**Montana Critical Access Hospital Survey Self-Assessment Tool**

**The Survey Self-Assessment Tool**

Critical Access Hospitals (“CAHs”) are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (“CoPs”) in order to participate in Medicare and be eligible to receive Medicare/Medicaid payment. The goal of a CAH survey is to determine if the CAH is in compliance with the CoPs. Certification of CAH compliance with the CoPs is accomplished through the survey process and involves observations, interviews, and document/record reviews. Surveyors take direction from the [State Operations Manual - Appendix W](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_w_cah.pdf) (“SOM”) and use unique identifiers called "C-Tags" to assess compliance with the CoPs. This Survey Self-Assessment Tool (“Tool”) lists each C-Tag which captures the requirements in the CoPs, related state licensing regulations specific to CAHs, and information from the SOM[[1]](#footnote-1) that details what the surveyors will be assessing. Additionally, below are Survey Preparation Recommendations to assist with considerations prior to a survey being conducted.

**How To Use The Tool[[2]](#footnote-2)**

CAHs may use this Tool to prepare for upcoming surveys or may use the Tool on an ongoing basis to evaluate, identify gaps, and document internal compliance with CAH-specific requirements. Each row of the Tool describes a C-Tag, the underlying CoP, and guidance from the SOM on how the CAH can demonstrate compliance with the C-Tag. Review each row of the Tool and evaluate whether the CAH does or does not comply with the standard. The review should be dated and initialed by the reviewer. Where appropriate, the reviewer should include information in the Notes/Comments column that indicates where applicable compliance documentation can be found or steps that are being taken to address ongoing compliance with the C-Tag. Note that the Tool captures only a summary of the applicable standards, the standard in its entirety may be found in the applicable SOM cited in the Notes/Comments column.

**Limitations of The Tool**

This Tool is intended to comprehensively address CAH-specific requirements but is not meant to address all potentially applicable laws and may exclude other relevant requirements (e.g. HIPAA/IT, specialty services, etc.). Please ensure that this Tool is used to supplement existing compliance and operational review activities and documents taking into consideration our CAH's specific operations. This Tool does not fulfill CAH-specific requirements itself, but rather provides a mechanism for the CAH to check its internal compliance. The content of this Tool may not be current at all times, as changes occur to applicable laws and to the SOM from time to time.

Special Note Re: Swing Beds and Distinct Part Units: CAHs may also have swing beds or distinct part rehabilitation or psychiatric units affiliated with their facilities. While these operations will also be reviewed for compliance at the time of the survey, swing bed or distinct part unit compliance is outside of the scope of this tool.

**SURVEY PREPARATION RECOMMENDATIONS**

1. ***Create a Survey Team within your CAH***. 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.
2. ***Plan for Surveyor Resources***. To minimize the time and impact of the survey on your facility, plan out the following resources for the survey team[[3]](#footnote-3):
   1. A location (e.g. conference room) where the survey team may work privately and conduct interviews, as applicable.
   2. Access to policies, procedures, patient care protocols, and medical records and availability of nurses or staff to help provide access.
   3. Access to a copy machine so that the survey team may make copies of records.
   4. Direct access to the EHR and availability of an IT or other experienced CAH EHR user to help provide access.
3. ***Survey documents***. Have a folder ready with the following documents or have a plan to make the following documents that are updated and current available immediately upon commencement of the survey.
   1. Names, locations, and telephone numbers of key staff to whom questions should be addressed
   2. Map/floor plan
   3. Organizational chart
   4. Names and addresses of all off-site locations operating under the same CCN
   5. List of employees
   6. Medical staff bylaws and rules and regulations
   7. List of contracted services
   8. Quality Assurance/Quality Improvement Plans
   9. Infection Control Plan
   10. Copy of CLIA or other certifications and the most recent survey documentation
   11. A list of current inpatients providing each patient’s name, room number, diagnosis, admission date, age, attending physician, and other significant information as it applies to that patient (must be made available within 3 hours after the request).
   12. All applicable policies and procedures.
4. ***Policy documentation and processes***. The CoPs frequently refer to the process taken to review and revise 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 C-Tag C-1008 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.
5. ***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 would.

TABLE OF CONTENTS

[Miscellaneous 4](#_Toc66702677)

[Compliance with Federal, State, and Local Laws and Regulations 6](#_Toc66702678)

[Status and Location 8](#_Toc66702679)

[Compliance with CAH Requirements at the Time of Application 13](#_Toc66702680)

[Agreements 14](#_Toc66702681)

[Emergency Services 22](#_Toc66702682)

[Number of Beds and Length of Stay 31](#_Toc66702683)

[Physical Plant and Environment 33](#_Toc66702684)

[Emergency Preparedness 41](#_Toc66702685)

[Organizational Structure 51](#_Toc66702686)

[Staffing and Staff Responsibilities 53](#_Toc66702687)

[Provision of Services 63](#_Toc66702688)

[Clinical Records 90](#_Toc66702689)

[Surgical Services 99](#_Toc66702690)

[Infection Prevention and Antibiotic Stewardship Program 107](#_Toc66702691)

[Discharge Planning 117](#_Toc66702692)

[Organ, Tissue, and Eye Procurement 121](#_Toc66702693)

