resident representative information, including contact information
- · Advance directive information
- · All special instructions or precautions for ongoing care, when appropriate
- Comprehensive care plan goals
- All other necessary information, including a copy of the residents discharge summary, consistent with 42 CFR 483.21(c)(2), and any other documentation, as applicable, to support a safe and effective transition of care

CoP(s): §482.43(b), §483.15(c)(2)(iii)(A), §483.15(c)(2)(iii)(B), §483.15(c)(2)(iii)(C), §483.15(c)(2)(iii)(D), §483.15(c)(2)(iii)(E), §483.15(c)(2)(iii)(F), §485.642(b), §485.645(d)(2)

PC.15.01.01

For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital safely provides blood and blood components.

Element(s) of Performance for PC.15.01.01

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital develops and implements written policies and procedures addressing potentially infectious blood and blood components, consistent with Centers for Medicare & Medicaid Services requirements at 42 CFR 482.27. Note 1: The procedures for notification and documentation conform to federal, state, and local laws, including requirements for the confidentiality of medical records and other patient information. Note 2: See Glossary for the definition of potentially infectious blood and blood components.

CoP(s): §482.27(b)(1)(i), §482.27(b)(1)(ii), §482.27(b)(1)(iii), §482.27(b)(2), §482.27(b)(9)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital receives notification of blood that is reactive to the human immunodeficiency virus (HIV) or hepatitis C virus (HCV) screening test, the critical access hospital determines the disposition of the blood or blood components and quarantines all previously donated blood and blood components in inventory.

CoP(s): §482.27(b)(4)

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital receives notification that the result of the supplemental (additional, more specific) test for potentially infectious blood or blood components or other follow-up testing required by the US Food and Drug Administration is

negative and there are no other informative test results, the critical access hospital may release the blood and blood components from quarantine.

CoP(s): §482.27(b)(4)(i)

- 4. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital receives notification that the result of the supplemental (additional, more specific) test for potentially infectious blood or blood components or other follow-up testing required by the US Food and Drug Administration is positive, the critical access hospital does the following:
 - · Disposes of the blood and blood components
 - Notifies the transfusion recipients as set forth in 42 CFR 482.27(b)(6)

CoP(s): §482.27(b)(4)(ii)(A), §482.27(b)(4)(ii)(B)

5. For rehabilitation or psychiatric distinct part units in critical access hospitals: If the critical access hospital receives notification that the result of the supplemental (additional, more specific) test for potentially infectious blood or blood components or other follow-up testing required by the US Food and Drug Administration (FDA) is indeterminate, the critical access hospital destroys or labels prior collections of blood or blood components held in quarantine, consistent with FDA requirements 21 CFR 610.46(b)(2) and 610.47(b)(2).

CoP(s): §482.27(b)(4)(iii)

- 6. For rehabilitation and psychiatric distinct part units in critical access hospitals: When potentially human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infectious blood or blood components are administered (either directly through the critical access hospital's own blood collecting establishment or under an agreement) or released to another entity or individual, the critical access hospital takes the following actions:
 - Attempts to notify the patient, the attending physician or other licensed practitioner, or the physician or other licensed practitioner who ordered the blood or blood component and ask the practitioner to notify the patient, or other individuals as permitted under 42 CFR 482.27, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling
 - Attempts to notify to the patient, legal guardian, or relative if the practitioner is unavailable or declines to make the notification
 - · Documents in the patient's medical record the notification or attempts to give the required notification

CoP(s): §482.27(b)(6)(i), §482.27(b)(6)(ii), §482.27(b)(6)(iii)

- 7. For rehabilitation and psychiatric distinct part units in critical access hospitals: If the critical access hospital receives notification that it received potentially human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infectious blood and blood components, the critical access hospital makes reasonable attempts to give notification over a period of 12 weeks unless one of the following occurs:
 - The patient is located and notified.
 - The critical access hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the critical access hospital's control that caused the notification timeframe to exceed 12 weeks.

Note: For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 610.47, the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components

CoP(s): §482.27(b)(7), §482.27(b)(7)(i), §482.27(b)(7)(ii)

- 8. For rehabilitation and psychiatric distinct part units in critical access hospitals: When notifying patients who have received potentially human immune deficiency virus (HIV) or hepatitis C virus (HCV) infectious blood or blood components, the notification includes the following:
 - Oral or written information explaining the need for HIV or HCV testing and counseling, so that the patient can make an informed decision about whether to obtain HIV or HCV testing and counseling
 - A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose

CoP(s): §482.27(b)(8)(i), §482.27(b)(8)(ii), §482.27(b)(8)(iii)

- 9. For rehabilitation and psychiatric distinct part units in critical access hospitals: If a patient has received an infectious blood or blood component, the critical access hospital notifies the specified individual(s) under the following circumstances:
 - A legal representative designated in accordance with state law if the patient has been adjudged incompetent by a state court
 - The patient or his or her legal representative or relative if the patient is competent but state law permits a legal representative or relative to receive the information on the patient's behalf
 - The patient's legal representative or relative if the beneficiary of the potentially human immunodeficiency virus infectious transfusion is deceased
 - The parents or legal guardian if the patient is a minor

CoP(s): §482.27(b)(10)

- 10. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital complies with US Food and Drug Administration regulations pertaining to blood safety issues in the following areas:
 - Appropriate testing and quarantining of infectious blood and blood components
 - Notification and counseling of potential recipients of infectious blood and blood components.

 Note: This applies to lookback activities only related to new blood safety issues that are identified.

Note: This applies to lookback activities only related to new blood safety issues that are identified after August 24, 2007.

CoP(s): §482.27(c)(1), §482.27(c)(2)

Physical Environment (PE) Chapter

PE.01.01.01

The critical access hospital has a safe and adequate physical environment.

Element(s) of Performance for PE.01.01.01

1. The critical access hospital's building is constructed, arranged, and maintained to allow safe access and to protect the safety and well-being of patients.

Note 1: Diagnostic and therapeutic facilities are located in areas appropriate for the services provided. Note 2: When planning for new, altered, or renovated space, the critical access hospital uses state rules and regulations or the current Guidelines for Design and Construction of Hospitals published by the Facility Guidelines Institute. If the state rules and regulations or the Guidelines do not address the design needs of the critical access hospital, then it uses other reputable standards and guidelines that provide equivalent design criteria.

CoP(s): §482.41, §482.41(a), §482.41(d), §482.41(d)(1), §482.42(a)(3), §485.614(c)(2), §485.623(a), §485.640(a)(3)

2. The critical access hospital has adequate space and facilities for the services it provides, including facilities for the diagnosis and treatment of patients and for any special services offered to meet the needs of the community served.

Note: The extent and complexity of facilities is determined by the services offered.

CoP(s): §482.41, §482.41(a), §482.41(d), §482.41(d)(3), §485.623(a)

The critical access hospital's premises are clean and orderly.
 Note: Clean and orderly means an uncluttered physical environment where patients and staff can function.
 This includes but is not limited to storing equipment and supplies in their proper spaces, attending to spills, and keeping areas neat.

CoP(s): §482.41(a), §485.623(b)(4)

PE.02.01.01

The critical access hospital manages risks related to hazardous materials and waste.

Element(s) of Performance for PE.02.01.01

- 1. The critical access hospital maintains a written, current inventory of hazardous materials and waste that it uses, stores, or generates. The only materials that need to be included on the inventory are those whose handling, use, and storage are addressed by law and regulation.
- 2. For managing hazardous materials and waste, the critical access hospital has the permits, licenses, manifests, and safety data sheets required by law and regulation.
- 3. The critical access hospital labels hazardous materials and waste. Labels identify the contents and hazard warnings.
 - Note: The Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens and Hazard Communications Standards and the National Fire Protection Association (NFPA) provide details on labeling requirements.
- 4. The critical access hospital develops and implements policies and procedures to protect patients and staff from exposure to hazardous materials. The policies and procedures address the following:

- Minimizing risk when selecting, handling, storing, transporting, using, and disposing of radioactive materials, hazardous chemicals, and hazardous gases and vapors
- · Disposal of hazardous medications
- · Minimizing risk when selecting and using hazardous energy sources, including the use of proper shielding
- Periodic inspection of radiology equipment and prompt correction of hazards found during inspection
- Precautions to follow and personal protective equipment to wear in response to hazardous material and waste spills or exposure

Note 1: Hazardous energy is produced by both ionizing equipment (for example, radiation and x-ray equipment) and nonionizing equipment (for example, lasers and MRIs).

