

# Critical Access Hospital Medicare Survey Preparation

The information in this document is provided to assist critical access hospital staff preparing for the next Medicare survey, and is divided into three sections: Survey Preparation Recommendations, Conditions of Participation Guidance, and Additional Resources.

## Survey Preparation Recommendations

**Create a Survey Team within your hospital.** The team should be responsible for gathering necessary and preferred documentation (and keeping it current), working with department managers and other staff to ensure everyone understands their role in the survey process, and checking for compliance on a regular basis.

- **Survey documents.** Have a folder ready with the following documents. Be sure to keep these documents updated.
  - Map/floor plan
  - Organizational chart
  - List of staff and hours of operation
  - List of services including those that are contracted
  - Quality Assurance/Quality Improvement Plans
  - Infection Control Plan
  - Network agreement
  - Copy of CLIA or other certifications and the most recent survey documentation
  
- **Policy documentation and processes.** The Conditions of Participation (see Guidance, below) frequently refer to the process taken to review (and revise, as necessary) all patient care policies. Although each department should be responsible for the review of their policies, it is important to have a written explanation of how the group described in TAG C272 is involved in this process. Both a description of the process and evidence of this group's involvement must be readily available for a surveyor's review.

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- **Environmental Walk-through.** Part of the survey process includes a walk-through of the facility. The survey team makes observations and interviews staff during the walk-through. These observations often lead to further policy review. One of the functions of your survey team should be to periodically conduct a walk-through, observing as a surveyor.

The following checklist provides a good starting point for conducting your own walk-through:

- Locks: Are all areas that should be locked secure? Who has access to locked areas? Where are keys kept? Who knows codes to cipher locks? How often are codes changed?
- Are expiration dates on ALL supplies?
- Are boxes and other items off the floor?
- Pretend to be a confused visitor or patient; what can you find? (Open doors with no one around? Chemicals? Drugs? Information on your neighbor? Things to trip on or to purposely hurt oneself with?)
- Signage: Enter the building from ALL doors possible. Is there appropriate signage directing those who enter?

## Conditions of Participation Guidance

The following table draws on the current CAH Interpretive Guidelines (as printed in the CMS State Operations Manual, Appendix W at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_w\\_cah.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_w_cah.pdf) (PDF). It is meant to serve as a tool for understanding and preparing for the CAH Medicare survey. The table is divided into four columns:

- **TAG:** This is the reference number range for a specific Condition of Participation
- **Condition of Participation:** This is the actual regulation. The Interpretive Guidelines list the regulations in a two-tiered hierarchy. The Condition of Participation is the higher overall regulation. Most Conditions of Participation are divided with more detail with the second-level Standard. Both the Conditions of Participation and the Standard must be met. The table includes a column for the Condition of Participation. The Standard, though not stated, is usually discussed in the Notes column.
- **Notes:** This is a general description of the regulation and each of its subparts. It includes comments and tips for how to demonstrate compliance with the Conditions of Participation.
- **CAH Notes:** This column is intended for CAH use.

TAG	Condition of Participation	Notes	CAH Notes
C150-152	§485.608: Compliance with federal, state, and local laws and regulations	<p><b>Overview:</b> This section verifies the hospital is licensed and employs appropriately licensed and certified personnel.</p> <p><b>C151: (a) Compliance with Federal laws and regulations.</b></p> <p>Surveyors are required to note noncompliance with federal laws and regulations (such as EMTALA, blood borne pathogens, universal precautions, disposal of medical waste, occupational health) and refer them to the appropriate agency.</p> <p><b>Advance Directives:</b> CAH must provide written notice of its policies regarding the implementation of patients’ rights to make decisions concerning medical care.</p> <p>Required disclosures to patients:</p> <ul style="list-style-type: none"> <li>• Whether the CAH is physician owned</li> <li>• If there is no physician on site 24 hours per day</li> </ul> <p><b>C152: (b) Compliance with state and local laws and regulations.</b></p> <p>State-specific mandated policies and procedures should be in place (e.g., scope of practice for physician assistants).</p>	

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<b>C153-154</b>	§485.608: Compliance with federal, state, and local laws and regulations	<p><b>C153: (c) Licensure of CAH</b></p> <p>If the hospital is new or re-opening after being closed, it must first be licensed and certified as a Medicare provider.</p> <p><b>C154: (d) Licensure, certification or registration of personnel.</b></p> <p>The state requires all staff to be licensed (e.g., nurses, physicians, physician assistants, dieticians, radiology technicians, respiratory therapists). Staff must, at minimum, have current license or certification, possess minimum qualifications, and meet training and education requirements.</p>	