**Survey Self-Assessment Tool**

| **Self-Assessment Questions** | **Yes** | **No** | **N/A** | **Date/Name of Reviewer** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| ***Miscellaneous*** | | | | | |
| If the CAH is a member of a rural health network, does it have the following agreements in place with other rural health network hospitals:   1. Patient referral and transfers; 2. Use of communications systems for electronic sharing of patient data; 3. Provision of emergency and nonemergency transportation among network members; and 4. Credentialing and quality assurance (this agreement may also be with another appropriate or qualified entity identified in the State rural health care plan).   C-0802  42 C.F.R. § 485.603 |  |  |  |  | \*No SOM Guidance for this C-Tag (SOM, C-Tag 0802, at 32-33. Impl. 2-21-2020). |
| Is every clinical nurse specialist (CNS) a person who:   1. Is a registered nurse licensed to practice in the state in which the services are performed and in accordance with state nurse licensing laws and regulations; and 2. Holds a master’s or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.   C-0804  42 C.F.R. § 485.604(a) |  |  |  |  | \*No SOM Guidance for this C-Tag (SOM, C-Tag 0804, at 33-35. Impl. 2-21-2020). |
| Is every nurse practitioner (NP) a registered professional nurse who is currently licensed to practice in the State, meets the State’s requirements governing the qualification of NPs, and meets one of the following conditions:   1. Is currently certified as a primary care NP by the American Nurses’ Association or by the National Board of Pediatric NPs and Associates; or 2. Has successfully completed an academic 1-year program that    1. prepares registered nurses to perform an expanded role in the delivery of primary care;    2. includes at least 4 months of classroom instruction and a component of supervised clinical research; and    3. awards a degree, diploma or certificate to persons who successfully complete the program.   C-0804  42 C.F.R. § 485.604(b) |  |  |  |  | For any NPs who have been practicing since June 25, 1993 and who do not meet the other standards listed, review 42 C.F.R. § 485.604(b)(3) for compliance guidance.  \*No SOM Guidance for this C-Tag (SOM, C-Tag 0804, at 33-35. Impl. 2-21-2020). |
| Does each physician assistant (PA) meet the applicable State requirements governing the qualifications for assistants to primary care physicians and meet at least one of the following conditions:   1. Is currently certified by the National Commission on Certification of PAs; or 2. Has satisfactorily completed a program for preparing PAs that (i) was at least one academic year in length; (ii) consisted of supervised clinical practice and at least 4 months of classroom instruction toward preparing students to deliver health care; and (iii) was accredited by the AMA’s Committee on Allied Health Education and Accreditation.   C-0804  42 C.F.R. § 485.604(c) |  |  |  |  | For any PAs who have been practicing since June 25, 1993 and who do not meet the other standards listed, review 42 C.F.R. § 485.604(c)(3) for compliance guidance.  \*No SOM Guidance for this C-Tag (SOM, C-Tag 0804, at pg. 33-35. Impl. 2-21-2020). |
| ***Compliance with Federal, State, and Local Laws and Regulations*** | | | | | |
| Is the CAH in compliance with applicable Federal, State and local laws and regulations?  C-0810  42 C.F.R. § 485.608 |  |  |  |  | \*No additional SOM Guidance for this C-Tag (SOM, C-Tag 0810, at pg. 35. Impl. 2-21-2020). |
| Is the CAH in compliance with applicable federal laws and regulations related to the health and safety of patients?  Specifically, does the CAH comply with relevant Medicare regulations, specifically the following Medicare provider agreement regulation provisions:   1. Advanced Directives; 2. Disclosure to Patients of Physician Ownership; and 3. MD/DO 24/7 On-Site Presence.   (SOM at 36-43)  C-0812  42 C.F.R. § 485.608(a) |  |  |  |  | \*Note, there is significantly more detail included in the SOM than is listed here. The SOM details what should be included in the provisions listed here and should be reviewed for evaluation of compliance with this section. (SOM 36-43) |
| Are all patient care services furnished in accordance with applicable State and local laws and regulations?  C-0814  42 C.F.R. § 485.608(b) |  |  |  |  | \*Note: the SOM specifically identify state/local scope of practice laws applicable to CNS, NP, and PAs as relevant to compliance with this provision. (SOM 43-44).  In order to document compliance with this requirement, ensure that the CAH maintains appropriate supervision and collaboration agreements that apply to the practitioner, including any applicable prescriptive authority agreements, and documents that services are provided in accordance with each practitioner’s scope of practice. |
| Is the CAH licensed in accordance with applicable Federal, State and local laws and regulations?  C-0816  42 C.F.R. § 485.608(c)  As part of its licensure, is the CAH open to inspection from the department of public health and human services or its authorized agent and does the CAH provide the department with access to all records at such reasonable times? |  |  |  |  |  |
| Are CAH staff licensed, certified, or registered in accordance with applicable Federal, State and local laws and regulations?  Additionally:   1. Did the CAH establish, and does it follow, procedures for determining that personnel providing patient care services are properly licensed, including contracted personnel? 2. Is all personnel licensure information up to date? 3. Are the CAH certification, licensure, and registration policies (policies that address personnel licensure, certification or registration) compliant with state and local laws? 4. Are personnel in compliance with the CAH policy?   (SOM at 44-45)  C-0818  42 C.F.R. § 485.608(d) |  |  |  |  | \*Note: Examples of healthcare professionals that a state may require to be licensed could include: nurses, MD/DOs, physician assistants, dieticians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory technicians and facility administrators. (SOM at 44-45) |
| ***Status and Location***  ***Note: As indicated below, some of the following status and location criteria are designated upon the CAH’s initial certification by the CMS Regional Office. Necessary Provider status is designated by the State according to State requirements. The CAH may primarily assess compliance with the following status and location criteria through its certification, recertification, and necessary provider documentation (as applicable). The State Survey Agency will confirm the CAH’s compliance with these criteria in advance of the survey. If the Survey Agency identifies any changes or circumstances that may call the CAH’s status or location certifications into question, the Survey Agency will follow-up with the CMS Regional Office. (SOM at 45).***  ***Note: The following requirements should be closely reviewed prior to survey particularly if any of the following apply:***   1. ***CAH moved locations of its main provider or any of its provider-based locations and has not been recertified by the CMS Regional Office;*** 2. ***CAH changed licensure categories and has not been recertified by the CMS Regional Office;*** 3. ***CAH built new facilities and has not been recertified by the CMS Regional Office;*** 4. ***CAH added new provider-based locations;*** 5. ***CAH entered into any co-location arrangements.*** | | | | | |
| Does the CAH meet the basic requirements for status and location?  Additionally, If the CAH has moved, has its eligibility for continued CAH status been reassessed and determined by the CMS Regional Office?  (SOM at 45)  C-0822  42 C.F.R. § 485.610 |  |  |  |  | \*Note: Maintenance of certification, recertification, and necessary provider documentation from the CMS Regional Office will help the CAH assess its compliance with the ***Status and Location*** requirements. |
| In order to qualify for CAH status, is the facility:   1. A currently participating hospital that meets all conditions of participation set forth by this subpart; 2. A health clinic or health center that:    1. is licensed by the State as a health clinic or health center;    2. was a hospital that was downsized to a health clinic or health center; and    3. as of the effective date of its designation, meets the criteria for designation set forth in this subpart.   C-0824  C.F.R. § 485.610(a) |  |  |  |  | \*Note: Maintenance of the CAH’s provider agreement with CMS and the applicable license documents may help the CAH self-assess this criteria in advance of the survey. |
| Does the CAH meet one of the following requirements:   1. The CAH is rural; or 2. The CAH is treated as rural in accordance with 42 CFR 412.103.   (SOM at 46-48)  C-0826  42 C.F.R. § 485.610(b) |  |  |  |  | \*Note: Maintenance of certification, recertification, and necessary provider documentation from the CMS Regional Office or State will help the CAH assess its compliance with the ***Status and Location*** requirements. |
| Does the CAH meet the minimum distance requirement: Is the CAH located more than a 35-mile drive (or, in mountainous terrain or areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH (with an exception for Indian Health Service or Tribal CAHs/hospitals that are located less than the 35 or 15 miles from another CAH/hospital)?  Additionally, If the distance requirements are not met, was the CAH designated by the State as a necessary provider prior to January 1, 2006? If the CAH is not a necessary provider, the minimum distance requirement applies or the CAH must convert to a certified Medicare hospital after demonstrating compliance with the general hospital CoPs.  (SOM at 48-49)  C-0830  42 C.F.R. § 485.610(c) |  |  |  |  | \*Note: Recall that necessary provider status is designated by the State and described elsewhere in the ***Status and Location*** requirements section.  \*Note: Maintenance of certification, recertification, and necessary provider documentation from the CMS Regional Office or State will help the CAH assess its compliance with the ***Status and Location*** requirements. |
| If a CAH has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocated its facility after January 1, 2006, does it meet the following requirements to maintain its location requirement for the necessary provider designation:   1. The CAH serves at least 75% of the same service area that it served prior to its relocation; 2. The CAH provides at least 75% of the same services that it provided prior to the relocation; and 3. The CAH is staffed by 75% of the same staff that were on staff at the original location.   C-0832  42 C.F.R. § 485.610(d) |  |  |  |  | \*Note: Renovation or expansion of a CAH’s existing building does not count as relocation, but any newly-constructed, necessary provider CAH facilities, including entirely new replacement facilities constructed on the same site as the existing CAH main campus, are considered relocated facilities (SOM C-0832, at 49-50. Impl. 2-21-2020).  \*Note: Maintenance of necessary provider documentation from the CMS Regional Office or State will help the CAH assess its compliance with the ***Status and Location*** requirements. |
| If the CAH has a necessary provider designation from the State, does the facility meet one of the following requirements:   1. Is the facility located in a county with fewer than six residents per square mile? 2. Is the state licensed facility located within the boundaries of an Indian reservation? 3. Is the facility located in a county where the percentage of the population age 65 and older exceeds the statewide average? Or 4. Does the facility have combined inpatient days for Medicaid and Medicare beneficiaries that account for at least 50% of its total acute inpatient days in the last full year for which data is available?   ARM 37.106.704(3) |  |  |  |  | \*Note: These are the State necessary provider designation requirements.  \*Note: Maintenance of necessary provider documentation from the CMS Regional Office or State will help the CAH assess its compliance with the ***Status and Location*** requirements. |
| In order to maintain the location designation, if the CAH with necessary provider designation is co-located (it shares a campus and/or building with another hospital or CAH) was the co-location arrangement in effect before January 1, 2008 and did the type and scope of services offered by the co-located facility remain the same?  C-0834  42 C.F.R. § 485.610(e)(1) |  |  |  |  |  |
| In order to maintain its location designation, if the CAH operates an off-campus provider-based location or an off-campus distinct part psychiatric or rehabilitation unit, was it created or acquired by the CAH on or after January 1, 2008? This does not apply to an off-campus Rural Health Clinic but includes an off-campus provider-based department or remote location.  If so, is the off-campus provider-based location or off-campus part unit located more than a 35-mile drive (or 15-mile drive in mountainous terrain or areas with only secondary roads available) from another hospital or CAH, (calculated from the provider-based facility to the main campus of the other hospital or CAH)?  Additionally, If the CAH is seeking a provider-based determination for newly created or acquired provider-based departments, remote locations and/or psychiatric or rehabilitation units located off-campus did it submit an attestation to the Regional Office (RO)?  (SOM at 52-54)  C-0836  42 C.F.R. § 485.610(e)(2) |  |  |  |  | \*Note: this requirement does not apply to IHSs or Tribal CAHs.  \*Note: this requirement does not apply to:   * Ambulatory surgical centers * Comprehensive outpatient rehabilitation facilities * Home health agencies * Skilled nursing facilities * Hospices * Independent diagnostic testing facilities furnishing only services paid under a fee schedule, facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services * ESRD facilities * Departments of providers that perform functions necessary for the successful operation of the CAH, but for which separate CAH payment may not be claimed under Medicare or Medicaid, e.g. laundry, or medical records dept * Ambulance and EMS Departments of the hospital |
| In order to maintain the location designation, if the CAH does not meet the requirements associated with co-location or off-campus provider-based location / off-campus distinct unit, did or will the CAH terminate the off-campus arrangement, and/or the co-location arrangement?  C-0834 & C-0836  42 C.F.R. § 485.610(e)(3) |  |  |  |  |  |
| ***Compliance with CAH Requirements at the Time of Application*** | | | | | |
| Was the facility a hospital with a provider agreement to participate in the Medicare program as a hospital at the time the hospital applied for CAH designation (except for recently closed facilities, or health clinics or health centers)?  Additionally:   1. If a facility has never been a Medicare participating hospital and wishes to be a CAH, has the CAH first met the certification as a hospital, then put in a change of status request to be a CAH? 2. This will required two surveys (first for compliance with the hospital CoPs and second, for compliance with the CAH CoPs upon receipt of the change request).   (SOM at 54)  C-0840  42 C.F.R. § 485.612 |  |  |  |  |  |
| ***Agreements*** | | | | | |
| Is the CAH a member of a rural health network (“RHN”) (defined as an organization that includes at least one hospital that the State has designated or plans to designate as a CAH, and at least one hospital that furnishes acute care (hospital) services)?  Additionally:   1. If the CAH is a member of a RHN with a communications system, does the CAH have the agreement? 2. Does the CAH have a procedure for participation with other hospitals and facilities in the communication system? 3. Does the CAH keep a communications log? 4. Does the CAH have a procedure for dealing with communication delays? 5. Does the CAH have a procedure for sharing patient data with other network members, for when the communications system is not in operation? 6. Does the CAH educate staff on the use of communications system utilized by the facility? 7. Does the CAH have any agreements with local EMS services?   (SOM at 55)  C-0860  C-0862  42 C.F.R. § 485.616(a) |  |  |  |  |  |
| If the CAH is a member of a RHN, does the CAH have an agreement with at least one hospital that is a member of the network for patient referral and transfer?  C-0860  C-0864  42 C.F.R. § 485.616(a)(1) |  |  |  |  | \*No SOM Guidance for this C-Tag (SOM, C-Tag 0864, at 56. Impl. 2-21-2020) |
| If the CAH is a member of a RHN, does the CAH have an agreement with at least one hospital that is a member of the network for the development and use of communications systems, including the network’s system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system?  C-0860  C-0866  42 C.F.R. § 485.616(a)(2) |  |  |  |  | \*No SOM Guidance for this C-Tag (SOM, C-Tag 0866, at 56. Impl. 2-21-2020) |
| If the CAH is a member of a RHN, does the CAH have an agreement with at least one hospital that is a member of the network for **t**he provision of emergency and nonemergency transportation between the facility and the hospital?  C-0860  C-0868  42 C.F.R. § 485.616(a)(3) |  |  |  |  | \*No SOM Guidance for this C-Tag (SOM, C-Tag 0868, at 56 Impl. 2-21-2020) |
| If the CAH is a member of a RHN, does it have an agreement with respect to credentialing and quality assurance (“QA”) with at least:   1. One hospital that is a member of the network; 2. One QIO or equivalent entity; or 3. One other appropriate and qualified entity identified in the State rural health care plan (including another CAH or any licensed firms, businesses or agencies that provide credentialing or QA services, not limited to local entities (SOM, 56-57)); and 4. Do the agreements for QA include medical record review as part of the determination of quality and medical necessity of medical care at the CAH?   (SOM at 56-57)  C-0860  C-0870  42 C.F.R. § 485.616(b) |  |  |  |  |  |