Note 2: Hazardous gases and vapors include but are not limited to ethylene oxide and nitrous oxide gases; vapors generated by glutaraldehyde; cauterizing equipment, such as lasers; waste anesthetic gas disposal (WAGD); and laboratory rooftop exhaust. (For full text, refer to NFPA 99-2012: 9.3.8; 9.3.9)

CoP(s): §482.26(b), §482.26(b)(1), §482.26(b)(2), §482.53(b), §482.53(b)(2), §485.635(b)(3)

5. Radiation workers are checked periodically, using exposure meters or badge tests, for the amount of radiation exposure.

CoP(s): §482.26(b)(3), §485.635(b)(3)

6. The critical access hospital has procedures for the proper routine storage and prompt disposal of trash and regulated medical waste.

CoP(s): §482.41(b)(4), §485.623(b)(2)

PE.03.01.01

The critical access hospital designs and manages the physical environment to comply with the Life Safety Code.

Element(s) of Performance for PE.03.01.01

- 1. The critical access hospital maintains current and accurate drawings denoting features of fire safety and related square footage. Fire safety features include the following:
 - Areas of the building that are fully sprinklered (if the building is partially sprinklered)
 - · Locations of all hazardous storage areas
 - · Locations of all fire-rated barriers
 - · Locations of all smoke-rated barriers
 - · Sleeping and non-sleeping suite boundaries, including the size of the identified suites
 - · Locations of designated smoke compartments
 - · Locations of chutes and shafts
 - Any approved equivalencies or waivers
- 2. The critical access hospital maintains current Basic Building Information (BBI) within the Statement of Conditions (SOC).
- 3. The critical access hospital meets the applicable provisions of the Life Safety Code (NFPA 101-2012 and Tentative Interim Amendments [TIA] 12-1, 12-2, 12-3, and 12-4).
 - Note 1: Outpatient surgical departments meet the provisions applicable to ambulatory health care occupancies, regardless of the number of patients served.

Note 2: The provisions of the Life Safety Code do not apply in a state where the Centers for Medicare & Medicaid Services (CMS) finds that a fire and safety code imposed by state law adequately protects patients in critical access hospitals.

Note 3: In consideration of a recommendation by the state survey agency or accrediting organization or at the discretion of the Secretary for the US Department of Health & Human Services, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a critical access hospital, but only if the waiver will not adversely affect the health and safety of the patients.

Note 4: After consideration of state survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the critical access hospital, but only if the waiver does not adversely affect the health and safety of patients.

Note 5: All inspecting activities are documented with the name of the activity; date of the activity; inventory of devices, equipment, or other items; required frequency; name and contact information of person who performed the activity; NFPA standard(s) referenced for the activity; and results of the activity.

 $\begin{array}{l} \text{CoP(s): } \$482.15(e)(1), \$482.15(h)(1)(ix), \$482.15(h)(1)(vii), \$482.15(h)(1)(viii), \$482.15(h)(1)(x), \$482.15$

4. The critical access hospital has written fire control plans that include provisions for prompt reporting of fires; extinguishing fires; protection of patients, staff, and guests; evacuation; and cooperation with firefighting authorities.

CoP(s): §482.41(b)(5), §485.625(d)(1)(i)

5. The critical access hospital maintains written evidence of regular inspection and approval by state or local fire control agencies.

CoP(s): §482.41(b)(6), §485.623(c)(4)

6. Regardless of the provisions of the Life Safety Code, corridor doors and doors to rooms containing flammable or combustible materials have positive latching hardware. Roller latches are prohibited on these doors.

CoP(s): §482.41(b)(1)(ii), §485.623(c)(1)(ii)

7. When the critical access hospital installs alcohol-based hand rub dispensers, it installs the dispensers in a manner that protects against inappropriate access.

CoP(s): §482.41(b)(7), §485.623(c)(5)

8. When a sprinkler system is shut down for more than 10 hours, the critical access hospital either evacuates the building or portion of the building affected by the system outage until the system is back in service, or the critical access hospital establishes a fire watch until the system is back in service.

CoP(s): §482.41(b)(8)(i), §482.41(b)(8)(ii), §485.623(c)(6)(i), §485.623(c)(6)(ii)

- 9. Buildings have an outside window or outside door in every sleeping room. For any building constructed after July 5, 2016, the sill height does not exceed 36 inches above the floor.
 - Note 1: Windows in atrium walls are considered outside windows for the purposes of this requirement.
 - Note 2: The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.
 - Note 3: The sill height in special nursing care areas of new occupancies does not exceed 60 inches.
 - CoP(s): §482.41(b)(9), §482.41(b)(9)(i), §482.41(b)(9)(ii), §485.623(c)(7), §485.623(c)(7)(i), §485.623(c)(7)(ii)

PE.03.02.01

The critical access hospital protects occupants during periods when the Life Safety Code is not met or during periods of construction.

Element(s) of Performance for PE.03.02.01

- 1. The critical access hospital has a written interim life safety measures (ILSM) policy that covers situations when Life Safety Code deficiencies cannot be immediately corrected or during periods of construction. The policy includes criteria for evaluating when and to what extent the critical access hospital implements PE.04.02.01, EPs 2–15, to compensate for increased life safety risk. The criteria include the assessment process to determine when interim life safety measures are implemented.
 - Note: For any Life Safety Code (LSC) deficiency that cannot be immediately corrected during survey, the critical access hospital identifies which ILSMs in its policy will be implemented until the issue is corrected.
- 2. When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital evacuates the building or notifies the fire department (or other emergency response group) and initiates a fire watch when a fire alarm system is out of service more than 4 out of 24 hours in an occupied building. Notification and fire watch times are documented. (For full text, refer to NFPA 101-2012: 9.6.1.6; 9.7.6; NFPA 25-2011: 15.5.2)
- 3. When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital posts signage identifying the location of alternative exits to everyone affected.
- 4. When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital inspects exits in affected areas on a daily basis. The need for these inspections is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.
- 5. When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital provides temporary but equivalent fire alarm and detection systems for use when a fire system is impaired. The need for equivalent systems is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.
- 6. When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital provides additional firefighting equipment. The need for this equipment is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.
- 7. When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital uses temporary construction partitions that are smoketight or made of noncombustible or limited-combustible material that will not contribute to the development or spread of fire. The need for these partitions is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.

- 8. When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital increases surveillance of buildings, grounds, and equipment, giving special attention to construction areas and storage, excavation, and field offices. The need for increased surveillance is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.
- 9. When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital enforces storage, housekeeping, and debris-removal practices that reduce the building's flammable and combustible fire load to the lowest feasible level. The need for these practices is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.
- 10. When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital provides additional training to those who work in the critical access hospital on the use of firefighting equipment. The need for additional training is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.
- When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital conducts one additional fire drill per shift per quarter. The need for additional drills is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.
- 12. When the critical access hospital identifies Life Safety Code deficiencies that cannot be immediately corrected or during periods of construction, the critical access hospital inspects and tests fire protection systems monthly. The completion date of the tests is documented. The need for these inspections and tests is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.
- 13. The critical access hospital conducts education to promote awareness of building deficiencies, construction hazards, and temporary measures implemented to maintain fire safety. The need for education is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.
- 14. The critical access hospital trains those who work in the critical access hospital to compensate for impaired structural or compartmental fire safety features. The need for training is based on criteria in the critical access hospital's interim life safety measures (ILSM) policy.
 Note: Compartmentalization is the concept of using various building components (for example, fire-rated walls
 - and doors, smoke barriers, fire-rated floor slabs) to prevent the spread of fire and the products of combustion so as to provide a safe means of egress to an approved exit. The presence of these features varies, depending on the building occupancy classification.
- 15. The critical access hospital's policy allows the use of other interim life safety measures (ILSMs) not addressed in EPs 3–14.
 - Note: The other ILSMs used are documented by selecting "other" and annotating the associated text box in the critical access hospital's Survey-Related Plan for Improvement (SPFI) within the Statement of Conditions™ (SOC).