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C-160 -165	§485.610 Status and Location	<p><b>Overview:</b> Hospitals are eligible for CAH conversion based on their Necessary Provider, location, and current Medicare status. Compliance must be recertified at every survey (see C162).</p> <p><b>C162: Location in a Rural Area of Treatment as Rural</b> Surveyors will verify compliance prior to visiting the CAH for the survey.</p> <p>CAHs must meet the requirements described in (1) OR (2) below:</p> <ul style="list-style-type: none"> <li>(1) Is located outside of a metropolitan statistical area, not deemed to be located in an urban area, and has not been classified as an urban CAH</li> <li>(2) The CAH is located within a metropolitan statistical area, but is being treated as being located in a rural area in accordance with regulations.</li> </ul> <p><i>(Please refer to the full Interpretive Guidelines for definitions and more explanation).</i></p> <p><b>C165: Location Relative to Other Facilities or Necessary Provider Certification</b></p> <p>The CAH is located more than a 35-mile drive (or in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or a state certifies the CAH as being a necessary provider of health care services to residents in the area. After January 1, 2006, the necessary provider waiver is no longer applicable. Those CAHs designated as necessary providers prior to January 1, 2006, will retain the necessary provider waiver issued by the state.</p>	

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C166	§ 485.610 (d): Relocation of CAHs With a Necessary Provider	<p><b>Overview:</b> CAHs designated prior to January 1, 2006, that relocate must meet the following requirements to retain necessary provider and CAH status:</p> <p>At its new location, the CAH must:</p> <ul style="list-style-type: none"> <li>(1) Serve at least 75 percent of the same service area that it served prior to its relocation</li> <li>(2) Provide at least 75 percent of the same services that it provided prior to the relocation; and</li> <li>(3) Be staffed by 75 percent of the same staff (including medical staff, contracted staff and employees) as the original location.</li> </ul>	

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C170	§485.612: Compliance with CAH Requirements at the Time of Application.	<p><b>Overview:</b> This CoP applies only to initial surveys. The hospital must be a Medicare provider at the time of CAH application, and must adhere to Medicare CoPs for acute care hospitals until certified as a CAH.</p>	

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<b>C190-195</b>	§485.616 Agreements	<p><b>Overview:</b> Each state’s Rural Health Plan dictated how this section has been implemented. In Minnesota, each CAH was required to enter into a Network Agreement with a tertiary care hospital. Network agreements must address patient referral and transfer, development and use of a mode of communication, the provision of emergency and non-emergency transportation, and credentialing and quality assurance.</p> <p>Surveyors are likely to request copies of agreements for emergency and nonemergency transportation, communications systems (as well as communication system policies and procedures), and peer review. As with any contract, be sure these are reviewed and updated periodically.</p>	

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<b>C200-201</b>	§485.618 Emergency Services	<p><b>Overview:</b> This section stipulates the CAH meets the emergency needs of patients in accordance with acceptable standards of practice. Respiratory therapy services are included in this section.</p> <p><b>C201: Availability.</b> The CAH must provide emergency services 24 hours a day. A practitioner with training and experience in emergency care must be on call and immediately available by telephone or radio, and available on site within 30 minutes (or one hour in frontier areas).</p>	

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C202-206	§485.618 Emergency Services	<p><b>Overview:</b> This section stipulates the CAH meets the emergency needs of patients in accordance with acceptable standards of practice. Respiratory therapy services are included in this section.</p> <p><b>C202-204: Equipment, supplies and medication.</b> The CAH should have policies and procedures addressing the availability, storage and proper use and disposal of required and necessary equipment, supplies and medications used in treating emergency cases. Surveyors are likely to inspect the emergency room for general emergency equipment such as crash carts, intubation equipment, defibrillators, suction, and oxygen. They will look for evidence that everything is in working order with no expiration dates and that documentation exists that it has been checked and maintained in a manner consistent with current standards.</p> <p><b>C205-206: Blood and blood products.</b> The CAH must provide blood or blood products on an emergency basis. CAHs are not required to store blood on site. Policies and procedures should address availability, agreements or arrangements with suppliers, etc. If blood collection and testing is performed on site, the CAH must have a CLIA certificate, FDA registration, and the appropriate policies and procedures. CAHs should demonstrate evidence that the blood bank is under the control and supervision of a pathologist or other qualified MD/DO.</p>	

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C207-209	§485.618 Emergency Services	<p><b>Overview:</b> This section stipulates the CAH meets the emergency needs of patients in accordance with acceptable standards of practice. Respiratory therapy services are included in this section.</p> <p><b>C207: Personnel.</b> The practitioner (MD, DO, PA, NP, or CNS with training or experience in emergency care) on call must be available immediately by phone and able to be on site within 30 minutes (or one hour in frontier areas).</p> <p>An RN with training and experience can be utilized to conduct MSE if:</p> <ul style="list-style-type: none"> <li>• The RN is on site and immediately available and</li> <li>• The nature of the patient’s request for medical care is within the scope of practice of the RN and consistent with applicable State laws and CAH’s bylaws or rules and regulations.</li> </ul> <p><b>C209: Coordination with emergency response systems.</b> CAHs should provide documentation regarding the local ambulance service and its relationship (ownership or contracted) with the CAH. Surveyors are likely to look at the hospital’s policies and procedures in place to ensure that an MD or DO is available by telephone or radio, on a 24-hour a day basis to receive emergency calls and provide medical direction in emergency situations.</p>	

