State Operations Manual
Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

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Transmittals for Appendix W

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Survey Protocol

Introduction

Critical Access Hospitals (CAHs) are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoP) 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 CoP set forth at 42 CFR Part 485 Subpart F.

Certification of CAH compliance with the CoP is accomplished through observations, interviews, and document/record reviews. The survey process focuses on a CAH's performance of organizational and patient-focused functions and processes as well as the safety of the environment of care within the CAH. The CAH survey is the means used to assess compliance with Federal health, safety, and quality standards that will assure that the beneficiary receives safe, quality care and services within an environment that is safe.

Regulatory and Policy Reference

- The Medicare Conditions of Participation for CAHs are found at 42 CFR Part 485 Subpart F.

- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A.

- If an individual or entity (CAH) refuses to allow immediate access to either a State Survey Agency (SA) or CMS surveyor, the Office of Inspector General (OIG) may terminate the CAH from participation in the Medicare/Medicaid programs in accordance with 42 CFR 1001.1301.

- If a CAH fails to grant immediate access upon a reasonable request to an SA or other CMS-authorized entity for the purpose of determining, in accordance with 42 CFR 488.3, whether the CAH meets the applicable CoP, CMS may terminate the CAH Medicare provider agreement in accordance with 42 CFR 489.53(a)(18).

- If a CAH refuses to permit copying of any records or other information by, or on behalf of , CMS, as necessary to determine or verify compliance with participation requirements, CMS may terminate the CAH's Medicare provider agreement in accordance with 42 CFR 489.53(a)(13).

- The CMS State Operations Manual (SOM) provides CMS policy regarding survey and certification activities.

Surveyors assess CAH compliance with the CoPs for all services, areas and locations in which the provider receives reimbursement for patient care services billed under its CMS Certification Number (CCN), as well as certain entities that provide services to the CAH on a contractual basis. These areas include all inpatient and outpatient services and

practice locations, buildings and facilities (including, but not limited to, generators, electrical rooms, food services, HVAC, supply areas, sterilization areas, etc.).

Although the survey generally occurs during daytime working hours (Monday through Friday), surveyors may conduct the survey at other times. These survey hours may include weekends and times outside of daytime (Monday through Friday) working hours. When the survey begins at times outside of normal work times, the survey team modifies the survey, if needed, in recognition of patients' activities and the staff available.

All CAH surveys are unannounced. Do not provide CAHs with advance notice of the survey. The SAs, Accreditation Organizations (AOs), and CMS may not make any communications or requests to a CAH that would amount to advance notice of a survey (with the exception of providing resurvey timeframes as stated in the SOM).

Tasks in the Survey Protocol

Listed below, and discussed in this document, are the tasks that comprise the survey protocol for CAH surveys.

Task 1	Off-Site Survey Preparation
Task 2	Entrance Activities
Task 3	Information Gathering/ Investigation
Task 4	Preliminary Decision Making and Analysis of Findings
Task 5	Exit Conference
Task 6	Post-Survey Activities

Survey Modules for Specialized CAH services

The modules for CAH distinct part psychiatric units and rehabilitation units and CAH swing beds are attached to this document. The survey team is expected to use all the modules that apply to the CAH being surveyed. For example if the CAH has swing beds, a distinct part rehabilitation unit, and a distinct part psychiatric unit, the team will use all three modules to conduct the survey of those activities.

Survey Team

Size and Composition

The SA (or the CMS Regional Office (RO) for Federal teams) decides the composition and size of the team. In general, a suggested survey team for a full survey of a CAH would include 1-4 surveyors who will be at the facility for one or more days. Each survey team should include at least one RN with hospital/CAH survey experience, as well as other surveyors who have the expertise needed to determine whether the CAH is in compliance. Survey team size and composition are normally based on the following factors:

- Size of the facility to be surveyed, based on average daily census;

- Complexity of services offered, including outpatient services;
- Type of survey to be conducted;
- Whether the facility has special care units or off-site clinics or locations;
- Whether the facility has a historical pattern of serious deficiencies or complaints; and
- Whether new surveyors are to accompany a team as part of their training.

Qualifications for CAH Surveyors

Minimum qualifications. Surveys must be conducted by individuals who meet minimum qualifications prescribed by CMS. In addition, before any State or Federal surveyor may serve on a CAH survey team (except as a trainee), he/she must have successfully completed the relevant CMS-sponsored basic CAH surveyor training courses and any associated prerequisites. New surveyors may accompany the team as part of their training prior to completing the basic training courses.

Team Coordinator

Surveyors conduct the survey under the leadership of a Team Coordinator. The SA (or the RO for Federal teams) should designate the Team Coordinator. The Team Coordinator is responsible for assuring that all survey preparation and survey activities are completed within the specified timeframes and in a manner consistent with this protocol, SOM, and SA procedures.

Responsibilities of the Team Coordinator include:

- Scheduling the date and time of survey activities;
- Acting as the spokesperson for the team;
- Assigning staff to areas of the CAH or tasks for the survey;
- Facilitating time management;
- Encouraging and facilitating on-going communication among team members;
- Evaluating team progress;
- Coordinating daily team meetings;
- Coordinating any ongoing discussions with CAH leadership (as determined

appropriate by the circumstances and SA/RO policy) and providing on-going feedback, as appropriate, to CAH leadership on the status of the survey;

- Coordinating Task 2 Entrance Conference;
- Facilitating Task 4 Preliminary Decision Making;
- Coordinating Task 5 Exit Conference;
- Ensuring that all survey team activities are conducted in accordance with CMS procedures;
- Ensuring that the team completes all applicable forms prescribed by CMS, including Form CMS-2567.

Task 1 - Off-Site Survey Preparation

General Objective

The objective of this task is to analyze information about the CAH in order to identify areas of potential concern to be investigated during the survey and to determine if those areas, or any special features of the CAH (e.g., provider-based clinics, specialty units, services offered, etc.) require the addition of any specialty surveyors to the team. Information obtained about the CAH will also allow the SA (or the RO for Federal teams) to determine survey team size and composition, and to develop a preliminary survey plan. The type of CAH information needed includes:

- Information from the provider file (to be updated on the survey using the Hospital/CAH Medicare Database Worksheet, Exhibit 286), such as the facility's ownership, the type(s) of services offered, whether the facility is a provider of swing-bed services, any distinct part units, the number, type and location of any off-site locations; and the number and categories of personnel.
- Previous Federal and state survey results for patterns, number, and nature of deficiencies, as well as the number, frequency, and types of complaint investigations and the findings;
- Information from CMS databases available to the SA and CMS. Note the exit date of the most recent survey;
- Waivers and variances, if they exist. Determine if there are any applicable survey directive(s) from the SA or the CMS RO; and
- Any additional information available about the CAH (e.g. the CAH's Web site, any media reports about the CAH, etc.).

Off-Site Survey Preparation Team Meeting

The team should prepare for the survey off-site so they are ready to begin the survey immediately upon entering the CAH. The Team Coordinator should arrange an off-site preparation meeting with as many team members as possible, including specialty surveyors. This meeting may be a conference call if necessary.

During the meeting, discuss at least the following:

- Information gathered by the Team Coordinator;
- Significant information from the CMS databases that are reviewed;
- Update and clarify information from the provider file (a surveyor can update the Medicare data base on survey using the Hospital/CAH Medicare Database Worksheet, Exhibit 286);
- Layout of the CAH (if available);
- Preliminary team member assignments;
- Date, location and time team members will meet to enter the CAH;
- The time for the daily team meetings; and
- Potential date and time of the exit conference.

Gather copies of or have access to resources that may be needed. These may include:

- CAH Regulations and Interpretive Guidelines (Appendix W);
- Survey protocol and modules;
- Immediate Jeopardy (Appendix Q);
- Responsibilities of Medicare Participating Hospitals in Emergency Cases (Appendix V);
- Hospital/CAH Medicare Database Worksheet (Exhibit 286);
- Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey (Exhibit 287); and
- Worksheets, as applicable, for swing bed and CAH distinct part rehabilitation and psychiatric units.

Task 2 - Entrance Activities

General Objectives

The objectives of this task are to explain the survey process to the CAH and obtain the information needed to conduct the survey.

General Procedures

Arrival

The entire survey team should enter the facility together. Upon arrival, surveyors should present their identification. The Team Coordinator should announce to the Administrator, or whoever is in charge, that a survey is being conducted. If the Administrator (or person in charge) is not on site or available (e.g., if the survey begins outside normal daytime, Monday – Friday working hours), ask that they be notified that a survey is being conducted. Do not delay the survey because the Administrator or other staff is/are not on site or available.

Entrance Conference

The entrance conference sets the tone for the entire survey. Be prepared and courteous, and make requests, not demands. The entrance conference should be informative, concise, and brief; it should not utilize a significant amount of time. Conduct the entrance conference with administrative staff available at the time of entrance (do not delay the survey to wait for additional management staff to arrive). During the entrance conference, the Team Coordinator should address the following:

- Explain the purpose and scope of the survey;
- Briefly explain the survey process;
- Introduce survey team members, including any additional surveyors who may join the team at a later time. Discuss the general area that each will be responsible for, and the various documents that they may request;
- Clarify that all CAH areas and locations, departments, and patient care settings under the CAH CCN may be surveyed, including any contracted patient care activities or patient services;
- Explain that all interviews will be conducted privately with patients, staff, and visitors, unless requested otherwise by the interviewee;
- Discuss and determine how the CAH will ensure that surveyors are able to obtain the photocopies of material, records, and other information as they are needed;
    - Explain that surveyors will need to have access to one or more copying

machines so they can personally make copies as needed;

  - If the CAH uses electronic medical records or uses electronic documents for its policies, procedures, or other activities, explain that surveyors will need access to one or more printers so they can personally print documents as needed;

  - Explain that if the CAH wishes, surveyors will make the CAH an additional copy of every document that surveyors copy;

- Obtain the names, locations, and telephone numbers of key staff to whom questions should be addressed;

- Explain that the survey team will not be providing the hospital with a list of all patients, staff, or visitors interviewed or records reviewed during the survey;

- Discuss the approximate time, location, and possible attendees of any meetings to be held during the survey. The Team Coordinator should coordinate any meetings with facility leadership; and

- Propose a date and time for the exit conference.

During the entrance conference, the Team Coordinator will arrange with the CAH administrator, or available CAH administrative/supervisory staff if he/she is unavailable, to obtain the following:

- A location (e.g., conference room) where the team may meet privately during the survey;

- A telephone for team communications, preferably in the team meeting location;

- A list of current inpatients**,** providing each patient's name, room number, diagnosis (es), admission date, age, attending physician, and other significant information as it applies to that patient. The Team Coordinator will explain to the CAH representative that in order to complete the survey within the allotted time it is important the survey team is given this information as soon as possible, and request that it be no later than 3 hours after the request is made. SAs may develop a worksheet to give to the CAH for obtaining this information;

- A list of department heads with their locations and telephone numbers;

- A copy of the CAH's organizational chart;

- The names and addresses of all off-site locations operating under the same CCN;

- The CAH's infection control plan;

- A list of employees;
- The medical staff bylaws and rules and regulations;
- A list of contracted services; and
- A copy of the CAH's floor plan, indicating the location of patient care and treatment areas.
- The Team Coordinator will inform the CAH that this is not an all-inclusive list and other documents/manuals may be requested throughout the survey depending on potential issues that may be identified.

During the entrance conference the Team Coordinator will inquire whether the CAH wishes to have CAH personnel accompany surveyors during their survey activities. The Team Coordinator must explain that this is allowed as long as the CAH personnel do not interfere or delay the survey. For example:

- When a patient or another CAH staff person is interviewed, the accompanying CAH staff must not provide the answers or interject information,
- The surveyor will inform the accompanying CAH staff when an interview with a patient, patient family member, or CAH staff person is confidential and they cannot be present,
- When the surveyor is to go to another unit, department or survey location and the CAH guide is not present, the surveyor is never to delay while waiting for the arrival of the CAH staff person. The survey must be conducted whether or not those personnel are present.
- The CAH personnel must never be allowed to be present during discussions of findings. If a CAH staff person enters the conference area during discussions, the discussions must stop until the CAH staff person departs.

During the entrance conference for a validation survey, the survey team presents to the hospital a letter signed by the SA Director announcing the validation survey (SOM Exhibit 37), as well as an "Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey," (SOM Exhibit 287). The SA requires the signature of the provider/supplier CEO or other authorized individual on the authorization document, acknowledging that the provider/supplier must permit the validation survey by the SA to take place, as well as SA monitoring of the correction of any substantial noncompliance identified during the validation survey.

Surveying CAHs with electronic health records (EHR) and other documents, such as, policies, procedures, or data related to compliance efforts.

During the entrance conference surveyors will establish with the CAH the process they will follow in order to have unrestricted access to the medical record. Inform the CAH as to whether the team will use one or a combination of the following:

- Surveyors will directly access the CAH's EHR or other electronic documents. If this is the case, inform the CAH that it must provide surveyor(s) with passcodes that will provide sufficient system access permissions that ensure the surveyor's ability to retrieve complete medical records, including, when requested, information from built-in audit features that enable identification of the date, time, and author for entries or changes made to the record. Inform the CAH that the surveyor(s) must have sufficient access to review any CAH documents needed to evaluate the CAH's compliance with the CoPs (for example policies, procedures, schedules, Infection Control information, etc.) Whenever possible, the CAH must provide surveyors electronic access to records in a read-only format or other secure format to avoid any inadvertent changes to the record. The provider is solely responsible for ensuring that all necessary back up of data and security measures are in place.

- Surveyors will utilize staff, such as nurses assigned to patient care units to review medical records, or Infection Control staff to review those activities. If this is the case, inform the CAH that staff will be requested to access and display medical records for review by the surveyor. In other situations the surveyor may request CAH staff to access policies, procedures, Infection Control information, committee minutes, etc.

- Surveyors will request that experienced CAH EHR users with appropriate system permissions be assigned as "navigators" to assist surveyors with retrieval of medical record information and other electronically stored information as needed for evaluation of the CAH's compliance. If this is the case, an EHR navigator would assist a surveyor in retrieving medical records and other electronically stored information that the surveyor has identified as needed to evaluate compliance. The navigator is expected to have sufficient system access permissions that ensure the navigator's ability to retrieve electronically stored CAH records such as policies, committee minutes, and complete medical records. In addition, when requested, information from built-in audit features that enable identification of the date, time and author of entries or changes made to the record.

In CAHs that use hybrid mixes of electronic and paper medical record systems, CAH staff are expected to know which portions of the medical record are not captured in the EHR, to inform the surveyor of this, and to be able to retrieve those paper-based portions of the records as well.

Note: If a CAH declines to provide the requested means of access to the surveyor when requested, the surveyor will first remind the CAH that failure to provide access to records may, in accordance with 42 CFR 489.53(a)(5), be grounds for terminating the Medicare provider agreement. In a situation where the survey team requests a method of access

other than surveyor direct access, and the CAH offers to furnish only direct surveyor access to the EHR system, the SA must determine whether it is willing and able to continue the survey with the surveyor directly accessing the EHR system.

Arrange an interview with a member of the administrative staff to update and clarify information from the provider file.

CAH Tours

Guided tours of the CAH are not encouraged and should be avoided. A tour of a CAH could consume several man-hours of allocated survey time and resources that are needed to conduct the survey.

Initial On-Site Team Meeting

After the conclusion of the Entrance Conference, the team will meet in order to evaluate information gathered and modify surveyor assignments, as necessary. The team should not delay the continuation of the survey process waiting for information from the provider, and should adjust survey activities as necessary. During the initial on-site team meeting, team members should:

- Review the scope of services;
- Identify all locations to be surveyed, including all off-site locations;
- Adjust surveyor assignments, as necessary, based on new information;
- Discuss issues such as change of ownership, sentinel events, construction activities, and disasters, if they have been reported;
- Discuss any issues that have been observed or reported while surveyors have been at the CAH;
- Make an initial patient sample selection (the patient list may not be available immediately after the entrance conference, therefore the team may delay patients completing the initial patient sample selection a few hours as meets the needs of the survey team); and
- Set the next meeting time and date.

Sample Size and Selection

To select the patient sample, review the patient list provided by the facility and select patients who represent a cross section of the patient population and services, to include contracted services (e.g.: Telemedicine: teleICU or telestroke, etc.) provided. The sample should include inpatients, outpatients and closed records of discharged patients. Inpatients should have a length of stay sufficient to assure knowledge of the various

services they received. Their open record should include information about care already provided by all services and departments. The anticipated discharge date should be used to assist in determining which patients will be in the CAH long enough for the surveyor to contact the patient during the course of the survey. Patient logs (ED, OB, OR, etc.) in conjunction with the patient list provided by the facility, provide a good source to use when selecting patients for the sample. If the team finds it necessary during the survey to remove a patient from the sample (e.g., the patient refused to participate in an interview), replace this patient with another who fits a similar profile. Make the substitution as early in the survey as possible.

Whenever possible and appropriate, surveyors should interview patients that are in the facility during the time of the survey to assess the facility's compliance with the CoP. Therefore, open patient records should be selected whenever possible. Open records allow the surveyor to conduct a patient-focused survey and allow the surveyor to compare the medical record with patient observations and interviews. There are situations where closed records will be needed to assess compliance and there may be other situations where there are not adequate numbers of open records to assess compliance. The selected patient records should reflect the scope of services provided by the facility. The sample needs to be no fewer than 20 inpatient records, provided that number is adequate to determine compliance. Additionally, select a sample of outpatients in order to determine compliance in outpatient and emergency services.

Note:

- Open records are medical records of inpatients who are current inpatients of the hospital.

- Closed records are medical records of inpatients who have been discharged, transferred, or are deceased.

Give each patient in the sample a unique identifier. Appropriate identifiable information should be kept on a separate identifier list. Do not use medical record numbers, Social security numbers, care unit or billing record numbers to identify patients.

To conduct an initial survey of a CAH there must be enough inpatients currently in the CAH and patient records (open and closed) for surveyors to determine whether the CAH can demonstrate compliance with all the applicable CoPs. The number of current and discharged inpatients and outpatients in relation to the complexity of care provided to patients and the length of stay of those patients needs to be large enough for surveyors to evaluate the manner and degree to which the CAH satisfies all the standards within each CoP. Utilize the same sample size and selection methods as previously discussed.