PE.04.01.01

The critical access hospital addresses building safety and facility management.

Element(s) of Performance for PE.04.01.01

The critical access hospital meets the applicable provisions and proceeds in accordance with the Health Care Facilities Code (NFPA 99-2012 and Tentative Interim Amendments [TIA] 12-2, 12-3, 12-4, 12-5, and 12-6).
 Note 1: Chapters 7, 8, 12, and 13 of the Health Care Facilities Code do not apply.
 Note 2: If application of the Health Care Facilities Code would result in unreasonable hardship for the critical access hospital, the Centers for Medicare & Medicaid Services may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

Note 3: All inspecting activities are documented with the name of the activity; date of the activity; inventory of devices, equipment, or other items; required frequency; name and contact information of person who performed the activity; NFPA standard(s) referenced for the activity; and results of the activity.

$$\begin{split} &\text{CoP(s): } \$482.15(e)(1), \$482.15(h)(1)(i), \$482.15(h)(1)(ii), \$482.15(h)(1)(iii), \$482.15(h)(1)(iii), \$482.15(h)(1)(iv), \$482.15(h)(1)(iv)$$

2. The critical access hospital maintains essential mechanical, electrical, and patient care equipment in safe operating condition.

CoP(s): §482.41(d)(2), §485.623(b)(1)

3. The critical access hospital has proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

CoP(s): §482.41(d)(4), §485.623(b)(5)

4. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital maintains equipment and supplies appropriate for the types of nuclear medicine services offered. The equipment is maintained for safe operation and efficient performance.

CoP(s): §482.53(c), §482.53(c)(1)

For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital
maintains supplies to ensure an acceptable level of safety and quality.
Note: Supplies are stored in a manner to ensure the safety of the stored supplies and to not violate fire codes or
otherwise endanger patients.

CoP(s): §482.41(d)(2)

PE.04.01.03

The critical access hospital manages utility systems.

Element(s) of Performance for PE.04.01.03

- 1. The critical access hospital has emergency power and lighting in the following areas, at a minimum:
 - · Operating rooms
 - · Recovery rooms
 - · Intensive care
 - Emergency rooms
 - Stairwells

Battery lamps and flashlights are available in all other areas not serviced by the emergency power supply source.

CoP(s): §482.41(a)(1)

- 2. The critical access hospital has a system to provide emergency gas and water supply.
 - Note 1: The system includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas.
 - Note 2: Emergency gas includes fuels such as propane, natural gas, fuel oil, or liquefied natural gas, as well as any gases the critical access hospital uses in the care of patients, such as oxygen, nitrogen, or nitrous oxide.

CoP(s): §482.41(a)(2)

 The critical access hospital meets the emergency power system and generator requirements found in NFPA 99-2012 Health Care Facilities Code, NFPA 110-2010 Standard for Emergency and Standby Power Systems, and NFPA 101-2012 Life Safety Code requirements.

CoP(s): §482.15(e)(1), §482.15(e)(2), §482.15(h)(1)(xii), §485.625(e)(1), §485.625(e)(2), §485.625(g)(1)(xii)

PE.04.01.05

The critical access hospital has a water management program that addresses Legionella and other waterborne pathogens.

Note: The water management program is in accordance with law and regulation.

Element(s) of Performance for PE.04.01.05

1. The water management program has an individual or a team responsible for the oversight and implementation of the program, including but not limited to development, management, and maintenance activities.

CoP(s): §482.41(d)(2), §482.42(a)(3), §485.623(b)(1), §485.640(a)(3)

- 2. The individual or team responsible for the water management program develops the following:
 - A basic diagram that maps all water supply sources, treatment systems, processing steps, control measures, and end-use points

Note: An example would be a flow chart with symbols showing sinks, showers, water fountains, ice machines, and so forth.

- A water risk management plan based on the diagram that includes an evaluation of the physical and chemical conditions of each step of the water flow diagram to identify any areas where potentially hazardous conditions may occur (these conditions are most likely to occur in areas with slow or stagnant water)

 Note: Refer to the Centers for Disease Control and Prevention's "Water Infection Control Risk Assessment (WICRA) for Healthcare Settings" tool as an example for conducting a water-related risk assessment.
- A plan for addressing the use of water in areas of buildings where water may have been stagnant for a period of time (for example, unoccupied or temporarily closed areas)
- An evaluation of the patient populations served to identify patients who are immunocompromised
- · Monitoring protocols and acceptable ranges for control measures

Note: Critical access hospitals should consider incorporating basic practices for water monitoring within their water management programs that include monitoring of water temperature, residual disinfectant, and pH. In addition, protocols should include specificity around the parameters measured, locations where measurements are made, and appropriate corrective actions taken when parameters are out of range.(See also IC.04.01.01, EP 2)

CoP(s): §482.41(d)(2), §482.42(a)(3), §485.623(b)(1), §485.640(a)(3)

- 3. The individual or team responsible for the water management program manages the following:
 - · Documenting results of all monitoring activities
 - Corrective actions and procedures to follow if a test result outside of acceptable limits is obtained, including when a probable or confirmed waterborne pathogen(s) indicates action is necessary
 - Documenting corrective actions taken when control limits are not maintained

Note: See PE.07.01.01, EP 1 for the process of monitoring, reporting, and investigating utility system issues.

CoP(s): §482.41(d)(2), §485.623(b)(1)

- 4. The individual or team responsible for the water management program reviews the program annually and when the following occurs:
 - Changes have been made to the water system that would add additional risk.
 - New equipment or an at-risk water system(s) has been added that could generate aerosols or be a potential source for Legionella. This includes the commissioning of a new wing or building.

Note 1: The Joint Commission and the Centers for Medicare & Medicaid Services (CMS) do not require culturing for Legionella or other waterborne pathogens. Testing protocols are at the discretion of the critical access hospital unless required by law or regulation.

Note 2: Refer to ASHRAE Standard 188-2018 "Legionellosis: Risk Management for Building Water Systems" and the Centers for Disease Control and Prevention Toolkit "Developing a Water Management Program to Reduce Legionella Growth and Spread in Buildings" for guidance on creating a water management plan. For additional guidance, consult ANSI/ASHRAE Guideline 12-2020 "Managing the Risk of Legionellosis Associated with Building Water Systems."

CoP(s): §482.41(d)(2), §485.623(b)(1)

PE.05.01.01

The critical access hospital manages imaging safety risks.

Element(s) of Performance for PE.05.01.01

1. At least annually, a diagnostic medical physicist or nuclear medicine physicist inspects, tests, and calibrates all nuclear medicine (NM) imaging equipment. The results, along with recommendations for correcting any

problems identified, are documented. These activities are conducted for all of the image types produced clinically by each NM scanner (for example, planar and/or tomographic) and include the use of phantoms to assess the following imaging metrics:

- · Image uniformity/system uniformity
- · High-contrast resolution/system spatial resolution
- · Sensitivity
- · Energy resolution
- Count-rate performance
- · Artifact evaluation

Note 1: The following test is recommended but not required: Low-contrast resolution or detectability for non-planar acquisitions.