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C210-211	§ 485.620: Number of Beds and Length of Stay	<p><b>Overview:</b> CAHs are held to a maximum of 25 inpatient beds that can be used for inpatient acute care or swing bed services. The statute also requires CAHs to limit inpatient acute care to 96 hours per patient (annual basis).</p> <p><b>C211: Number of Beds</b> CAHs are permitted to operate a 10-bed psychiatric distinct part unit (DPU) and a 10-bed rehabilitation DPU without counting these beds toward the 25-bed inpatient limit.</p> <p>CAHs that were larger hospitals prior to converting to CAH status may not maintain more than 25 inpatient beds, plus a maximum of 10 psychiatric DPU inpatient beds, and 10 rehabilitation DPU inpatient beds.</p> <p><b>Beds Used For Observation Services</b></p> <p>Observation beds are not included in the 25-bed maximum as long as they are never used for inpatient stays at any time, nor are they included in the calculation of the average annual acute care patient length of stay. This makes it essential for surveyors to determine that CAHs with observation beds are using them appropriately, and not as a means to circumvent the CAH size and length-of-stay limits.</p> <p>Observation care is a well-defined set of specific, clinically appropriate services that include ongoing short-term treatment, assessment and reassessment, that are provided before a decision can be made regarding whether a patient will require further treatment as an inpatient, or may be safely discharged.</p>	

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C211	§ 485.620: Number of Beds and Length of Stay	<p>Policies and procedures should clearly describe when a patient is eligible for observation status. Procedures should also describe the process by which a patient is transferred to and from observation status. Observation services BEGIN and END with an order by a physician or other qualified licensed practitioner of the CAH.</p> <p><b>Other Types of Beds</b> Other bed types that do not count toward the 25 inpatient bed limit include:</p> <ul style="list-style-type: none"> <li>• Examination or procedure tables</li> <li>• Stretchers</li> <li>• Operating room tables</li> <li>• Beds in a surgical recovery room used exclusively for surgical patients during recovery from anesthesia</li> <li>• Beds in an obstetric delivery room used exclusively for OB patients in active labor and delivery of newborn infants (do count beds in birthing rooms where the patient remains after giving birth)</li> <li>• Newborn bassinets and isolettes used for well-baby boarders; however, if the baby is held for treatment at the CAH, his or her bassinet or isolette does count toward the 15-bed limit.</li> <li>• Stretchers in emergency departments and</li> <li>• Inpatient beds in Medicare-certified distinct part rehabilitation or psychiatric units.</li> </ul> <p><b>Beds Used For Hospice Services</b> Beds can be dedicated to a hospice under arrangement, but the beds <i>do</i> count as part of the maximum bed count. The computation contributing to the 96-hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care.</p>	

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<b>C212</b>	§ 485.620: Number of Beds and Length of Stay	<p><b>C212: Length of Stay</b>  <i>The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient. The fiscal intermediary (FI) will determine compliance with this CoP.</i></p> <p><i>(Please refer to the full Interpretive Guidelines for definitions and more clarification).</i></p>	

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<b>C220-221</b>	§485.623 Physical Plant and Environment	<p><b>Overview:</b> All patient care locations of the CAH must be appropriately constructed for the number and type of patients served.</p> <p>The CAH's departments or services responsible for the CAH's building and equipment maintenance (both facility equipment and patient care equipment) must be incorporated into the CAH's QA program and be in compliance with the QA requirements.</p> <p><b>C221: Construction</b> The CAH is constructed, arranged and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.</p>	

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C222-226	§ 485.623 (b) Maintenance	<p><b>Overview:</b> The CAH must develop and maintain the condition of the physical plant and overall CAH environment to ensure the safety and well-being of patients. This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with federal and state laws, regulations and guidelines and manufacturers’ recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the CAH’s QA plan.</p> <p><b>Facilities</b> must be maintained to ensure an acceptable level of safety and quality.  <b>Supplies</b> must be maintained to ensure an acceptable level of safety and quality.  <b>Equipment</b> must be maintained to ensure an acceptable level of safety and quality.</p> <p>The CAH has housekeeping and preventive maintenance programs to ensure that:</p> <ul style="list-style-type: none"> <li>• All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition</li> <li>• There is proper routine storage and prompt disposal of trash</li> <li>• Drugs and biologicals are appropriately stored</li> <li>• The premises are clean and orderly</li> <li>• There is proper ventilation, lighting and temperature control in all pharmaceutical, patient care and food preparation areas.</li> </ul> <p><i>(Please refer to the full Interpretive Guidelines for definitions and more explanation).</i></p>	