If a complaint is being investigated during the survey, patients who have been identified as part of a complaint should be added to the sample. Issues or concerns identified in complaints may be a focus of concern when selecting sample patients.

Task 3 - Information Gathering/Investigation

General Objective

The objective of this task is to determine the CAH's compliance with the Medicare CoPs through observations, interviews, and documentation review.

Guiding Principles

- Focus attention on actual and potential patient outcomes, as well as required processes.
- Assess the care and services provided, including the appropriateness of the care and services within the context of the regulations.
- Visit patient care settings, including inpatient units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, etc.
- Observe the actual provision of care and services to patients and the effects of that care, in order to assess whether the care provided meets the needs of the individual patient.
- Use the interpretive guidelines and other published CMS policy statements to guide the survey.
- Use Appendix Q for guidance if Immediate Jeopardy is suspected.

General Procedures

During the Survey

- Visit as many patient care settings as possible, including all on campus and off-campus patient care locations that bill for services under the CAH's CCN. Because the CAH's compliance with the requirements is being assessed, all patient care locations should be part of the total CAH survey. A surveyor should observe what activities are taking place and assess the CoP that represent the scope and complexity of the patient care services located at each location, as well as, any other CoP that apply to those locations. Observation of the care environment must include assessing for safety risks in the patient care setting. The depth of assessment of the CoPs will be determined by what the surveyor observes at each location. The surveyor expands the survey activities as necessary.
- On any Medicare survey, contracted patient care activities or patient services (such as dietary services, treatment services, diagnostic services, etc.) located on the CAH campus or at CAH provider based locations should be included in the survey.

- The SA and surveyors have discretion whether to allow, or to refuse to allow, facility personnel to accompany the surveyors during a survey. Sometimes facility personnel may be helpful and may answer questions or point out concerns to the survey team. Conversely, facility personnel may sometimes hinder the surveyor, and argue about observed problems. Surveyors should make a decision whether to allow facility personnel to accompany them based on the circumstances at the time of the survey.

- The team must meet at least daily in order to assess the status of the survey, to discuss each surveyor's findings, progress of completion of assigned tasks, areas of concern, and to identify areas for additional investigations. All issues must be discussed at the next available team meeting. Surveyors must not withhold their findings or areas of concern while individually attempting to make a final conclusion or while attempting to obtain conclusive evidence. The team meetings should include a briefing/update by each surveyor to the entire team that addresses findings and areas of concern that have been identified. It is important to note that team meetings are not to be individual briefings to the Team Coordinator; rather they must be briefings to the entire team so that the entire team is aware of all findings and the entire team can discuss how the presented findings are impacting their own findings. If areas of concern are identified in the discussion, the team should coordinate efforts to obtain additional information. Additional team meetings can be called at any time during the survey to discuss crucial problems or issues. The format for the daily team meetings is:

  - In an organized manner, each surveyor, in turn, will report their compliance concerns and identified or potential deficient practices to the entire team,

    - Other team members will add any of their own observations related to the issues brought up.

    - The Team Coordinator and other team members will suggest other ideas as to where to look or other survey methods to evaluate identified concerns,

  - The Team Coordinator will maintain organized notes of the discussions for future follow-up.
    - **Note:** As needed, members of the team may participate by conference calls. This method works well with surveys of multi-location hospitals.

  - All significant issues or significant adverse events must be brought to the Team Coordinator's attention immediately.

  - Maintain open and ongoing dialogue with the CAH staff throughout the survey process. Informal discussions with CAH staff may be held in order to inform them of survey findings. This affords CAH staff the opportunity to present additional information or to offer explanations concerning identified issues. Survey information must not be discussed unless the investigation process and data

collection for the specific concerns is completed. Regular meetings with CAH leadership are not encouraged, but a meeting may be needed when a problem conducting the survey has arisen and the Team Coordinator needs to explain procedures to CAH leadership. Additionally, CAH leadership may request a meeting with the Team Coordinator to address any concerns with the survey. If meetings with CAH leadership are held, the Team Coordinator must be the spokesperson for the team.

- Surveyors should always maintain a professional working relationship with CAH staff.

- Surveyors need to respect patient privacy and maintain patient confidentiality at all times during the survey.

- Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided upon request, the surveyor is not a consultant.

Patient Review

A comprehensive review of care and services received by each patient in the sample should be part of the survey. A comprehensive review includes observations of care/services provided to the patient, patient and/or family interview(s), staff interview(s), and medical record review. After obtaining the patient's permission, observe each sample patient receiving treatments (e.g., intravenous therapy, tube feedings, and wound dressing changes) and observe the care provided in a variety of treatment settings, as necessary, to determine if patient needs are met.

Observations

Observations provide first-hand knowledge of CAH practice and the provision of care and services to inpatients and outpatients. The regulations and interpretive guidelines offer guidance for conducting observations. Observation of the care environment provides valuable information about how the care delivery system works and how CAH departments work together to provide care. Surveyors are encouraged to make observations, complete interviews, and review records and policies/procedures by stationing themselves as physically close to patient care as possible. While completing a chart review, for instance, it may be possible to also observe the environment and the patients, staff interactions with patients, safety hazards, and infection control practices. When conducting observations, particular attention should be given to the following:

- Patient care, including treatments and therapies in all patient care settings;

- Staff member activities, equipment, documentation, building structure, sounds and smells;

- People, care, activities, processes, documentation, policies, equipment, etc., that

are present that should not be present, as well as, those that are not present that should be present;

- Integration of all services, such that the CAH is functioning as one integrated whole;

- Whether quality assurance (QA) is a CAH-wide activity, incorporating every service and activity of the provider and whether every facility department and activity reports to, and receives reports from, the CAH's central organized body managing the facility-wide QA program; and

- Storage, security, and confidentiality of medical records.

- Environmental risks. Examples may include, but are not limited to, unattended cleaning carts, unattended hazardous cleaning solutions, unlocked medications, and ligature risks in areas where psychiatric patients may have care provided.

A surveyor should take complete notes of all observations and should document: the date and time of the observation(s); location; patient identifiers, individuals present during the observation, and the activity being observed (e.g., therapy, treatment modality, etc.).

A surveyor should have observations verified by the patient, family, CAH staff, other survey team member(s), or by another mechanism. For example, when finding an outdated medication in the pharmacy, ask the pharmacist to verify that the drug is outdated. In addition, a surveyor should integrate the data from observations with data gathered through interviews and document reviews.

A surveyor must not touch or examine patients by themselves. However, in certain circumstances, it is permissible and necessary to determine the physical condition of patients. Whenever a surveyor views it necessary to determine the physical condition of the patient, the surveyor must request that a staff member examine the patient in the surveyor's presence. The health and dignity of the patient is always of paramount concern. Additionally, if the surveyor believes that blankets or clothing are hiding bedsores, bruises, or incontinence, and with the patient's permission, they may remove the coverings and make a determination based on observation.

In all situations, surveyor's must obtain the patient's (or authorized representative's) permission prior to making any examination. The health and dignity of the patient is always of paramount concern. A surveyor must respect the patient's right to refuse to be examined.

Interviews

Interviews provide a method to collect information, and to verify and validate information obtained through observations. Informal interviews should be conducted throughout the duration of the survey. Use the information obtained from interviews to determine what additional observations, interviews, and record reviews are necessary.

When conducting interviews, observe the following:

- Maintain detailed documentation of each interview conducted. Document the interview date, time, and location; the full name and title of the person interviewed; and key points made and/or topics discussed. To the extent possible, document quotes from the interviewee.

- Interviews with CAH staff should be brief. Use a few well-phrased questions to elicit the desired information. For example, to determine if a staff member is aware of disaster procedures and his/her role in such events, simply ask, "If you smelled smoke, what would you do?"

- When interviewing staff, begin your interviews with staff that work most closely with the patient.

- Conduct patient interviews regarding their knowledge of their plan of care, the implementation of the plan, and the quality of the services received. Other topics for patient or family interview may include advanced directives and the CAH's grievance/complaint procedure.

- Interviews with patients must be conducted in privacy and with the patient's prior permission.

- Use open-ended questions during your interview.

- Validate all information obtained.

- Telephone interviews may be conducted if necessary, but a preference should be made for in-person interviews.

- Integrate the data from interviews with data gathered through observations and document reviews.

Staff interviews should gather information about the staff's knowledge of the patient's needs, plan of care, and progress toward goals. Problems or concerns identified during a patient or family interview should be addressed in the staff interview in order to validate the patient's perception, or to gather additional information.

Patient interviews should include questions specific to the patient's condition, reason for admission, quality of care received, and the patient's knowledge of their plan of care. For instance, a surgical patient should be questioned about the process for preparation for surgery, the patient's knowledge of and consent for the procedure, pre-operative patient teaching, post-operative patient goals and discharge plan.

Document Review

Document review focuses on a CAH's compliance with the CoPs. When conducting a

document review, document the source and date of the information obtained. When making document copies identify the original date of the document and indicate the date and time the copies were made. Once a document review is completed, integrate the data obtained with data gathered through observations and interviews to decide if the CAH is in compliance with the CoP. Documents reviewed may be both written and electronic and include the following:

- Patient's clinical records, to validate information gained during the interviews, as well as for evidence of advanced directives, discharge planning instructions, and patient teaching. This review will provide a broad picture of the patient's care. Plans of care and discharge plans should be initiated immediately upon admission, and be modified, as patient care needs change. The record review for that patient who has undergone surgery would include a review of the pre-surgical assessment, informed consent, operative report, and pre-, inter-, and post-operative anesthesia notes. Although team members may have a specific area assigned during the survey, the team should avoid duplication of efforts during review of medical records and each surveyor should review the record as a whole instead of targeting the assigned area of concern. Surveyors should use open patient records rather than closed records, whenever practical.

- Closed medical records may be used to determine past practice, and the scope or frequency of a deficient practice. Closed records should also be reviewed to provide information about services that are not being provided by the CAH at the time of the survey. For example, if there are no obstetrical patients in the facility at the time of the survey, review closed OB records to determine care practices, or to evaluate past activities that cannot be evaluated using open records. In the review of closed clinical records, review all selected medical records for an integrated plan of care, timelines of implementation of the plan of care, and the patient responses to the interventions.

- Personnel files to determine if staff members have the appropriate qualifications including educational requirements, have had the necessary training required, and are licensed, if it is required (the sample selection, both numbers and types of personnel files to be reviewed, will be based on individual CoPs and issues being investigated);

- Privileging files to determine if the CAH complies with CMS requirements and State law, as well as, follows its own written policies for medical staff privileges and credentialing;

- Maintenance records to determine if equipment is periodically examined and to determine if it is in good working order and if environmental requirements have been met;

- Staffing documents to determine if adequate numbers and types of staff are provided according to the number and acuity of patients;

- Policy and procedure manuals. When reviewing policy and procedure manuals, verify with the person in charge of an area that the policy and procedure manuals are current;

- Contracts, if applicable, to what requirements are provided under arrangements or agreements.

- Diet menus to ensure they meet the needs of the sample patients.

Electronic Documents Including EHR

Electronic access to records will not eliminate the need for a surveyor to print a paper copy or to request a paper copy of certain parts of certain records. However, the surveyor shall make reasonable efforts to avoid, where possible, the printing of entire records. It is neither expected nor advisable to ask that all requested records be printed out for the surveyor to review. Surveyors will request print-outs or screen shots selectively, based on their preliminary survey findings. The surveyor should print or request a paper copy of only those parts of records that are needed to support findings of noncompliance.

The goal of the surveyor's observation of how the EHR is used by CAH staff is to determine whether staff can enter into and retrieve the information necessary for their patient's care in a timely fashion.

- Healthcare staff must be able to demonstrate their ability to access parts of the record necessary for the provision of care for their patients.

- The focus of the review is determining staff competence in using the EHR system as opposed to the surveyor's ability to navigate the system.

Surveyors must investigate what happens when the computer is unavailable or offline, whether planned or unplanned. Some examples might include:

- How to register, admit, transfer, move, or discharge patients.
- How to order, determine, and record medications and administration of medications.
- How to order or determine diets.
- How to order, determine, and record treatments.
- How to obtain laboratory reports and other testing results.

Photocopies

Surveyors must make photocopies of all documents needed to support survey findings. Photocopies support survey findings, and therefore in order to ensure accurate copies of the documents needed, the survey team must either make their own copies or hand carry the material to the copy machine where they directly observe hospital staff make the requested copies and then take immediate possession of the copies. If requested by the

CAH, the surveyor should make the CAH a copy of all items photocopied. All photocopies need to be dated and timed as to when photocopied, and identified such as "CAH IV management policy-12/05/17 page 3" or "Patient # 6, progress note – 12/05/17."

Completion of Hospital/CAH Medicare Database Worksheet

Interview a member of the administrative staff to update and clarify information from the provider file. The Hospital/CAH Medicare Database worksheet will be used to collect information about the CAH services, locations, and staffing by the Medicare CAH surveyors during the CAH survey. The worksheet will be completed by the surveyors using observation, staff interviews, and document review. **The worksheet will not be given to the CAH staff to complete**. The worksheet is used to collect information that will later be entered into the Medicare Database.

Clarify any inconsistencies from prior information or information gathered during the survey.

Task 4 - Preliminary Decision Making and Analysis of Findings

General Objectives

The general objectives of this task are to integrate findings, review and analyze all information collected from observations, interviews, and record reviews, and to determine whether or not the CAH meets the Conditions of Participation found at 42 CFR Part 485. The team's preliminary decision-making and analysis of findings assist it in preparing the exit conference report. Based on the team's decisions, additional activities may need to be initiated.

General Procedures

Preparation

Prior to beginning this Task, each team member should review his/her notes, worksheets, records, observations, interviews, and document reviews to assure that all investigations are complete and organized for presentation to the team.

Discussion Meeting

Prior to the preliminary decision-making meeting all members of the team should review their findings and concerns regarding the CAH's compliance and be prepared to present their findings during the meeting. Each team member should be familiar with the team's findings as discussed during the daily team meetings.

The preliminary decision-making meeting is not organized or conducted in the same manner as daily team meetings. The meeting will be conducted as a team.

- The entire survey team that is at the CAH must be present. Additionally:
    - Survey team members who are off-site must join the meeting by conference call,
    - Survey team members who have already departed the survey should join the meeting by conference call when possible,
- The Team Coordinator will sequentially discuss the regulations in order as they appear in the regulations, CoP, Standard, or Tag, depending on what issues have been identified during the survey,
- Surveyors will share their findings, evaluate the evidence, and make team decisions regarding compliance with each requirement when that requirement is discussed,
    - Team discussion is to include the official interpretation of the regulation as put forth in the interpretive guidelines for each regulation (Note: citations of non-compliance must be based on non-compliance with regulation; citations of non-compliance cannot be based on non-compliance with the interpretive guidelines),
    - The discussion must address potential outcomes (Note that actual adverse outcomes are not needed to identify or cite a deficient practice),
    - The Team Coordinator must verify with the team whether all evidence has been collected to support any citations (this must be done at the time each requirement is discussed). If not, the Team Coordinator must direct someone to collect that evidence prior to the exit conference,
    - The Team Coordinator must take accurate notes for later reference and to assist him/her in preparation for the exit conference.

Decisions about deficiencies are to be team decisions, with each member having input. The team should document their decisions, the substance of the evidence, and the numbers of patients impacted, in order to identify the extent of CAH's noncompliance. The team must ensure that their findings are supported by adequate documentation of observations, interviews, and document reviews, and includes any needed evidence such as photocopies. Any additional documentation or evidence needed to support identified noncompliance should be gathered prior to the exit conference but at a minimum prior to exiting the CAH.

Determining the Severity of Deficiencies

The regulations at 42 CFR 488.26 states, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage, depends upon the manner and degree to which the provider or supplier satisfies the

various standards within each condition." When noncompliance with a condition of participation is noted, the determination of whether a lack of compliance is at the standard or condition level depends upon the degree (how severe, how dangerous, how critical, etc.) and manner (how prevalent, how many, how pervasive, how often, etc.) of the lack of compliance. The cited level of noncompliance is determined by the interrelationship between the degree and manner of the noncompliance.

A deficiency at the condition level may be due to noncompliance in a single standard or several standards, or parts of standards within the condition, or because of noncompliance with a single part (tag) representing a severe or critical health or safety breach. Even a seemingly small breach in critical actions or at critical times can kill or severely injure a patient, and represents a critical or severe health or safety threat.

A deficiency is at the standard level when there is noncompliance with any single requirement or several requirements within a particular standard that are not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

On a complaint investigation where the CAH states that it has corrected the deficient practice/issue (noncompliance) that is the basis of the complaint, issues for the survey team to consider would include:

- Is the corrective action superficial or inadequate, or is the corrective action adequate and systemic?
- Is the deficient practice still present?
- Has the CAH implemented the corrective intervention(s) or action(s)?
- Has the CAH taken a QA approach to the corrective action to ensure monitoring, tracking and sustainability?
- Have the CAH's corrective actions made it unlikely for the deficient practice to recur?

The survey team uses their judgment to determine if any action(s) taken by the CAH prior to the survey is sufficient to correct the noncompliance and to prevent the deficient practice from continuing or recurring. If the deficient practice is corrected prior to the survey, do not cite noncompliance. However, if the noncompliance with any requirements is noted during the survey, even when the CAH corrects the noncompliance during the survey, cite noncompliance.

All noted noncompliance must be cited even when corrected on site during the survey. Identified non-compliance must be cited at either Immediate Jeopardy, Condition level or Standard level. Citing noncompliance at the appropriate level is important to the integrity of the survey process. Citing too high a level is unfair to the CAH. Citing noncompliance

at a level below the noted degree and manner of the noncompliance does not ensure that the CAH will develop acceptable plans of correction and implement corrective actions, does not depict whether the care provided adversely affects the health and safety of patients, and whether continued deficient practices may lead to adverse patient outcomes such as injury or death.

Gathering Additional Information

If it is determined that the survey team needs additional information to determine CAH's compliance or noncompliance, the Team Coordinator should decide the best way to conduct the additional review.

Task 5 - Exit Conference

General Objective

The general objective of this task is to inform the CAH staff of the team's preliminary findings.

Prior to the Exit Conference

- The Team Coordinator is responsible for organization of the presentation of the exit.
- The team determines who will present the findings.
- If the team feels it may encounter a problem during the exit, they should contact their immediate supervisor.