Note 2: The medical physicist or nuclear medicine physicist is accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the medical physicist or nuclear medicine physicist. (For more information, refer to HR.11.01.03, EPs 1 and 2; HR.11.02.01, EP 2)

CoP(s): §482.53(c)(2)

- 2. At least annually, a diagnostic medical physicist conducts a performance evaluation of all positron emission tomography (PET) imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluations are conducted for all of the image types produced clinically by each PET scanner (for example, planar and/or tomographic) and include the use of phantoms to assess the following imaging metrics:
 - · Image uniformity/system uniformity
 - High-contrast resolution/system spatial resolution
 - Low-contrast resolution or detectability (not applicable for planar acquisitions)
 - · Artifact evaluation

Note 1: The following tests are recommended but not required for PET scanner testing: sensitivity, energy resolution, and count-rate performance.

Note 2: Medical physicists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the medical physicist. (For more information, refer to HR.11.01.03, EPs 1 and 2; HR.11.02.01, EP 2)

- 3. For computed tomography (CT), positron emission tomography (PET), nuclear medicine (NM), or magnetic resonance imaging (MRI) services: The annual performance evaluation conducted by the diagnostic medical physicist or MRI scientist (for MRI only) includes testing of image acquisition display monitors for maximum and minimum luminance, luminance uniformity, resolution, and spatial accuracy.
 - Note 1: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.
 - Note 2: Medical physicists or MRI scientists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the physicist or MRI scientist. (For more information, refer to HR.11.01.03, EPs 1 and 2; HR.11.02.01, EP 2)
- 4. For critical access hospitals that provide fluoroscopic services: At least annually, a diagnostic medical physicist conducts a performance evaluation of fluoroscopic imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes an assessment of the following:
 - · Beam alignment and collimation

- Tube potential/kilovolt peak (kV/kVp) accuracy
- Beam filtration (half-value layer)
- · High-contrast resolution
- · Low-contrast detectability
- Maximum exposure rate in fluoroscopic mode
- Displayed air-kerma rate and cumulative-air kerma accuracy (when applicable)

Note 1: Medical physicists conducting performance evaluations may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the physicist.

Note 2: This element of performance does not apply to fluoroscopy equipment used for therapeutic radiation treatment planning or delivery.

Performance Improvement (PI) Chapter

PI.11.01.01

The critical access hospital has an ongoing quality assessment and performance improvement program.

Element(s) of Performance for PI.11.01.01

- 1. The performance improvement program addresses outcome indicators related to the following:
 - · Improved health outcomes and the prevention and reduction of medical errors
 - · Adverse events
 - · Sentinel events

outcomes.

- · Health care-acquired conditions
- Transitions of care, including unplanned readmissions

CoP(s): §485.641(b)(5)

2. The critical access hospital has an ongoing quality assessment and performance improvement program that shows measurable improvement for indicators that are selected based on evidence that they will improve health outcomes and aid in the identification and reduction of medical errors. The program incorporates quality indicator data, including patient care data and other relevant data to achieve the goals of the program.
Note: For rehabilitation and psychiatric distinct part units in critical access hospitals: Relevant data includes data submitted to or received from Medicare quality reporting and quality performance programs including but not limited to data related to hospital readmissions and hospital-acquired conditions.

CoP(s): §482.21(a)(1), §482.21(b)(1), §485.641(e)

3. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital conducts performance improvement projects as part of its quality assessment and performance improvement program. The number and scope of distinct improvement projects conducted annually is proportional to the scope and complexity of the critical access hospital's services and operations.
Note 1: The critical access hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. In the initial stage of development, this project does not need to demonstrate measurable improvement in indicators related to health

Note 2: The critical access hospital is not required to participate in a quality improvement organization cooperative project, but its own projects are required to be of comparable effort.

CoP(s): §482.21(d), §482.21(d)(1), §482.21(d)(2), §482.21(d)(4)

PI.12.01.01

The critical access hospital collects data.

Element(s) of Performance for PI.12.01.01

- 1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital tracks medical errors and adverse patient events, analyzes their causes, and implements preventive actions and mechanisms that include feedback and learning throughout the critical access hospital. Medical errors and adverse patient events include but are not limited to the following:
 - · Medication administration errors
 - · Surgical errors
 - · Equipment failure
 - · Infection control errors
 - Blood transfusion-related errors
 - · Diagnostic errors

CoP(s): §482.21(c)(2)

2. The critical access hospital documents what quality improvement projects it is conducting, the reasons for conducting these projects, and the measurable progress achieved on these projects.

CoP(s): §482.21(d)(3)

3. The critical access hospital measures, analyzes, and tracks quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service, and operations.

CoP(s): §482.21(a)(2)

4. The critical access hospital takes action to improve its performance. After implementing changes, the critical access hospital measures its success and tracks performance to ensure that improvements are sustained.

CoP(s): §482.21(c)(3)

- 5. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home collects data on the following:
 - Disease management outcomes
 - Patient access to care within time frames established by the critical access hospital
 - Patient experience and satisfaction related to access to care, treatment, or services and communication
 - · Patient perception of the comprehensiveness of care, treatment, or services
 - · Patient perception of the coordination of care, treatment, or services
 - · Patient perception of the continuity of care, treatment, or services

PI.13.01.01

The critical access hospital compiles, analyzes, and uses data.

Element(s) of Performance for PI.13.01.01

- 1. The critical access hospital analyzes and compares internal data over time and uses the results of data analysis to do the following:
 - · Monitor the effectiveness and safety of services
 - · Monitor the quality of care
 - · Identify opportunities for improvement and changes that will lead to improvement

CoP(s): §482.21(b)(2)(i), §482.21(b)(2)(ii)

PI.14.01.01

The critical access hospital improves performance.

Element(s) of Performance for PI.14.01.01

1. The critical access hospital acts on improvement priorities.

CoP(s): §482.21, §482.21(c)(3), §482.21(d)(4), §482.21(e)(1), §485.641(e)

- 2. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home uses the data it collects on the patient's perception of the safety and quality of care, treatment, or services to improve its performance. This data includes the following:
 - · Patient experience and satisfaction related to access to care, treatment, or services and communication
 - · Patient perception of the comprehensiveness of care, treatment, or services
 - · Patient perception of the coordination of care, treatment, or services
 - · Patient perception of the continuity of care, treatment, or services

Record of Care, Treatment, and Services (RC) Chapter

RC.11.01.01

The critical access hospital maintains complete and accurate medical records for each individual patient.

Element(s) of Performance for RC.11.01.01

1. The critical access hospital maintains a medical record for every inpatient and outpatient in the critical access hospital.

CoP(s): §482.24, §482.24(b)

- 2. The medical record includes the following:
 - · Information needed to justify the patient's admission and continued care, treatment, and services
 - Information needed to support the patient's diagnosis and condition
 - Information about the patient's care, treatment, and services that promotes continuity of care among staff and providers

Note: For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: This requirement refers to care provided by both internal and external providers.

CoP(s): §482.24(c), §485.645(d)(2)

- 3. The medical record of a patient who receives urgent or immediate care, treatment, and services contains the following:
 - · Time and means of arrival
 - Indication that the patient left against medical advice, when applicable
 - Conclusions reached at the termination of care, treatment, and services, including the patient's final disposition, condition, and instructions given for follow-up care, treatment, and services
 - · A copy of any information made available to the provider furnishing follow-up care, treatment, or services
- 4. The critical access hospital develops and implements policies and procedures for accurate, legible, complete, signed, dated, and timed medical record entries that are authenticated by the person responsible for providing or evaluating the service provided. Medical records are promptly completed, systematically organized, and readily accessible.