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C227-230	§ 485.623(c) Emergency Procedures	<p><b>Overview:</b> The CAH must demonstrate they can ensure the safety of patients in nonmedical emergencies.</p> <p><b>C227: Training:</b> Surveyors will look for evidence of staff training in handling emergencies, evacuation of patients, personnel and guests, and cooperation with fire and disaster authorities.</p> <p><b>C228: Emergency power and lighting in the emergency room and battery lamps and flashlights in other areas.</b> Surveyors will use the Life Safety Code Survey Report Form (CMS-2786) to evaluate compliance.</p> <p><b>C229: Emergency fuel and water supply</b> Surveyors will review the system used to determine emergency needs for gas and water. It must account for not only inpatients, but also staff and others who come to the CAH in need of care during an emergency. They will also determine the source and quantity of emergency gas and water, and will verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities.</p> <p><b>C230: Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.</b> Most disaster plans will provide necessary documentation for this condition of participation. CAHs should take into consideration special risks and factors associated with their geographic location (such as proximity to a flood zone, tourist area or wilderness).</p>	

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C231-235	§ 485.623(d) Life Safety From Fire	<p><b>Overview:</b> CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.</p> <p>Life Safety Code inspections are conducted separately by the State Fire Marshall.</p>	

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C240-244	§485.627 Organizational Structure	<p><b>Overview:</b> This section stipulates that documentation regarding the hospital’s governing board structure and responsibilities, ownership and responsible staff persons is on file, current and available.</p> <p><b>C241: Governing body or responsible individual.</b> CAHs should be prepared to provide the following:</p> <ol style="list-style-type: none"> <li>1. Organizational chart.</li> <li>2. Documentation of the individual or individuals who are responsible for operations of CAH.</li> <li>3. Job description for responsible person or body of the CAH.</li> <li>4. Documentation that the governing body has approved medical staff bylaws and rules and regulations.</li> <li>5. Documentation that the governing body has approved categories of practitioners eligible for medical staff appointment.</li> <li>6. Documentation of governing body approval of the criteria required for approval of appointment to the medical staff (minimal criteria: individual character, competence, training, experience and judgment).</li> <li>7. Documentation that hospital policies are updated and pertain to services provided by the CAH.</li> <li>8. Documentation that the governing board periodically reviews medical staff QA.</li> <li>9. Documentation of policies and procedures for periodic review of medical staff QA by the governing body.</li> <li>10. Credential files for medical staff that identify approval by the governing body.</li> </ol>	

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C250-261	§485.631 (a) and (b) Staffing and Staff Responsibility	<p><b>Overview:</b> This section describes the acceptable staffing and roles/responsibilities of certain key staff positions.</p> <p><b>C251-255: Staffing.</b> A CAH may operate with an MD or DO on staff as well as with any combination of mid-level practitioners (with documented physician oversight). The surveyors will ask to see staffing schedules and organizational charts to determine if the hospital provides for adequate medical coverage. Also, be prepared show documentation regarding mid-level practitioners’ scope of practice, documented physician oversight). The surveyors will ask to see staffing schedules and organizational charts to determine if the hospital provides for adequate medical coverage. Also, be prepared show documentation regarding mid-level practitioners’ scope of practice, including their role in medical record review, quality improvement and periodic review of policies and procedures. Medical staff bylaws may also be reviewed.</p> <p><b>C256—261: Responsibilities of MD or DO.</b></p> <ol style="list-style-type: none"> <li>1. Provides medical direction of CAH’s health care activities and supervises health care staff.</li> <li>2. Participates in periodic review of policies and records.</li> <li>3. Reviews and signs all inpatient records of patients cared for by mid-level practitioners. Physicians must review and sign 25% of outpatient records cared for by Physician Assistants and other mid-level practitioners except Certified APRNs in Minnesota.</li> <li>4. Is present for sufficient periods of time to provide medical direction, consultation and supervision for services provided in the CAH, and is available through direct radio, telephone, or electronic communication for consultation, assistance with medical emergencies, or patient referral.</li> </ol>	

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C262-268	§485.631 (c) Staffing and Staff Responsibility	<p><b>C262-268: Responsibilities of Physician Assistant, Nurse Practitioner, and Clinical Nurse Specialist.</b></p> <ol style="list-style-type: none"> <li>1. Participates in periodic review of policies and records, and performs services in accordance with CAH policies.</li> <li>2. Arranges for or refers patients to needed services that cannot be furnished at the CAH, and assures adequate patient health records are maintained and transferred as required.</li> <li>3. Notifies MD or DO whenever admitting a patient to the CAH.</li> </ol>	