Discontinuation of an Exit Conference

It is CMS general policy to conduct an exit conference at the conclusion of each survey. However, there are some situations that justify refusal to continue or to conduct an exit conference. For example:

- If the provider is represented by counsel (all participants in the exit conference should identify themselves), surveyors may refuse to conduct the conference if the lawyer tries to turn it into an evidentiary hearing; or
- Any time the provider creates an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, surveyors may refuse to conduct or continue the conference. Under such circumstances, it is suggested that the Team Coordinator stop the exit conference and call the State agency for further direction.

Recording the Exit Conference

If the CAH wishes to audio record the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously. In order for this to occur, the CAH must be able to supply a copy of the recording, or transmit a copy in a format the survey team can utilize (or if the survey team has the capability to record the discussion, the team can use its own recording device for its purposes).

General Principles

The following general principles apply when conducting an exit conference:

- The CAH's leadership determines which CAH staff will attend the exit conference.
- The identity of an individual patient or staff member must not be revealed in discussing survey results. Identity includes not just the name of an individual patient or staff member, but also includes any references by which identity might be deduced.
- Because of the ongoing dialogue between surveyors and CAH staff during the survey, there should be few instances in which the CAH is unaware of surveyor concerns or has not had an opportunity to present additional information prior to the exit conference.

Exit Conference Sequence

The following discusses the sequence of events in conducting an exit conference.

A - Introductory Remarks:

- Thank everyone for cooperation during the survey.
- Introduce all team members, mentioning any that have concluded their portion of the survey and have left the CAH.
- Briefly mention the reason for the survey.
- Explain that the exit conference is an informal meeting to discuss preliminary findings.
- Indicate that official findings are presented in writing on the Form CMS-2567.

B - Ground Rules

- Explain how the team will conduct the exit conference and any ground rules.
- Ground rules may include waiting until the surveyor finishes discussing each

deficiency before accepting comments from CAH staff.

- State that the CAH staff will have an opportunity to present new information or evidence of compliance after the exit conference for consideration after the survey.

C - Presentation of Findings

- Avoid referring to data tag numbers.

- Present the preliminary findings of noncompliance, explaining why the findings are a violation. If the provider asks for the regulatory basis, provide it.

- Refrain from making any general comments (e.g., "Overall the CAH is very good"). Stick to the facts. Do not rank findings. Treat requirements as equal as possible.

- Refrain from making global statements, such as, "The CAH does not have any Condition level citations", or "The CAH only has lower level citations". Except in citations of Immediate Jeopardy, the survey team does not discuss citation levels for individual citations or for the overall survey.

- Do not identify unmet requirements as condition or standard level. Avoid statements such as, "the condition was not met" or "the standard was not met." It is better to state, "the requirement is not met."

- If immediate jeopardy was identified, explain the significance and the need for immediate correction. Follow instructions in Appendix Q.

- Assure that all findings are discussed at the exit conference.

D - Closure

- Explain that a statement of deficiencies (Form CMS-2567) will be mailed within 10 business days to the CAH.

- Explain that the Form CMS-2567 is the document disclosed to the public about the CAH's deficiencies and what is being done to remedy them. The Form CMS-2567 is made public no later than 90 calendar days following completion of the survey. It documents specific deficiencies cited, the CAH's plans for correction and timeframes, and it provides an opportunity for the CAH to refute survey findings and furnish documentation that requirements are met.

- Inform the CAH that a written plan of correction (POC) must be submitted to the survey agency within 10 business days following receipt of the written statement of deficiencies.

- Explain the required characteristics of a plan of correction. The characteristics of an acceptable POC include:

    - Separately addressing each citation;

    - A Quality Assessment and Performance Improvement (QAPI) methodology for each citation and address improvements in the hospital's systems in order to prevent the likelihood of the cited deficient practice from recurring;

    - A procedure for implementing each corrective action taken;

    - A procedure for monitoring the corrective actions taken for each citation Providing the identity or position of the person who will monitor the corrective action and the frequency of monitoring;

    - Dates each corrective action for each citation was/will be completed;

    - The administrator or appropriate individual must sign and date the Form CMS-2567 before returning it to the survey agency.

- The submitted plan of correction must meet the approval of the State agency, or in some cases the CMS Regional Office for it to be acceptable.

All team members should leave the CAH together immediately following the exit conference. If the CAH staff provides further information for review, the Team Coordinator should decide the best way to conduct the further review. It is usually prudent for at least two individuals to remain.

Task 6 - Post-Survey Activities

General Objective

The general objective of this task is to complete the survey and certification requirements, in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each State agency and CMS Regional Office should follow directives in the State Operations Manual. The procedures include:

- Timelines for completing each step of the process;

- Responsibilities of the team coordinator and other team members to complete the Form CMS-2567, Statement of Deficiencies, using the **Principles of Documentation** as reference;

- Notification to the facility staff regarding survey results;
- Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the Regional Office for further action/direction);
- Compilation of documents for the provider file;
- Obtain signed Letter of Authorization to obtain facilities most recent accreditation survey and send to RO;
- Enter the information collected on the Hospital/CAH Medicare Database Worksheet into the Medicare database.

Plan of Correction

Regulations at 42 CFR 488.28(a) allow certification of providers with deficiencies at the Standard or Condition level "only if the facility has submitted an acceptable Plan of Correction (POC) for achieving compliance within a reasonable period of time acceptable to the Secretary." Failure to submit a POC may result in termination of the provider agreement as authorized by 42 CFR §§488.28(a) and 489.53(a)(1). After a POC is submitted, the surveying entity makes the determination of the appropriateness of the POC.

CAH Swing-Bed Survey Module

An onsite survey must be conducted and the CAH must meet all the requirements of 42 CFR 485.645 before the CAH can obtain swing-bed approval.

Additionally, a survey of the CAH swing-bed CoP at 42 CFR 485.645 will be conducted:

- When conducting a full survey of a CAH that has swing-bed approval;
- When conducting a complaint survey of the swing-bed CoP; or
- When a CAH without current swing-bed approval, that has been determined to meet the eligibility criteria, is requesting swing-bed approval.

These requirements, as well as interpretive guidelines, are found in Appendix W of the State Operations Manual (SOM).

Background

Swing-bed services are an optional services that may be provided in CAHs that meet the eligibility criteria in 42 CFR 485.645(a). Swing-bed patients are CAH patients who are situated in the CAH but for whom the CAH is receiving reimbursement for post-acute CAH extended care (skilled nursing services), as opposed to acute-care reimbursement. The reference to swing-bed is a patient care and reimbursement status and has no relationship to geographic location in the CAH. The patient may be in acute-care status one day and change to swing-bed status the next day. It is not necessary for the patient to change location in the CAH when the reimbursement status changes, but moving to a different location is allowed. A qualifying 3-day inpatient stay in a participating or qualified hospital or participating CAH is required prior to admission to swing-bed status in order for a beneficiary to be eligible for Medicare coverage of post-hospital swing-bed care. The 3-day qualifying stay does not need to be in the same CAH as the swing-bed admission.

NOTE: Surveyors do not evaluate compliance with the 3-day qualifying stay requirement.

Regulatory Authority and Requirements for CAH Providers of Extended Care Services ("Swing Beds")

CAH swing-bed care is regulated by both the CAH requirements and the swing-bed requirements at 42 CFR Part 485. The actual swing-bed survey requirements are referenced in the Medicare Nursing Homes requirements at 42 CFR Part 483.

Section 1883 of the Act authorizes payment under Medicare for post-hospital SNF services provided by any CAH that meets the requirements found in the swing-bed CoP at 42 CFR 482.645. By regulation, the Secretary has specified these requirements at 42 CFR 485.645 as the following:

- The CAH has a Medicare provider agreement;

- The total number of beds that may be used at any time for furnishing swing-bed services or acute inpatient services does not exceed 25 beds; and

- The CAH meets the swing-bed CoP on Resident Rights; Admission, Transfer, and Discharge Rights; Freedom from Abuse, Neglect and Exploitation; Patients Activities; Social Services; Comprehensive Assessment, Comprehensive Care Plan, and Discharge Planning; Specialized Rehabilitative Services; Dental Services; and Nutrition. Use the interpretive guidelines from SOM Appendix PP to evaluate compliance with the individual referenced requirements from 42 CFR 483.

Activities Conducted Prior to Swing-Bed Survey

Prior to conducting the swing-bed survey, verify the following:

- The CAH's swing-bed approval is in effect; and

- The CAH meets distance/location requirements (confirm with RO).

Survey Procedures

In conducting the survey, verify that the CAH has fewer than 25 hospital-type beds. Count the hospital-type beds in each nursing unit. Count any hospital-type bed that is located in or adjoining any location where the bed could be used for inpatient care. Do not count beds in recovery rooms, labor and delivery rooms (do count birthing beds where patients remain after giving birth), operating rooms, newborn nurseries or stretchers in emergency departments. Do not count examination tables, procedure tables or stretchers. Do not count beds in Medicare certified rehabilitation or psychiatric distinct part units (DPUs).

Swing bed certification is limited to the CAH itself and does not include any distinct part rehabilitation or psychiatric units. Swing bed services may not be provided in CAH distinct part units.

Evaluate the CAH's compliance with the swing-bed requirements at 42 CFR 485.645 found in appendix W of the SOM and for those requirements referenced from 42 CFR 483 use Appendix PP. Swing-bed requirements apply to any patient discharged from a hospital or CAH and admitted to a swing-bed for skilled nursing services. The requirements for acute-care CAHs also apply to swing-bed patients.

If swing-bed patients are present during the on-site inspection, conduct an open record review and an environmental assessment. Include patient interviews and observations of care and services. However, if no swing-bed patients are present during the on-site inspection, review at a minimum two closed records for compliance with swing-bed

requirements. Additionally, review policies, procedures, and contracted services to assure that the CAH has the capability to provide the services needed.

It is important for surveyors to maintain on-going documentation of their findings during the course of the survey for later reference. Surveyors may use the optional swing-bed worksheet as note-taking tool to document and record their findings on the survey.

Exit Conference

Preliminary findings of noncompliance may be discussed during the time of the CAH exit conference.

Post-Survey Activities

As is the case for any CAH CoPs, the findings for swing-bed deficiencies must be documented on the same Form CMS-2567.

Regulations and Interpretive Guidelines for CAHs

(Rev. 149, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)

NOTE: in the regulations or guidance which follow, in every instance where the following terms appear:

- **"spouse" means an individual who is married to another individual as a result of marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.**

- **"marriage" means a marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages;**

- **"family" includes, but is not limited to, an individual's "spouse" (see above); and**

- **"relative" when used as a noun, includes, but is not limited to, an individual's "spouse" (see above).**

Furthermore, except where CMS regulations explicitly require an interpretation in accordance with State law, wherever the text of a regulation or associated guidance uses the above terms or includes a reference to a patient's "representative," "surrogate," "support person," "next-of-kin," or similar term in such a manner as would normally implicitly or explicitly include a spouse, the terms are to be interpreted consistent with the guidance above.

A CAH is expected to recognize all state-sanctioned marriages and spouses for purposes of compliance with the Conditions of Participation, regardless of any laws to the contrary of the state or locality where the CAH is located.

C-0800

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.601 Basis and Scope

(a) Statutory basis. This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) Scope. This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.

C-0802

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.603 Rural Health Network

A rural health network is an organization that meets the following specifications:

(a) It includes—

(1) At least one hospital that the State has designated or plans to designate as a CAH; and

(2) At least one hospital that furnishes acute care services.

(b) The members of the organization have entered into agreements regarding—

(1) Patient referral and transfer;

(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and

(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network when applicable;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

C-0804

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.604 Personnel Qualifications

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) Clinical nurse specialist. A clinical nurse specialist must be a person who—

(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed 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.

(b) Nurse practitioner. A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that—

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) Physician assistant. A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that—

(i) Was at least one academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on

Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

C-0808

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.606 Designation and Certification of CAHs

(a) Criteria for State Designation.

(1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in §482.58 of this chapter.

(b) Criteria for CMS certification. CMS certifies a facility as a CAH if—

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this part and all other applicable requirements for participation in part 489 of this chapter.
(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a CAH by the State under the rules in this subpart.

C-0810

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.608 Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

Interpretive Guidelines §485.608
Failure of the CAH to meet a Federal, State or local law may only be cited when the Federal, State or local authority having jurisdiction has made both a determination of

noncompliance and has taken a final adverse action as a result.

Refer or report suspected violations to the appropriate Federal, State, or local agency.

C-0812

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.608(a) Standard: Compliance with Federal Laws and Regulations

The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

Interpretive Guidelines §485.608(a)
Each CAH must be in compliance with applicable Federal laws and regulations related to the health and safety of patients. This includes other Medicare regulations and Federal laws and regulations not specifically addressed in the CoPs. State Survey Agencies are expected to assess the CAH's compliance with the following Medicare provider agreement regulation provisions when surveying for compliance with §485.608(a):

Advance Directives

An advance directive is defined at 42 CFR 489.100 as "a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated." In accordance with the provisions of 42 CFR 489.102(a), the advance directives regulations apply to CAHs. The CAH patient (inpatient or outpatient) has the right to formulate advance directives, and to have CAH staff implement and comply with the individual's advance directive. The regulation at 42 CFR 489.102 specifies the rights of a patient (as permitted by State law) to make medical care decisions, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives.

In the advance directive, the patient may provide guidance as to his/her wishes concerning provision of care in certain situations; alternatively, the patient may delegate decision-making authority to another individual, as permitted by State law. (In addition, the patient may use the advance directive to designate a "support person," as specified in §485.635(f), for purposes of exercising the patient's visitation rights.) When a patient who is incapacitated has executed an advance directive designating a particular individual to make medical decisions for him/her when incapacitated, the CAH must, when presented with the document, provide the designated individual the information required to make informed decisions about the patient's care. The CAH must also seek the consent of the patient's representative when informed consent is required for a care decision. The explicit designation of a representative in the patient's advance directive takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or, as applicable, outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.

§489.102 also requires the CAH to:

- Provide written notice of its policies regarding the implementation of patients' rights to make decisions concerning medical care, such as the right to formulate advance directives. If an individual is incapacitated or otherwise unable to communicate, the CAH may provide the advance directive information required under §489.100 to the individual's "family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law." (§489.102(e)) §489.102(b)(1) requires that notice of the CAH's advance directive policy be provided at the time an individual is admitted as an inpatient. However, the CAH should also consider providing the advance directive notice at the time of registration, to outpatients (or their representatives) who are in the emergency department, who are in an observation status, or who are undergoing same-day surgery.

- The notice must include a clear and precise statement of limitation if the CAH cannot implement an advance directive on the basis of conscience. At a minimum, a statement of limitation should:

  - Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians or other practitioners;

  - Identify the State legal authority permitting such an objection; and

  - Describe the range of medical conditions or procedures affected by the conscience objection.

  It should be noted that this provision allowing for certain conscience objections to implementing an advance directive is narrowly focused on the directive's content related to medical conditions or procedures. This provision would not allow a CAH or individual physician or practitioner to refuse to honor those portions of an advance directive that designate an individual as the patient's representative and/or support person, given that such designation does not concern a medical condition or procedure.

  Issuance of the written notice of the CAH's advance directive policies to the patient or the patient's representative must be documented in the patient's medical record.

- Document in a prominent part of the patient's medical record whether or not the patient has executed an advance directive;

- Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

- Assure compliance with requirements of State law concerning advance directives and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;

- Provide for the education of staff concerning its policies and procedures on advance directives. The right to formulate advance directives includes the right to formulate a psychiatric advance directive (as allowed by State law); and

- Provide community education regarding advance directives and the CAH must document its efforts.

A **psychiatric advance directive** is akin to a traditional advance directive for health care. This type of advance directive might be prepared by an individual who is concerned that at some time he or she may be subject to involuntary psychiatric commitment or treatment. The psychiatric advance directive may cover a range of subjects, and may name another person who is authorized to make decisions for the individual if he or she is determined to be legally incompetent to make his/her own choices. It may also provide the patient's instructions about hospitalization, alternatives to hospitalization, the use of medications, types of therapies, and the patient's wishes concerning restraint or seclusion. The patient may designate who should be notified upon his/her admission to the CAH, as well as who should not be permitted to visit him or her. State laws regarding the use of psychiatric advance directives vary.

In accordance with State law, a psychiatric advance directive should be accorded the same respect and consideration that a traditional advance directive for health care is given. CAHs should carefully coordinate how the choices of a patient balance with the rights of other patients, staff, and individuals in the event that a dangerous situation arises.

However, even if State law has not explicitly spoken to the use of psychiatric advance directives, consideration should be given to them. When the patient is, for whatever reason, unable to communicate his/her wishes, the preferences expressed in the psychiatric advance directive can give critical insight to the CAH's professional staff as they develop a plan of care and treatment for the patient.

Required CAH Disclosures to Patients:

Physician Ownership

- 42 CFR 489.3 defines a "physician-owned hospital" as any participating hospital, including a CAH, in which a physician or immediate family member of a physician (as defined in §411.351) has an ownership or investment interest in the CAH, except for those satisfying an exception found at §411.356(a) or (b). Surveyors are not required to make an independent determination regarding whether a CAH meets the Medicare definition of "physician-owned," but they must ask whether the CAH is physician-owned.

- However, the notice requirement does not apply to any physician-owned CAH that does not have at least one referring physician (as defined at §411.351 of this chapter) who has an ownership or investment interest in the CAH or who has an immediate family member who has an ownership or investment interest in the CAH. In such cases, the CAH must sign an attestation statement that it has no referring physician with an ownership or investment interest or whose immediate family member has an ownership or investment interest in the CAH. The CAH must maintain this attestation in its records.

- 42 CFR 489.20(u)(1) requires that all physician-owned CAHs provide written notice to their patients at the beginning of each patient's CAH inpatient stay or outpatient visit stating that the CAH is physician-owned, in order to assist the patient in making an informed decision about his or her care.

    - A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the CAH.

- The notice must disclose, in a manner reasonably designed to be understood by all patients, that the CAH is physician-owned and that a list of owners or investors who are physicians or immediate family members of physicians is available upon request. If the patient (or someone on behalf of the patient) requests this list, the CAH must provide it at the time of the request.
- 42 CFR 489.20(u)(2) provides that physician-owned CAHs must require each physician owner who is a member of the hospital's medical staff to agree, as a condition of obtaining/retaining CAH medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the CAH their ownership or investment interest or that of any immediate family member in the CAH. The CAH must require that this disclosure be made at the time of the referral and the requirement should be reflected in the hospital's policies and procedures governing privileges for physician owners.