| Does the CAH ensure that, when telemedicine services are furnished through an agreement with a distant-site hospital, the agreement in writing?  Does the written agreement explicitly specify that it is the responsibility of the distant-site hospital to meet the following requirements regarding its physicians/practitioners providing telemedicine services:   1. Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff; 2. Appoint members of the medical staff after considering the recommendations of existing members of the medical staff; 3. Assure that the medical staff has bylaws; 4. Approve medical staff bylaws and other medical staff rules and regulations; 5. Ensure that medical staff is accountable to the governing body for the quality of care provided to patients; 6. Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and 7. Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.   C-0860  C-0872  42 C.F.R. § 485.616(c)(1) |  |  |  |  | SOM, C-Tag 0872, at 57-61. Impl. 2-21-2020 |
| If telemedicine services are furnished to the CAH’s patients through an agreement with a distant-site hospital, and the CAH chooses to rely upon the credentialing and privileging decisions made by the distant-site hospital, does the CAH ensure that the following provisions are met:   1. The distant-site hospital providing telemedicine services is a Medicare-participating hospital; 2. The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician’s or practitioner’s privileges at the distant-site hospital; 3. The individual distant-side physician or practitioner holds a license issued or recognized by the State in which the CAH is located; and 4. The CAH has evidence of an internal review of distant-site physicians/practitioners’ performance at the CAH and sends the distant-site hospital such information in the use of periodic appraisal of the individual physician/practitioner.   Additionally:   1. Does the CAH have documentation indicating that it granted privileges to each telemedicine physician and practitioner? 2. Does the documentation indicate that the CAH made the privileging decision based on the privileging decisions of the distant-site hospital? 3. Does the agreement address the required elements concerning the distant-site hospital’s Medicare participation, appropriate licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges, and review by the CAH of the telemedicine physicians’ and practitioners’ services?   (SOM at 57-62)  C-0860  C-0872  42 C.F.R. § 485.616(c)(2) |  |  |  |  | SOM, C-Tag 0872, at 57-61. Impl. 2-21-2020 |
| If telemedicine services are furnished to the CAH’s patients through an agreement with a distant-site telemedicine entity, is the agreement written and does it explicitly specify that the distant-site entity is a contractor of services to the CAH and as such furnishes the contracted services in a manner that enables the CAH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements regarding its physicians/practitioners?  Additionally:   1. Does the CAH have documentation indicating that it granted privileges to each telemedicine physician and practitioner? 2. Does the documentation indicate that the CAH’s governing body or responsible individual made the privileging decision based on the privileging decisions of the distant-site telemedicine entity? 3. If so, does the written agreement with the distant-site telemedicine entity address the required elements concerning the distant-site telemedicine entity’s utilization of a medical staff credentialing and privileging process that meets the requirements of the hospital CoPs, licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges at the distant-site telemedicine entity, and written review by the CAH of the telemedicine physicians’ and practitioners’ services?   (SOM at 61-64)  C-0860  C-0874  42 C.F.R. § 485.616(c)(3) |  |  |  |  |  |
| If the CAH relies on the credentialing and privileging decisions made by the distant-site telemedicine entity regarding individual distant-site physicians/practitioners, does the CAH ensure through its written agreement with the distant-site telemedicine entity, that:   1. The distant-site telemedicine entity’s medical staff credentialing and privileging process and standards at least meet the standards outline in 42 C.F.R. § 485.616(c)(1) (above and captured in C-0872); 2. The individual distant-site physician/practitioner is privileged at the distant-site telemedicine entity, and the entity provides a current list to the CAH of the physician’s / practitioner’s privileges at the distant-site entity; 3. The individual distant-site physician/practitioner holds a license issued or recognized by the State in which the CAH’s patients receiving the telemedicine services are located; and 4. The CAH has evidence of an internal review of the distant-site physician’s/practitioner’s performance of these privileges and sends the distant-site telemedicine entity such information for use in the periodic appraisal of the distant-site physician/practitioner, including all adverse events that result from the telemedicine services provided by the distant-site physician/practitioner to the CAH’s patients and all complaints the CAH has received about the distant-site physician/practitioner.   Additionally, If the CAH does not rely on the privileging decisions of the distant-site telemedicine entity, does it follow the CAH’s standard process for review of credentials and granting of privileges to physicians and practitioners providing telemedicine services under an agreement?  (SOM at 61-64)  C-0860  C-0874  42 C.F.R. § 485.616(c)(4) |  |  |  |  |  |
| ***Emergency Services*** | | | | | |
| Does the CAH provide emergency care necessary to meet the needs of its inpatients and outpatients, following acceptable standards of practice, including the following:   1. Emergency services must be organized under the direction of a practitioner member of the medical staff. A practitioner is a physician, physician's assistant certified, or an advanced practice registered nurse; 2. The services must be integrated with other departments of the facility; 3. The medical staff must establish and assume continuing responsibility for policies and procedures governing medical care provided in the emergency services; and 4. A practitioner is on duty or on call and physically available at the facility within one hour at all times, unless the following procedures are adopted and implemented.   C-0880  42 C.F.R. § 485.618 |  |  |  |  | \*Note: This C-Tag is accompanied by significant, lengthy, and detailed guidance in the SOM as well as relevant state law requirements which are included here for review. We recommend detailed review of the SOM at 65-68 for self-assessment purposes. |
| As it relates to on-call requirements, facilities with 10 or fewer beds that are located in frontier areas having fewer than six persons per square mile and who have one medical provider regularly available in the area may provide emergency services through a registered nurse if they have requested and been granted a waiver by the state survey agency for Medicare and Medicaid. In these instances:   1. An on-call practitioner must be immediately available by phone or radio for the registered nurse to contact, following completion of a nursing assessment, to determine whether the patient requires discharge, further examination, treatment or stabilization, and transfer to a facility capable of providing the appropriate level of care; 2. All registered nurses providing emergency service coverage must have documented education and competency in emergency care; 3. A registered nurse meeting the qualifications specified in (ii) is either on duty or on call and physically available at the facility within 30 minutes at all times; and 4. The facility may not use a registered nurse to provide emergency services coverage for more than a 72-hour continuous period of time.   ARM 37.106.704(4) |  |  |  |  | \*Note, this is only in the MT Regulation and therefore is not associated with a C-Tag. However, compliance with state licensure laws are part of the CAH’s preparation for C-Tag C-0810 and CoP  42 C.F.R. § 485.608. |
| Are emergency services available as a direct service on a 24-hours a day basis?  Additionally, Does the CAH’s system ensure that a practitioner with training and experience in emergency care is on call or immediately available by telephone or radio, and available on site within 30 minutes (or 1 hour in certain frontier areas), 24 hours per day?  (SOM at 68-69)  C-0882  42 C.F.R. § 485.618(a) |  |  |  |  |  |
| Are equipment, supplies, and medication used in treating emergency cases kept readily available for treating emergency cases?  Additionally, Does the CAH maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by state and local law and in accordance with accepted standards of practice?  (SOM at 69)  C-0884  42 C.F.R. § 485.618(b) |  |  |  |  |  |
| Do such supplies include drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrhythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes replacement solutions?  Additionally:   1. Does the CAH ensure that staff know where drugs and biologicals are kept? 2. Does the CAH have a system to maintain inventory? 3. Does the CAH have someone responsible for monitoring the drugs and biologicals? 4. Does the CAH have a system for replacing drugs and biologicals?   (SOM at 69)  C-0886  42 C.F.R. § 485.618(b)(1) |  |  |  |  |  |
| Do such supplies include equipment and supplies commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitors, chest tubes, and indwelling urinary catheters?  Additionally:   1. Does the CAH ensure that required equipment and supplies are available to staff? 2. Does the CAH ensure that staff knows where emergency equipment and supplies are kept? 3. Does the CAH have a procedure for maintaining supply inventory? 4. Did the CAH assign someone to be responsible for monitoring supplies? 5. Does the CAH have a procedure for replacing supplies? 6. Does the CAH track the last time emergency supplies were used? 7. Does the CAH have equipment maintenance schedule (e.g. for defibrillator)? 8. Does the CAH maintain current (non-expired) sterilized equipment? 9. Does the oxygen supply system function properly? 10. Is the force of vacuum (suction) equipment in operating condition?   (SOM at 69-70)  C-0888  42 C.F.R. § 485.618(b)(2) |  |  |  |  |  |
| Does the facility provide services for procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis (either by directly providing blood/blood products or having them available through arrangement (SOM at 70-71)?  Additionally:   1. If the CAH performs CLIA tests on blood on-site, does it have a CLIA certificate? 2. Does the CAH ensure blood is appropriately stored to prevent deterioration, including documenting refrigerator temperatures? 3. If the CAH receives blood services from a testing laboratory, is there a written agreement/arrangement in place? 4. If the CAH is collecting blood, is it registered with the FDA? 5. If a CAH performs type and compatibility testing, does it have the necessary equipment, (i.e., serofuge and heat block), as well as typing and cross matching reagents, some of which have a 30-day expiration date? Alternatively, does the CAH properly store 4 units of O negative packed red blood cells (the universal donor type) for availability at all times for emergencies only?   (SOM at 70-71)  C-0890  42 C.F.R. § 485.618(c)(1) |  |  |  |  |  |
| Does the facility provide blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified MD or DO? If blood banking services are provided under an arrangement, is the arrangement approved by the facility’s medical staff and by the persons directly responsible for the operation of the facility?  Additionally:   1. If blood banking services are provided on site, does the CAH have evidence showing the blood facility is under the control or supervision of a pathologist or MD/DO? 2. If blood banking services are provided under arrangement, does the CAH have evidence that the medical staff and person responsible for CAH operations have approved the arrangement?   (SOM at 71-72)  C-0892  42 C.F.R. § 485.618(c)(2) |  |  |  |  |  |
| Does the CAH have a MD or DO, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact and available on site within the following timeframes:   1. Within 30 minutes, on a 24-hour a day basis; or 2. Within 60 minutes on a 24-hour a day basis, if all of the following requirements are met: 3. The CAH is located in an area designated as a frontier area (fewer than 6 residents per square mile) or an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS; 4. The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH; and 5. The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.   C-0894  42 C.F.R. § 485.618(d)(1)  ARM 37.106.704(4) |  |  |  |  | \*Note: The Montana state licensure requirements in ARM 37.106.704(4) overlap with this requirement and are previously addressed in C-0880. |
| Does the CAH utilize a registered nurse with training and experience in emergency care to conduct specific medical screening examinations only if (i) the registered nurse is on site and immediately available at the CAH when a patient requests medical care; and (ii) the nature of the patient’s request for medical care is within the scope of a practice of a registered nurse and consistent with applicable State laws and the CAH’s bylaws and rules/regulations?  C-0894  42 C.F.R. § 485.618(d)(2) |  |  |  |  |  |
| Does the CAH operate in such a way that a registered nurse satisfies the personnel requirement for a temporary period if:   1. the CAH has no greater than 10 beds; 2. the CAH is located in an area designated as a frontier area or remote location; 3. the State in which the CAH is located submits a letter to CMS signed by the governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a RN with training and experience in emergency care be included in the list of acceptable personnel; 4. once a governor submits a letter, a CAH must submit documentation to the State survey agency demonstrating it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage.   Additionally:   1. Does the CAH have a system to determine who is on call? 2. Does the CAH have documentation demonstrating that the on-call personnel with emergency training or experience has been on call and available within 30 or 60 minutes, as appropriate?   (SOM at 72-74)  C-0894  42 C.F.R. § 485.618(d)(3) |  |  |  |  |  |
| Did the CAH, in coordination with emergency response systems in the area, establish procedures under which a MD/DO is immediately available by telephone or radio contact on a 24-hour a day basis to receive emergency calls, provide information on treating emergency patients, and refer patients to the CAH or other appropriate locations for treatment?  Additionally:   1. Does the CAH have evidence demonstrating that procedures are followed and evaluated for effectiveness? 2. Do CAH staff know how a MD/DO is contacted when emergency instructions are needed?   (SOM at 74)  C-0898  42 C.F.R. § 485.618(e) |  |  |  |  |  |
| ***Number of Beds and Length of Stay*** | | | | | |
| Unless otherwise permitted, does the CAH maintain no more than 25 inpatient beds?  Additionally:   1. Does the CAH have policies and procedures for its use of observation services? 2. Does the policy/procedure include that patients are never pre-registered for observation services (there should not be scheduled observation stays)? 3. Does the CAH have specific clinical criteria for placement in and discharge from observation status (such that the criteria are distinguishable from those used for inpatient admission and discharge)? 4. If the CAH has a special unit of observation beds, does the CAH have evidence of how its criteria for observation differ from that for an inpatient bed? 5. Does the CAH ensure that medical records for patients in observation status include an order to place the patient in observation status (including the clinical reason)? 6. Does the CAH ensure that observation services are not ordered as a standing order following outpatient surgery or prior to admission from the emergency department?   (SOM at 74-79)  C-0902  42 C.F.R. § 485.620(a)  Are the 25 beds used interchangeably for acute care and swing-bed services?  ARM 37.106.704(2) |  |  |  |  |  |
| Does the CAH provide acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient?  C-0904  42 C.F.R. § 485.620(b) |  |  |  |  |  |
| ***Physical Plant and Environment*** | | | | | |
| Does the CAH ensure that all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations adhere to these conditions of participation?  Additionally, Does the CAH ensure that building and equipment maintenance departments/services responsible for equipment maintenance are incorporated into the CAH’s QA program?  (SOM at 79)  C-0910  42 C.F.R. § 485.623 |  |  |  |  |  |
| Is the CAH constructed, arranged, and maintained to ensure access to and safety of all patients, and provide adequate space for the provision of services?  Additionally:   1. Is the CAH large enough for the scope of services the CAH is required to provide on-site, as well as any additional services it offers on-site or at a provider-based, off-site location? 2. Are the CAH’s buildings maintained in a manner to ensure the safety and well-being of patients (e.g. condition of ceilings, walls, floors, other hazards, etc.)? 3. Does the design of the CAH assure that staff can readily reach patients?   (SOM at 79-80)  C-0912  42 C.F.R. § 485.623(a) |  |  |  |  |  |
| Does the CAH have written housekeeping and preventative maintenance programs to ensure that all essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition?   1. Has the CAH identified equipment that is essential for both regular operations and in an emergency situation? 2. Does the CAH have adequate provisions to ensure the availability and reliability of that equipment when needed? 3. Does the CAH follow the manufacturer-recommended maintenance activities and schedule? Does the CAH maintain documentation of those recommendations and the CAH’s associated maintenance? 4. Do equipment failures occur and cause problems for patient health or safety? 5. Is there a complete inventory of equipment required to meet patient needs?   C-0914  42 C.F.R. § 485.623(b)(1) |  |  |  |  |  |
| Does the CAH have a written maintenance program describing the procedures to keep the building, grounds, and equipment in good repair and free of hazards?  ARM 37.106.320  Does the CAH ensure all electrical, mechanical, plumbing, fire protection, heating, and sewage disposal systems are kept in operational condition?  ARM 37.106.320(3) |  |  |  |  | \*Note, this is only in the MT Regulation and therefore is not associated with a C-Tag. However, compliance with state licensure laws are part of the CAH’s preparation for C-Tag C-0810 and CoP  42 C.F.R. § 485.608. |