CoP(s): §482.24(b), §482.24(c)(1), §482.53(d), §482.53(d)(2), §485.638(a)(2)

- 6. For psychiatric distinct part units in critical access hospitals: The medical record reflects the degree and intensity of treatment and contains the following information:
 - History of findings and treatment provided for the psychiatric condition for which the patient is hospitalized
 - · Identification data, including the patient's legal status
 - Provisional or admitting diagnosis for the patient at the time of admission that includes the diagnoses of intercurrent diseases as well as the psychiatric diagnoses
 - · Reasons for admission, as stated by the patient and/or others significantly involved
 - Social service records, including reports of interviews with patients, family members, and others; an assessment of home plans, family attitudes, and community resource contacts; and a social history
 - When indicated, record of a complete neurological examination, recorded at the time of the admission physical examination
 - · Documentation of treatment received, including all active therapeutic efforts
 - Discharge summary of the patient's hospitalization that includes a recapitulation of the patient's hospitalization in the unit, recommendations from appropriate services concerning follow-up or aftercare, and a brief summary of the patient's condition on discharge

CoP(s): §412.27(c), §412.27(c)(1), §412.27(c)(1)(i), §412.27(c)(1)(ii), §412.27(c)(1)(iii), §412.27(c)(1)(iii), §412.27(c)(1)(iv), §412.27(c)(3)(ii), §412.27(c)(5)

7. The critical access hospital develops and implements policies and procedures for the maintenance of its medical records system(s). A designated member of the professional staff is responsible for maintaining the records.

CoP(s): §485.638(a)(1), §485.638(a)(3)

8. For rehabilitation and psychiatric distinct part units in critical access hospitals: Admission and discharge records for rehabilitation and psychiatric distinct part units are separately identified from those of the critical access hospital in which the units are located.

CoP(s): §412.25(a)(3)

9. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The medical record includes the patient's self-management goals and their progress toward achieving those goals. (Refer to PC.11.03.01, EP 7)

RC.11.02.01

Entries in the medical record are authenticated.

Element(s) of Performance for RC.11.02.01

1. All orders, including verbal orders, are dated, timed, and authenticated by the ordering physician or other licensed practitioner who is responsible for the patient's care and who is authorized to write orders, in accordance with critical access hospital policy, law and regulation, and medical staff bylaws, rules, and regulations.

CoP(s): §482.24(c)(2), §485.638(a)(4)(iv)

2. The critical access hospital uses a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

CoP(s): §482.24(b)

RC.11.03.01

The critical access hospital retains its medical records.

Element(s) of Performance for RC.11.03.01

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The retention time of the original or legally reproduced medical record is determined by its use and critical access hospital policy, in accordance with law and regulation.

Note: Medical records are retained in their original or legally reproduced form for at least five years. This includes nuclear medicine reports; radiological reports, printouts, films, and scans; and other applicable image records.

CoP(s): §482.24(b)(1), §482.26(d)(2), §482.26(d)(2)(i), §482.26(d)(2)(ii), §482.53(d)(1)

2. The medical record is retained for at least six years from the date of its last entry and longer if required by state statute or if the record is needed in any pending proceeding.

CoP(s): §485.638(c)

RC.12.01.01

The medical record contains information that reflects the patient's care, treatment, and services.

Element(s) of Performance for RC.12.01.01

- 1. The medical record contains the following demographic information for the patient:
 - · Name, address, and date of birth, and the name of any legally authorized representative
 - Sex

- Communication needs, including preferred language for discussing health care
- · Race and ethnicity

Note: If the patient is a minor, is incapacitated, or has a designated advocate, the communication needs of the parent or legal guardian, surrogate decision-maker, or legally authorized representative are documented in the clinical record.

CoP(s): §485.638(a)(4)(i)

- 2. The medical record contains the following clinical information:
 - · Admitting diagnosis
 - · Any emergency care, treatment, and services provided to the patient before their arrival
 - · Any allergies to food and medications
 - · Any findings of assessments and reassessments
 - Results of all consultative evaluations of the patient and findings by clinical and other staff involved in the care
 of the patient
 - · Treatment goals, plan of care, and revisions to the plan of care
 - Documentation of complications, health care—acquired infections, and adverse reactions to drugs and anesthesia
 - · All practitioners' orders
 - Nursing notes, reports of treatment, laboratory reports, vital signs, and other information necessary to monitor the patient's condition
 - Medication records, including the strength, dose, route, date and time of administration, access site for medication, administration devices used, and rate of administration

Note: When rapid titration of a medication is necessary, the critical access hospital defines in policy the urgent/ emergent situations in which block charting would be an acceptable form of documentation. For the definition and a further explanation of block charting, refer to the Glossary.

- Administration of each self-administered medication, as reported by the patient (or the patient's caregiver or support person where appropriate)
- · Records of radiology and nuclear medicine services, including signed interpretation reports
- · All care, treatment, and services provided to the patient
- Patient's response to care, treatment, and services
- Medical history and physical examination, including any conclusions or impressions drawn from the information
- · Discharge plan and discharge planning evaluation
- Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care, including any medications dispensed or prescribed on discharge
- Any diagnoses or conditions established during the patient's course of care, treatment, and services Note: Medical records are completed within 30 days following discharge, including final diagnosis.

CoP(s): §482.23(c)(6)(i)(E), §482.23(c)(6)(ii)(E), §482.24(c), §482.24(c)(4)(ii), §482.24(c)(4)(iii), §482.24(c)(4)(iii), §482.24(c)(4)(iii), §482.24(c)(4)(viii), §482.26(d), §482.26(d)(1), §482.43(a)(3), §482.53(d), §482.56(b)(1), §482.57(b)(4), §485.638(a)(4)(i), §485.638(a)(4)(ii), §485.638(a)(4)(iii), §485.638(a)(4)(iiii), §485.642(a) (3)

3. The medical record contains any informed consent, when required by critical access hospital policy or federal or state law or regulation.

Note: The properly executed informed consent is placed in the patient's medical record prior to surgery, except in emergencies. A properly executed informed consent contains documentation of a patient's mutual understanding of and agreement for care, treatment, and services through written signature; electronic signature; or, when

a patient is unable to provide a signature, documentation of the verbal agreement by the patient or surrogate decision-maker.

CoP(s): §482.24(c)(4)(v), §482.51(b)(2), §485.638(a)(4)(i)

- 4. For psychiatric distinct part units in critical access hospitals: Progress notes are recorded at least weekly for the first two months of a patient's stay and at least monthly thereafter by the following individuals involved in the active treatment of the patient:
 - Physician(s), psychologist(s), or other licensed practitioner(s) responsible for the care of the inpatient
 - Nurse
 - Social worker
 - · Others involved in active treatment modalities

The progress notes include revisions to the treatment plan and assessments of the patient's progress in accordance with the original or revised treatment plan.

CoP(s): §412.27(c)(4)

- 5. The critical access hospital uses preprinted and electronic standing orders, order sets, and protocols for patient orders only if the following occurs:
 - Orders and protocols are reviewed and approved by the medical staff and the critical access hospital's nursing and pharmacy leadership.
 - · Orders and protocols are consistent with nationally recognized and evidence-based guidelines.
 - Orders and protocols are periodically and regularly reviewed by the medical staff and the critical access hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols.
 - Orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with state law, including scope-of-practice laws, critical access hospital policies, and medical staff bylaws, rules, and regulations.

CoP(s): §482.24(c)(3)(i), §482.24(c)(3)(ii), §482.24(c)(3)(iii), §482.24(c)(3)(iv)

6. The medical history and physical examination or updates to the medical history and physical examination are placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

CoP(s): §482.24(c)(4)(i)(A), §482.24(c)(4)(i)(B)

- 7. An assessment of the patient (in lieu of a medical history and physical examination as described in 42 CFR 482.24(c)(4)(i)(A) and (B)) is completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the following conditions are met:
 - The patient is receiving specific outpatient surgical or procedural services.
 - The medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at § 482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

CoP(s): §482.24(c)(4)(i)(C)

RC.12.01.03

The patient's medical record contains documentation on any operative or other high-risk procedures and the use of moderate or deep sedation or anesthesia.