    - The CAH may exempt from this disclosure requirement any physician owner who does not refer any patients to the CAH.

- 42 CFR 489.12 permits CMS to refuse to enter into a provider agreement with a physician-owned CAH applicant that does not have procedures in place to notify patients of physician ownership in the hospital, as required under §483.20(u).

- 42 CFR 489.53(c) permits CMS to terminate the provider agreement of a physician-owned CAH if the CAH fails to comply with the requirements at §489.20(u).

MD/DO 24/7 On-Site Presence

42 CFR 489.20(w) mandates that if there is no doctor of medicine or osteopathy present in the CAH 24 hours per day, seven days per week the CAH must provide written notice to all inpatients at the beginning of a planned or unplanned inpatient stay, and to outpatients for certain types of outpatient visits. The purpose of the requirement is to assist the patient in making an informed decision about his/her care. CAHs that have an MD/DO (including residents who are MDs or DOs) on-site 24/7 do not need to issue any disclosure notice about emergency services capability.

- The notice must be provided to all inpatients and to those outpatients who are under observation or who are having surgery or any other procedure using anesthesia.

- The notice must be provided at the beginning of the planned or unplanned inpatient stay, or applicable outpatient visit.

- A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the CAH.

- Individual notices are not required in the CAH's dedicated emergency department (DED) (as that term is defined in 42 CFR 489.24(b)), but the DED must post a notice conspicuously, in a place or places likely to be noticed by all individuals entering the dedicated emergency department. The posted notice must state that the CAH does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the CAH will meet the medical needs of any patient with an emergency medical condition, as defined in 42 CFR 489.24(b) [the EMTALA definition], at a time when there is no doctor of medicine or doctor of osteopathy present in the CAH. If an emergency department patient is determined to require admission, then the individual notice provisions of 42 CFR 489.20(w) would apply to that patient.

- Before admitting an inpatient or providing outpatient services requiring notice, the CAH must obtain a signed acknowledgement from the patient stating that he/she understands that a doctor of medicine or doctor of osteopathy may not be present during all hours services are furnished to him/her.
  - In the event of an unplanned surgery or inpatient admission to treat an emergency medical condition, it may in some cases be necessary in the interest of the patient's safety to proceed with treatment before the required notice can be given and acknowledgement can be obtained. In such circumstances the CAH must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.

- For a CAH that participates in Medicare with multiple campuses providing inpatient services (e.g., a main provider campus and a separate remote location for a

psychiatric or rehabilitation distinct part unit (DPU)) under one CMS Certification Number) a separate determination is made for each campus/location with inpatient services as to whether the disclosure notice is required. For example, if a CAH has a main campus with 25 inpatient beds and a remote location with 10 psychiatric DPU beds and 10 rehabilitation DPU beds, and a physician is present 24/7 on the main campus, but not at the DPU remote location, the CAH is required to provide the disclosure notice at the DPU location. No notice is required for patients coming to the main provider campus. In this same example, if the CAH also has a provider-based, off-campus ambulatory surgery department, no notice is required at that off-campus surgery site, since the CAH's main campus does have an MD/DO present 24/7.

- 42 CFR 489.53(c) permits CMS to terminate a provider agreement with a CAH if the CAH fails to comply with the requirements at §489.20(w) when it does not have an MD or DO on-site 24/ 7.

Other Federal Requirements

Other Federal requirements also apply to patient health and safety in the CAH. For example, Federal laws and regulations govern both the disposal of medical waste and occupational health. However, surveyors are not expected to be knowledgeable about the requirements of other Federal agencies and therefore do not assess compliance with non-CMS regulations. A surveyor who suspects a CAH may not be in compliance with other Federal requirements may refer the matter to the appropriate Federal agency. If CMS is notified or becomes aware of another Federal agency's final enforcement action, action will be taken only if the final enforcement action remains in effect.

Survey Procedures §485.608(a)

Assessing Compliance with Advance Directives Requirements

- Review the CAH's advance directive notice. Does it advise inpatients or applicable outpatients, or their representatives, of the patient's right to formulate an advance directive and to have CAH staff comply with the advance directive (in accordance with State law)? Does it include a clear, precise, and valid statement of limitation if the CAH cannot implement an advance directive on the basis of conscience?

- Review the records of a sample of patients for evidence of CAH compliance with advance directive notice requirements. Does every inpatient or applicable outpatient record contain documentation that notice of the CAH's advance directives policy was provided at the time of admission or registration? Is there documentation of whether or not each patient has an advance directive? For those patients who have reported an advance directive, has a copy of the patient's advance directive been placed in the medical record?

- What mechanism does the CAH have in place to allow patients to formulate an advance directive or to update their current advance directive? Is there evidence that

the CAH is promoting and protecting each patient's right to formulate an advance directive?

- Determine to what extent the CAH complies, as permitted under State law, with patient advance directives that delegate decisions about the patient's care to a designated individual.

- Determine to what extent the CAH educates its staff regarding advance directives.

- Interview staff to determine their knowledge of the advance directives of the patients in their care.

- Determine to what extent the CAH provides education for the patient population regarding one's rights under State law to formulate advance directives.

Assessing Required Disclosures

Physician Ownership

- If the CAH indicates that it is physician-owned but is exempt under §489.20(v) from the disclosure requirement of §489.20(u)(2), ask to see the signed attestation that it does not have any referring physicians with an ownership/investment interest or whose immediate family member was has an ownership/investment interest in the CAH. (As with any other on-the-spot correction of a deficiency during a survey, creation of an attestation at the time of a survey does not mean that there was no deficiency and that the CAH would not be cited.)

- If the CAH is physician-owned but not exempt from the physician ownership disclosure requirements:

    - Verify that appropriate policies and procedures are in place to assure that written notices are provided to all patients at the beginning of an inpatient or outpatient stay.

    - Review the notice the CAH issues to each patient to verify that it discloses, in a manner reasonably designed to be understood by all patients, that the CAH meets the Federal definition of "physician-owned," that a list of owners and investors who are physicians or immediate family members of physicians is available upon request, and that such list is provided to the patient at the time the request is made by or on behalf of the patient.

    - Determine through staff interviews, observation, and a review of policies and procedures whether the CAH furnishes its list of physician owners and investors at the time a patient or patient's representative requests it.

    - Determine through staff interviews and review of policies, procedures, and

staff records whether a physician-owned CAH's medical staff membership and admitting privileging requirements include a requirement that, as a condition of continued membership or admitting privileges, physician owners who refer patients to the CAH agree to provide written disclosure of their own or any immediate family member's ownership or investment interest to all patients at time of the referral to the CAH.

MD/DO 24/7 On-site Presence

- Determine through interviews, observation, and medical record review whether an MD/DO is present in the CAH 24 hours per day, 7 days per week. For each required location where an MD/DO is not present:

  - Verify that appropriate policies and procedures are in place to assure that written notices that a MD/DO is not present at all times are provided at the beginning of a planned or unplanned inpatient stay or outpatient visit to all inpatients and to all outpatients receiving observation services, surgery or another procedure requiring anesthesia.

  - Verify that there is a signed acknowledgement by the patient of such disclosure, obtained by the CAH prior to the patient's admission or before applicable outpatient services were provided.

  - Ask a sample of inpatients and affected outpatients whether they were provided notice about an MD/DO not being present at all times in the CAH.

  - Verify that the CAH's emergency department has signage with the appropriate disclosure information.

  - Review the notice the CAH issues to verify that it indicates how the CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present at that CAH, including any remote location.

Other Federal Requirements

Surveyors do not assess compliance with Medicare payment provisions or non-Medicare requirements. However, a surveyor may refer suspected noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., hazardous chemical and waste issues to EPA, blood-borne pathogens and TB control to OSHA, etc.).

C-0814

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.608(b) Standard: Compliance With State and Local Laws and Regulations

All patient care services are furnished in accordance with applicable State and local laws and regulations.

Interpretive Guidelines §485.608(b)
There are wide variations in the States' practice acts relative to the extent to which MD/DOs may delegate responsibilities to nurse practitioners, clinical nurse specialists, and physician assistants. Some states have updated their practice acts to include definitions and specific references to permitted/prohibited activities, supervision/guidance required by a MD/DO, and local situations in which nurse practitioners, clinical nurse specialists, and physician assistants may function.

Survey Procedures §485.608(b)

Prior to going on the survey, determine what professional specialists provide patient care services at the CAH and review State practice act requirements.

C-0816
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.608(c) Standard: Licensure of CAH

The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

Survey Procedures §485.608(c)

Prior to the survey, determine whether the CAH is subject to licensure requirements and verify that the licensing agency has approved the CAH as meeting the standards for licensure as set forth by the agency of the State or locality responsible for licensing CAHs.

C-0818
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.608(d) Standard: Licensure, Certification or Registration of Personnel

Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

Interpretive Guidelines §485.608(d)
All staff required by the State to be licensed must possess a current license. The CAH must ensure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. 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.

All CAH staff must meet all applicable standards required by State or local law for CAH personnel. This would include at a minimum:

- Certification requirements;
- Minimum qualifications; and
- Training/education requirements.

Survey Procedures §485.608(d)

- Verify for those personnel required to be licensed by the State, that the CAH has established, and follows, procedures for determining that personnel providing patient care services are properly licensed.
- Check a sample of personnel files to verify that licensure information is up to date. Verify that appropriate categories of staff and personnel are licensed in accordance with State requirements. Verify state licensure compliance of the direct care personnel, as well as administrators and supervisory personnel, and any contracted personnel.
- Verify that there are procedures in place to guarantee licensure of employees working at the CAH under contract or agreement.
- Review CAH policies regarding certification, licensure, and registration of personnel. Are the CAH policies compliant with State and local laws? Are the personnel in compliance with CAH policy?

C-0822

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.610 Condition of Participation: Status and Location

Interpretive Guidelines §485.610

The CAH must meet the location requirements of §485.610(b) and §485.610(c) at the time of the initial survey. Compliance with these location requirements must be reconfirmed at the time of every subsequent recertification (including the recertification of a deemed status CAH whose accreditation has been renewed). If the CAH moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(b) and (c). If a CAH that has been certified on the basis of having been designated by the State as a necessary provider moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(b) and §485.610(d).

C-0824

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.610(a) Standard: Status

The facility is--

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility--

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that--

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

Interpretive Guidelines §485.610(a)
Confirm that a CAH meets the basic status requirement prior to scheduling the survey. The appropriate RO will reverify the status requirement prior to approving a CAH for Medicare certification.

C-0826

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.610(b) Standard: Location in a Rural Area or Treatment as Rural

The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section or the requirements of paragraph (b)(3), (b)(4), or (b)(5) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(e) of this chapter and is not among

a group of hospitals have been redesignated to an adjacent urban area under §412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103 of this chapter.

(3) Effective for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on June 3, 2003.

(4) Effective for October 1, 2009 through September 30, 2011, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2009, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2010, was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on November 20, 2008.

(5) Effective on or after October 1, 2014, for a period of 2 years beginning with the effective date of the most recent Office of Management and Budget (OMB) standards for delineating statistical areas adopted by CMS, the CAH no longer meets the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, prior to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, was located in a rural area as defined by OMB, but under the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, is located in an urban area.

Interpretive Guidelines §485.610(b)

Among other requirements, pursuant to 42 CFR 485.610(b), all CAH applicants and existing CAHs, including necessary provider CAHs, must either be:

- located in a rural area; or
- treated as rural in accordance with 42 CFR 412.103

in order to be eligible for CAH designation and certification. (The temporary provisions at 42 CFR 485.610(b)(3) and (4) have expired and no longer apply.)

Only the CMS Regional Office makes the determination whether a CAH applicant or existing CAH meets the rural location requirement, following the instructions below. However, State Survey Agencies (SA) may wish to make informal assessments prior to conducting a survey, following the guidance provided in Section 2256A of the SOM. If

the SA's informal assessment suggests the CAH applicant or existing CAH is not rural, it should consult with the RO before conducting a survey.

Survey Procedures §485.610(b)

Conduct an informal assessment of the CAH's rural status, following the procedures in Section 2256A of the SOM, and if it appears the CAH no longer has rural status, confer with the CMS RO prior to scheduling the initial or recertification survey.

C-0830

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification]

The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

Interpretive Guidelines §485.610(c)

A CAH that has not been designated by a State as a necessary provider prior to December 31, 2005 must be located more than a 35-mile drive (or in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from any other CAH or hospital. An exception is made for Indian Health Service (IHS) or Tribal CAHs and hospitals that are located less than the 35 or 15 miles from another hospital or CAH. Given that IHS and Tribal CAHs and hospitals serve distinctly different populations, IHS CAHs and hospitals are excluded from consideration when determining the proximity of non-IHS hospitals seeking CAH certification to other CAHs or hospitals. For the same reason, when an IHS or Tribal hospital applies for certification to participate in Medicare as a CAH, CMS will consider only its proximity to other IHS and Tribal CAHs and hospitals in determining whether it meets the location requirement under section 485.610(c).

If a CAH is located on an island and the location meets the following characteristics, the CAH is considered to be in compliance with the distance requirements relative to other hospitals and CAHs under §485.610(c):

- The island is entirely surrounded by water;
- The CAH is the only hospital or CAH on the island; and
- The island is not accessible by any roads.

CAHs located on islands that meet the criteria above are still required to comply with the rural location requirement under §485.610(b).

A CAH that can document that it was designated by a State as a necessary provider CAH prior to January 1, 2006, does not have to meet the location relative to other facilities standard at §485.610(c). As of January 1, 2006, States do not have the authority to designate any new necessary provider CAHs. Necessary provider CAHs that were designated prior to that date are grandfathered by statute, subject to certain conditions if they relocate (see the discussion related to §485.610(d)). ROs and SAs should have the documentation related to a CAH's original designation as a necessary provider in the file on each CAH. If they do not, they should ask the CAH to supply copies of the original necessary provider designation documents.

For applicants seeking a new CAH provider agreement, or for CAHs that seek to relocate and do not have a grandfathered necessary provider designation, ROs will review the application and make the determination whether it satisfies the CAH location relative to other facilities standard at §485.610(c), using the guidance found in Chapter 2, §2256A of the State Operations Manual. At the conclusion of its review, the RO will notify the SA of its determination. Existing CAHs that are not grandfathered necessary provider CAHs must be periodically evaluated to determine whether there are any more recently certified Medicare-participating hospitals that are not more than a 35-mile drive, or 15-mile drive, as applicable, from the CAH. In the event that an existing CAH that is not a grandfathered necessary provider no longer meets the minimum distance requirement, it is provided the opportunity to avoid termination of its provider agreement by converting to a certified Medicare hospital after demonstrating compliance with the hospital CoPs.

C-0832

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.610(d) Standard: Relocation of CAHs With a Necessary Provider Designation

A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location--

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff,

contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in §489.52(b)(3).

Interpretive Guidelines §485.610(d)

Renovation or expansion of a CAH's existing building or addition of building(s) on the existing main campus of the CAH is not considered a relocation. However, as discussed in the adoption of this regulation (70 FR 47472), all 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. The determination of whether or not CAHs with a necessary provider designation have met the requirements at §485.610(d) will be made by the RO, generally prior to an SA or accreditation survey. The RO will utilize the evaluation criteria set forth in the SOM, Chapter 2, §2256F to make this determination. At the conclusion of its review, the RO will notify the SA of its results.

C-0834

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.610(e) Standard: Off-campus and Co-Location Requirements for CAHs

Standard: Off-campus and co-location requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following:

(1) **If a CAH with a necessary provider designation is co-located (that is, it shares a campus, as defined in §413.65(a)(2) of this chapter, with another hospital or CAH), the necessary provider CAH can continue to meet the location requirement of paragraph (c) of this section only if the co-location arrangement was in effect before January 1, 2008, and the type and scope of services offered by the facility co-located with the necessary provider CAH do not change. A change of ownership of any of the facilities with a co-location arrangement that was in effect before January 1, 2008, will not be considered to be a new co-location arrangement.**

(3) If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1, 2008, [or creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section,] the

CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.

Interpretive Guidelines §485.610(e)(1) & (3)

A CAH may not be co-located with another hospital or CAH, because this would violate the minimum distance requirement found at §485.610(c). However, some CAHs that were designated as necessary providers prior to January 1, 2006, and therefore exempted from this distance requirement, also chose to co-locate with another hospital. Co-location occurs when a necessary provider CAH shares the same campus and/or building in which the CAH is currently located with another hospital or necessary provider CAH. For example, a necessary provider CAH shares the same campus with an unrelated psychiatric or rehabilitation hospital.

Effective January 1, 2008, grandfathered necessary provider CAHs may no longer enter into co-location arrangements with another CAH or hospital (72 FR 66878). However, necessary provider CAHs that had co-location arrangements in effect prior to January 1, 2008, are permitted to continue these arrangements as long as the type and scope of services offered by the facility co-located with the CAHs do not change. An example of a change in type of services would be when a hospital that provides only rehabilitation services chooses to provide general hospital acute care services. An example of a change in scope of services would be when a grandfathered necessary provider CAH is currently co-located with a 20 bed psychiatric hospital and the psychiatric hospital now decides to increase the number of beds to 30.

The determination of whether or not CAHs with a grandfathered necessary provider designation have met the requirements at §485.610(e)(1) is made by the RO. If the SA or accreditation organization (AO) becomes aware of a co-location arrangement, the SA or AO must notify the RO. The RO will utilize the co-location guidance in §2256G of the SOM to determine if such CAHs satisfy the co-location requirements at §485.610(e)(1). The RO will notify the CAH as well as the SA (and the AO, if applicable) of its determination.

A CAH found out of compliance with the requirements is subject to termination of its Medicare provider agreement under §489.53(a)(3). In such cases the CAH is placed on a 90-day termination track, as outlined in §3012 of the SOM. If the CAH corrects the situation, by terminating the co-location arrangement that led to the non-compliance during this 90 day period, then the provider agreement is not terminated.

A facility facing termination of its CAH designation as a result of non-compliance with §485.610(e)(1) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions at 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital, with the effective date coinciding with the date of termination of CAH status. A new CMS Certification Number (CCN) would be assigned accordingly.