| Does the CAH have an Alternative Equipment Management ("AEM") program (equipment maintenance activities/frequencies that differ from those recommended by the manufacturer)?  Additionally:   1. If so, is the AEM program based on generally accepted standards of practice for facility/medical equipment maintenance? 2. Was the decision to implement an AEM program made by qualified personnel, employees, or contractors? 3. Is the equipment in the program readily identified? 4. Does the CAH have documentation of the qualifications of CAH personnel responsible for the AEM program?   (SOM at 80-90)  C-0914  42 C.F.R. § 485.623(b)(1)  ARM 37.106.320 |  |  |  |  | \*Note: The SOM Guidance for this C-Tag requirements related to AEM Programs is extensive. Recommend further review of SOM at 80-90 to evaluate compliance. |
| Does the CAH have written housekeeping and preventative maintenance programs to ensure that there is proper storage and disposal of trash?  C-0920  42 C.F.R. § 485.623(b)(2) |  |  |  |  | \*Note, SOM Guidance is pending, C-0920, at 90. Impl. 2-21-2020. |
| Does the CAH have written housekeeping and preventative maintenance programs to ensure that drugs and biologicals are appropriately stored?  C-0922  42 C.F.R. § 485.623(b)(3)  (SOM at 90) |  |  |  |  |  |
| Does the CAH have written housekeeping and preventative maintenance programs to ensure that the premises are clean and orderly?  Additionally:   1. Are equipment and supplies stored in proper spaces, not corridors? 2. Are spills not left unattended? 3. Are there no floor obstructions? 4. Is the area neat and well kept? 5. Is there no evidence of peeling paint, visible water leaks, or plumbing problems?   (SOM at 90-91)  C-0924  42 C.F.R. § 485.623(b)(4) |  |  |  |  |  |
| Does the CAH provide housekeeping services on a daily basis?  ARM 37.106.320(2)  Does the CAH ensure that floors are kept clean and in good repair at all times  ARM 37.106.320(4)  Does the CAH ensure that walls and ceilings are kept in good repair and be of a finish that can be easily cleaned?  ARM 37.106.320(5)  Is the CAH constructed and maintained so as to prevent entrance and harborage of rats, mice, insects, flies, or other vermin?  ARM 37.106.321(1)  Are hand cleansing soap or detergent and individual towels available at each lavatory in the facility? Is a waste receptacle located near each lavatory?  ARM 37.106.321(2)  Do the cleaners used to clean bathtubs, showers, lavatories, urinals, toilet bowls, toilet seats, and floors contain fungicides or germicides with current EPA registration for that purpose? ARM 37.106.321(3)  Are the cleaning devices used for lavatories, toilet bowls, showers, or bathtubs not be used for other purposes? Are those tools used to clean toilets or urinals not allowed to contact other cleaning devices?  ARM 37.106.321(4) |  |  |  |  | \*Note, this is only in the MT Regulation and therefore is not associated with a C-Tag. However, compliance with state licensure laws are part of the CAH’s preparation for C-Tag C-0810 and CoP  42 C.F.R. § 485.608. |
| Does the CAH have written housekeeping and preventative maintenance programs to ensure that there is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas?  C-0926  42 C.F.R. § 485.623(b)(5) |  |  |  |  | \*Note, SOM Guidance is pending, C-0926, at 91. Impl. 2-21-2020. |
| Is the CAH kept clean and free of odors? (Deodorants may not be used for odor control in lieu of proper ventilation).  ARM 37.106.320(6)  Does the CAH maintain minimum of 10 foot-candles of light in all rooms and hallways, with the following exceptions:   1. All reading lamps must have a capacity to provide a minimum of 30 foot-candles of light; 2. All toilet and bathing areas must be provided with a minimum of 30 foot-candles of light; 3. General lighting in food preparation areas must be a minimum of 50 foot-candles of light; and 4. Hallways must be illuminated at all times by at least a minimum of five foot-candles of light at the floor.   ARM 37.106.321(5)(a)-(d) |  |  |  |  | \*Note, this is only in the MT Regulation and therefore is not associated with a C-Tag. However, compliance with state licensure laws are part of the CAH’s preparation for C-Tag C-0810 and CoP  42 C.F.R. § 485.608. |
| Does the CAH prevent the temperature of hot water supplied to handwashing and bathing facilities from exceeding 120° F?  ARM 37.106.320(7) |  |  |  |  | \*Note, this is only in the MT Regulation and therefore is not associated with a C-Tag. However, compliance with state licensure laws are part of the CAH’s preparation for C-Tag C-0810 and CoP  42 C.F.R. § 485.608. |
| Does the CAH meet the applicable provisions and proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.)?  Does the CAH have positive latching hardware on corridor doors and doors to rooms containing flammable or combustible materials (roller latches are prohibited on such doors)?  C-0930  42 C.F.R. § 485.623(c)(1)  ARM 37.106.302(2)(b) |  |  |  |  | \*Note, SOM Guidance is pending, C-0930, at 91. Impl. 2-21-2020. |
| If CMS waived specific provisions of the Life Safety Code does the CAH maintain documentation of the waivers and the determination that the waiver is necessary to avoid unreasonable hardship upon the CAH, and the waiver will not adversely affect the health and safety of the patients?  C-0932 & C-0942  42 C.F.R. § 485.623(c)(2)-(3) |  |  |  |  | \*Note, SOM Guidance is pending, C-0932, at 91-92 & C-0942, at 93. Impl. 2-21-2020. |
| Does the CAH maintain written evidence of regular inspection and approval by State or local fire control agencies?  C-0934  42 C.F.R. § 485.623(c)(4) |  |  |  |  | \*Note, SOM Guidance is pending, C-0934, at 92. Impl. 2-21-2020. |
| If the CAH installed alcohol-based hand rub dispensers in its facility, are they installed in a madder that adequately protects against inappropriate access?  C-0936  42 C.F.R. § 485.623(c)(5) |  |  |  |  | \*Note, SOM Guidance is pending, C-0936, at 92. Impl. 2-21-2020. |
| When a sprinkler system is shut down for more than 10 hours, does the CAH (i) evacuate the building or portion of the building affected by the system outage until the system is back in service, or (ii) establish a fire watch until the system is back in service?  C-0938  42 C.F.R. § 485.623(c)(6) |  |  |  |  | \*Note, SOM Guidance is pending, C-0938, at 92-93. Impl. 2-21-2020. |
| Does the CAH’s building have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 does the still height not exceed 36 inches above the floor (Windows in atrium walls are considered outside windows for this requirement; the still height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours; special nursing care areas of new occupancies shall not exceed 60 inches)?  C-0940  42 C.F.R. § 485.623(c)(7) |  |  |  |  | \*Note, SOM Guidance is pending, C-0940, at 93. Impl. 2-21-2020. |
| Does the CAH meet the applicable provisions of and proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).  C-0944  42 C.F.R. § 485.623(d) |  |  |  |  | \*Note, SOM Guidance is pending, C-0944, at 94. Impl. 2-21-2020. |
| ***Emergency Preparedness*** | | | | | |
| Does the CAH comply with all applicable Federal, State, and local emergency preparedness requirements, including developing and maintaining a comprehensive emergency preparedness program, utilizing an all-hazards approach?  C-0950  42 C.F.R. § 485.625  Does the CAH have a written disaster plan in conjunction with other emergency services in the community, which are developed such that they can be followed in the event of a natural or man-caused disaster?  ARM 37.106.322(1)(a)-(b) |  |  |  |  | \*Note: The Emergency Preparedness guidance in the SOM (SOM Guidance, 94-100), states “Please refer to Appendix Z of the State Operations Manual to cite the specific Emergency Preparedness C-Tags, interpretive guidelines, and survey procedure.” Currently, the only available copy of [Appendix Z](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Advanced-Copy-SOM-Appendix-Z-EP-IGs.pdf) is an undated document identified as an “Advanced Copy” indicating that it may be revised. It is worth reviewing the sections specifically addressing CAHs for requirements specific to emergency preparedness (at pgs. 3, 5-7, 10-11, 36, 42, 49-50, 53-55, 62-67). |
| Does the CAH prepare and retain on file for at least three years a written report of the review/exercise including:   1. date and time of the review or exercise; 2. the names of staff involved in the review/exercise; 3. the names of other health care facilities involved in the review/exercise (if any); 4. names of other persons involved in the review/exercise; 5. description of all phases of the procedure and suggestions for improvement; and 6. the signature of the person conducting the review/exercise.   ARM 37.106.322(2)(a)-(f) |  |  |  |  | \*Note, this is only in the MT Regulation and therefore is not associated with a C-Tag. However, compliance with state licensure laws are part of the CAH’s preparation for C-Tag C-0810 and CoP  42 C.F.R. § 485.608. |
| Did the CAH develop and maintain an emergency preparedness plan that is reviewed and tested every year which does the following:   1. Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach; 2. Include strategies for addressing emergency events identified by the risk assessment; 3. Address patient population, including, but not limited to, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans; and 4. Include a process for cooperation and collaboration with local, tribal, regional, state and federal emergency preparedness officials’ efforts to maintain an integrated response during a disaster or emergency situation.   C-0950  42 C.F.R. § 485.625(a)  ARM 37.106.322 |  |  |  |  | \*Note: The CoPs only require review of these policies biannually, but State licensure laws require annual review. |
| Did the CAH develop and implement emergency preparedness policies and procedures, based on the emergency plan, risk assessment, and the communication plan, which are reviewed and updated every year and include, at minimum:   1. The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to (i) Food, water, medical, and pharmaceutical supplies; (ii) Alternate sources of energy to maintain: (A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; (B) Emergency lighting; (C) Fire detection, extinguishing, and alarm systems; and (D) Sewage and waste disposal; 2. A system to track the location of on-duty staff and sheltered patients in the CAH's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the CAH must document the specific name and location of the receiving facility or other location; 3. Safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance; 4. A means to shelter in place for patients, staff, and volunteers who remain in the facility; 5. A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records; 6. The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency; 7. The development of arrangements with other CAHs or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to CAH patients; and 8. The role of the CAH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.   C-0950  42 C.F.R. § 485.625(b) |  |  |  |  |  |
| Did the CAH develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and is reviewed and updated at least every years, and includes:   1. Names and contact information for (i) staff, (ii) entities providing services under arrangement, (iii) patients’ physicians, (iv) other CAHs and hospitals, and (v) volunteers; 2. Contact information for: (i) Federal, State, tribal, regional, and local emergency preparedness staff and (ii) other sources of assistance; 3. Primary and alternate means for communicating with: (i) CAH’s staff and (ii) Federal, State, tribal, regional, and local emergency management agencies; 4. A method for sharing information and medical documentation for patients under the CAH’s care, as necessary, with other health care providers to maintain the continuity of care; 5. A means, in the event of an evacuation, to release patient information; 6. A means of providing information about the general condition and location of patients under the facility’s care; and 7. A means of providing information about the CAH’s occupancy, needs, and its ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee.   C-0950  42 C.F.R. § 485.625(c) |  |  |  |  |  |
| Did the CAH develop and maintain an emergency preparedness training and testing program based on the emergency plan, risk assessment, policies and procedures, and the communication plan, which is reviewed and updated at least annually?  With regard to training, does the CAH do all of the following:   1. Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles; 2. Provide emergency preparedness training at least annually; 3. Maintain documentation of the training; 4. Demonstrate staff knowledge of emergency procedures; and 5. If the emergency preparedness policies and procedures are significantly updated, the CAH must conduct training on the updated policies and procedures.   With regard to testing, does the CAH conduct exercises to test the emergency plan at least twice per year? Does CAH do the following:   1. Participate in an annual full-scale exercise that is community-based; or When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event; 2. Conduct an annual additional exercise, that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan; and 3. Analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed.   C-0950  42 C.F.R. § 485.625(d) |  |  |  |  | \*Note: The CoPs only require review of these policies biannually, but State licensure laws require annual review. |
| Does the CAH conduct at least four fire drills annually, no closer than two months apart, with at least one drill occurring on each shift?  Are the drill observations documented and maintained for at least two years?  Does the documentation include   1. location of the drill; 2. documentation that identifies participating staff; 3. problems identified during the drill; 4. steps taken to correct such problems; and 5. signature of the individual responsible for the day-to-day operation of the health care facility.   ARM 37.106.322(4) |  |  |  |  | \*Note, this is only in the MT Regulation and therefore is not associated with a C-Tag. However, compliance with state licensure laws are part of the CAH’s preparation for C-Tag C-0810 and CoP  42 C.F.R. § 485.608. |
| Did the CAH implement emergency and standby power systems based on the emergency plan?  Is the generator located in accordance with the location requirements found in the Health Care Facilities Code, Life Safety Code, and NFPA 110, when a new structure is built or when an existing structure or building is renovated?  Did the CAH implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code?  If the CAH maintains an onsite fuel source to power emergency generators, does it have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates?  C-0950  42 C.F.R. § 485.625(e) |  |  |  |  |  |
| If a CAH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, does the CAH choose to participate in the healthcare system's coordinated emergency preparedness program?  If elected, does the unified and integrated emergency preparedness program do all of the following:   1. Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program; 2. Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered; 3. Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program; 4. Include a unified and integrated emergency plan that meets the requirements of this section. The unified and integrated emergency plan must also be based on and include (i) A documented community-based risk assessment, utilizing an all-hazards approach and (ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach; and 5. Include integrated policies and procedures that meet the requirements of the coordinated communication plan and training and testing programs.   C-0950  42 C.F.R. § 485.625(f) |  |  |  |  |  |
|  |  |  |  |  |  |
| ***Organizational Structure*** | | | | | |
| Does the CAH have a single governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment?  Additionally:   1. If there is no governing body, does the CAH have written documentation that identifies the individual/s responsible for the conduct of CAH operations? 2. Has the governing body determined and stated which categories of practitioners are eligible candidates for appointment to the medical staff? 3. Have the CAH’s operating policies been updated to fully reflect its responsibilities as a CAH? 4. Does the CAH have documentation that the governing body or responsible individual is involved in the day-to-day operation of the CAH and is fully responsible for its operations? 5. Does the governing body appoint all members to the medical staff in accordance with established policies based on the individual practitioner’s scope of clinical practice? 6. Does the medical staff operate under the current bylaws, in accordance with state and federal laws and regulations and approved by the governing body? 7. Are any revisions to the medical staff bylaws, rules, and policies approved by medical staff and governing body? 8. Is the governing body periodically apprised of medical staff evaluation of patient care services? 9. Is any person providing patient services a member of the medical staff or accountable to a member of the medical staff qualified to evaluate the quality of services provided? 10. Is qualification of medical staff for membership based on an individual practitioner’s compliance with the medical staff’s membership criteria? 11. Are individual character, competence, training, experience, and judgment the minimum criteria for selection to the medical staff?   (SOM at 100-103)  C-0960  C-0962  42 C.F.R. § 485.627(a) |  |  |  |  |  |
| Does the CAH disclose the names and addresses of the person principally responsible for the operation of the CAH?  Additionally, Does the CAH have a process for implementing its policy or procedure for reporting changes in operating officials to the state agency?  (SOM at 103)  C-0960  C-0964  42 C.F.R. § 485.627(b)(1) |  |  |  |  |  |