Element(s) of Performance for RC.12.01.03

- 1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has a complete and up-to-date operating room register or equivalent record that includes the following:
 - · Patient's name
 - · Patient's critical access hospital identification number
 - · Date of operation
 - · Inclusive or total time of operation
 - · Name of surgeon and any assistants
 - · Name of nursing staff
 - · Type of anesthesia used and name of person administering it
 - · Operation performed
 - · Pre- and postoperative diagnosis
 - · Age of patient

CoP(s): §482.51(b)(5)

- 2. For rehabilitation and psychiatric distinct part units in critical access hospitals: An operative report is written or dictated immediately following surgery and signed by the surgeon. The report includes the following:
 - Name and hospital identification number of the patient
 - · Date and times of the surgery
 - Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues)
 - Preoperative and postoperative diagnosis
 - Name of the specific surgical procedure(s) performed
 - · Type of anesthesia administered
 - · Complications, if any
 - · Description of techniques, findings, and tissues removed or altered
 - Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any
 - · Any estimated blood loss

Note 1: The exception to this requirement occurs when an operative or other high-risk procedure progress note is written immediately after the procedure, in which case the full report can be written or dictated within a time frame defined by the critical access hospital.

Note 2: If the physician or other licensed practitioner performing the operation or high-risk procedure accompanies the patient from the operating room to the next unit or area of care, the report can be written or dictated in the new unit or area of care.

CoP(s): §482.51(b)(6)

RC.12.02.01

Qualified staff receive and record verbal orders.

Element(s) of Performance for RC.12.02.01

1. Only staff authorized by critical access hospital policies and procedures consistent with federal and state law accept and record verbal orders.

CoP(s): §482.23(c)(3)(ii)

RC.12.03.01

The patient's medical record contains discharge information.

Element(s) of Performance for RC.12.03.01

1. For swing beds in critical access hospitals: Documentation in the medical record includes discharge information provided to the resident and/or to the receiving organization. A physician document in the resident's medical record when the resident is being transferred or discharged because the safety of other residents would otherwise be endangered. The resident's physician documents in the medical record when the transfer is due to the resident improving and no longer needing long term care services or when the transfer is due to the resident's welfare and resident's needs cannot be met in the critical access hospital's swing bed.

CoP(s): §482.58(b)(2), §483.15(c)(2), §483.15(c)(2), §483.15(c)(2)(ii)(A), §483.15(c)(2)(ii)(A), §483.15(c)(2)(ii)(B), §483.15(c)(2)(ii)(B), §485.645(d)(2)

- 2. For swing beds in critical access hospitals: The resident's discharge information includes the following:
 - Reason for transfer, discharge, or referral
 - · Treatment provided, diet, medication orders, and orders for the resident's immediate care
 - Referrals provided to the resident, the referring physician's or other licensed practitioner's name, and the name of the physician or other licensed practitioner who has agreed to be responsible for the resident's medical care and treatment, if this person is someone other than the referring physician or other licensed practitioner
 - Medical findings and diagnoses; a summary of the care, treatment, and services provided; and progress reached toward goals
 - Information about the resident's behavior, ambulation, nutrition, physical status, psychosocial status, and potential for rehabilitation
 - Nursing information that is useful in the resident's care
 - · Any advance directives
 - Instructions given to the resident before discharge
 - · Attempts to meet the resident's needs

CoP(s): §482.58(b)(2), §483.15(c)(2)(i)(A), §483.15(c)(2)(i)(A), §485.645(d)(2)

3. For swing beds in critical access hospitals: When the resident is transferred or discharged because the critical access hospital cannot meet their needs, the critical access hospital documents which needs could not be met, the critical access hospital's attempts to meet the resident's needs, and the services available at the receiving organization that will meet the resident's needs.

CoP(s): §482.58(b)(2), §483.15(c)(2)(i)(B), §483.15(c)(2)(i)(B), §485.645(d)(2)

4. For swing beds in critical access hospitals: The critical access hospital records the reasons for the transfer or discharge in the resident's medical record in accordance with 42 CFR 483.15(c)(2).

CoP(s): §482.58(b)(2), §483.15(c)(3)(ii), §483.15(c)(3)(ii), §485.645(d)(2)

- 5. For swing beds in critical access hospitals: When the critical access hospital anticipates the discharge of a resident, the discharge summary includes but is not limited to the following:
 - A summary of the resident's stay that includes at a minimum the resident's diagnosis, course of illness/ treatment or therapy, and pertinent laboratory, radiology, and consultation results
 - A final summary of the resident's status to include items in 42 CFR 483.20 (b)(1) at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or resident's representative.
 - Reconciliation of all predischarge medications with the resident's postdischarge medications (both prescribed and over-the-counter).
 - A postdischarge plan of care, which will assist the resident to adjust to his or her new living environment, that is developed with the participation of the resident and, with the resident's consent, the resident representative(s). The postdischarge plan of care indicates where the individual plans to reside, any arrangements that have been made for the resident's follow up care, and any postdischarge medical and nonmedical services

CoP(s): §482.58(b)(5), §483.21(c)(2)(i), §483.21(c)(2)(i), §483.21(c)(2)(ii), §483.21(c)(2)(iii), §483.21(c)(2)(iii), §483.21(c)(2)(iv), §483.21(c)(2)(iv), §485.645(d)(5)

Rights and Responsibilities of the Individual (RI) Chapter

RI.11.01.01

The critical access hospital respects, protects, and promotes patient rights.

Element(s) of Performance for RI.11.01.01

1. The critical access hospital develops and implements written policies to protect and promote patient rights.

CoP(s): §482.13, §482.58(b)(1), §485.614

2. The critical access hospital informs each patient, or when appropriate, the patient's representative (as allowed, under state law) of the patient's rights in advance of providing or discontinuing care, treatment, or services whenever possible.

CoP(s): §482.13(a)(1), §485.614(a)(1)

3. The patient has the right to receive care in a safe setting.

CoP(s): §482.13(c)(2)

4. The critical access hospital prohibits discrimination based on age, race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, and gender identity or expression.

Note: This includes prohibiting discrimination through restricting, limiting, or otherwise denying visitation privileges. The critical access hospital allows all visitors to have full and equal visitation privileges consistent with patient preferences.

CoP(s): §482.13(h)(3), §482.13(h)(4), §485.614(h)(3), §485.614(h)(4)

5. The critical access hospital respects the patient's right to personal privacy.

Note 1: This element of performance (EP) addresses a patient's personal privacy. For EPs addressing the privacy of a patient's health information, refer to Standard IM.12.01.01.

Note 2: For swing beds in critical access hospitals: Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.

CoP(s): §482.13(c)(1), §482.58(b)(1), §483.10(h)(1), §483.10(h)(1), §483.10(h)(2), §483.10(h)(2), §485.614(c) (1), §485.645(d)(1)

6. The critical access hospital provides the patient, upon an oral or written request, with access to medical records, including past and current records, in the form and format requested (including in electronic form or format when available). If electronic is unavailable, the medical record is provided in hard copy or another form agreed to by the critical access hospital and patient. The critical access hospital does not impede the legitimate efforts of individuals to gain access to their own medical records and fulfills these electronic or hard-copy requests within a reasonable time frame (that is, as quickly as its recordkeeping system permits).

CoP(s): §482.13(d)(2), §485.614(d)(2)

7. The critical access hospital develops and implements policies and procedures for patient visitation rights. Visitation rights include the right to receive visitors designated by the patient, including but not limited to a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend. The patient also has the right to withdraw or deny consent for visitors at any time.

Note 1: The critical access hospital's written policies and procedures include any restrictions or limitations that are clinically necessary or reasonable that need to be placed on visitation rights and the reasons for the restriction or limitation.

Note 2: The critical access hospital informs the patient (or support person, where appropriate) of the patient's visitation rights, including any clinical restriction or limitation on such rights.