C-0836
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[§485.610(e) Standard: Off-campus and Co-Location Requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following:]

(2) **If a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in §405.2401(b) of this chapter, but including a department or remote location, as defined in §413.65(a)(2) of this chapter, or an off-campus distinct part psychiatric or rehabilitation unit, as defined in §485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of paragraph (c) of this section only if the off-campus provider-based location or off-campus distinct part unit is located more than a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH.**

(3) If either a CAH or a CAH that has been designated as a necessary provider by the State [does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1, 2008, or] creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section, the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.

Interpretive Guidelines §485.610(e)(2) & (3)

Section 42 CFR 485.610(e)(2) requires that if a CAH operates an off-campus provider-based facility as defined in §413.65(a)(2) (except for a rural health clinic (RHC)) or off-campus rehabilitation or psychiatric distinct part unit as defined at §485.647, that was created or acquired on or after January 1, 2008, then the off-campus facility must meet the requirement at 42 CFR 485.610(c) to be more than a 35 mile drive (or 15 miles in the case of mountainous terrain or an area with only secondary roads) from any other CAH or hospital. Off-campus CAH facilities that were in existence prior to January 1, 2008, are not subject to this requirement.

If a non-IHS or non-Tribal CAH operates an off-campus provider-based facility, its proximity to an IHS or Tribal CAH or hospital is not considered when assessing compliance with the requirements of this section. Similarly, if an IHS or Tribal CAH operates an off-campus provider-based facility, its proximity to a non-IHS or non-Tribal CAH or hospital is not considered when assessing compliance.

The drive to another hospital or CAH is to be calculated from the provider-based facility's location to the main campus of the other hospital or CAH.
The distance to another hospital or CAH requirement does not apply to the following types of facilities/services, because such facilities or services are not eligible for provider-based status in accordance with §413.65(a)(1)(ii):

- Ambulatory surgical centers (ASCs);
- Comprehensive outpatient rehabilitation facilities (CORFs);
- Home Health Agencies (HHAs);
- Skilled nursing facilities (SNFs);
- Hospices;
- Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services, 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 department; and
- Ambulances.

In the case of Federally Qualified Health Centers (FQHCs), although CMS rules permit them to be provider-based departments of a hospital or CAH, it is unlikely that there are new FQHCs that meet the provider-based criteria, since the Health Resources and Services Administration (HRSA) requirements for separate FQHC governance make it unlikely an FQHC could meet provider-based governance requirements. However, there are grandfathered FQHCs that were in operation prior to April 7, 2000 which are permitted to retain their provider-based status.

Those CAHs seeking a provider-based determination for newly created or acquired provider-based departments, remote locations and/or psychiatric or rehabilitation units located off-campus must submit an attestation to the Regional Office (RO), as specified in §2254H of the SOM, who makes the determination of whether it satisfies the CAH provider-based criteria at §485.610(e)(2), and the provider-based rules at §413.65. At the conclusion of its review, the RO will notify the CAH and the SA (and accreditation organization (AO), if applicable) of its determination.

If the SA or AO becomes aware of a provider-based off-campus facility that appears not to comply with the provider-based location requirements, the SA or AO must notify the

RO. The RO will utilize the guidance in §2254H of the SOM to determine if the CAH satisfies the provider-based location requirements at §485.610(e)(2). The RO will notify the CAH as well as the SA (and the AO, if applicable) of its determination.

A CAH found out of compliance with the off-campus location requirements at §485.610(e)(2) is subject to termination of its Medicare provider agreement. In such cases the CAH is placed on a 90-day termination track, as outlined in §3012 of the SOM. If the CAH corrects the situation, by terminating the off-campus provider-based arrangement that led to the non-compliance during this 90 day period, then the provider agreement is not terminated.

A facility facing termination of its CAH status as a result of non-compliance with §485.610(e)(2) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions at 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital, with the effective date coinciding with the date of termination of CAH status. A new CCN number would be assigned accordingly.

C-0840

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§485.612 Condition of Participation: Compliance With CAH Requirements at the Time of Application

Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

Interpretive Guidelines §485.612

This COP only applies to initial surveys. All facilities that apply to become a CAH are surveyed using the CAH CoP to determine compliance, whether they are:

- A currently operating CAH; or
- A re-opened CAH; or
- A CAH that down-sized to become a clinic.

If a facility has never been a Medicare participating hospital and wishes to be a CAH, the facility is a new provider to Medicare and must first meet the certification as a hospital and then put in a change of status request to be a CAH. In these cases, the facility must be surveyed twice. They must be initially surveyed using the hospital CoP and, when the change request is received, they must be surveyed again using the CAH CoP. In addition, these facilities are to be treated as new providers to Medicare necessitating completion of an application package as a new Medicare provider.

C-0860
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§485.616 Condition of Participation: Agreements

C-0862
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§485.616(a) Standard: Agreements With Network Hospitals

In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for:

Interpretive Guidelines §485.616(a)
Section 485.603 defines a rural health network 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.

Survey Procedures §485.616(a)

- If the CAH is a member of a rural health network having a communications system, ask to see the agreement.
- How does the CAH participate with other hospitals and facilities in the network communications system?
    - Is a communications log kept at the facility?
    - Ask staff if there have been difficulties in contacting network members. If so, ask how the CAH deals with communication delays.
- How does the network's communications system compare with any available communications equipment in the CAH?
- When the network communications system is not in operation, how does the CAH communicate and share patient data with other network members?
- Review any policies and procedures related to the operation of any communications system.
- How is the CAH staff educated on the use of any communication system utilized in the facility?
- Review any written agreements with the local EMS service.

C-0864
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§485.616(a)(1) Patient referral and transfer;

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§485.616(a)(2) The development and use of communications systems of the network, 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; and

C-0868
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§485.616(a)(3) The provision of emergency and non-emergency transportation between the facility and the hospital.

C-0870
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§485.616(b) Standard: Agreements for Credentialing and Quality Assurance

Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance 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.

Interpretive Guidelines §485.616(b)
Other qualified entities could include another CAH or any licensed firms, businesses, or agencies that provide credentialing and QA services. The location for these other qualified entities is not limited to local entities.

Agreements for QA need to include medical record review as part of the determination of the quality and medical necessity of medical care at the CAH.

Survey Procedures §485.616(b)

- Review any agreements related to credentialing or quality assurance to determine

the level of assistance to be provided and the responsibilities of the CAH.

- Review policies and procedures to determine how information is to be obtained, utilized, and how confidentiality of information will be maintained.

C-0872

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§485.616(c) Standard: Agreements for credentialing and privileging of telemedicine physicians and practitioners.

(1) The governing body of the CAH must ensure that, when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the agreement is written and specifies that it is the responsibility of the governing body of the distant-site hospital to meet the following requirements with regard to its physicians or practitioners providing telemedicine services:

(i) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

(ii) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

(iii) Assure that the medical staff has bylaws.

(iv) Approve medical staff bylaws and other medical staff rules and regulations.

(v) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

(vi) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

(vii) 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.

(2) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site hospital regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site hospital, that the following provisions are met:

(i) The distant-site hospital providing telemedicine services is a

Medicare-participating hospital.

(ii) 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;

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH is located; and

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such information for use in the periodic appraisal of the individual distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.

Interpretive Guidelines §485.616(c) §485.616(c)(1)&(2)

"Telemedicine," as the term is used in this regulation, means the provision of clinical services to patients by physicians and practitioners from a distance via electronic communications. The distant-site telemedicine physician or practitioner provides clinical services to the CAH patient either simultaneously, as is often the case with teleICU services, for example, or non-simultaneously, as may be the case with many teleradiology services. "Simultaneously" means that the clinical services (for example, assessment of the patient with a clinical plan for treatment, including any medical orders needed) are provided to the patient in "real time" by the telemedicine physician or practitioner, similar to the actions of an on-site practitioner when called in by a patient's attending physician to see the patient. "Non-simultaneously" means that, while the telemedicine physician or practitioner still provides clinical services to the patient, such services may involve after-the-fact interpretation of diagnostic tests in order to provide an assessment of the patient's condition and do not necessarily require the telemedicine practitioner to directly assess the patient in "real time." This would be similar to the services provided by an on-site radiologist who interprets a patient's x-ray or CT scan and then communicates his or her assessment to the patient's attending physician who then bases his or her diagnosis and treatment plan on these findings. . (See 76 FR 25552, May 5, 2011)

A CAH may make arrangements with a distant-site Medicare-participating hospital for the provision of telemedicine services to the CAH's patients by physicians or practitioners granted privileges by the distant-site hospital.

If a CAH enters into an agreement for telemedicine services with a distant-site hospital,

the agreement must be in writing. Furthermore, the written agreement must specify that it is the responsibility of the distant-site hospital to conduct its credentialing and privileging process for those of its physicians and practitioners providing telemedicine services such that the distant-site hospital:

- Determines, in accordance with State law, which categories of practitioners are eligible candidates for privileges or membership on the distant-site hospital's medical staff.

- Appoints members and grants medical staff privileges after considering the recommendations of the existing members of the distant-site hospital's medical staff.
- Assures that the distant-site hospital's medical staff has bylaws.

- Approves the distant-site hospital's medical staff bylaws and other medical staff rules and regulations.

- Ensures that the medical staff is accountable to the distant-site hospital's governing body for the quality of care provided to patients.

- Ensures the criteria for granting medical staff membership/privileges to an individual are the individual's character, competence, training, experience, and judgment.

- Ensures that under no circumstances is the accordance of distant-site hospital medical staff membership or privileges dependent solely upon certification, fellowship or membership in a specialty body or society.

Since the distant-site hospital must also participate in Medicare, it has an independent obligation to comply with these same requirements for all of its medical staff under §§482.12(a)(1) through (a) (7). Nevertheless, the written telemedicine services agreement between the CAH and the distant-site hospital must explicitly include a provision addressing the distant-site hospital's obligation to comply with these provisions.

The CAH's governing body (or the individual responsible for the CAH if it has no governing body) has the option, when considering granting privileges to telemedicine physicians and practitioners, to rely upon the credentialing and privileging decisions of the distant-site hospital for these physicians and practitioners. In order to exercise this alternative credentialing and privileging option, the CAH's governing body must ensure that its written agreement with the distant-site hospital addresses all of the following:

- That the distant-site hospital participates in the Medicare program. If the distant-site hospital's participation in Medicare is terminated, either voluntarily or involuntarily, at any time during the agreement, then as of the effective date of the termination, the CAH may no longer receive telemedicine services under the agreement;

- That the distant-site hospital provides a list to the CAH of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site hospital. The list may not include any physician or practitioner who does not hold privileges at the distant-site hospital. The list must be current, so the agreement must address how the distant-site hospital will keep the list current;

- That each physician or practitioner who provides telemedicine services to the CAH's patients under the agreement holds a license issued or recognized by the State where the CAH is located. States may have varying requirements as to whether they will recognize an out-of-state license for purposes of practicing within their State, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the State where the CAH whose patients are receiving the telemedicine services is located must be satisfied, whatever they may be; and

- That the CAH has evidence that it reviews the telemedicine services provided to its patients and provides feedback based on this review to the distant-site hospital for the latter's use in its periodic appraisal of each physician and practitioner providing telemedicine services under the agreement. At a minimum, the CAH must review and send information to the distant-site hospital on all adverse events that result from a physician or practitioner's provision of telemedicine services and on all complaints the CAH has received about a telemedicine physician or practitioner.

If the CAH's governing body or responsible individual does not rely on the privileging decisions of the distant-site hospital, then it must for each physician or practitioner providing telemedicine services under an agreement follow the CAH's standard process for review of credentials and granting of privileges to physicians and practitioners.

Survey Procedures §485.616(c)(1)&(2)

- Ask the CAH's leadership whether it uses telemedicine services. If yes,

- Ask to see a copy of the written agreement(s) with the distant-site hospital(s). Does each agreement include the required elements concerning credentialing and privileging of the telemedicine physicians and practitioners by the distant-site hospital?

- Does the CAH have documentation indicating that it granted privileges to each telemedicine physician and practitioner?

- 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 hospital? If yes:

- 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?

- Ask to see the list provided by the distant-site hospital of the telemedicine physicians and practitioners, including their privileges and pertinent licensure information.

- Ask for evidence that the CAH conducts the required review of the telemedicine services provided by the telemedicine physicians and practitioners, including any associated adverse events and complaints, and that it provides the required feedback to the distant-site hospital.

C-0874

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§485.616(c)(3) The governing body of the CAH must ensure that when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to the CAH and as such, in accordance with §485.635(c)(4)(ii), 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 in this section with regard to its physicians and practitioners providing telemedicine services.

§485.616(c)(4) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site telemedicine entity regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at (c)(1)(i) through (c)(1)(vii).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides a current list to the CAH of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a

license issued or recognized by the State in which the CAH whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such information for use in periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.

Interpretive Guidelines §485.616(c)(3)&(4)

For the purposes of this rule, a distant-site telemedicine entity is defined as an entity that -- (1) provides telemedicine services; (2) is not a Medicare-participating hospital; and (3) provides contracted services in a manner that enables a CAH using its services to meet all applicable CoPs, particularly those requirements related to the credentialing and privileging of physicians and practitioners providing telemedicine services to the patients of a CAH. A distant-site telemedicine entity would include a distant-site hospital that does not participate in the Medicare program that is providing telemedicine services to a Medicare-participating CAH. (See 76 FR 25553, May 5, 2011)

A CAH may have an agreement with a distant-site telemedicine entity for the provision of telemedicine services to the CAH's patients by physicians or practitioners granted privileges by the distant-site telemedicine entity.

If a CAH enters into an agreement for telemedicine services with a distant-site telemedicine entity, the agreement must be in writing. Furthermore, the written agreement must specify that under the agreement the distant-site telemedicine entity is a contractor providing services to the CAH, and that, in accordance with the requirements of §485.635(c)(4)(ii), the distant-site telemedicine entity furnishes its telemedicine services in a manner that enables the CAH to comply with all applicable CAH Conditions of Participation (CoPs), including, but not limited to, the specific requirements governing telemedicine services. Under §485.635(c)(4)(ii,) the CAH's governing body or responsible individual is obligated to ensure that all contractors of services furnish those services in a manner that enables the CAH to comply with all applicable CoPs.

The CAH's governing body (or the individual responsible for the CAH if it has no governing body) has the option, when considering granting privileges to telemedicine physicians and practitioners, to rely upon the credentialing and privileging decisions of the distant-site telemedicine entity for these physicians and practitioners. In order to exercise this alternative credentialing and privileging option, the CAH's governing body

must ensure through its written agreement with the distant-site telemedicine entity that all of the following requirements are included in the agreement and that the contractor fulfills these requirements:

- The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meets the standards at §485.616(c)(1)(i) through (c)(1)(vii). In other words, the distant-site telemedicine entity must at a minimum:

  - Determine, in accordance with State law, which categories of practitioners are eligible candidates for medical staff privileges or membership at the telemedicine entity;

  - Appoint members and grant medical staff privileges after considering the recommendations of the existing members of its medical staff;

  - Assure that its medical staff has bylaws;

  - Approve its medical staff's bylaws and other medical staff rules and regulations;

  - Ensure that the medical staff is accountable to the distant-site telemedicine entity's governing body for the quality of care provided to patients;

  - Ensure the criteria for granting distant-site telemedicine medical staff membership/privileges to an individual are the individual's character, competence, training, experience, and judgment; and

  - Ensure that under no circumstances is the accordance of medical staff membership or privileges dependent solely upon certification, fellowship or membership in a specialty body or society.

- The distant-site telemedicine entity provides to the CAH a list of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site telemedicine entity. The list may not include any physician or practitioner who does not hold privileges at the distant-site telemedicine entity. The list must be current, so the agreement must address how the distant-site telemedicine entity will keep the list current;

- Each physician or practitioner who provides telemedicine services to the CAH's patients under the agreement holds a license issued or recognized by the State where the CAH is located. States may have varying requirements as to whether they will recognize an out-of-state license for purposes of practicing within their State, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the State where the hospital whose patients are receiving the telemedicine services is located must be satisfied, whatever they may be; and

- The CAH reviews the performance of the physicians and practitioners providing telemedicine services to its patients and provides a written review to the distant-site telemedicine entity for the latter's use in its periodic appraisal of each physician and practitioner providing telemedicine services under the agreement. At a minimum, the CAH must review and send information to the distant-site telemedicine entity on all adverse events that result from a physician's or practitioner's provision of telemedicine services and on all complaints the CAH has received about a telemedicine physician or practitioner.

If the CAH's governing body or responsible individual does not rely on the privileging decisions of the distant-site telemedicine entity, then it must for each practitioner providing telemedicine services under an agreement follow the CAH's standard process for review of credentials and granting of privileges to physicians and practitioners.

Survey Procedures §485.616(c)(3)&(4)

- Ask the CAH's leadership whether it uses telemedicine services. If yes,

  - Ask to see a copy of the written agreement(s) with the distant-site telemedicine entity(ies). Does each agreement explicitly state that the distant-site telemedicine entity will provide telemedicine services in a manner that enables the CAH to comply with all applicable CoPs?

  - Does the CAH have documentation indicating that it granted privileges to each telemedicine physician and practitioner?

  - 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? If yes:

    - 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?

    - Is there a list provided by the distant-site telemedicine entity of the telemedicine physicians and practitioners covered by the agreement, including their privileges and pertinent licensure information?

    - Is there evidence that the CAH reviews the services provided by the telemedicine physicians and practitioners, including any adverse events and complaints, and provides written feedback to the distant-site telemedicine entity?

- Ask the CAH how it verifies that the telemedicine entity fulfills the terms of the agreement with respect to its credentialing and privileging process and otherwise assures that services are provided in a manner that enables the CAH to meet all applicable CAH requirements? (Surveyors do not attempt to independently verify whether or not the distant-site telemedicine entity's credentialing and privileging process fulfills the regulatory requirements. Surveyors focus only on what actions the CAH takes to ensure that the distant-site telemedicine entity complies with the terms of the agreement.)

C-0880

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§485.618 Condition of Participation: Emergency Services

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

Interpretive Guidelines §485.618

All emergency services must be provided as a direct service in the CAH. The ED cannot be a provider-based off-site location. Emergency needs of patients must be met in accordance with acceptable standards of practice.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations, and guidelines governing all services provided in the CAH'S emergency department, as well as any standards and recommendations promoted by or established by nationally recognized professional organizations such as the American Medical Association, American Association for Respiratory Care, American Society of Emergency Medicine, American College of Surgeons, American Nursing Association, etc.