| Does the CAH disclose the names and addresses of the person responsible for medical direction?  Additionally, Does the CAH have a process for implementing its policy or procedure for reporting changes in medical director to the state agency?  (SOM at 103)  C-0960  C-0966  42 C.F.R. § 485.627(b)(2) |  |  |  |  |  |
| ***Staffing and Staff Responsibilities*** | | | | | |
| Does the CAH have a professional health care staff that includes one or more MD/DO, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists?  Additionally:   1. Does the CAH have listings or organizational charts showing the names of all professional medical staff? 2. Does the CAH have work schedules showing normal CAH hours of operation and coverage by members of CAH staff?   (SOM at 103-104)  C-0971  42 C.F.R. § 485.631(a)(1) |  |  |  |  |  |
| Does the CAH maintain a file on each employee and substitute personnel and make such files available to the State department within 24 hours of request?  Does the CAH maintain the following information in the employee file:   1. The employee’s name; 2. A job description signed by the employee; 3. Documentation of employee orientation, signed by the employee; and 4. A copy of current credentials, certification, or professional licenses required to perform the duties described in the job description.   Does the CAH maintain a file at the facility for each volunteer that performs duties commonly performed by facility staff that documents:   1. Orientation to the facility and its residents; and 2. Orientation to and training of the duties to be performed.   ARM 37.106.315(2)(d) |  |  |  |  | \*Note, this is only in the MT Regulation and therefore is not associated with a C-Tag. However, compliance with state licensure laws are part of the CAH’s preparation for C-Tag C-0810 and CoP  42 C.F.R. § 485.608. |
| Are any ancillary personnel supervised by the professional staff?  Additionally, Does the CAH have listings or organizational charts showing how the CAH ensures that professional staff supervises all ancillary personnel?  (SOM at 104)  C-0972  42 C.F.R. § 485.631(a)(2) |  |  |  |  |  |
| Is the staff is sufficient to provide the services essential to the operation of the CAH?  Additionally, Does the CAH have a process to ensure that staff coverage is sufficient to provide essential services at the facility (e.g. emergency service, direct services, nursing services)?  (SOM at 104)  C-0974  42 C.F.R. § 485.631(a)(3) |  |  |  |  |  |
| Is a MD/DO, nurse practitioner, clinical nurse specialist, or physician assistant available to furnish patient care services at all times the CAH operates?  Additionally:   1. Can the CAH demonstrate that its practitioners are physically present and prepared to treat patients at the CAH when patients present at the CAH outpatient clinic during announced hours of outpatient clinic operation? 2. Does the CAH have arrangements to ensure that a practitioner is available on site at all times the CAH operates to furnish patient care services?   (SOM at 104-105)  C-0976  42 C.F.R. § 485.631(a)(4) |  |  |  |  |  |
| Is a registered nurse, clinical nurse specialist, or licensed practical nurse on duty whenever the CAH has one or more inpatients?  C-0978  42 C.F.R. § 485.631(a)(5) |  |  |  |  |  |
| Does a MD/DO provide medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff?  Additionally:   1. Does the CAH have a MD or DO on staff? 2. Does the MD or DO perform all medical oversight functions?   (SOM at 105)  C-0981  42 C.F.R. § 485.631(b)(1)(i) |  |  |  |  |  |
| Do MDs/DOs, in conjunction with the physician assistant and/or nurse practitioner member(s), participate in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes?  Additionally:   1. Does the CAH have evidence that an MD/DO participated in the development of policies governing CAH services? 2. Does the CAH have a way to ensure that an MD/DO periodically reviews these policies?   (SOM at 106)  C-0982  42 C.F.R. § 485.631(b)(1)(ii) |  |  |  |  |  |
| Do the MDs/DOs, in conjunction with the physician assistant and/or nurse practitioner members, periodically review the CAH's patient records, provide medical orders, and provide medical care services to the patients of the CAH?  Additionally:   1. Does the CAH have a way to ensure that a MD/DO periodically reviews CAH patient records in conjunction with staff mid-level practitioners and provides health care to CAH patients? 2. Does the CAH have evidence of such periodic review?   (SOM at 106)  C-0984  42 C.F.R. § 485.631(b)(1)(iii) |  |  |  |  |  |
| Do the MDs/DOs periodically review and sign the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants?  Additionally:   1. Does the MD/DO’s inpatient review cover all applicable inpatient records open at the time of the review, as well as all applicable inpatient records closed since the last review (except those inpatients whose care is/was managed by an MD/DO)? 2. Did the CAH specify a maximum interval between inpatient record reviews in its policies and procedures? 3. Did the CAH develop a logistical way for MD/DOs to review and sign records (e.g. electronic medical records, if available, paper copy, etc.)?   (SOM at 107)  C-0986  42 C.F.R. § 485.631(b)(1)(iv) |  |  |  |  |  |
| Do the MDs/DOs periodically review and sign a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician?  C-0986  42 C.F.R. § 485.631(b)(1)(v) |  |  |  |  |  |
| Is a MD/DO present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the CAH, and available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral?  Additionally:   1. Does the CAH have a policy in place to ensure there is adequate MD/DO presence for the services it provides? 2. Does the CAH evaluate and adjust its MD/DO on-site schedule as appropriate, given the volume and services offered? 3. Is there documentation showing that an MD or DO is on-site for the frequency and duration specified in the CAH’s policies? 4. Can the CAH demonstrate that an MD or DO is always available by telecommunications contact for consultation, assistance and/or patient referral?   (SOM at 108-110)  C-0988  42 C.F.R. § 485.631(b)(2) |  |  |  |  |  |
| Do the physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes?  Additionally, Does the CAH ensure that policies are updated to remain consistent with State standards of practice requirements for mid-level practitioners?  (SOM at 110)  C-0991  42 C.F.R. § 485.631(c)(1)(i) |  |  |  |  |  |
| Do the physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff participate with a MD/DO in a periodic review of the patients' health records?  Additionally, Does the CAH ensure that mid-level practitioners at the CAH participate with an MD/DO in the review of their patients' health records?  (SOM at 110)  C-0993  42 C.F.R. § 485.631(c)(1)(ii) |  |  |  |  |  |
| Does the physician assistant, nurse practitioner, or clinical nurse specialist perform the following functions to the extent they are not being performed by a MD/DO: provide services in accordance with the CAH's policies?  Additionally, Do mid-level practitioners have knowledge and understand application of CAH policies?  (SOM at 110-111)  C-0995  42 C.F.R. § 485.631(c)(2)(i) |  |  |  |  |  |
| Does the physician assistant, nurse practitioner, or clinical nurse specialist perform the following functions to the extent they are not being performed by a MD/DO: arrange for, or refer patients to, needed services that cannot be furnished at the CAH, and assure that adequate patient health records are maintained and transferred as required when patients are referred?  Additionally, Does the CAH have policies and procedures for transferring patients to other facilities?  (SOM at 111)  C-0997  42 C.F.R. § 485.631(c)(2)(ii) |  |  |  |  |  |
| Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, is a MD/DO on the staff of the CAH notified of the admission?  Additionally:   1. Are patients admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body (or responsible individual) in accordance with State laws and medical staff bylaws? 2. Is a MD/DO responsible for and is monitoring the care of each Medicare or Medicaid patient for all medical problems during the hospitalization? 3. If mid-level practitioners admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical problem outside the scope of practice of the admitting practitioners.   (SOM at 111-112)  C-0998  42 C.F.R. § 485.631(c)(3) |  |  |  |  |  |
| Does the CAH require that the quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialist, and physician assistants at the CAH are evaluated by a CAH MD/DO or by another MD/DO under contract with the CAH?  C-0999  42 C.F.R. § 485.631(d)(1) |  |  |  |  | \*SOM Guidance is pending and will be updated on future release (as of 2-21-2020 implementation date). At pg. 111. |
| Does the CAH require that the quality and appropriateness of the diagnosis and treatment furnished by MD/DOs at the CAH are evaluated by   1. One hospital that is a member of the network, when applicable; 2. One Quality Improvement Organization (QIO) or equivalent entity; 3. One other appropriate and qualified entity identified in the State rural health care plan; 4. In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patient under an agreement between the CAH and a distant-site hospital, the distant-site hospital; or 5. In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, one of the entities listed in (i) through (iii) of this section.   C-0999  42 C.F.R. § 485.631(d)(2) |  |  |  |  | \*SOM Guidance is pending and will be updated on future release (as of 2-21-2020 implementation date). At pg. 111. |
| Does the CAH require that the CAH staff consider the findings of evaluations and make the necessary changes as specified in the previous requirements for C-Tags 0971 through 0999?  C-0999  42 C.F.R. § 485.631(d)(3) |  |  |  |  | \*SOM Guidance is pending and will be updated on future release (as of 2-21-2020 implementation date). At pg. 111. |
| ***Provision of Services*** | | | | | |
| Are the CAH's health care services furnished in accordance with appropriate written policies that are consistent with applicable State law?  Additionally:   1. Does the CAH have written policies covering the health care services furnished in the CAH? 2. Does staff provide services consistent with the CAH’s written policies?   (SOM at 113)  C-1004  C-1006  42 C.F.R. § 485.635(a) |  |  |  |  | \*Note: The CoPs only require review of these policies biannually, but State licensure laws require annual review. |
| Does the CAH’s written policy and procedure manual describe all services provided in the facility?  Is the manual available to staff, residents, resident family members, resident legal representatives, and the department?  Are the policies and procedures reviewed at least annually by the administrator or medical director with written documentation of the review?  ARM 37.106.330 |  |  |  |  | \*Note, this is only in the MT Regulation and therefore is not associated with a C-Tag. However, compliance with state licensure laws are part of the CAH’s preparation for C-Tag C-0810 and CoP  42 C.F.R. § 485.608. |
| Are the CAH’s policies developed with the advice of members of the CAH's professional healthcare staff, including one or more MDs/DOs and one or more physician assistants, nurse practitioners, or clinical nurse specialists?  Are these policies reviewed at least annually by the group of professional personnel required under the previous standard, and reviewed as necessary by the CAH?  Additionally:   1. Do the meeting minutes of the group of healthcare professionals that advises the CAH’s governing body/responsible individual meet the regulatory requirements? 2. Do the staff listed as part of the advisory group have the opportunity to express opinions and make recommendations to the group? 3. Can the CAH provide documentation that the advisory group developed written recommendations on the CAH’s patient care policies for consideration by the CAH’s governing body/responsible individual? 4. Is there evidence that the group reviewed the CAH’s existing policies at least every year (ARM 37.106.330) and indicated whether or not it made changes?   (SOM at 114-115)  C-1004  C-1008  42 C.F.R. § 485.635(a)(2) & (4)  ARM 37.106.330 |  |  |  |  | \*Note: Both §§485.635(a)(2) & (4) are associated with this C-Tag and the applicable SOM apply to both CoPs (pg. 114). Section (a)(4) is also associated with another C-tag, C-1022 which is addressed below.  \*Note: The CoPs only require review of these policies biannually, but State licensure laws require annual review. |
| Do the CAH’s policies include a  description of the services the CAH furnishes, including those furnished through agreement or arrangement?   1. Do the policies describe which services are provided on- and off-site?   (SOM at 115)  C-1004  C-1010  42 C.F.R. § 485.635(a)(3)(i) |  |  |  |  |  |
| Do the CAH’s policies include policies and procedures for emergency medical services?   1. Do the written policies and procedures address the following: 2. How the CAH provides 24 hour emergency care to its patients; 3. What equipment, supplies, medications, blood and blood products are maintained onsite and which are readily available for treating emergency cases by agreement at other facilities; 4. What types of personnel are available to provide emergency services and what are their required onsite response times. 5. Do the written policies address how the CAH coordinates with local emergency response systems?   (SOM at 116)  C-1004  C-1012  42 C.F.R. § 485.635(a)(3)(ii) |  |  |  |  |  |
| Do the CAH’s policies include 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 furnished by the CAH?   1. Do the CAH’s policies address the circumstances under which consultation with an MD or DO should occur and which situations require them to consult with or refer to an MD/DO for advice on how to treat a patient? 2. Do the CAH’s policies must also address the circumstances under which patient referral outside the CAH should occur? 3. Do the policies address maintenance of medical records, consistent with the requirements at §485.638?   (SOM at 116-117)  C-1004  C-1014  42 C.F.R. § 485.635(a)(3)(iii) |  |  |  |  |  |
| Do the CAH’s policies include rules for the storage, handling, dispensation, and administration of drugs and biologicals?  Do such rules provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use?  Additionally:   1. Does the CAH ensure that drugs and biologicals are managed in a manner that is safe and appropriate? 2. Does the CAH ensure that its pharmacy system provides all drugs and biologicals prescribed by the CAH’s practitioners in a timely manner for administration to its patients? 3. Do the CAH’s rules address specific requirements outlined in SOM at 117-129?   C-1004  C-1016  42 C.F.R. § 485.635(a)(3)(iv) |  |  |  |  | \*Note: The SOM contain detailed requirements for the content of such policies and rules related to drugs and biologicals. Self-assessment should include review of the SOM at 117-129. |
| Do the CAH’s policies include procedures for reporting adverse drug reactions and errors in the administration of drugs?  Additionally:   1. Does the CAH ensure that medication administration errors and adverse drug reaction (ADR) are reported in a timely manner? 2. Is nursing staff familiar with concepts of medication errors that do and do not reach the patient, as well as ADRs? 3. Are nursing staff trained on how to handle a medical administration error that reaches the patient or an ADR? 4. In the event of an ADR, does the CAH have reports to practitioners documented in the medical record? 5. Are ADRs reported immediately in accordance with written procedures? 6. Are medications administered and/or drug reactions promptly recorded in patient’s medical record? 7. Can the CAH demonstrate that it has a system for reporting/identifying ADRs and medication administration errors for quality assurance/improvement purposes? 8. Is staff aware of the CAH’s policy for reporting medication administration errors and ADRs for quality improvement purposes? 9. Does the CAH have evidence of training staff on reporting expectations?   (SOM at 129-133)  C-1004  C-1018  42 C.F.R. § 485.635(a)(3)(v) |  |  |  |  |  |
| Do the CAH’s policies include procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices?  Are all patient diets, including therapeutic diets ordered by the practitioner responsible for the care of the patients or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff in accordance with State law governing dietitians and nutrition professionals and that the requirement of § 483.25(i) of this chapter is met with respect to inpatients receiving post CAH SNF care?  C-1004  C-1020  42 C.F.R. § 485.635(a)(3)(vi) |  |  |  |  | \*Note, guidance is pending and will be updated in future release (as of 2-21-2020 implementation), at page 133. |
| Do the CAH’s policies include policies and procedures that address the post-acute care needs of patients receiving CAH services?  42 C.F.R. § 485.635(a)(3)(viii) |  |  |  |  | \*Note: There is no specific C-tag for this provision, but compliance with this CoP is still required and relates to these substantive provisions. |
| Are the CAH policies reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section and updated as necessary by the CAH?  C-1004  C-1022  42 C.F.R. § 485.635(a)(4)  ARM 37.106.330 |  |  |  |  | \*Note, SOM Guidance is pending and will be updated in future release (as of 2-21-2020 implementation date) (at pg. 133-134).  \*Note: The CoPs only require review of these policies biannually, but State licensure laws require annual review. |
| Does the CAH provide diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department?  Do these CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions?  Additionally:   1. Are the outpatient services integrated with the appropriate CAH inpatient services in accordance with the needs of the patient care provided? 2. Are the types and number of qualified personnel appropriate for the scope and complexity of the outpatient services offered? 3. Do personnel hold appropriate licensure, certification, and training consistent with applicable state laws? 4. Are the equipment, staff, and facilities adequate to provide the outpatient services in accordance with acceptable standards of practice?   (SOM at 134-135)  C-1004  C-1024  42 C.F.R. § 485.635(b)(1)(i) |  |  |  |  |  |