CoP(s): §482.13(h), §482.13(h)(1), §482.13(h)(2), §485.614(h), §485.614(h)(1), §485.614(h)(2)

8. For swing beds in critical access hospitals: The critical access hospital provides immediate family and other relatives immediate access to the resident, except when the resident denies or withdraws consent. The critical access hospital provides others who are visiting immediate access to the resident, except when reasonable clinical or safety restrictions apply or when the resident denies or withdraws consent.

CoP(s): §482.58(b)(1), §483.10(f)(4)(ii), §483.10(f)(4)(ii), §483.10(f)(4)(iii), §483.10(f)(4)(iii), §485.645(d)(1)

RI.11.02.01

The critical access hospital respects the patient's right to receive information in a manner the patient understands.

Element(s) of Performance for RI.11.02.01

The critical access hospital provides information, including but not limited to the patient's total health status, in a
manner tailored to the patient's age, language, and ability to understand.
 Note: The critical access hospital communicates with the patient during the provision of care, treatment, and
services in a manner that meets the patient's oral and written communication needs.

CoP(s): §482.58(b)(1), §483.10(c)(1), §483.10(c)(1), §483.15(c)(3)(i), §483.15(c)(3)(iii), §485.614(a)(2)(i), §485.645(d)(1), §485.645(d)(2)

RI.12.01.01

The critical access hospital respects the patient's right to participate in decisions about their care, treatment, and services.

Note: This right is not to be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

Element(s) of Performance for RI.12.01.01

1. The patient or their representative (as allowed, in accordance with state law) has the right to make informed decisions regarding their care. The patient's rights include being informed of their health status, being involved in care planning and treatment, and being able to request or refuse treatment. This does not mean the patient has the right to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

CoP(s): §482.13(b)(2), §482.58(b)(1), §483.10(c), §483.10(c), §485.614(b)(2), §485.645(d)(1)

2. The critical access hospital asks the patient whether they want a family member, representative, or physician or other licensed practitioner notified of their admission to the critical access hospital. The critical access hospital promptly notifies the identified individual(s).

Note: The patient is informed, prior to the notification occurring, of any process to automatically notify the patient's established primary care practitioner, primary care practice group/entity, or other practitioner group/entity, as well as all applicable post—acute care service providers and suppliers. The critical access hospital has a process for documenting a patient's refusal to permit notification of registration to the emergency department, admission to an inpatient unit, or discharge or transfer from the emergency department or inpatient unit. Notifications with primary care practitioners and entities are in accordance with all applicable federal and state laws and regulations.

CoP(s): §482.13(b)(4), §485.614(b)(4)

3. For swing beds in critical access hospitals: If a resident is adjudged incompetent under state law by a court of proper jurisdiction, the rights of the resident automatically transfer to and are exercised by a resident representative appointed by the court under state law to act on the resident's behalf. The resident representative exercises the resident's rights to the extent allowed by the court in accordance with state law. Note 1: If a resident representative's decision-making authority is limited by state law or court appointment, the resident retains the right to make those decisions outside the representative's authority. Note 2: The resident's wishes and preferences are considered by the representative when exercising the patient's rights.

Note 3: To the extent practicable, the resident is provided with opportunities to participate in the care planning process.

4. For swing beds in critical access hospitals: The resident has the right to request, refuse, and/or discontinue treatment; to participate in or refuse to participate in experimental research; and to formulate an advance directive.

CoP(s): §482.58(b)(1), §483.10(c)(6), §483.10(c)(6), §485.645(d)(1)

5. Staff and licensed practitioners who provide care, treatment, or services in the critical access hospital honor the patient's right to formulate advance directives and comply with these directives, in accordance with law and regulation.

Note: Law and regulation includes, at a minimum, 42 CFR 489.100, 489.102, and 489.104.

CoP(s): §482.13(b)(3), §485.614(b)(3)

6. For swing beds in critical access hospitals: The critical access hospital supports the residents right to choose a licensed attending physician.

Note: If the physician chosen by the resident refuses to or does not meet the requirements for attending physicians at 42 CFR 483, the critical access hospital may seek alternative physician participation to assure provision of appropriate and adequate care and treatment. The critical access hospital informs the resident if it determines that the physician chosen by the resident is unlicensed or unable to serve as the attending physician. The critical access hospital also discusses alternative physician participation with the resident and honors the resident's preferences, if any, among the options.

CoP(s): §482.58(b)(1), §483.10(d), §483.10(d), §483.10(d)(1), §483.10(d)(1), §483.10(d)(2), §483.10(d)(2), §483.10(d)(4), §483.10(d)(4), §483.10(d)(5), §483.10(d)(5), §485.645(d)(1)

- 7. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home allows the patient to select their primary care clinician.
- 8. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home respects the patient's right to make decisions about the management of the patient's care.
- 9. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home respects the patient's rights and provides the patient the opportunity to do the following:
 - · Obtain care from other clinicians of the patient's choosing within the primary care medical home
 - · Seek a second opinion from a clinician of the patient's choosing
 - Seek specialty care

Note: This element of performance does not imply financial responsibility for any activities associated with these rights.

RI.12.02.01

The critical access hospital respects the patient's right to receive information about the individual(s) responsible for, as well as those providing, the patient's care, treatment, and services.

Element(s) of Performance for RI.12.02.01

1. For swing beds in critical access hospitals: The critical access hospital provides the resident and the resident's family with the name and specialty of the physician or other licensed practitioner primarily responsible for the resident's care and a method to contact them.

CoP(s): §483.10(d)(3)

RI.12.02.03

For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides patients with information about its functions and services.

Element(s) of Performance for RI.12.02.03

- 1. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides information to the patient about its mission, vision, and goals.

 Note: This may include how it provides for patient-centered and team-based comprehensive care, a systems-based approach to guality and safety, and enhanced patient access.
- 2. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides information to the patient about the scope of care and types of services it provides.
- 3. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides information to the patient about how it functions, including the following:
 - · Processes supporting patient selection of a primary care clinician
 - · Involving the patient in their treatment plan
 - · Obtaining and tracking referrals
 - · Coordinating care
 - Collaborating with patient-selected clinicians who provide specialty care or second opinions Note: Supporting patients in selecting a primary care clinician may include providing patients with information regarding the clinician's credentials, area(s) of specialty, interests, languages spoken, and gender.
- 4. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides information to the patient about how to access the organization for care or information.
- 5. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides information to the patient about patient responsibilities, including providing health history and current medications, and participating in self-management activities.
- 6. For critical access hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides information to the patient about the patient's right to obtain care from other clinicians within the primary care medical home, to seek a second opinion, and to seek specialty care. (Refer to RI.11.02.01, EPs 1 and 3)

RI.13.01.01

The patient has the right to be free from harassment, neglect, exploitation, and verbal, mental, physical, and sexual abuse.

Element(s) of Performance for RI.13.01.01

- 1. The critical access hospital protects the patient from harassment, neglect, exploitation, corporal punishment, involuntary seclusion, and verbal, mental, sexual, or physical abuse that could occur while the patient is receiving care, treatment, and services.
 - For swing beds in critical access hospitals: The critical access hospital also protects the resident from misappropriation of property.
 - CoP(s): §482.13(c)(3), §482.13(e), §482.58(b)(3), §483.12, §483.12(a)(1), §483.12(a)(1), §485.614(c)(3), §485.614(e), §485.645(d)(3)
- 2. For swing beds in critical access hospitals: The critical access hospital reports to the state nurse aide registry or licensing authorities any knowledge it has of any actions taken by a court of law against an employee that would indicate unfitness for service as a nurse aide or other facility staff.
 - CoP(s): §482.58(b)(3), §483.12(a)(4), §483.12(a)(4), §483.12(c)(1), §485.645(d)(3)
- For critical access hospitals with swing beds: The critical access hospital develops and implements written
 policies and procedures that prohibit and prevent mistreatment, neglect, and abuse of residents and
 misappropriation of resident property. The policies and procedures also address investigation of allegations
 related to these issues.
 - CoP(s): §482.58(b)(3), §483.12(b)(1), §483.12(b)(1), §483.12(b)(2), §483.12(b)(2), §485.645(d)(3)
- 4. The critical access hospital reports allegations, observations, and suspected cases of neglect, exploitation, and abuse to appropriate authorities based on its evaluation of the suspected events or as required by law.