The CAH'S emergency services must be under the direction of a qualified member of the CAH'S medical staff. The CAH'S medical staff establishes criteria for the qualifications for the director of the CAH'S emergency services in accordance with State law and acceptable standards of practice.

The CAH'S medical staff must establish policies and procedures governing the medical care provided in the emergency services or emergency department. Emergency services or emergency department policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff and the emergency service or department QA activities. The CAH'S emergency services must be integrated into the CAH-wide QA program.

The medical staff must establish criteria, in accordance with State law, regulations, and guidelines, delineating the qualifications a medical staff member must possess in order to be granted privileges for the provision of emergency care services. Qualifications include necessary education, experience and specialized training, consistent with State law and acceptable standards of practice.

The CAH must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility. There must be sufficient medical and nursing personnel to respond to the emergency medical needs and care of the patient population being served.

The CAH must determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, and emergency department support staff the CAH needed to meet its anticipated emergency needs. The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).

The CAH must conduct ongoing assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

Emergency care necessary to meet the needs of its inpatients and outpatients would include the provision of respiratory services as needed by the CAH'S emergency patients. When respiratory services are provided those services must be provided in accordance with acceptable standards of practice. The scope of diagnostic and/or therapeutic respiratory services offered by the CAH should be defined in writing, and approved by the medical staff.

The CAH must provide the appropriate equipment and qualified personnel necessary to furnish all services offered in a safe manner in accordance with acceptable standards of practice.

There should be written policies for the delivery of any services provided. The policies and procedures must be developed and approved by the medical staff and include the participation of any mid-level practitioners working in the ED. The written policies should address the following services, as appropriate:

- Each type of service provided by the CAH;
- The qualifications, including job title, licensure requirements, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision;
- Equipment assembly and operation;
- Safety practices, including infection control measures;
- Handling, storage, and dispensing of therapeutic gases;

- Cardiopulmonary resuscitation;
- Procedures to follow in the advent of adverse reactions to treatments or interventions;
- Pulmonary function testing;
- Therapeutic percussion and vibration;
- Bronchopulmonary drainage;
- Mechanical ventilatory and oxygenation support;
- Aerosol, humidification, and therapeutic gas administration;
- Administration of medications; and
- Procedures for obtaining and analyzing blood samples (arterial blood gases).

Survey Procedures §485.618

- Verify that emergency services are organized under the direction of a qualified member of the medical staff.
- Verify that procedures and policies for emergency medical services (including triage of patients and any respiratory services provided) are established, evaluated, and updated on an ongoing basis.
- Verify that there are sufficient medical and nursing personnel qualified in the needs anticipated by the facility and that there are specific assigned duties for emergency care
- Review any policies and procedures for emergency services in the CAH. What evidence indicates that the CAH is capable of providing necessary emergency care for its inpatients and outpatients?
- Review a sample of patient records for patients treated in the emergency services department to see if the CAH followed its own policies and procedures.
- Verify that emergency services are provided in accordance with acceptable standards of practice.
- Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including:
    - Parenteral administration of electrolytes, fluids, blood and blood components;

    - Care and management of injuries to extremities and central nervous system;
    - Prevention of contamination and cross infection; and
    - Provision of emergency respiratory services.

- Determine if the CAH provides any degree of respiratory care services and that the type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with acceptable standards of practice.
- Review the CAH policies and procedures to verify that the scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing and approved by the medical staff.
- Review staffing schedules to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished.
- If blood gases or other laboratory tests are performed as part of the delivery of respiratory services, verify that there is a current CLIA certificate.

C-0882

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.618(a) Standard: Availability

Emergency services are available on a 24-hours a day basis.

Interpretive Guidelines §485.618(a)
The CAH "makes available 24-hour emergency services." This does not mean that the CAH must remain open 24 hours a day when it does not have inpatients (including swing-bed patients). A CAH that does not have inpatients may close with no staff present, provided that it has an effective system in place to meet the requirement. The system must ensure that a practitioner with training and experience in emergency care is on call and immediately available by telephone or radio, and available on site within 30 minutes, (or 1 hour in certain frontier areas), 24 hours a day.

In addition to these items, the CAH must 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.

Survey Procedures §485.618(a)

Ascertain by record review of patients admitted through the emergency department, interviews with staff, patients, and families, and/or observations that ED services were made available to patients presenting on a 24-hour a day basis. How does the CAH

ensure that emergency services are made available on a 24-hour a day basis?

C-0884

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.618(b) Standard: Equipment, Supplies, and Medication

Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

Interpretive Guidance §485.618(b)
In addition to these items, the CAH must 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.

Survey Procedures §485.618(b)

- How does the CAH ensure that the required equipment, supplies and medications are always readily available in the CAH?
- Interview staff and tour the ER to ascertain compliance and ability to provide emergency services.

C-0886

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.618(b)(1) Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

Survey Procedures §485.618(b)(1)

- How does the CAH ensure that staff knows where drugs and biologicals are kept?
- How is the inventory maintained?
- Who is responsible for monitoring drugs and biologicals?
- How are drugs and biologicals replaced?

C-0888

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.618(b)(2) 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 monitor, chest tubes, and indwelling urinary catheters.

Survey Procedures §485.618(b)(2)

- How does the CAH ensure that required equipment and supplies are readily available to staff?
- How does the CAH ensure that staff knows where emergency equipment and supplies are kept?
- How is the supply inventory maintained?
- Who is responsible for monitoring supplies?
- How are supplies replaced?
- When was the last time emergency supplies were used?
- Is there an equipment maintenance schedule (e.g., for the defibrillator)?
- Ask staff if equipment has ever failed to work when needed.
- Examine sterilized equipment (e.g., tracheostomy sets) for expiration dates when applicable.
- Examine the oxygen supply system to determine functional capabilities.
- Check the force of the vacuum (suction) equipment to see that it is in operating condition.

C-0890

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.618(c) Standard: Blood and Blood Products

The facility provides, either directly or under arrangements, the following--

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

Interpretive Guidelines §485.618(c)(1)

This requirement can be met at a CAH by providing blood or blood products on an emergency basis at the CAH, either directly or through arrangement, if that is what the patient's condition requires. There is no requirement in the regulation for a CAH to store blood on site, although it may choose to do so. In some cases, it may be more practical to

transport a patient to the source of the blood supply than to bring blood to the patient at the CAH. A facility that has the capability of providing blood services on site would be in compliance even if, in virtually all cases, the patients were actually taken to the blood rather than vice versa.

A CAH that performs CLIA tests on blood on-site must have a CLIA certificate and is subject to survey under CLIA. A CAH that is only storing blood for transfusion and refers all related testing out to another laboratory, is not performing testing as defined by CLIA. However, under this regulation, the CAH must ensure that blood is appropriately stored to prevent deterioration, including documenting refrigerator temperatures. The provision of blood services between the CAH and the testing laboratory should be reflected in the written agreement or arrangement between the two. Also, if the CAH is collecting blood, it must register with the Food and Drug Administration.

"**Availability**" in this context, means that the blood and blood products must be accessible to CAH staff in time to effectively treat emergency patients at the CAH. In order to comply with this requirement, a CAH must demonstrate that it has the capability (i.e., an effective system is in place regardless of whether, in actual practice, it has been utilized) of making blood products available to its emergency patients 24 hours a day.

If a CAH performs type and compatibility testing it must 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. Another way for a CAH to meet this requirement would be to properly store 4 units of O negative packed red blood cells (the universal donor type) for availability at all times for emergencies only. CAHs that choose to store O negative packed red blood cells for emergency release of uncross matched blood will require a release form to be signed by a doctor, prior to transfusion, acknowledging that the blood has not been cross matched for the patient. Facilities that elect to store units of O negative packed red blood cells should be able to demonstrate that they have an arrangement (e.g., with the Red Cross or other similar product provider) for the provision of fresh units of O negative packed red blood cells.

C-0892

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.618(c)(2) 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 doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

Survey Procedures §485.618(c)(2)

- If blood banking services are provided on site, what evidence shows that the blood facility is under the control and supervision of a pathologist or other qualified MD/DO?

- For blood banking services provided under arrangement, what evidence shows that the CAH medical staff and the person responsible for CAH operations have approved the arrangement?

C-0894

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.618(d) Standard: Personnel

(1) Except as specified in paragraph (d)(3) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner or a clinical nurse specialist with training or experience in emergency care on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) 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.

(C) 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.

(2) A registered nurse with training and experience in emergency care can be utilized 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 practice of a registered nurse and consistent with applicable State laws and the CAH's bylaws or rules and regulations.

(3) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if--

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) 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 health care plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(3)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(4) The request, as specified in paragraph (d)(3)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

Interpretive Guidance § 485.618(d)

When State laws are more stringent and require more stringent staffing or expanded operational hours, the CAH must staff its emergency department in accordance with state laws. For example, if State law requires the CAH emergency department be open and be staffed with a MD/DO 24/7 then the CAH must comply.

Survey Procedures §485.618(d)

- Review on-call schedules to determine how the CAH ensures that a qualified staff member is on call 24 hours a day and available on site at the CAH within 30 minutes, or 60 minutes in certain frontier areas.

- Interview staff to determine how the CAH staff knows who is on call.

- What documentation demonstrates that a MD/DO, nurse practitioner, physician assistant, clinical nurse specialist or registered nurse (as allowed under (d)(3))

with emergency training or experience has been on call and available on site at the CAH within 30 or 60 minutes, as appropriate?

C-0898

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.618(e) Standard: Coordination With Emergency Response Systems

The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

Interpretive Guidelines §485.618(e)

The CAH, not the local ambulance service, is responsible for ensuring that an effective procedure is in place to meet this requirement.

Survey Procedures §485.618(e)

- Verify that the CAH has policies and procedures in place to ensure an MD/DO is available by telephone or radio, on a 24-hour a day basis to receive emergency calls and provide medical direction in emergency situations?

- What evidence demonstrates that the procedures are followed and evaluated for effectiveness?

- Interview staff to see how an MD/DO is contacted when emergency instructions are needed.

C-0900

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.620 Condition of Participation: Number of Beds and Length of Stay

C-0902

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.620(a) Standard: Number of Beds

Except as permitted for CAHs having distinct part units under §485.647, the CAH maintains no more than 25 inpatient beds. Inpatient beds may be used for either inpatient or swing-bed services.

Interpretive Guidelines §485.620(a)

Section 1820(c)(2)(B)(iii) of the Social Security Act limits a CAH to a maximum of 25 inpatient beds that can be used for inpatient acute care or swing bed services. The statute also requires CAHs to provide inpatient acute care limited, on an annual average basis, to 96 hours per patient (see interpretive guidelines for §485.620(b)).

Section 1820(c)(2)(E) of the Act also permits a CAH to operate a 10-bed psychiatric distinct part unit (DPU) and a 10-bed rehabilitation DPU, without counting these beds toward the 25-bed inpatient limit.

The limit applies to the number of inpatient beds; not to the number of inpatients on any given day. CAHs that were larger hospitals prior to converting to CAH status may not maintain more than 25 inpatient beds, plus a maximum of 10 psychiatric DPU inpatient beds, and 10 rehabilitation DPU inpatient beds. Any bed used for inpatient services at any time must be counted when assessing compliance with the 25 inpatient bed limit. Beds used for outpatient services, such as observation services, sleep studies, emergency services, etc. do not count towards the CAH's 25-bed limit only if they are never used for inpatient services.

Beds Used for Observation Services

Beds used solely for patients receiving observation services are not included in the 25-bed maximum, nor in the calculation of the average annual acute care patient length of stay. This makes it essential for surveyors to determine that CAHs with observation beds are using them appropriately, and not as a means to circumvent the CAH size and length-of-stay limits.

Inappropriate use of observation services also subjects Medicare beneficiaries to an increased beneficiary coinsurance liability that could have been avoided, had the beneficiary been properly admitted as an inpatient. This is the case because, as CAHs are not paid under the hospital Outpatient Prospective Payment System (OPPS), the beneficiary in an observation status will be liable for a coinsurance charge equal to 20 percent of the CAH's customary charges for the services. Further, as CAHs are also not subject to the preadmission payment window, a Medicare beneficiary would be liable for the coinsurance charges for the observation status services even when subsequently admitted. Depending on the terms of their health insurance coverage, other CAH patients may also face similar increased and avoidable costs when inappropriately placed in an observation status.

Observation care is a well-defined set of specific, clinically appropriate services that include ongoing short-term treatment, assessment, and reassessment, that are provided before a decision can be made regarding whether a patient will require further treatment as an inpatient, or may be safely discharged. Observation status is commonly assigned to patients with unexpectedly prolonged recovery after outpatient surgery, and to patients who present to the emergency department and who then require a significant period of treatment or monitoring before a clinical decision is made concerning their next placement. The CAH should ensure that once there is sufficient information to render this clinical decision, the patient should be expeditiously admitted, appropriately

transferred, or discharged.

A patient may be in an observation status even though the CAH furnishes the patient overnight accommodation, food, and nursing care.

Observation services are **NOT** appropriate:

- As a substitute for an inpatient admission;
- For continuous monitoring;
- For medically stable patients who need diagnostic testing or outpatient procedures (e.g., blood transfusion, chemotherapy, dialysis) that are routinely provided in an outpatient setting;
- For patients awaiting nursing home placement;
- To be used as a convenience to the patient, his or her family, the CAH, or the CAH's staff;
- For routine prep or recovery prior to or following diagnostic or surgical services; or
- As a routine "stop" between the emergency department and an inpatient admission.

Observation services **BEGIN** and **END** with an order by a physician or other qualified licensed practitioner of the CAH.

- The order for observation services must be written prior to initiation of the service, as documented by a dated and timed order in the patient's medical record. The order may not be backdated. Orders should be clear for the level of care intended, such as "admit to inpatient" or "place in observation." (**NOTE**: It is not uncommon for hospitals and practitioners to refer to "admitting" a patient for observation. Technically, only inpatients are "admitted," while patients receiving observation services are in an outpatient status. However, usage of the term "admit" in an order placing a patient in observation status does not violate any CAH CoP and is not cited.)
- Observation services end when the physician or other qualified licensed practitioner orders an inpatient admission, a transfer to another health care facility, or discharge. The inpatient stay begins on the date and time of the new order.
- Standing orders for observation services are not acceptable, since it is not necessary to employ observation services for every patient in a given category, e.g., every emergency department patient, in order to reach a clinical decision about the appropriate next step in the patient's care.

Medicare generally will not pay for observation services lasting more than 48 hours.

However, some States may have more stringent limits in their licensure or other regulatory requirements on the length of observation services, e.g., 24 hours. In such cases the State's more stringent limit on the length of an observation stay applies to Medicare beneficiaries as well, but is not enforced through the Federal survey process, unless the State has taken a final enforcement action.

The CAHs must provide appropriate documentation upon surveyor request to show that an observation bed is not an inpatient bed. The CAH must be able to document that it has specific clinical criteria for placing a patient in and discharging from, the observation service, and that these criteria are clearly distinguishable from those used for inpatient admission and discharge. CMS expects a CAH to employ the same type of clinical criteria for observation versus inpatient status for all patients, regardless of their payer status. For example, if a CAH were routinely placing only Medicare beneficiaries in its dedicated observation unit, then this could suggest that non-clinical criteria were being used in the decision to admit versus place in observation status. This would not only call the observation bed status into question, but could also violate the CAH's provider agreement requirement that prohibits differential treatment of Medicare beneficiaries. (See 42 CFR 489.53(a)(2)).

If a CAH maintains beds that are dedicated to observation services, the CAH must be able to provide evidence, such as the clinical criteria for admission to that unit and how patients in the unit meet those criteria, to demonstrate that its observation beds are not being used for inpatient services. CMS expects there to be a reasonable relationship between the size of the CAH's inpatient and observation operations. For example, a 10-bed observation unit in a 25-bed CAH might be disproportionately large, and the surveyor must determine whether the observation unit is actually functioning as an inpatient overflow unit. A CAH observation unit that routinely operates at a high occupancy rate could also be an indicator of the need to probe further.

Other Types of Beds

Other bed types that do not count toward the 25 inpatient bed limit include, but are not limited to:

- Examination or procedure tables;
- Stretchers;
- Operating room tables;
- Beds in a surgical recovery room used exclusively for surgical patients during recovery from anesthesia;
- Beds in an obstetric delivery room used exclusively for OB patients in labor or recovery after delivery of newborn infants;
- Newborn bassinets and isolettes used for well-baby boarders (**NOTE**: If the baby is being held for treatment at the CAH, his or her bassinet or isolette

does count towards the CAHs 25-bed limit);

- Stretchers in emergency departments; and

- Inpatient beds in Medicare-certified distinct part rehabilitation or psychiatric units.

Beds Used for Hospice Services

A CAH can dedicate beds to a hospice under arrangement, but the beds must count as part of the maximum bed count. The computation contributing to the 96 hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care.

Medicare does not reimburse the CAH for the hospice CAH benefit. Medicare reimburses the hospice. The CAH must negotiate payment for services from the hospice through an agreement.

Survey Procedures §485.620(a)

- Count the number of inpatient beds the CAH maintains, excluding any DPU beds.

- Ask the CAH how frequently it uses observation services, and for its policies and procedures governing use of observation services.

- Verify that patients are never pre-registered for observation services; there should be no scheduled observation stays.

- Check to see if the CAH has specific clinical criteria for placement in and discharge from observation status, and that these clinical criteria are clearly distinguishable from those used for inpatient admission and discharge.

- If there is a separate unit of observation beds, ask the CAH for evidence of how its criteria for placement in the observation unit differ from admission criteria for an inpatient bed. Count the number of beds in the observation unit and compare them to the number of inpatient beds. The higher the proportion of observation beds, the greater is the CAH's burden to prove these are not being used as inpatient beds. Ask for the occupancy rates for the observation unit; the higher the occupancy rate, particularly if there are more than a couple of beds, the greater is the CAH's burden to prove these are not being used as inpatient beds.

- Review the medical records for patients who are in observation status at the time of survey. Verify that the medical record includes an order to place the patient in observation status, including the clinical reason for observation, e.g., as "Place patient in observation to rule out possible myocardial infarction (MI)."