| Does the CAH furnish acute care inpatient services?  Additionally:   1. For each Medicare beneficiary, in accordance with Medicare payment law and regulations, does the CAH have the practitioner who admits the beneficiary as an inpatient certify that the beneficiary may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH? 2. However, does the CAH furnish treatment to patients who present to the CAH so long as the CAH has an available inpatient bed and the treatment required to appropriately care for the patient is within the scope of services offered by the CAH? 3. Is the CAH furnishing acute care inpatient services by reviewing data on the number of patients admitted over the prior year? 4. What percentage of ED visits result in an admission to the CAH? If fewer than eight percent of ED visits lead to an inpatient admission, is the data on transfers of ED patients, overall staffing, the volume and type of outpatient services offered, including observation services, and swing bed services reasonably proportionate among the various services the CAH provides? 5. In general, are transfers appropriate based on services available to the CAH?   (SOM at 135-139)  C-1026  42 C.F.R. § 485.635(b)(1)(ii) |  |  |  |  |  |
| Does the CAH provide basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a), including:   1. Chemical examination of urine by stick or tablet method or both (including urine ketones); 2. Hemoglobin or hematocrit; 3. Blood glucose; 4. Examination of stool specimens for occult blood; 5. Pregnancy tests; and 6. Primary culturing for transmittal to a certified laboratory.   Additionally:   1. Are the laboratory services offered by the CAH available on its main campus? 2. Does the CAH have CLIA certificate or waiver, as applicable, for all laboratory tests performed in CAH facilities? 3. Does the CAH have a procedure in place for obtaining tests needed but unavailable at the CAH laboratory? 4. If the CAH refers specimens to another laboratory for testing, does it have documentation that the referral laboratory is CLIA certified for the appropriate tests? 5. Has the CAH identified laboratory services which must be available to support the emergency services the CAH provides?   (SOM at 139-141)  C-1004  C-1028  42 C.F.R. § 485.635(b)(2) |  |  |  |  |  |
| Are the radiology services furnished by the CAH provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards?  Additionally:   1. Does the CAH have written policies, developed and approved by the governing body or responsible individual, that are consistent with state law and designate which personnel are qualified to use the radiological equipment and administer procedures? 2. If telemedicine is used to provide teleradiology services, do the radiologists interpreting the tests satisfy the telemedicine privileging requirements in §485.616(c)(3)? 3. Is the radiologic services staff familiar with the policies and procedures related to safety? 4. Are patient shielding (e.g. aprons, etc.) properly maintained and routinely inspected by the CAH? 5. Are hazardous materials clearly labeled? Are they tracked, handled, and stored properly in a safe manner with the requisite containers? 6. Are periodic tests of radiology personnel by exposure meters or test badges performed? 7. Are equipment inspections and maintenance conducted in accordance with manufacturer recommendations? 8. Are studies interpreted only by qualified staff approved to do so by the CAH’s governing body or responsible individual? 9. Do all staff using various pieces of radiological equipment meet the qualifications for tasks they perform, as established by the CAH’s policies and consistent with state law?   (SOM at 141-145)  C-1004  C-1030  42 C.F.R. § 485.635(b)(3) |  |  |  |  |  |
| In accordance with requirements of the emergency services CoP (addressed previously for C-Tag C-0880), does the CAH provide medical services as a first response to common life-threatening injuries and acute illness?  Additionally:   1. Are emergency services provided by the CAH at the CAH campus by CAH staff or by individuals providing services under agreement or arrangement? 2. Do these personnel have the ability to recognize a patient’s need for emergency care at all times? 3. Does the CAH provide medically appropriate initial interventions, treatment, and stabilization of any patient who requires emergency services?   (SOM at 145)  C-1004  C-1032  42 C.F.R. § 485.635(b)(4) |  |  |  |  |  |
| Does the CAH have agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, *except* in the case of distant-site physicians and practitioners providing telemedicine services to the CAH’s patients under a written agreement between the CAH and a distant-site telemedicine entity, the distant-site entity is not required to be a Medicare-participating provider or supplier?  Additionally, Does the CAH verify that every entity providing health care services to the CAH’s patients under an agreement participates in Medicare (except distant-site telemedicine providers under agreement/arrangement)?  (SOM at 145-146)  C-1004  C-1034  42 C.F.R. § 485.635(c)(1) & (5) |  |  |  |  |  |
| Does the CAH have agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including services of MDs/DOs?  If the agreements are not in writing, is the CAH able to present evidence that patients referred by the CAH are being accepted and treated?  Additionally:   1. Does the CAH have arrangements with one or more MDs/Dos for referral of discharged patients who need medical services not available at the CAH? 2. Are the referral arrangements in writing? If not, can the CAH document that patients referred to an outside MD/DO have been offered appointments and treatment? 3. Does the CAH have policies and procedures addressing referral of discharged patients? 4. Are the CAH professionals and staff who handle discharges familiar with these policies and procedures?   (SOM at 146-147)  C-1004  C-1036  42 C.F.R. § 485.635(c)(1)(i) & (c)(2) |  |  |  |  |  |
| Does the CAH have agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including additional or specialized diagnostic and clinical laboratory services that are not available at the CAH?  If the agreements are not in writing, is the CAH able to present evidence that patients referred by the CAH are being accepted and treated?  Additionally:   1. Does the CAH have an agreement or arrangement with an outside laboratory and an outside diagnostic imaging facility for services not provided in the CAH? 2. Does the CAH have evidence for how it ensures that the laboratory with which it has an agreement or arrangement holds the necessary CLIA certification? 3. If the agreement or arrangement is not in writing, can the CAH document that it is sending specimens to an outside laboratory and patients to an outside diagnostic imaging facility when needed, and that it is receiving test results? 4. Do policies and procedures address which imaging and lab services are provided under arrangement, as well as, for lab services, collection, preservation, transportation, receipt, and reporting of tissue specimen results?   (SOM at 147-148)  C-1004  C-1038  42 C.F.R. § 485.635(c)(1)(ii) and (c)(2) |  |  |  |  |  |
| Does the CAH have agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH?  Additionally, Does the CAH have an agreement / arrangement with a vendor to provide dietary services to inpatients if the CAH does not use its own staff to provide these services?  (SOM at 149)  C-1004  C-1040  42 C.F.R. § 485.635(c)(1)(iii) |  |  |  |  |  |
| Does the CAH maintain a list of all services furnished under arrangements or agreements, describing the nature and scope of the services provided?  Additionally:   1. Does the list of contracted services include, at a minimum, the following information:    * The service(s) being offered;    * The individual(s) or entity providing the service(s);    * Whether the services are offered on- or off-site;    * Whether there is any limit on the volume or frequency of the services provided; and    * When the service(s) are available. 2. Does the CAH have evidence the list is updated whenever there are changes? 3. Does staff work directly for the CAH or some other entity? Are all other entities documented in the list of contracted services?   (SOM at 149-150)  C-1004  C-1042  42 C.F.R. § 485.635(a) |  |  |  |  |  |
| Is the person principally responsible for the operation of the CAH (e.g. the CEO) also responsible for the following:  Additionally:   1. Services furnished in the CAH whether or not they are furnished under arrangements or agreements, and 2. Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services? 3. Can the responsible person demonstrate how he or she provides oversight of all contracted services related to patient care? 4. Does the responsible person have specific examples of how he/she assures that services furnished in the CAH comply with the CoPs?   (SOM at 150-151)  C-1004  C-1044  42 C.F.R. § 485.635(d) |  |  |  |  |  |
| Does the CAH ensure that nursing services meet the needs of patients by ensuring that a registered nurse provides (or assigns to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH?  Additionally:   1. Has the care been provided in accordance with the patient’s needs and the specialized qualifications and competence of the staff available? 2. Have nursing policies and procedures been developed and maintained and are reviewed at least annually? 3. Is the nursing staff is supervised either directly or through other nursing managers? 4. Is the quality of nursing care subject to ongoing review and analysis? 5. Do written staffing schedules adhere to the CAH’s policies and procedures for staffing levels and types of nursing personnel? 6. Does each nursing unit have supervision of personnel performance and nursing care? 7. Do nursing staff have required licenses and competencies?   (SOM at 151-153)  C-1004  C-1046  42 C.F.R. §485.635(d) and (d)(1)  ARM 37.106.330(1) |  |  |  |  | \*Note: The CoPs only require review of these policies biannually, but State licensure laws require annual review. |
| Does the CAH ensure that either a registered nurse or physician assistant (where permitted by State law) supervises and evaluates the nursing care for each inpatient including patients at a SNF level of care in a swing-bed CAH?  Additionally, Do evaluations include assessment of the patient’s care needs, health status/conditioning, and response to interventions  (SOM at 154)  C-1004  C-1048  42 C.F.R. §485.635(d)(2) |  |  |  |  |  |
| Does the CAH ensure that all drugs, biologicals, and intravenous medications administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws?  Additionally:   1. Do the medication orders include the patient’s name, age and weight; the date and time of the order; the drug name; the exact strength or concentration; the dose, frequency, and route; dose calculation requirements; quantity and/or duration; specific instructions for use; and name of the prescriber? 2. When verbal or standing orders used, are they authenticated in writing as soon as possible after the fact? 3. If the hospital permits patient self-administration of medications, are there policies and procedures addressing this? 4. Does medication administration education and training include the topics of safe handling and preparation of medications; knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications; and equipment, devices, special procedures, and/or techniques required for medication administration? 5. Do the medication policies and procedures address medications eligible and not eligible for scheduled dosing times? 6. Do the policies and procedures ensure timely administration of medications? 7. Do the policies and procedures address the actions to be taken when medications eligible for scheduled dosing times are missed or late? 8. Are the patients receiving medications, especially those receiving high-alert medications, being monitored and assessed to evaluate the efficacy of medication therapy or adverse effects? 9. Are there policies and procedures in place regarding blood administration procedures? 10. Is each medication administration properly documented to include all orders, reports of treatments and medications, nursing notes and documentation of complications and other pertinent information to monitor the patient’s progress? 11. Is the proper administration procedure followed when administering medication to patients?     1. Is the patient’s identity confirmed prior to medication administration?     2. Are procedures to assure the correct medication, dose, and route followed?     3. Are drugs administered in accordance with the hospital’s established policies and procedures for timely medication administration?     4. Does the nurse remain with the patient until medication is taken, unless they are permitted to self-administer?   (SOM at 154-175)  C-1004  C-1049  42 C.F.R. §485.635(d)(3) |  |  |  |  | \*Note: The SOM contain detailed requirements related to this C-Tag. Self-assessment should include review of the SOM at 154-175. |
| Has the CAH developed and kept current a nursing care plan for each inpatient?  Additionally:   1. Are the care plans created as soon as possible after admission for each patient? 2. Are the care plans based on the nurse’s assessment of the individual patient? 3. Is there evidence that the care plans are reviewed on an ongoing basis? 4. Is there evidence that the nursing care plan is revised as needed and is there documentation of nursing reassessment? 5. Has the nursing care plan been included in the patient’s clinical record?   (SOM at 177)  C-1004  C-1050  42 C.F.R. §485.635(d)(4) |  |  |  |  |  |
| If physical therapy, occupational therapy, and speech-language pathology services are furnished at the CAH, are such services provided by staff qualified under State law, and consistent with the requirements for therapy services in §409.17 of this subpart?  Additionally:   1. Does one of the following practitioners establish the plan before treatment begins:    1. A physician;    2. A nurse practitioner, a clinical nurse specialist or a physician assistant;    3. The physical therapist furnishing the physical therapy services;    4. A speech-language pathologist furnishing the speech-language pathology services; and    5. An occupational therapist furnishing the occupational therapy services. 2. Does the plan contain the following information:    1. Prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and    2. Indicates the diagnosis and anticipated goals. 3. Are changes in the plan are implemented in accordance with the provider’s policies and procedures? 4. Do the employee personnel files of those who provide rehabilitation service providers demonstrate that they have the necessary education, experience, training, and documented competencies to provide rehabilitation services? 5. Is there documentation to support that the rehabilitation services are being provided according to national standards of practice as established by professional organizations?   (SOM at 178-79)  C-1004  C-1052  42 C.F.R. §485.635(e)  42 C.F.R § 409.17  Does the employee personnel file contain a copy of current credentials, certification, or professional licenses required to perform the duties described in the job description?  ARM 37.106.315 |  |  |  |  |  |
| Does the CAH maintain written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation?  Additionally:   1. Are the rationales for the restrictions or limitations clear and reasonably related to clinical concerns? 2. Is there documentation of how the CAH identifies and trains staff who play a role in facilitating or limiting/restricting access of visitors to patients? 3. Are CAH staff aware of the visitation policies and procedures? Can staff on a given unit correctly describe the CAH’s visitation policies for that unit?   (SOM at 179-181)  C-1004  C-1054  42 C.F.R. §485.635(f) |  |  |  |  |  |
| Has each patient (or support person, where appropriate) been informed of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible?  Has each patient (or support person, where appropriate) been informed of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, **and** his or her right to withdraw or deny such consent at any time?  Additionally:   1. Does the CAH accept a patient’s designation, orally or in writing, of an individual as the patient’s support person? 2. Does each patient’s medical records document that the required notice was provided and if it was provided in advance of care, unless circumstances made this not feasible? 3. Has the CAH adopted policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual is the patient’s support person, given the critical role of the support person in exercising the patient’s visitation rights? 4. Are refusals by the CAH of an individual’s request to be treated as the patient’s support person with respect to visitation rights documented in the patient’s medical record, along with the specific basis for the refusal?   (SOM at 181-83)  C-1004  C-1056  42 C.F.R. §485.635(f)(1) and (2) |  |  |  |  |  |
| Does the CAH ensure that its visitation policies and procedures are implemented in a nondiscriminatory manner and 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?  Has the CAH ensured that all visitors enjoy full and equal visitation privileges consistent with patient preferences?  Additionally, Have all staff who play a role in facilitating or controlling visitors been educated on the CAH’s visitation policies and procedures?  (SOM at 184-185)  C-1004  C-1058  42 C.F.R. §485.635(f)(3) and (4) |  |  |  |  |  |
| ***Clinical Records*** | | | | | |
| Does the CAH maintain a clinical records system in accordance with written policies and procedures?  Additionally:   1. Is a medical record maintained for each inpatient and outpatient evaluated or treated in any part or location of the CAH? 2. Does the medical record system correctly identify the author of every medical record entry? (SOM at 186) 3. Does the medical record system protect the security of all medical record entries? 4. Does the medical record system ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner? 5. Does the CAH have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the CAH within the past 6 years to be accessed by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed? 6. Does the CAH employ adequate medical record personnel who have the qualifications to ensure the CAH is in compliance with these records regulations?   (SOM at 186-187)  C-1100  C-1102  42 C.F.R. §485.638(a)(1)  ARM 37.106.314 |  |  |  |  |  |