 Note: For swing beds in critical access hospitals: Alleged violations involving abuse, neglect, exploitation, or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported to the administrator of the facility and to other officials (including the state survey agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with state law and established procedures. The alleged violations are reported in the following time frames:
 - No later than 2 hours after the allegation is made if the allegation involves abuse or serious bodily injury
 - No later than 24 hours after the allegation is made if the allegation does not involve abuse or serious bodily injury
 - CoP(s): §482.58(b)(3), §483.12(c)(1), §483.12(c)(1), §485.645(d)(3)
- 5. For critical access hospitals with swing beds: The critical access hospital has evidence that all alleged violations of abuse, neglect, exploitation, or mistreatment are thoroughly investigated and that it prevents further abuse, neglect, exploitation, or mistreatment while the investigation is in progress. The results of all investigations are reported to the administrator or their designated representative and to other officials in accordance with state

law, including the state survey agency, within five working days of the incident. If the alleged violation is verified, appropriate corrective actions is taken.

 $CoP(s): \S 482.58(b)(3), \S 483.12(c)(2), \S 483.12(c)(2), \S 483.12(c)(3), \S 483.12(c)(3), \S 483.12(c)(4), \S 4$

RI.13.01.03

The patient has the right to an environment that preserves respect and dignity.

Element(s) of Performance for RI.13.01.03

1. For swing beds in critical access hospitals: The critical access hospital allows the resident to keep and use personal clothing and possessions, unless this infringes on others' rights or is medically or therapeutically contraindicated, based on the setting or service.

CoP(s): §482.58(b)(1), §483.10(e)(2), §483.10(e)(2), §485.645(d)(1)

2. For swing beds in critical access hospitals: The critical access hospital allows the resident to share a room with their spouse when married residents are living in the same critical access hospital and when both individuals consent to the arrangement.

CoP(s): §482.58(b)(1), §483.10(e)(4), §483.10(e)(4), §485.645(d)(1)

3. For swing beds in critical access hospitals: The critical access hospital supports the resident's right to send and promptly receive unopened mail and to receive letters, packages, and other materials delivered to the critical access hospital for the resident through a means other than a postal service. The critical access hospital respects the resident's right to privacy of such communications and allows access to stationery, postage, and writing implements at the resident's expense.

4. For swing beds in critical access hospitals: Room changes in an organization that is a composite distinct part (a distinct part consisting of two or more noncontiguous components that are not located within the same campus, as defined in 42 CFR 413.65(a)(2)) are limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.

CoP(s): §483.15(c)(9), §485.645(d)(2)

RI.14.01.01

The patient and their family have the right to have grievances reviewed by the critical access hospital.

Element(s) of Performance for RI.14.01.01

1. The process for resolving grievances includes a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization.

CoP(s): §482.13(a)(2), §485.614(a)(2)

2. The critical access hospital develops and implements policies and procedures for the prompt resolution of patient grievances. The policies clearly explain the procedure for patients to submit written or verbal grievances and specify timeframes for the review of and response to the grievance.

CoP(s): §482.13(a)(2), §482.13(a)(2)(i), §482.13(a)(2)(ii), §485.614(a)(2), §485.614(a)(2)(i), §485.614(a)(2)(ii)

- 3. In its resolution of grievances, the critical access hospital provides the patient with a written notice of its decision, which contains the following:
 - -Name of the critical access hospital contact person
 - -Steps taken on behalf of the individual to investigate the grievances
 - -Results of the process
 - -Date of completion of the grievance process

CoP(s): §482.13(a)(2)(iii), §485.614(a)(2)(iii)

Transplant Safety (TS) Chapter

TS.11.01.01

The critical access hospital, with the medical staff's participation, develops and implements written policies and procedures for donating and procuring organs, tissues, and eyes.

Element(s) of Performance for TS.11.01.01

- 1. The critical access hospital develops and implements written policies and procedures for organ procurement responsibilities that include the following:
 - A written agreement with an organ procurement organization (OPO) that requires the critical access hospital
 to notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death
 is imminent or who have died in the critical access hospital, and that includes the OPO's responsibility to
 determine medical suitability for organ donation
 - A written agreement with at least one tissue bank and at least one eye bank to cooperate in retrieving, processing, preserving, storing, and distributing tissues and eyes to make certain that all usable tissues and eyes are obtained from potential donors, to the extent that the agreement does not interfere with organ procurement
 - Designation of an individual, who is an organ procurement representative, an organizational representative of a tissue or eye bank, or a designated requestor, to notify the family regarding the option to donate or decline to donate organs, tissues, or eyes

- Procedures for informing the family of each potential donor about the option to donate or decline to donate organs, tissues, or eyes, in collaboration with the designated OPO
- Education and training of staff in the use of discretion and sensitivity to the circumstances, views, and beliefs of the family when discussing potential organ, tissue, or eye donations

Note 1: The critical access hospital has an agreement with an OPO designated under 42 CFR part 486.

Note 2: The requirements for a written agreement with at least one tissue bank and at least one eye bank may be satisfied through a single agreement with an OPO that provides services for organ, tissue, and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the critical access hospital.

Note 3: A designated requestor is an individual who has completed a course offered or approved by the OPO. This course is designed in conjunction with the tissue and eye bank community to provide a methodology for approaching potential donor families and requesting organ and tissue donation.

Note 4: The term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

Note 5: Note: For additional information about criteria for the determination of brain death, see the American Academy of Neurology guidelines available at https://n.neurology.org/content/early/2023/09/13/WNL.00000000207740, the American Academy of Pediatrics guidelines available at https://www.aan.com/Guidelines/Home/GuidelineDetail/1085, and the interactive tool that can be used alongside the new guidance to help walk clinicians through the BD/DNC evaluation process at https://www.aan.com/Guidelines/BDDNC.

CoP(s): §482.45(a)(1), §482.45(a)(2), §482.45(a)(3), §482.45(a)(4), §482.45(b)(2), §485.643(a), §485.643(b), §485.643(d), §485.643(f)

- 2. The critical access hospital develops and implements policies and procedures for working with the organ procurement organization (OPO) and tissue and eye banks to do the following:
 - Review death records in order to improve identification of potential donors
 - Maintain potential donors while the necessary testing and placement of potential donated organs, tissues, and eyes takes place in order to maximize the viability of donor organs for transplant
 - · Educate staff about issues surrounding donation

CoP(s): §482.45(a)(5), §485.643(e)

3. The individual designated by the critical access hospital documents that the patient or family accepts or declines the opportunity for the patient to become an organ, tissue, or eye donor.

CoP(s): §485.643(c)

TS.12.01.01

For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital complies with organ transplantation responsibilities.

Element(s) of Performance for TS.12.01.01

1. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital performing organ transplants belongs to and abides by the rules of the Organ Procurement and Transplantation Network (OPTN) established under section 372 of the Public Health Service (PHS) Act.

Note: The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary of the US Department of Health & Human Services in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B)

of the Act, or with the requirements of this element of performance, unless the Secretary has given the OPTN formal notice that the Secretary approves the decision to exclude the critical access hospital from the OPTN and has notified the critical access hospital in writing.

CoP(s): §482.45(b)(1)

2. For rehabilitation and psychiatric distinct part units in critical access hospitals: If requested, the critical access hospital provides all data related to organ transplant to the Organ Procurement and Transplantation Network (OPTN), the Scientific Registry of Transplant Recipients, the critical access hospital's designated organ procurement organization (OPO), and, when requested by the Office of the Secretary, directly to the US Department of Health & Human Services.

CoP(s): §482.45(b)(3)