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C270-271	§485.635 Provision of Services	<p><b>Overview:</b> This section details the necessary policy and procedure development and review process the CAH must follow.</p> <p><b>C271: Health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.</b></p> <ul style="list-style-type: none"> <li>• CMS does not interpret or enforce local law. If the surveyors suspect services are not consistent with State law, they will refer to appropriate State authorities.</li> <li>• Surveyors will ask to see written policies and observe staff delivering health care services to patients.</li> </ul>	

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C272	§485.635 Provision of Services	<p><b>C272: Policies and procedures are developed with the advice of a group of members of the CAH’s healthcare staff, including one or more MDs or DOs, and one or more PAs, NPs, or CNSs if they are on the staff.</b> Clearly describe this group’s function, meeting schedule membership, and expected outcomes. The group makes recommendations for new policies and reviews existing policies at least annually. Policies must be revised more often in response to applicable changes in Federal or State regulations. Final decision is made by the governing body or individual responsible for the CAH after the review is completed and recommendations are made.</p> <p>Surveyors may want to see meeting minutes, interview staff who are on the advisory group to document that the advisory group developed written recommendations on patient care policies for consideration by the governing body and to find evidence that the group reviewed existing policies at least annually.</p>	

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C273-275	§485.635 Provision of Services	<p><b>C273-279: Policies include:</b></p> <ul style="list-style-type: none"> <li>• <b>A description of services provided directly or via contract or arrangement.</b> Identify the services available at the CAH, and which are available through contract, agreement or arrangement. Also identify the services available through referral.</li> <li>• <b>C274: Policies and procedures for EMS. (See also C200).</b></li> <li>• <b>C275: Guidelines for the medical management of health problems.</b></li> </ul>	

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C276	§485.635 Provision of Services	<ul style="list-style-type: none"> <li>• <b>C276: Rules for storage, handling, dispensation and administration of drugs and biologicals.</b> The pharmacist, with input from appropriate CAH staff and committees, develops, implements and periodically reviews and revises policies and procedures governing provision of pharmaceutical services. Be prepared to show policies regarding:               <ol style="list-style-type: none"> <li>1. Responsibility for pharmacy services.</li> <li>2. Storage of drugs and biologicals.</li> <li>3. Proper environmental conditions.</li> <li>4. Security.</li> <li>5. Handling of drugs and biologicals.</li> <li>6. Compounding.</li> <li>7. Use of outside compounders (outsourcing facilities).</li> <li>8. Use of compounding pharmacies.</li> <li>9. Dispensing drugs and biologicals.</li> <li>10. Administration of drugs and biologicals to patients.</li> <li>11. Record keeping for the receipt and disposition of all scheduled drugs.</li> <li>12. Ensuring that outdated, mislabeled, or otherwise unusable drugs are not used for patient care.</li> <li>13. Assessing adverse drug reactions and medication administration errors.</li> </ol> </li> </ul> <p>The pharmacy department must also participate in the CAH QA programs.</p>	

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TAG	Condition of Participation	Notes	CAH Notes
C277-280	§485.635 Provision of Services	<ul style="list-style-type: none"> <li>• <b>C277: Procedures for reporting adverse drug reactions and medication administration errors.</b> Be prepared to provide documentation regarding the system for identifying and reporting adverse drug reactions and medication administration errors for surveyor review. Also demonstrate involvement with QA/QI.</li> <li>• <b>C278: A system for identifying reporting, investigating, and controlling infections and communicable diseases of patients and personnel.</b> Provide an updated and accurate Infection Control Plan. Also provide written designation of an individual or group as infection control officer(s).</li> <li>• <b>C279: Nutrition and dietary policies.</b> Policies must include procedures that ensure the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients. The dietary manual must be reviewed and signed off by a dietician and physician.</li> <li>• <b>C280: The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician’s office or other entry point into the health care delivery system.</b> This regulation addresses the minimum level of outpatient services, with the exception of emergency services that a CAH must provide.</li> </ul>	

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TAG	Condition of Participation	Notes	CAH Notes
C285-288	§485.635(c) Services Provided Through Agreement or Arrangement	<p><b>Overview: Services provided through agreements or arrangements</b> should be listed or described. It is useful to have a table of all services provided through arrangement or contract, noting the following:</p> <ul style="list-style-type: none"> <li>• Contracted entity.</li> <li>• Whether the contract is auto-renewable.</li> <li>• How the CAH ensures the services meet their standards.</li> </ul> <p>Provide evidence that these services are part of the facility-wide QA program.</p> <p><b>C287: Services of doctors of medicine or osteopathy.</b> Document that the CAH has arrangements with MDs or DOs for referral of discharged patients who need medical services not available at the CAH, and that the CAH has policies and procedures addressing the referral of discharged patients.</p> <p><b>C288: Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.</b> Lab services not required under §485.635(b) (2) may be provided by the CAH under arrangement or agreement. A written agreement is not required, but the CAH must document that an outside lab to which it sends specimens provides the CAH with test result, show evidence that the outside lab holds a current CLIA certificate or waiver, and must have policies and procedures that address the specific lab services provided under arrangement, as well as the collection, preservation, transportation, receipt and reporting of tissue specimen results.</p> <p>As needed, the CAH must have an arrangement or agreement with other providers of suppliers of diagnostic imaging services including advanced diagnostic imaging services, such as MRI or CT. A written agreement is not required, but the CAH must document that an outside diagnostic imaging facility to which it sends patients provides the CAH with the resulting studies and reports.</p> <p>All studies and reports and lab results must be included in the patient’s medical record and meet all requirements of §485.638(a)(4)(ii)</p>	