- Select a sample of closed medical records for patients who were in an observation status. Verify that the medical record includes an order to place the patient in observation status, as well as a later order to admit, discharge, or transfer the patient.

- Verify through medical record review that observation services are not ordered as a standing order following outpatient surgery or prior to admission from the emergency department.

C-0904

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.620(b) Standard: Length of Stay

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

Interpretive Guidelines §485.620(b)

The Fiscal Intermediary (FI) will determine compliance with this CoP. The FI will calculate the CAH'S length of stay based on patient census data. If a CAH exceeds the length of stay limit, the FI will send a report to the CMS-RO as well as a copy of the report to the SA. The CAH will be required to develop and implement a plan of correction (POC) acceptable to the CMS Regional Office or provide adequate information to demonstrate compliance.

C-0910

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623 Condition of Participation: Physical Plant and Environment

Interpretive Guidelines §485.623

This CoP applies to all locations of the CAH, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations.

The CAH'S departments or services responsible for the CAH'S building and equipment maintenance (both facility equipment and patient care equipment) must be incorporated into the CAH'S QA program and be in compliance with the QA requirements.

C-0912

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(a) Standard: Construction
The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.

Interpretive Guidelines §485.623(a)

The CAH's physical facilities must be constructed, designed and maintained such that patients are always accessible and the safety of patients is assured. The CAH's construction must be in accordance with applicable Federal, State and local law, as determined by the authorities having jurisdiction to enforce such law.

The CAH's physical plant must provide sufficient space to support those services the CAH provides on-site. There must also be adequate space to support all additional services the CAH offers.

Survey Procedures §485.623(a)

- Verify through observation that the physical facilities are 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. The adequacy of the space depends on both the nature of the services provided and the number of patients to whom the CAH typically provides those services.

- Verify through observation that the CAH's building(s) is/are maintained in a manner to ensure the safety and well being of patients (e.g., condition of ceilings, walls, and floors, presence of patient hazards, etc.).

- Verify through observation that the design of the CAH assures that staff can reach patients readily.

C-0914

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(b) Standard: Maintenance

The CAH has housekeeping and preventive maintenance programs to ensure that--

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

Interpretive Guidelines §485.623(b)(1)

In order to ensure all essential mechanical, electrical and patient-care equipment is maintained in safe operating condition, the CAH must identify the essential equipment required to meet its patients' needs for both day-to-day operations and in a likely emergency/disaster situation, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc. In addition, the CAH must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the CAH (e.g., elevators, generators, air

handlers, medical gas systems, air compressors and vacuum systems, electrical systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the CAH (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades. Equipment to be used for the first time should be inspected and tested for performance and safety in accordance with manufacturer recommendations, unless a sufficient amount of maintenance history has been acquired, either based on its contractor's records or available publicly from nationally recognized sources, to determine whether the alteration of initial inspection and testing activities and frequencies would be safe.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using CAH personnel, contracted services, or through a combination of CAH personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The CAH maintains records of CAH personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules fall under the purview of the CAH's clinical maintenance personnel, safety department personnel or other personnel who have been assigned responsibility for equipment maintenance by CAH leadership.

CAHs comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. CAHs may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the CAH must maintain documentation of those recommendations and the CAH's associated maintenance activity for the affected equipment.

Alternate Equipment Management (AEM) Program

A CAH may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. CAHs that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the CAH associated with the use of facility or medical equipment. The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance. An example of guidelines for a medical equipment medical equipment maintenance program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56:1999/ (R) 2013, Recommended Practice for a Medical Equipment Management

Program. Likewise, an example of guidelines for physical plant equipment may be found in the American Society for Healthcare Engineering (ASHE) 2009 document: Maintenance Management for Health Care Facilities. There may be similar documents issued by other nationally recognized organizations which CAHs might choose to reference.

Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are CAH employees or contractors. CAHs must be able to verify that qualified personnel, employees or contractors, are making the decisions to place equipment in the AEM program, performing the risk-based assessments, establishing the alternate equipment maintenance requirements, managing the AEM program, and performing the maintenance in accordance with the AEM policies and procedures.

In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.

In the case of facility equipment, a Healthcare Facility Management professional (e.g., facility manager, director of facilities, vice president of facilities) would be considered qualified.

The CAH must maintain records of the qualifications of CAH personnel who make decisions on placing equipment in an AEM program, and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

In determining whether or not to include equipment in an AEM program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the CAH must take into account the typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the CAH where it is used.

A CAH is expected to identify any equipment in its AEM program which is critical equipment, i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. Surveyors must focus their review of a CAH's AEM program on critical equipment in that program and the CAH's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for a CAH to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to:

- How the equipment is used and the likely consequences of equipment failure or

malfunction: would failure or malfunction of the equipment CAH-wide or in a particular setting be likely to cause harm to a patient or a staff person?

- How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.

- How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.

- Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations;

- Maintenance requirements of the equipment:

- Are they simple or complex?
- Are the manufacturer's instructions and procedures available in the CAH, and if so can the CAH explain how and why it is modifying the manufacturer's instructions?
- If the manufacturer's instructions are not available in the CAH, how does the CAH assess whether the AEM uses appropriate maintenance strategies?
- How readily can the CAH validate the effectiveness of AEM methods for particular equipment? For example, can the CAH explain how it ensures there is no reduction in the quality of the performance of biomedical equipment subjected to alternate maintenance methods?

- The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction; and

- Incident history of identical or very similar equipment – is there documented evidence, based on the experience of the CAH (or its third party contractor), or on evidence publicly reported by credible sources outside the CAH, which:

  - Provides the number, frequency and nature of previous failures and service requests?

  - Indicates use of an AEM strategy does not result in degraded performance of the equipment?

Generally multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The CAH is expected to be able to demonstrate to a surveyor the factors it considered in its risk

assessment for equipment placed in its AEM program.

Equipment not Eligible for Placement in the AEM Program:

Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:

- Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements. In these instances, the CAH must comply with these other Federal or State requirements, but State Surveyors conducting Federal surveys assess compliance only with the CAH Conditions of Participation (CoPs).

- Other CoPs require adherence to manufacturer's recommendations and/or set specific standards which preclude their inclusion in an AEM program. For example:

    - The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 485.623(d) have provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys. Further, §485.623(d)(7)(v) requires CAHs to adhere to the manufacturer's maintenance guidelines for alcohol-based hand-rub dispensers. Compliance with these requirements is assessed on Federal surveys.

- Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, must be maintained per manufacturer's recommendations.

- The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any other parties requesting them.

- New equipment for which sufficient maintenance history, either based on the CAH's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination must not be immediately included in the AEM program. New equipment must be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequencies would be safe. If a CAH later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the CAH must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.

Alternative Maintenance Frequencies or Activities

Maintenance strategies are various methodologies used for determining the most efficient

and effective maintenance activities and frequencies. Manufacturers' recommendations may be based on one or more such strategies. A CAH may also use one or more maintenance strategies for its AEM program in order to determine the appropriate maintenance, inspection, and testing activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM program.

In developing AEM maintenance strategies, CAHs may rely upon information from a variety of sources, including, but not limited to: manufacturer recommendations and other materials, nationally recognized expert associations, and/or the CAH's (or its third party contractor's) own experience. Maintenance strategies may be applied to groups or to individual pieces of equipment.

The CAH is expected to adhere strictly to the AEM activities or strategies it has developed.

Background Information on Types of Maintenance Strategies

- **Preventive Maintenance (Time-based Maintenance)** – a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. Most preventive maintenance is "interval-based maintenance" performed at fixed time intervals (e.g., annual or semi-annual), but may also be "metered maintenance" performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.

- **Predictive Maintenance (Condition-based Maintenance)** – a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer's recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.

- **Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance)** – a maintenance strategy based upon a "run it until it breaks" philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost, and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily

available in supply.

- **Reliability-Centered Maintenance** – a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.

Maintenance Tools

Tools (e.g., hand tools, test equipment, software, etc.) necessary for performing equipment maintenance must be available and maintained to ensure that measurements are reliable. Tools used for maintenance are not required to be those specifically recommended by the manufacturer, but tools utilized must be capable of providing results equivalent to those required by the equipment manufacturer.

AEM Program Documentation

For each type of equipment subject to the AEM program, there must be documentation indicating:

- The pertinent types and level of risks to patient or staff health and safety;

- Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the CAH is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations;

- Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 – 24 months." It could also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality.

- The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and

- Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual. (***NOTE***: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the CAH's required tracking of patient safety-related incidents. However, there is no

requirement to include operator failures in equipment maintenance documentation.)

When the CAH has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The CAH must have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program, the CAH is expected to address factors including, but not limited to:

- How equipment is evaluated to ensure there is no degradation of performance, particularly for equipment where such degradation may not be readily apparent to staff using the equipment, e.g., miscalibration.

- How incidents of equipment malfunction are investigated, including:

  - whether or not the malfunction could have been prevented, and what steps will be taken to prevent future malfunctions; and

  - how a determination is made whether or not the malfunction resulted from the use of an AEM strategy;

- The process for the removal from service of equipment determined to be unsafe or no longer suitable for its intended application; and

- The use of performance data to determine if modifications in the AEM program procedures are required.

Equipment Inventory

All CAH facility and medical equipment essential to the operation of the CAH, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program, is expected to be listed in an inventory which includes a record of maintenance activities. For low cost/low risk essential equipment, such as housekeeping cleaning equipment, it is acceptable for the inventory to indicate under one item the number of such pieces of equipment in the CAH, e.g., “15 vacuum cleaners for cleaning patient rooms and common areas.”

If the CAH is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.

To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, CAHs have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage

their equipment.

- A unique identification number;
- The equipment manufacturer;
- The equipment model number;
- The equipment serial number;
- A description of the equipment;
- The location of the equipment (for equipment generally kept in a fixed location);
- The identity of the department considered to “own” the equipment;
- Identification of the service provider;
- The acceptance date; and
- Any additional information the CAH believes may be useful for proper management of the equipment.

Survey Procedures §485.623(b)(1)

Interview personnel in charge of equipment maintenance:

- Determine if the CAH has identified equipment that is essential for both regular operations and in an emergency situation.
- Determine if the CAH has made adequate provisions to ensure the availability of those and equipment when needed.

Concerning facility and medical equipment:

- Interview equipment users when surveying the various units/departments of the CAH to determine if equipment failures are occurring and causing problems for patient health or safety.
- Determine if there is a complete inventory of equipment required to meet patient needs, regardless of ownership.
    - Is critical equipment readily identified?
    - If the CAH employs an AEM program, is equipment in this program readily identified?

- Determine if the CAH has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of CAH personnel responsible for the AEM program (if one is being used by the CAH) as well as for those performing maintenance.

- Determine if the CAH is able to demonstrate how it assures contractors use qualified personnel.

If the CAH is following the manufacturer-recommended equipment maintenance activities and frequencies:

In addition to reviewing maintenance records on equipment observed while inspecting various CAH locations for multiple compliance assessment purposes, select a sample of equipment from the CAH's equipment inventory to determine whether the CAH is following the manufacturer's recommendations. Critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. should make up the sample majority.

For the sample selected, determine if:

- The CAH has available manufacturer's recommendations (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.);

- Maintenance is being performed in accordance with manufacturer's recommendations

If a CAH is using an AEM for some equipment:

- Does the CAH's inventory include equipment which is not eligible for AEM, for example, any diagnostic imaging or therapeutic radiologic equipment?

- Determine if the CAH's development of alternate maintenance activities and frequencies for equipment in the AEM program as well as AEM activities are being performed by qualified personnel.

- Verify the CAH has documented maintenance activities and frequencies for all equipment included in the AEM program;

- Verify the CAH is evaluating the safety and effectiveness of the AEM program.

- If there is equipment on the inventory the CAH has identified as having such a very low level of risk that it has determined it can use a broad interval range or departmental "sweeps," ask the CAH for the evidence used to make this determination. Does it seem reasonable?

Select a sample of equipment in the AEM program. The majority of the sample must include critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. For the sample selected:

- Ask the responsible personnel to explain how the decision was made to place the equipment in an AEM program. Does the methodology used consider risk factors and make use of available evidence?

- Ask the responsible personnel to describe the methodology for applying maintenance strategies and determining alternative maintenance activities or frequencies for the sampled equipment. Can they readily provide an explanation and point to sources of information they relied upon?

- Determine if maintenance is being performed in accordance with the maintenance activities and frequencies defined in the AEM program.

  Verify the CAH is evaluating the safety and effectiveness of the AEM maintenance activities for this equipment and taking corrective actions when needed.

C-0920

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(b)(2) There is proper routine storage and prompt disposal of trash;

Interpretive Guidelines §485.623(b)(2)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(b)(2)

Survey Procedures are pending and will be updated in future release.

C-0922

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(b)(3) Drugs and biologicals are appropriately stored;

Survey Procedures §485.623(b)(3)

What standards, guidelines, State and Federal law is the CAH following to ensure that drugs and biologicals are appropriately stored (e.g., properly locked) in all storage areas?

C-0924

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(b)(4) The premises are clean and orderly; and

Interpretive Guidelines §485.623(b)(4)

"**Clean and orderly**" means an uncluttered physical environment where patients and staff can function safely. Equipment and supplies are stored in proper spaces, not in corridors. Spills are not left unattended. There are no floor obstructions. The area is neat and well kept. There is no evidence of peeling paint, visible water leaks, or plumbing problems.

C-0926

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(b)(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

Interpretive Guidelines §485.623(b)(5)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(b)(5)

Survey Procedures are pending and will be updated in future release.

C-0930

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(*c*) Standard: Life Safety From Fire

(1) Except as otherwise provided in this section,

(i) **the CAH must meet the applicable provisions** ***and must 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.)***

(ii) Notwithstanding paragraph (d)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

Interpretive Guidelines §485.623(*c*)(1)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(*c*)(1)

Survey procedures are pending and will be updated in future release.

C-0932

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(*c*)(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidelines §485.623(*c*)(3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(*c*)(3)

Survey procedures are pending and will be updated in future release.

C-0934

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(*c*)(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

Interpretive Guidelines §485.623(*c*)(4)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(*c*)(4)

Survey procedures are pending and will be updated in future release.

C-0936

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(*c*)(5) ***A CAH may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.***

Interpretive Guidelines §485.623(c)(5)

Guidance is pending and will be updated in future release.
Survey Procedures §485.623(c)(5)

Survey Procedures are pending and will be updated in future release.

C-0938

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(c)(6) When a sprinkler system is shut down for more than 10 hours, the CAH must:

(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.

Interpretive Guidelines §485.623(c)(6)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(6)

Survey Procedures are pending and will be updated in future release.

C-0940

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(c)(7) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.

(i) The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.

(ii) Special nursing care areas of new occupancies shall not exceed 60 inches.

Interpretive Guidelines §485.623(c)(7)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(7)

Survey Procedures are pending and will be updated in future release.

C-0942

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(*c*)(2) ***In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a CAH, but only if the waiver will not adversely affect the health and safety of the patients.***

Interpretive Guidelines §485.623(*c*)(2)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(2)

Survey Procedures are pending and will be updated in future release.

C-0944

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.623(d) Standard: Building safety. Except as otherwise provided in this section, the CAH must meet the applicable provisions and must 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).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a CAH.

(2) If application of the Health Care Facilities Code required under paragraph (e) of this section would result in unreasonable hardship for the CAH, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidelines §485.623(d)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(d)

Survey Procedures are pending and will be updated in future release.

Please refer to Appendix Z of the State Operations Manual to cite the specific Emergency Preparedness E-Tags, interpretive guidelines, and survey procedures.

C-0950

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.625 Condition of Participation: Emergency Preparedness

The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness plan must include, but not be limited to, the following elements:

(a) Emergency plan. The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of 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.

(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.

(b) Policies and procedures. The CAH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

(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.

(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) Communication plan. The CAH must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CAHs and hospitals.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) CAH's staff.

(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 as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(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.

(d) Training and testing. The CAH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) Training program. The CAH must do all of the following:

(i) 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.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Maintain documentation of the training.
(iii) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the CAH must conduct training on the updated policies and procedures.

(2) Testing. The CAH must conduct exercises to test the emergency plan at least twice per year. The CAH must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or,

(B) 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.

(ii) 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.

(iii) 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.

(e) Emergency and standby power systems. The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) Emergency generator location. The generator must be located in accordance with the location requirements found in 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), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) Emergency generator inspection and testing. The CAH must implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

(3) Emergency generator fuel. CAHs that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) Integrated healthcare systems. 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, the CAH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must 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 paragraphs (a)(2), (3), and (4) 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.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11,

2011.

(ii) Technical interim amendment (TIA) 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(xii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

C-0960

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.627 Condition of Participation: Organizational Structure

C-0962

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.627(a) Standard: Governing Body or Responsible Individual

The CAH has a 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.

Interpretive Guidelines §485.627(a)

The CAH must have only one governing body (or responsible individual) and this governing body (or responsible individual) is responsible for the conduct of the CAH as

an institution. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the CAH operations.

The governing body (or responsible individual) must determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

It is the responsibility of the governing body (or responsible individual) to appoint, with the advice of the medical staff, the individual practitioners to the medical staff. After considering medical staff recommendations, and in accordance with established CAH medical staff criteria and State and Federal laws and regulations, the governing body (or responsible individual) decides whether or not to appoint new medical staff members or to continue current members of the medical staff.

The governing body (or responsible individual) must ensure that the medical staff has bylaws that comply with State and Federal law and the requirements of the CAH CoP.

The governing body (or responsible individual) decides whether or not to approve medical staff bylaws submitted by the medical staff. The medical staff bylaws and any revisions must be approved by the governing body (or responsible individual) before they are considered effective.

The governing body (or responsible individual) must ensure that the medical staff is accountable to the governing body (or responsible individual) for the quality of care provided to patients. The governing body (or responsible individual) is responsible for the conduct of the CAH and this conduct would include the quality of care provided to patients.

All CAH patients must be under the care of a member of the medical staff or under the care of a practitioner who is under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner granted privileges to provide or order that care and is in accordance with State law.

Criteria for selection of both new medical staff members and selection of current medical staff members for continued membership must be based on:

- Individual character;
- Individual competence;
- Individual training;
- Individual experience; and
- Individual judgment

Survey Procedures §485.627(a)

- Verify that the CAH has an organized governing body or has written documentation that identifies the individual that is responsible for the conduct of the CAH operations.