| Are the records in the records system legible, complete, accurately documented, readily accessible, and systematically organized?  C-1100  C-1104  42 C.F.R. §485.638(a)(2) |  |  |  |  |  |
| Has a member of the professional staff been designated as responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized?  Additionally, Does the CAH employ adequate medical record personnel?  (SOM at 188)  C-1100  C-1106  42 C.F.R. §485.638(a)(3) |  |  |  |  |  |
| For each patient receiving health care services, does the CAH maintain a record that includes, as applicable:   1. Identification and social data; 2. evidence of properly executed informed consent forms; 3. pertinent medical history; 4. assessment of the health status and health care needs of the patient; and 5. a brief summary of the episode, disposition, and instructions to the patient.   Additionally:   1. Does the consent form include the following?    1. Name of patient, and when appropriate, patient’s legal guardian;    2. Name of CAH;    3. Name of procedure(s);    4. Name of practitioner(s) performing the procedures(s);    5. Signature of patient or legal guardian;    6. Date and time consent is obtained;    7. Statement that procedure was explained to patient or guardian;    8. Signature of professional person witnessing the consent; and    9. Name/signature of person who explained the procedure to the patient or guardian. 2. Do discharge summaries exist for all CAH acute care stays prior to and following a swing-bed admission and discharge? 3. Has the medical staff specified which procedures or treatments require a written informed consent? 4. Do medical records contain consent forms for all procedures or treatment that are required by CAH policy? 5. Are all consent forms properly executed?   (SOM at 188-190)  C-1100  C-1110  42 C.F.R. §485.638(a)(4)(i) |  |  |  |  |  |
| As applicable, does the CAH maintain a record of reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings?  Additionally:   1. Do the CAH’s bylaws require a physical examination and medical history to be done for each patient? 2. Has the appropriate practitioner signed reports of physical examinations, diagnostic and laboratory test results, and consultative findings?   (SOM at 190-191)  C-1100  C-1114  42 C.F.R. §485.638(a)(4)(ii) |  |  |  |  |  |
| As applicable, does the CAH maintain a record that includes all orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient’s progress, such as temperature graphics, and progress notes describing the patient’s response to treatment?  Additionally:   1. Is the medical record complete with all documentation of orders, diagnosis, evaluations, treatments, test results, consents, interventions, discharge summary, and care provided along with the patient’s response to those treatments, interventions, and care? 2. Has every medical record been promptly completed so that health care staff involved in the care of the patient have access to the information necessary to monitor the patient’s condition?   (SOM at 191)  C-1100  C-1116  42 C.F.R. §485.638(a)(4)(iii) |  |  |  |  |  |
| As applicable, does the CAH maintain a record that includes dated signatures of the doctor of medicine or osteopathy or other health care professional?  Additionally:   1. Is each entry timed, dated, and authenticated? 2. Is authentication of documents only allowable after transcription? 3. Does the department maintain a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification? 4. Are computer or other code signatures authorized by the CAH’S governing body and is a list of these codes maintained under adequate safeguards by the CAH administration? 5. Do the CAH’s policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes? 6. When rubber stamps are authorized, has the individual whose signature the stamp represents placed in the administrative offices of the CAH a signed statement to the effect that he/she is the only one who has the stamp and uses it?   (SOM at 192-193)  C-1100  C-1118  42 C.F.R. §485.638(a)(4)(iv) |  |  |  |  |  |
| Does the CAH maintain the confidentiality of record information and provide safeguards against loss, destruction, or unauthorized use?  Additionally:   1. Are only authorized persons permitted access to records maintained by the medical records department? 2. Does the CAH have a policy to grant patients direct access to his/her medical record if the responsible official (e.g., practitioner responsible for patient's care) determines that direct access is not likely to have an adverse effect on the patient? 3. Are medical records released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or in accordance with Federal or State law, court orders, or subpoenas? 4. Are copies of medical records released outside the CAH only upon written authorization of the patient, legal guardian, or person with an appropriate “power of attorney” to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by statutes? 5. Are precautions taken to prevent unauthorized persons from gaining access to or altering patient records? 6. Are precautions taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records?   (SOM at 194)  C-1100  C-1120  42 C.F.R. §485.638(b)(1) |  |  |  |  |  |
| Do written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information?  Additionally:   1. Are patient records secure at all times (i.e., never unsecured or unattended in hallways, patient rooms, nurses stations, or on counters where an unauthorized person could gain access to patient records)? 2. Is access to patient records controlled? 3. Does the CAH have policies and procedures for the use and release of records and are these policies and procedures are enforced?   (SOM at 195)  C-1100  C-1122  42 C.F.R. §485.638(b)(2) |  |  |  |  |  |
| Is the patient’s written consent required for release of information not required by law?  C-1100  C-1124  42 C.F.R. §485.638(b)(3) |  |  |  |  |  |
| Are the records retained for at least 6 years from date of last entry, and longer if required by state or other applicable law, or if the records may be needed in any pending proceeding?  Additionally, Can the CAH promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the CAH within the last 6 years (or other applicable time period required for retention)?  (SOM at 195-96)  C-1100  C-1126  42 C.F.R. §485.638(c) |  |  |  |  |  |
| ***Surgical Services*** | | | | | |
| If providing surgical services, are the surgical procedures performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual of the CAH in accordance with the designation requirements under paragraph (a) of this section (requirements captured in C-Tag, C-1142 below)?  Additionally, do surgical services adhere to requirements applicable to the following processes:   1. Is access to the operative and recovery area limited to authorized personnel and does the traffic flow pattern adhere to accepted standards of practice? 2. Is there conformance to aseptic and sterile technique by all individuals in the surgical area? 3. Is there appropriate cleaning between surgical cases and is appropriate terminal cleaning applied? 4. Is operating room attire suitable for the kind of surgical case performed, are persons working in the operating suite wearing only clean surgical attire, and is surgical attire designed for maximum skin and hair coverage? 5. Is equipment available for rapid and routine sterilization of operating room materials and is the equipment monitored, inspected, tested, and maintained by the CAH’S biomedical equipment program? 6. Are sterilized materials packaged, handled, labeled, and stored in a manner that ensures sterility (e.g., in a moisture and dust controlled environment) and have policies and procedures for expiration dates been developed and followed in accordance with accepted standards of practice? 7. Does the operating room's organization chart indicate lines of authority and delegation of responsibility within the department or service? 8. If LPNs and surgical technologists (STs) are performing circulating duties, do they do so in accordance with applicable State laws and approved medical staff policies and procedures? If so, is a qualified RN supervisor available to respond to emergencies? 9. Is a complete history and physical examination by a surgeon completed prior to surgery, except in an emergency? 10. Do the medical records of surgical patients contain consent forms? 11. Does the operating room have the following items available: on-call system; cardiac monitor; resuscitator; defibrillator; aspirator (suction equipment); and tracheotomy set (a cricothyroidotomy set is not a substitute)? 12. Does all equipment work, and, as applicable, is the equipment in compliance with the CAH’S biomedical equipment inspection, testing, and maintenance program? 13. Are there provisions for post-operative care? 14. Are there are policies and procedures that govern the recovery room area? 15. Does the record which lists all surgeries performed by the surgery service (i.e., operating room register) include identification, date, total time of the operation, name of the surgeon, name of nursing personnel, type of anesthesia used and person administering it, operation performed, pre and post-op diagnosis, and the age of the patient? 16. Is each operative report signed and dated by the responsible surgeon and does it include the proper information (e.g., diagnoses, the name of the procedure performed, etc.)?   (SOM at 196-202)  C-1140 42 C.F.R. §485.639 |  |  |  |  | \*Note: The SOM contain detailed requirements related to this C-Tag. Self-assessment should include review of the SOM at 196-202, specifically regarding the following:   1. Supervision in the OR 2. Policies and Procedures 3. Pre-Operative H&P 4. Informed Consent 5. Post-Operative Care/Recovery 6. Operating Room Register 7. Operative Report |
| Has the CAH designated the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws?  Is surgery only performed by:   1. a doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act; 2. a doctor of dental surgery or dental medicine; or 3. a doctor of podiatric medicine.   Additionally:   1. Are surgical privileges reviewed and updated at least every 2 years? 2. Is there a current roster listing each practitioner's specific surgical privileges available in the surgical suite and the area where the scheduling of surgical procedures is done? 3. Is there a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges retained in the above-mentioned areas/locations? 4. Do the medical staff bylaws include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges?   (SOM at 203-204)  C-1142  42 C.F.R. §485.639(a) |  |  |  |  |  |
| Does a qualified practitioner, as specified in paragraph (a) of this section (addressed above in C-Tag, C-1142), examine the patient immediately before surgery to evaluate the risk of the procedure to be performed?  Does a qualified practitioner, as specified in paragraph (c) of this section (addressed below in C-Tags C-1145 and C-1147), examine each patient before surgery to evaluate the risk of anesthesia?  Before discharge from the CAH, is each patient evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section (addressed below in C-Tags C-1145 and C-1147)?  Additionally:   1. Is there documentation to show that each patient has a pre-anesthesia evaluation and a post-anesthesia follow-up report? 2. Does the pre-anesthesia evaluation include:    1. notation of anesthesia risk;    2. anesthesia, drug and allergy history;    3. any potential anesthesia problems identified; and    4. patient's condition prior to induction of anesthesia? 3. Does the post-anesthesia follow-up report include:    1. cardiopulmonary status;    2. level of consciousness;    3. any follow-up care and/or observations; and    4. any complications occurring during post-anesthesia recovery?   (SOM at 204-205)  C-1144  42 C.F.R. §485.639(b)(1)(2)(3) |  |  |  |  |  |
| Has the CAH designated the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws?  Is anesthesia administered by only one of the following:   1. a qualified anesthesiologist; 2. a doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act; 3. a doctor of dental surgery or dental medicine; 4. a doctor of podiatric medicine; 5. a certified registered nurse anesthetist (CRNA); 6. an anesthesiologist’s assistant; or 7. a supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter?   Additionally:   1. Do the medical staff bylaws include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges? 2. Are the anesthesia privileges specified for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner? 3. Is there documentation of current licensure or current certification status for all persons administering anesthesia?   (SOM at 206-207)  C-1145  42 C.F.R. §485.639(c)(1)  Does the employee personnel file contain a copy of current credentials, certification, or professional licenses required to perform the duties described in the job description?  ARM 37.106.315 |  |  |  |  |  |
| In the cases in which a CRNA administers the anesthesia, is the anesthetist under the supervision of the operating practitioner except as provided by the state exemption?  In the cases in which the anesthesiologist's assistant administers anesthesia, is the anesthesiologist’s assistant under the supervision of an anesthesiologist?  C-1147  42 C.F.R. §485.639(c)(2) |  |  |  |  |  |
| Are all patients discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure?  Additionally:   1. Are exceptions to this requirement made by the attending practitioner and annotated on the clinical record? 2. Does the CAH have policies and procedures in place to govern discharge procedures and instructions?   (SOM at 207)  C-1149  42 C.F.R. §485.639(d) |  |  |  |  |  |
| If the CAH is exempted from the requirement for MD/DO supervision of CRNAs, does it maintain adequate documentation of the exemption including:   1. The letter the CAH submitted to CMS signed by the Governor, following consultation with the State’s Boards of Medicine and Nursing, requesting exemption from MD/DO supervision for CRNAs. 2. A letter from the Governor attesting that he or she has 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 MD/DO supervision requirement, and that the opt-out is consistent with State law.   C-1150  42 C.F.R. §485.639(e) |  |  |  |  |  |
| ***Infection Prevention and Antibiotic Stewardship Program*** | | | | | |
| Does the CAH have active facility-wide programs, for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship?  Do the programs demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms?  Are the infection prevention and control problems and antibiotic use issues identified in the programs addressed in coordination with the facility-wide quality assessment and performance improvement (QAPI) program?  C-1200  42 C.F.R. §485.640 |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20.  \*Note: The CoPs only require review of these policies biannually, but State licensure laws require annual review. |
| Does the CAH develop, implement, and review, at least annually written policies and procedures regarding infection prevention and control which include at least the following:   1. procedures to identify high risk individuals; and 2. the identification of methods used to protect, contain, or minimize the risk to patients, residents, staff, and visitors.   Does the CAH designate an administrator or infection control office responsible for the direction, provision, and quality of infection prevention and control services?  ARM 37.106.313 |  |  |  |  | \*Note, this is only in the MT Regulation and therefore is not associated with a C-Tag. However, compliance with state licensure laws are part of the CAH’s preparation for C-Tag C-0810 and CoP  42 C.F.R. § 485.608. |
| Can the CAH demonstrate that:   1. An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program? 2. Is the appointment based on the recommendations of medical staff leadership and nursing leadership?   C-1204  42 C.F.R. §485.640(a)(1) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Can the CAH demonstrate that the infection prevention and control program, as documented in its policies and procedures, employ methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings?  C-1206  42 C.F.R. §485.640(a)(2) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Can the CAH demonstrate that the infection prevention and control includes and addresses:   1. surveillance, prevention, and control of HAIs; 2. maintaining a clean and sanitary environment to avoid sources and transmission of infection; and 3. infection control issues identified by public health authorities?   C-1208  42 C.F.R. §485.640(a)(3) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Can the CAH demonstrate that the infection prevention and control program reflect the scope and complexity of the CAH services provided?  C-1210  42 C.F.R. §485.640(a)(4) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Can the CAH demonstrate 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?  C-1212  42 C.F.R. §485.640(b)(1) |  |  |  |  | \*Note: SOM missing references to C-Tags C-1212 through C-1223, which is likely due to the fact that these are fairly new tags and CoPs. For self-assessment purposes, the CAH should still evaluate compliance with the applicable text and confirm that the SOM has not been updated to include new Guidelines or Survey Procedures applicable to these new tags. |
| Does the facility-wide antibiotic stewardship program demonstrate coordination among all components of the CAH 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?  C-1218 42 C.F.R. §485.640(b)(2)(i) |  |  |  |  | \*Note: SOM missing references to C-Tags C-1212 through C-1223, which is likely due to the fact that these are fairly new tags and CoPs. For self-assessment purposes, the CAH should still evaluate compliance with the applicable text and confirm that the SOM has not been updated to include new Guidelines or Survey Procedures applicable to these new tags. |