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TAG	Condition of Participation	Notes	CAH Notes
C289-292	§485.635(c) Services Provided Through Agreement or Arrangement	<p><b>C289: Food and other services to meet inpatients’ nutritional needs to the extent these services are not provide directly by the CAH</b> Surveyors assess compliance with §485.635(a) (3) (vii) in the same manner, whether the services are provided by the CAH staff or a vendor. The CAH must provide documentation of an agreement with a vendor.</p> <p><b>C291: Maintain a list of all services furnished under arrangements or agreements.</b></p> <p><b>C292: The person principally responsible for the operation of the CAH is responsible for the operation of all patient care services furnished at the CAH, including those provided under arrangement or agreement.</b></p>	

TAG	Condition of Participation	Notes	CAH Notes
C294-298	§485.635(d) Nursing Services	<p><b>Overview:</b> A registered nurse must provide (or assign) the nursing care of each patient, including patients at an SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patients’ needs and the specialized qualifications and competence of the staff available. Nursing care must be supervised and evaluated by a registered nurse. Drugs, biologicals and intravenous medications must be administered by or under the supervision of a registered nurse or doctor. Also, a nursing care plan must be developed and kept current for each inpatient. Policies and procedures should demonstrate compliance with these requirements. Additional documentation should provide evidence that the CAH is following the established policies and procedures.</p> <p><b>C294: Nursing services must meet the needs of patients.</b> The nurse in charge must develop and maintain nursing policies and procedures; supervise nursing staff; and provide ongoing review and analysis of the quality of nursing care.</p>	

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TAG	Condition of Participation	Notes	CAH Notes
C296-298	C294-298	<p><b>C296:</b> An RN must supervise and evaluate the nursing care for each patient, including Swing Bed patients.</p> <p><b>C297:</b> All drugs, biologicals and IV medications must be administered by or under the supervision of an RN, MD, or DO in accordance with written and signed orders, accepted standards of practice and federal and state laws. See Appendix W for detailed clarification.</p> <p><b>C298:</b> A nursing care plan must be developed and kept current for each inpatient.</p>	

TAG	Condition of Participation	Notes	CAH Notes
C299	§485.635(e)	<p><b>Overview: Rehabilitation Therapy Services</b> PT, OT, and speech-language therapy pathology services, if provided, are provided by staff qualified under State law, and consistent with the requirements for therapy services in §409.17 of this subpart. See Appendix W for detailed clarification.</p>	

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TAG	Condition of Participation	Notes	CAH Notes
<b>C1000-1002</b>	§485.635(f) Patient Visitation Rights	<p><b>Overview:</b> A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and reasons for the clinical restriction or limitation. Policies and procedures include the following:</p> <p><b>C1001</b></p> <ul style="list-style-type: none"> <li>• Inform each patient or appropriate support person of his or her visitation rights</li> <li>• Inform each patient or appropriate support person of the right, subject to his or her consent, to receive the visitors whom he or she designates and his/her right to withdraw that consent at any time.</li> </ul> <p><b>C1002</b></p> <ul style="list-style-type: none"> <li>• Do not restrict, limit or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation or disability.</li> <li>• Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.</li> </ul>	

TAG	Condition of Participation	Notes	CAH Notes
<b>C300-307</b>	§485.638 (a-c) Clinical Records	<p><b>Overview:</b> This section details the requirements for developing, maintaining and retaining patient records.</p> <p><b>C301-307: Records system.</b> There must be policies and procedures documenting the integrity, security and processes for creating, maintaining, retrieving and retaining all patient records. This is an area that may need to be updated if the CAH has converted to electronic medical records since the last survey. Be sure to have policies regarding medical record confidentiality, authentication of medical record authors and signatures (as well as a current authenticated signature list), processes for completion, and how verbal orders are communicated and signed.</p>	

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TAG	Condition of Participation	Notes	CAH Notes
<b>C308-311</b>	§485.638 (a-c) Clinical Records	<p><b>C308-310: Protection of record information.</b> Document the safeguards in place for protecting medical record information. Demonstrate that these policies are followed. Have clear policies regarding release and transfer of all medical record information, including release of information to patients and family members.</p> <p><b>C311: Retention of records.</b> Medical records must be retained for a minimum of seven years (Minnesota).</p>	