| Does the facility-wide antibiotic stewardship program document the evidence-based use of antibiotics in all departments and services of the CAH?  C-1219  42 C.F.R. §485.640(b)(2)(ii) |  |  |  |  | \*Note: SOM missing references to C-Tags C-1212 through C-1223, which is likely due to the fact that these are fairly new tags and CoPs. For self-assessment purposes, the CAH should still evaluate compliance with the applicable text and confirm that the SOM has not been updated to include new Guidelines or Survey Procedures applicable to these new tags. |
| Does the facility-wide antibiotic stewardship program document any improvements, including sustained improvements, in proper antibiotic use?  C-1220  42 C.F.R. §485.640(b)(2)(iii) |  |  |  |  | \*Note: SOM missing references to C-Tags C-1212 through C-1223, which is likely due to the fact that these are fairly new tags and CoPs. For self-assessment purposes, the CAH should still evaluate compliance with the applicable text and confirm that the SOM has not been updated to include new Guidelines or Survey Procedures applicable to these new tags. |
| Does the antibiotic stewardship program adhere to nationally recognized guidelines, as well as best practices, for improving antibiotic use?  C-1221 42 C.F.R. §485.640(b)(3) |  |  |  |  | \*Note: SOM missing references to C-Tags C-1212 through C-1223, which is likely due to the fact that these are fairly new tags and CoPs. For self-assessment purposes, the CAH should still evaluate compliance with the applicable text and confirm that the SOM has not been updated to include new Guidelines or Survey Procedures applicable to these new tags. |
| Does the antibiotic stewardship program reflect the scope and complexity of the CAH services provided?  C-1223  42 C.F.R. §485.640(b)(4) |  |  |  |  | \*Note: SOM missing references to C-Tags C-1212 through C-1223, which is likely due to the fact that these are fairly new tags and CoPs. For self-assessment purposes, the CAH should still evaluate compliance with the applicable text and confirm that the SOM has not been updated to include new Guidelines or Survey Procedures applicable to these new tags. |
| Has the governing body, or responsible individual, ensured that systems are in place and are operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities?  C-1225  42 C.F.R. §485.640(c)(1)(i) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Has the governing body, or responsible individual, ensured that all HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the CAH’s QAPI leadership?  C-1229  42 C.F.R. §485.640(c)(1)(ii) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the infection prevention and control professional(s) maintain responsibility for the development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines?  C-1231  42 C.F.R. §485.640(c)(2)(i) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the infection prevention and control professional(s) maintain responsibility for all documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities?  C-1235  42 C.F.R. §485.640(c)(2)(ii) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the infection prevention and control professional(s) maintain responsibility for communication and collaboration with the CAH’s QAPI program on infection prevention and control issues?  C-1237  42 C.F.R. §485.640(c)(2)(iii) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the infection prevention and control professional(s) maintain responsibility for the competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the practical applications of infection prevention and control guidelines, policies and procedures?  C-1239  42 C.F.R. §485.640(c)(2)(iv) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the infection prevention and control professional(s) maintain responsibility for the prevention and control of HAIs, including the auditing of adherence to infection prevention and control policies and procedures by CAH personnel?  C-1240  42 C.F.R. §485.640(c)(2)(v) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the infection prevention and control professional(s) maintain responsibility for communication and collaboration with the antibiotic stewardship program?  C-1242  42 C.F.R. §485.640(c)(2)(vi) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Doesthe leader(s) of the antibiotic stewardship program maintain responsibility for the development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics?  C-1244 42 C.F.R. §485.640(c)(3)(i) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Doesthe leader(s) of the antibiotic stewardship program maintain responsibility for all documentation, written or electronic, of antibiotic stewardship program activities?  C-1246 42 C.F.R. §485.640(c)(3)(ii) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Doesthe leader(s) of the antibiotic stewardship program maintain responsibility for communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the CAH's infection prevention and control and QAPI programs, on antibiotic use issues?  C-1248 42 C.F.R. §485.640(c)(3)(iii) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Doesthe leader(s) of the antibiotic stewardship program maintain responsibility for the competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAHs, on the practical applications of antibiotic stewardship guidelines, policies, and procedures?  C-1250  42 C.F.R. §485.640(c)(3)(iv) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| ***Quality Assessment and Performance Improvement***  ***In November 2019, the prior text of 42 C.F.R. §485.641(Periodic Evaluation and Quality Assurance Review) was wholly revised to reflect new standards for Quality Assessment and Performance Improvement (“QAPI”). As such, the current SOM does not address the new CoP requirements for QAPI but continues to contain outdated and no longer applicable guidance related to prior Periodic Evaluation and Quality Assurance requirements. For self-assessment purposes related to the following C-Tags, the CAH should evaluate compliance with the current CoP text addressing QAPI requirements contained in this Tool and confirm that the SOM has not yet been updated to address QAPI requirements.*** | | | | | |
| Has the CAH developed, implemented, and maintained an effective, ongoing, CAH-wide, data-driven quality assessment and performance improvement (QAPI) program?  Has the CAH maintained and demonstrated evidence of the effectiveness of its QAPI program?  C-1300  42 C.F.R. §485.641 |  |  |  |  |  |
| Is the CAH's QAPI program appropriate for the complexity of the CAH's organization and services provided?  C-1302  42 C.F.R. §485.641(b)(1) |  |  |  |  |  |
| Is the CAH's QAPI program ongoing and comprehensive, and does it involve all departments of the CAH and services (including those services furnished under contract or arrangement)?  C-1306  42 C.F.R. §485.641(b)(2) and (3) |  |  |  |  |  |
| Does the CAH's QAPI program use objective measures to evaluate its organizational processes, functions and services?  C-1309  42 C.F.R. §485.641(b)(4) |  |  |  |  |  |
| Does the CAH's QAPI program address outcome indicators related to improved health outcomes and the prevention and reduction of medical errors, adverse events, CAH-acquired conditions, and transitions of care, including readmissions?  C-1311  42 C.F.R. §485.641(b)(5) |  |  |  |  |  |
| Is the CAH's governing body or responsible individual ultimately responsible for the CAH's QAPI program and responsible and accountable for ensuring that the QAPI program meets the requirements of paragraph (b) of this section (addressed above in C-Tags C-1302 through C-1311)?  C-1313  42 C.F.R. §485.641(c) |  |  |  |  |  |
| For each of the areas listed in paragraph (b) of this section (addressed above in C-Tags C-1302 through C-1311) regarding the CAH QAPI program’s design and scope, does the CAH focus on measures related to improved health outcomes that are shown to be predictive of desired patient outcomes?  C-1315 42 C.F.R. §485.641(d)(1) |  |  |  |  |  |
| For each of the areas listed in paragraph (b) of this section (addressed above in C-Tags C-1302 through C-1311) regarding the CAH QAPI program’s design and scope, does the CAH use the measures to analyze and track its performance?  C-1319 42 C.F.R. §485.641(d)(2) |  |  |  |  |  |
| For each of the areas listed in paragraph (b) of this section (addressed above in C-Tags C-1302 through C-1311) regarding the CAH QAPI program’s design and scope, does the CAH set priorities for performance improvement, considering either high-volume, high-risk services, or problem-prone areas?  C-1321  42 C.F.R. §485.641(d)(3) |  |  |  |  |  |
| Does the QAPI program incorporate quality indicator data including patient care data, and other relevant data, in order to achieve the goals of the QAPI program?  C-1325  42 C.F.R. §485.641(e) |  |  |  |  |  |
| ***Discharge Planning*** | | | | | |
| Does the CAH have an effective discharge planning process that focuses on the patient’s goals and treatment preferences and that includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care?  Are the discharge planning process and the discharge plan consistent with the patient’s goals for care and his or her treatment preferences?  Do the discharge planning process and discharge plan ensure an effective transition of the patient from the CAH to post-discharge care?  Do the discharge planning process and discharge plan reduce the factors leading to preventable CAH and hospital readmissions?  C-1400  42 C.F.R. §485.642 |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the CAH’s discharge planning process identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning?  Does the CAH’s discharge planning process provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient’s representative, or patient’s physician?  C-1404  42 C.F.R. §485.642(a) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Are all discharge planning evaluations made on a timely basis to ensure that appropriate arrangements for post-CAH care will be made before discharge and to avoid unnecessary delays in discharge?  C-1406  42 C.F.R. §485.642(a)(1) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Do discharge planning evaluations include an evaluation of a patient’s likely need for appropriate post-CAH services, including, but not limited to, hospice care services, post- CAH extended care services, home health services, and non-health care services and community based care providers?  Do discharge planning evaluations also include a determination of the availability of the appropriate services as well as of the patient’s access to those services?  C-1408  42 C.F.R. §485.642(a)(2) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Are discharge planning evaluations included in the patient’s medical record for use in establishing an appropriate discharge plan?  Are the results of the evaluation discussed with the patient (or the patient’s representative)?  C-1410  42 C.F.R. §485.642(a)(3) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the CAH arrange for the development and initial implementation of a discharge plan for the patient upon the request of a patient’s physician?  C-1412  42 C.F.R. §485.642(a)(4) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Is every required discharge planning evaluation or discharge plan developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel?  C-1417  42 C.F.R. §485.642(a)(5) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the CAH’s discharge planning process require regular reevaluation of the patient’s condition to identify changes that require modification of the discharge plan?  Is the discharge plan updated, as needed, to reflect these changes?  C-1420  42 C.F.R. §485.642(a)(6) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the CAH assess its discharge planning process on a regular basis?  Does the assessment include ongoing, periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission, to ensure that the plans are responsive to patient post-discharge needs?  C-1422  42 C.F.R. §485.642(a)(7) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the CAH assist patients, their families, or the patient’s representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures?  Does the CAH ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient’s goals of care and treatment preferences?  C-1425  42 C.F.R. §485.642(a)(8) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20.  \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| Does the CAH discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient’s current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post- acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient’s follow-up or ancillary care?  C-1430  42 C.F.R. §485.642(b) |  |  |  |  | \*Note: SOM Guidance and Survey Procedures are pending and will be updated in future release. SOM 2-21-20. |
| ***Organ, Tissue, and Eye Procurement*** | | | | | |
| Does the CAH have implemented, written protocols to address its organ procurement responsibilities?  C-1500  42 C.F.R. §485.643 |  |  |  |  |  |
| Does the CAH maintain a written agreement with an Organ Procurement Organization (“OPO”) under which it must 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 CAH?  Pursuant to the written agreement and in the absence of an alternative arrangement addressing tissue and eye donation, does the OPO determine medical suitability for:   1. organ donation; and 2. tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose.   Does the written agreement with an OPO contain the following:   1. address the criteria for referral, including the referral of all individuals whose death is imminent or who have died in the CAH; 2. include a definition of “imminent death”; 3. include a definition of “timely notification”; 4. address the OPO’s responsibility to determine medical suitability for organ donation; 5. specify how the tissue and/or eye bank will be notified about potential donors using S notification protocols developed by the OPO in consultation with the CAH-designated tissue and eye bank(s); 6. provide for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement; 7. ensure that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the CAH; 8. permit the OPO, tissue bank, and eye bank access to the CAH’S death record information according to a designated schedule, e.g., monthly or quarterly; 9. include 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; and 10. address the interventions the CAH will utilize to maintain potential organ donor patients so that the patient organs remain viable.   (SOM at 226-27)  Additionally:   1. Does the CAH’s written agreement with the OPO address all required information? 2. Has the CAH’s governing body approved the CAH’s organ procurement policies? (SOM at 229) 3. Do the CAH’s death records address organ procurement policies, as applicable? 4. Are the CAH’s staff aware of the policies and procedures for organ, tissue, and eye procurement? 5. Is the organ, tissue, and eye donation program integrated into the CAH’s QA program?   (SOM at 229)  C-1503  42 C.F.R. §485.643(a) |  |  |  |  | \*Note: The SOM contains detailed requirements related to this C-Tag. Self-assessment should include review of the SOM at 226-229. |
| Does the CAH have an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement?  Additionally, does the agreement:   1. specify criteria for referral of all individuals who have died in the CAH; and 2. acknowledge that it is the OPO’s responsibility to determine medical suitability for tissue and eye donation, unless the CAH has an alternative agreement with a different tissue and/or eye bank?   (SOM at 230)  C-1505  42 C.F.R. §485.643(b) |  |  |  |  |  |
| Does the CAH ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes?  Is the individual designated by the CAH to initiate the request to the family a designated requestor (i.e., an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation)?  Additionally:   1. Does the CAH have mechanisms in place to ensure that only designated requestors are approaching families to ask them to donate? 2. Does the CAH maintain training schedules and personnel file documentation to verity that all designated requestors have completed the required training?   (SOM at 231)  C-1507  42 C.F.R. §485.643(c) |  |  |  |  |  |
| Do the CAH’s implemented written protocols encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors?  C-1509  42 C.F.R. §485.643(d) |  |  |  |  |  |
| Does the CAH work cooperatively with the designated OPO, tissue bank, and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place?  Is organ donation limited to human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs)?  Additionally:   1. Does the CAH maintain in-service training schedules and attendance sheets? 2. How does the CAH ensure that all appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank? 3. Does the CAH work with the OPO, tissue bank, and eye bank in reviewing death records regularly and document that work in policies and records? 4. Is the effectiveness of any protocols and policies monitored as part of the CAH’S quality improvement program? 5. Are there protocols in place that guide the frequency and completion of record reviews and analysis? 6. Does the CAH ensure confidentiality? 7. Are there policies and procedures in place to ensure coordination between the facility staff and the OPO staff in maintaining the potential donor? 8. Are there policies and procedures in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe?   (SOM at 233)  C-1511  42 C.F.R. §485.643(e) and (f) |  |  |  |  |  |

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1. Although there are multiple appendices to the State Operations Manual, for purposes of this Tool, all references to “SOM” are references to the [State Operations Manual – Appendix W](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_w_cah.pdf) (as linked) or as found at the following web address: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_w_cah.pdf> and which may be updated from time to time. [↑](#footnote-ref-1)
2. Completion of this Tool in its entirety and ongoing holistic review of the organization’s compliance with the standards captured in the Tool is a best practice and will ensure that the organization is optimally prepared for survey.  However, given time and resource limitations, it may be desirable to prioritize certain categories for self-assessment based on historical survey results or ongoing areas of concern.  [↑](#footnote-ref-2)
3. This level of access is permitted and in fact required by the CAH’s provider agreement with Medicare. [↑](#footnote-ref-3)