TAG	Condition of Participation	Notes	CAH Notes
<b>C320-326</b>	§485.639 Surgical Services	<p><b>Overview:</b> Qualified personnel provide surgical procedures in a safe manner, and patients are informed of necessary follow-up upon discharge. A full description of the scope of inpatient and outpatient surgical services offered is required (in addition to all of the relevant policies and procedures for providing surgical services). Be sure to include policies and procedures for:</p> <ol style="list-style-type: none"> <li>1. Supervision of the OR.</li> <li>2. Pre-operative history and physical.</li> <li>3. Informed consent.</li> <li>4. Post-operative care/recovery.</li> <li>5. Scope of practice and job descriptions of all providers of surgical services (including CRNAs).</li> <li>6. Anesthetic risk and evaluation.</li> <li>7. Discharge.</li> </ol>	

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TAG	Condition of Participation	Notes	CAH Notes
C330-335	§485.641 Periodic Evaluation and Quality Assurance Review	<p><b>Overview:</b> The CAH must conduct an evaluation and quality assurance review for ALL patient care services at least annually.</p> <p><b>C331--334: Periodic evaluation includes (at least once a year):</b></p> <ol style="list-style-type: none"> <li><b>1. Review of utilization of CAH services, including the number of patients and volume of services.</b></li> <li><b>2. Representative sample of active and closed clinical records.</b></li> <li><b>3. All CAH health care policies.</b></li> </ol> <p>CAHs should have a written description and policy regarding this required evaluation. A minimum of 10 percent of the CAH's annual census (both active and closed) records should be reviewed. Describe the process by which all health care policies will be reviewed annually, and be able to demonstrate evidence of it happening. Refer to C272 for more information.</p> <p><b>C335: The purpose of the evaluation is to determine whether utilization of services are appropriate, the established policies were followed, and any changes are needed.</b></p>	

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<b>C336-343</b>	§485.641 Periodic Evaluation and Quality Assurance Review	<p><b>C336: Quality Assurance</b></p> <p>The CAH must have a thorough Quality Assurance program in place. At minimum, the quality assurance program includes an evaluation of:</p> <ol style="list-style-type: none"> <li>1. All patient care services and other services affecting patient safety.</li> <li>2. Nosocomial infections and medication therapy provided.</li> <li>3. The “quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists and physician assistants” by a medical doctor.</li> <li>4. “The quality and appropriateness of diagnosis and treatment furnished by doctors of medicine or osteopathy” by an appropriate entity.</li> </ol> <p>The CAH must show evidence that:</p> <ol style="list-style-type: none"> <li>1. Staff have considered evaluation findings and taken correction action where needed.</li> <li>2. Remedial action is taken to address deficiencies found through the QA program.</li> </ol> <p>Policies regarding these evaluative components, written agreements regarding them, and evidence of the evaluation and related actions should be available for review during a survey.</p>	

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TAG	Condition of Participation	Notes	CAH Notes
C344-349	§485.643 Organ, Tissue, and Eye Procurement	<p><b>Overview:</b> CAHs must have written policies and procedures addressing its organ procurement responsibilities. Surveyors will review the written agreement with an Organ Procurement Organization (OPO). At minimum, the agreement must include:</p> <ol style="list-style-type: none"> <li>1. The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the CAH.</li> <li>2. A definition of “imminent death.”</li> <li>3. A definition of “timely notification.”</li> <li>4. The OPO’s responsibility to determine medical suitability for organ donation.</li> <li>5. How the tissue and/or eye bank will be notified about potential donors using notification protocols developed by the OPO in consultation with the CAH-designated tissue and eye bank(s).</li> <li>6. Provision for notification of death in a timely manner to the OPO (or designated third party).</li> <li>7. That the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank designated by the CAH.</li> <li>8. That the OPO, tissue bank and eye bank have access to the CAH’s death record information according to a designated schedule, (e.g., monthly or quarterly).</li> <li>9. That the CAH is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only “qualified, trained individuals” to perform organ recovery.</li> <li>10. The interventions the CAH will utilize to maintain potential organ donor patients.</li> </ol> <p>In addition, the following documentation may be reviewed during a survey:</p> <ol style="list-style-type: none"> <li>1. Policies regarding organ, tissue and eye procurement approved by the governing body.</li> <li>2. Policy regarding potential donors, identified and declared dead within an acceptable time frame.</li> <li>3. Criteria for record review.</li> <li>4. Training for staff regarding organ procurement.</li> </ol>	

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TAG	Condition of Participation	Notes	CAH Notes
<b>C350-380</b>	§485.645 Swing Bed Requirements	<p><b>Overview:</b> If the CAH provides swing bed care, the CAH must be in compliance with all swing bed regulations. Swing beds are counted in the 25-bed limit. Swing bed patients must have a prior qualifying hospital stay of at least three days. (Time designated as observation status does not count toward the qualifying stay time). The swing bed regulations include:</p> <p><b>C361-372: Resident Rights.</b> Inform and be able to provide evidence that all residents are informed of their rights. Resident rights should be posted in a public area (be sure the poster is the most current). Also, provide documentation regarding advanced directives.</p> <p><b>C373-380: Admission, Transfer, Discharge Rights.</b> Include policies regarding readmission. (Residents returned to skilled care within one to 30 days of discharge do not need a new qualifying stay; 31-60 days after discharge do require a new three-day qualifying stay in the hospital).</p> <p><i>(Please see Minnesota State Law for further clarification of exceptions in Minnesota: <a href="https://www.revisor.mn.gov/statutes/?id=144.562">https://www.revisor.mn.gov/statutes/?id=144.562</a>.)</i></p>	

TAG	Condition of Participation	Notes	CAH Notes
<b>C381-384</b>	§485.645 Swing Bed Requirements	<p><b>C381-384: Resident behavior and facility practices (Restraints and Vulnerable Adult).</b> Surveyors may review policies and procedures regarding restraints (physical and chemical).</p> <p>Demonstrate staff training regarding abuse and neglect as well as background checks on all employees.</p>	

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C385-399	§485.645 Swing Bed Requirements	<p><b>C385-386: Quality of Life (Activities).</b> A qualified Activities Director must be identified, and an activities calendar should be available for review.</p> <p><b>C388-399: Resident Assessment/Care Plan.</b> A comprehensive resident assessment must be completed and periodically updated for each resident. Each assessment must, at minimum, include:</p> <ol style="list-style-type: none"> <li>1. Identification and demographic information.</li> <li>2. Customary routine.</li> <li>3. Cognitive patterns.</li> <li>4. Communication.</li> <li>5. Vision.</li> <li>6. Mood and behavior patterns.</li> <li>7. Psychosocial well-being.</li> <li>8. Physical functioning and structural problems.</li> <li>9. Continence.</li> <li>10. Disease diagnoses and health conditions.</li> <li>11. Dental and nutritional status.</li> <li>12. Skin condition.</li> <li>13. Activity pursuit.</li> <li>14. Medications.</li> <li>15. Special treatments and procedures.</li> <li>16. Discharge potential.</li> <li>17. Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.</li> <li>18. Documentation of participation in assessment.</li> </ol> <p>Also, policies regarding the frequency of assessments (must be complete within 14 days after admission, following identification of a significant change, not less than every 12 months) as well as policies regarding care planning will be reviewed.</p>	

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TAG		Condition of Participation	Notes	CAH Notes
<b>C400-408</b>		§485.645 Swing Bed Requirements	<p><b>C400-401: Quality of Care – Nutrition.</b> Policy and practice should demonstrate that appropriate nutritional assessments and screenings take place. Also, be prepared to demonstrate through documentation policies and procedures related to nutritional consultation and care planning for nutritional needs.</p> <p><b>C402-403: Specialized Rehab Services.</b> If required in the resident’s care plan, specialized rehabilitative services such as physical therapy, occupational therapy, speech therapy, mental health services and cardiac rehabilitation must be available. Policies, procedures and practice should demonstrate the availability, processes and outcomes.</p> <p><b>C404-408: Dental Services.</b> The CAH must assist residents in obtaining routine and 24-hour emergency dental care. Policies, procedures and practice should demonstrate the availability, processes and outcomes.</p>	

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## Additional Resources

- The CAH Interpretive Guidelines are included within the State Operations Manual as Appendix W. They are available online on the Centers for Medicare and Medicaid Services (CMS) Web site at: [http://www.cms.hhs.gov/manuals/downloads/som107\\_Appendicestoc.pdf](http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf) (PDF: 1.1MB/271 pages).
- Additional CAH information from CMS is available on their *Critical Access Hospital Center* Web site: <http://www.cms.hhs.gov/center/cah.asp>.
- Joint Commission CAH information: [http://www.jointcommission.org/standards\\_information/cah\\_requirements.aspx](http://www.jointcommission.org/standards_information/cah_requirements.aspx)
- The American Hospital Association's Critical Access Hospital site: [http://www.aha.org/aha\\_app/issues/CAH/index.jsp](http://www.aha.org/aha_app/issues/CAH/index.jsp).
- The Minnesota State Swing Bed Statute: <https://www.revisor.mn.gov/statutes/?id=144.562>.
- The Minnesota Office of Rural Health and Primary Care provides ongoing assistance, tips and tools with CAH survey preparation. Contact Judy Bergh at [judith.bergh@state.mn.us](mailto:judith.bergh@state.mn.us), or (651) 201-3843 or toll free in Minnesota at (800) 366-5424.

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02/09/2018

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