- Review documentation and verify that the governing body (or responsible individual) has determined and stated the categories of practitioners that are eligible candidates for appointment to the medical staff.

- Have the facility's operating policies been updated to fully reflect its responsibilities as a CAH (e.g., PA responsibilities, provision of required CAH direct services)?

- What evidence (e.g., minutes of board meetings) demonstrates that the governing body or the individual who assumes responsibility for CAH operation is involved in the day-to-day operation of the CAH and is fully responsible for its operations?

- Evaluate records of medical staff appointments to substantiate the governing body's (or responsible individual's) involvement in appointments of medical staff members.

- Confirm that the governing body (or responsible individual) appoints all members to the medical staff in accordance with established policies based on the individual practitioner's scope of clinical expertise and in accordance with Federal and State law.

- Verify that the medical staff operates under current bylaws that are in accordance with Federal and State laws and regulations.

- Verify that the medical staff operates under current bylaws, rules and policies that have been approved by the governing body (or responsible individual).
- Verify that any revisions or modifications in the medical staff bylaws, rules, and policies, have been approved by the medical staff and the governing body (or responsible individual). For example, look at the bylaws and check for date of last review and initials by the person(s) responsible.

- Verify that the governing body (or responsible individual) is periodically apprised of the medical staff evaluation of patient care services provided in the CAH, at every patient care location of the CAH.

- Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medial staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body (or responsible individual) for the quality of services provided.

- Verify that there are written criteria for staff appointments to the medical staff.

- Verify that selection of medical staff for membership, both new and renewal, is based upon an individual practitioner's compliance with the medical staff's membership criteria.

- Verify that at a minimum, criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

C-0964

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.627(b) Standard: Disclosure

§485.627(b)(*1*) The person principally responsible for the operation of the CAH; and

Survey Procedures §485.627(b)(*1*)

How does the CAH implement its policy or procedure for reporting changes in operating officials to the State agency?

C-0966

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.627(b)(*2*) The person responsible for medical direction

Survey Procedures §485.627(b)(*2*)

How does the CAH implement its policy or procedure for reporting changes in medical director to the State agency?

C-0970

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631 Condition of Participation: Staffing and Staff Responsibilities

C-0971

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(a) Standard: Staffing

(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

Interpretive Guidelines §485.631(a)(1)

A CAH may operate with a MD/DO on staff as well as with any combination of mid-level practitioners.

Survey Procedures §485.631(a)(1)

- Review listings or organizational charts showing the names of all staff MD/DOs, nurse practitioners, clinical nurse specialists and physician assistants on the CAH staff.

- Review work schedules showing normal CAH hours of operation and coverage by members of the CAH staff.

C-0972

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(a)(2) Any ancillary personnel are supervised by the professional staff.

Survey Procedures §485.631(a)(2)

Use organizational charts and staff interviews to determine how the CAH ensures that the professional staff supervises all ancillary personnel.

C-0974

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(a)(3) The staff is sufficient to provide the services essential to the operation of the CAH.

Survey Procedures §485.631(a)(3)

- How does the CAH ensure that staff coverage is sufficient to provide essential services at the facility (e.g., emergency services, direct services, and nursing services)?

- Review staffing schedules and daily census records.

C-0976

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(a)(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

Interpretive Guidelines §485.631(a)(4)

Section 485.635(b)(1) requires CAHs to provide “those diagnostic and therapeutic services and supplies that are commonly furnished in “a physician’s office” such as low

intensity outpatient services. In order to demonstrate compliance, a CAH must demonstrate that a practitioner is 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. This requirement does not mean the CAH must have a practitioner physically present in the facility 24 hours per day, nor does it require their presence 24 hours per day when the CAH has inpatients, including swing-bed patients.

Survey Procedures §485.631(a)(4)

- If the CAH does not have regular announced hours of operation, ask the individual who is principally responsible for the operation of the CAH, when is the CAH is open to the public to provide outpatient services.

- What kinds of arrangements have been made by the CAH to ensure that a practitioner is available on site at all times the CAH operates to furnish patient care services?

C-0978

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(a)(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

Survey Procedures §485.631(a)(5)

Review nursing staff schedules to ensure that a registered nurse, clinical nurse specialist or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

C-0980

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(b) Standard: Responsibilities of the Doctor of Medicine or Osteopathy

C-0981

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

485.631(b)(1) The doctor of medicine or osteopathy--

> **(i) Provides medical direction for the CAH'S health care activities and consultation for, and medical supervision of, the health care staff;**

Interpretive Guidelines §485.631(b)(1)(i)

A CAH must have a MD/DO on its staff. That individual must perform all of the medical oversight functions.

Survey Procedures §485.631(b)(1)(i)

What evidence demonstrates that an MD/DO provides medical direction for the CAH'S health care activities and is available for consultation and supervision of the CAH health care staff?

C-0982

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(b)(1)(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH'S written policies governing the services it furnishes.

Survey Procedures §485.631(b)(1)(ii)

- What evidence demonstrates that an MD/DO has participated in the development of policies governing CAH services?
- How does the CAH ensure that an MD/DO periodically reviews these policies?

C-0984

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(b)(1)(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH'S patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

Survey Procedures §485.631(b)(1)(iii)

- How does the CAH ensure that an MD/DO periodically reviews CAH patient records in conjunction with staff mid-level practitioners and provides medical care to CAH patients?
- What evidence demonstrates that there is a periodic review of patient records by the CAH MD/DO(s)?

C-0986

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(b)(1)

[The doctor of medicine or osteopathy-]

(iv) Periodically reviews and signs the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(v) Periodically reviews and signs a sample of outpatient records of patients cared

for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician.

Interpretive Guidelines §485.631(b)(1)(iv) & (v)

All inpatient records for patients whose treatment is/was managed by a nonphysician practitioner in the CAH, i.e., nurse practitioners, clinical nurse specialists, or physician assistants, must be reviewed periodically by a CAH MD/DO who must sign the records after the review has been completed. The MD/DO review is expected to cover all applicable inpatient records open at the time of the review, as well as all applicable inpatient records closed since the last review.

In the case of inpatients whose care is/was managed by an MD/DO, as evidenced by an admission order, progress notes, and/or medical orders, etc., but who also receive services from a non-physician practitioner, a subsequent MD/DO review of the inpatient record is not required.

In States where State law requires a collaborating physician to review medical records, co-sign medical records, or both for outpatients whose care is managed by a non-physician practitioner, i.e., a nurse practitioner, a clinical nurse specialist, a certified nurse midwife, or a physician assistant, a CAH MD/DO must review and sign a sample of outpatient records. The outpatient medical record sample reviewed must be representative of all non-physician practitioners providing care to patients of the CAH. The CAH determines by policy the size of the sample reviewed and signed; however, CMS recommends, but does not require, a sample size of 25% of the records of all outpatient encounters managed by a non-physician practitioner since the prior MD/DO review. If State law requires MD/DO review or signature of a larger percentage of the outpatient records, the CAH must comply with State law.

In States where no physician record review or physician co-signature is required for patients managed by a non-physician practitioner, an MD/DO is not required to review or sign outpatient records of such patients.

Neither the regulation nor the preamble to the final rule adopting this regulation (79 Fed. Reg. 27105, May 12, 2014) specify a particular timeframe to satisfy the requirement for "periodic" review, but the CAH must specify a maximum interval between inpatient record reviews in its policies and procedures. The CAH is expected to take into account the volume and types of services it offers in developing its policy. For example, a CAH that has only four certified beds and one MD/DO on staff and which does not always have an inpatient in house would likely establish a different requirement for inpatient record review than a CAH with 25 certified beds, multiple MDs/DOs on staff and a high inpatient occupancy rate. Further, there is no regulatory requirement for the review of records to be performed on site and in person. Thus, if the CAH has electronic medical records that can be accessed and digitally signed remotely by the MD or DO, this method of review is acceptable. Therefore, CAHs with and without the capability for electronic record review and signature might also develop different policies for the maximum

interval between reviews.

Survey Procedures §485.631(b)(1)(iv) & (v)

Select a sample of inpatient and outpatient records, including both open and closed records.

- For inpatient records of patients whose care is/was managed by a non-physician practitioner, verify that:
    - An MD/DO has reviewed and signed all records that were open at the time of the review, and all inpatient records that were closed since the MD/DO's last review; and
    - That reviews take place within the timeframe specified by the CAH's policy.
    - If State law requires a physician to review or co-sign (or both) any outpatient records of patients whose care is/was managed by non-physician practitioner, determine whether an MD or DO has reviewed and/or co-signed a representative sample of these records within the timeframe specified in the CAH's policies.
    - Ask the CAH how many outpatient encounters are managed by non-physician practitioners, what sample size its policy requires to have an MD/DO review, and what timeframe its policy specifies for reviews.
    - Ask the CAH to explain how it ensures the sample is representative of the various non-physician practitioners as well as of the various types of outpatient services they provide.
    - Ask the CAH to describe the method it uses to make sure that reviews are performed in a timely manner on a sample that complies with the CAH's policy.
    - Review selected records from the CAH's outpatient sample to verify that there is evidence of an MD or DO review and/or signature.

C-0988

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(b)(2) A doctor of medicine or osteopathy is present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the CAH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

Interpretive Guidelines §485.631(b)(2)

An MD/DO must be present in the CAH for sufficient periods of time to provide overall medical direction, consultation and supervision of the healthcare services the CAH furnishes. Being "present" in the CAH means being physically on-site in the CAH. The regulation does not specify a minimum amount of time an MD/DO must spend on-site that applies to all CAHs. Instead, CAHs have the flexibility to develop policies appropriate for their circumstances. With the development of technology such as telemedicine, a CAH may use a variety of ways and timeframes for MDs/DOs to provide the necessary medical direction and oversight. For CAHs that offer a range of more complex services, have more than one MD/DO on staff, and have busy emergency departments and/or extensive outpatient services, an on-site visit by an MD/DO only once every week or every two weeks, for example, would be grossly inadequate. On the other hand, a bi-weekly on-site visit could be unduly burdensome as well as unnecessary for a small CAH in a remote rural area that offers very limited services and has a low patient volume.

CAHs are expected to have adequate staffing to provide the services they have chosen to furnish, including staffing or supervision by MDs/DOs as applicable. CMS expects each CAH to evaluate its services and adjust its MD/DO on-site schedule accordingly, as an appropriate MD/DO schedule must reflect the volume and nature of services offered.

Note that §485.618(d) also establishes a maximum timeframe for an MD, DO, PA, NP, or clinical nurse specialist to be on-call and available to be on-site to provide emergency care, and that §489.20(r)(2) requires the CAH to maintain an on-call list of MDs/DOs who are available to be on-site as part of the CAH's Emergency Medical Treatment and Labor Act obligations. The CAH must consider all pertinent requirements when developing its policies for MD/DO presence on site.

In addition to requiring an MD or DO to be on-site for sufficient periods of time, consistent with the requirement at §485.618(e), the CAH must also ensure an MD/DO is available through direct radio, telephone or other form of electronic communication, such as video conferencing, for consultation, assistance in handling patient medical emergencies and referral of patients to other healthcare facilities. An MD/DO providing telemedicine services to the CAH may be used to fulfill the requirement for availability via telecommunications. Further, consistent with the requirements for CAH provision of emergency services at §485.618(d), unless a, PA, NP, or clinical nurse specialist with training in emergency care is immediately available via one of these telecommunication methods and available on site within the timeframe specified at §485.618(d)(1), an MD or DO must fulfill these requirements.

Survey Procedures §485.631(b)(2)

- Does the CAH have policies and procedures that address the minimum amount of time and frequency of MD or DO presence on-site at the CAH? Can the CAH demonstrate how its policy reflects the volume and type of services the CAH provides such that there is sufficient MD/DO presence on-site to support the services provided?

- Is there documentation showing that an MD or DO is on-site for the frequency and duration specified in the CAH's policies?

- Can the CAH demonstrate that an MD or DO is always available by telecommunications contact for consultation, assistance and/or patient referral?

C-0990

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(c) Standard: Physician Assistant, Nurse Practitioner, and Clinical Nurse Specialist Responsibilities

C-0991

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(c)(1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH'S staff--

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

Survey Procedures §485.631(c)(1)(i)

- Interview any mid-level professional staff to ascertain their level of involvement in CAH policy development, execution, and periodic review.

- Does the CAH ensure that policies are updated to remain consistent with State standards of practice requirements for mid-level practitioners?

C-0993

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

485.631(c)(1)(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

Survey Procedures §485.631(c)(1)(ii)

How does the CAH ensure that mid-level practitioners at the CAH participate with an MD/DO in the review of their patients' health records?

C-0995

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(c)(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH'S policies.

Survey Procedures §485.631(c)(2)(i)

- Review policies and procedures.
- Interview mid-level practitioners to gauge their knowledge and application of CAH policies.

C-0997

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(c)(2)(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

Survey Procedures §485.631(c)(2)(ii)

Verify that there are policies and procedures for transferring patients to other facilities.

C-0998

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(c)(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

Interpretive Guidelines §485.631(c)(3)

The CAH regulations do permit licensed mid-level practitioners, as allowed by the State, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level practitioner to admit and care for patients, as allowed by State law, the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

Survey Procedures §485.631(c)(3)

- Verify that admitting privileges are limited to those categories of practitioners as allowed by State law.
- Verify that patients are 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.

- Verify that an MD/DO is responsible for and is monitoring the care of each Medicare or Medicaid patient for all medical problems during the hospitalization.

- 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.

C-0999

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.631(d) Standard: Periodic review of clinical privileges and performance. The CAH requires that—

(1) 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 member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH.

(2) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—

(i) One hospital that is a member of the network, when applicable;

(ii) One Quality Improvement Organization (QIO) or equivalent entity;

(iii) One other appropriate and qualified entity identified in the State rural health care plan;

(iv) 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

(v) 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 paragraphs (d)(2)(i) through (iii) of this section.

(3) The CAH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.

Interpretive Guidelines §485.631(d)(1),(2)(i)(ii)(iii)(iv)(v),(3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.631(d)(1),(2)(i)(ii)(iii)(iv)(v),(3)

Survey Procedures are pending and will be updated in future release.

C-1004

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635 Condition of Participation: Provision of Services

Interpretive Guidelines §485.635

This condition establishes requirements related to patient care policies, required CAH services, and CAH services provided through agreements or arrangements. Assessment of the manner and degree of noncompliance with any one of the following standards in this condition is required in order to determine whether there is noncompliance with this condition.

C-1006

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(a) Standard: Patient Care Policies

(1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

Interpretive Guidelines §485.635(a)(1)

The CAH must have written policies governing the health care services the CAH furnishes and these policies must be consistent with applicable State law. As discussed in relation to the requirements at §485.608, CMS does not interpret or enforce local law; that is the responsibility of State or local government. If surveyors identify practices related to delivery of health care services that they believe are not consistent with State law, they should refer the matter to the appropriate State authorities.

The regulation requires the CAH to furnish its health care services in accordance with its written policies. In other words, the CAH must not only have written policies, but must actually adhere to them in delivering services.

Survey Procedures §485.635(a)(1)

- Verify that the CAH has written policies covering the health care services that are furnished in the CAH.

- Observe staff delivering health care services to patients. Is the actual provision of services consistent with the CAH's written policies?

§485.635(a)(2) The policies are developed with the advice of members of the CAH's professional healthcare staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1).

§485.635(a)(4) These policies are reviewed at least *biennially* by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

Interpretive Guidelines §485.635(a)(2) & (4)

The CAH's written policies governing patient care services must be developed with the advice of members of the CAH's professional healthcare staff. This advisory group must include:

• At least one MD or DO; and

• One or more physician assistants, nurse practitioners, or clinical nurse specialists, at least one of these non-physician practitioners if these professionals are included in the CAH's healthcare staff, as permitted at §485.631(a)(1). A CAH with no non-physician practitioners on staff is not required to obtain the services of an outside non-physician practitioner to serve on the advisory group.

The advisory group not only makes recommendations for new CAH patient care policies, but is also expected to review the existing patient care policies at least *every 2 years* and, if it concludes that changes are needed, recommend those changes. Policies must be reviewed and, as applicable, revised more frequently when required, for example, in response to a change in Federal or State regulations to which the CAH is subject.

The CAH must maintain documentation that provides evidence that the advisory group has conducted its reviews and made recommendations concerning patient care policies.
Although a CAH's patient care policies are developed and periodically reviewed with the advice of members of the CAH's professional healthcare staff, the final decision on the content of the written policies is made by the CAH's governing body or individual responsible for the CAH, consistent with the requirement at §485.627(a). If recommendations of the advisory group are rejected, the governing body must include in the record of its adoption of the final written policies its rationale for adopting a different policy than that which was recommended.

Survey Procedures §485.635(a)(2) & (4)

• Review any meeting minutes for the group of healthcare professionals that advises the CAH's governing body or responsible individual on patient care policies to determine if the group's composition meets the regulatory requirements.

• Interview all staff listed as part of the policy development advisory group to determine if they had the opportunity to express opinions and make recommendations to the group, for the group's consideration as a group recommendation.

• 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?

• Is there evidence that the group reviewed the CAH's existing policies at least *every 2 years* and indicated whether or not it recommended any changes?

C-1010

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(a)(3) The policies include the following:

(i) A description of the services the CAH furnishes, including those furnished through agreement or arrangement.

Interpretive Guidelines §485.635(a)(3)(i)

The CAH's written patient care policies must describe the types of health care services that are available at the CAH, including whether those services are furnished by CAH staff or through agreements or arrangements. The types of health services described must include services provided both on-site and off-site.

Healthcare services provided through agreement or under arrangement include those provided through formal contracts, informal agreements, or lease arrangements. Services furnished under arrangement or by agreement may include both healthcare services provided on-site at the CAH by a contractor, as well as healthcare services provided to the CAH's patients outside the CAH. For example, the CAH may contract with a laboratory to provide certain laboratory services on-site, and others at an off-site laboratory; or it may contract with an imaging center for provision of certain advanced radiologic diagnostic services, such as MRI, to CAH inpatients who are temporarily moved to the center for the test and then returned to the CAH.

The descriptions of the services provided may be brief but informative, for example, statements like "taking complete medical histories, providing complete physical examinations, laboratory tests including" (with a list of tests provided), radiologic tests and their interpretation, surgery (with a list of the types of surgery available) would satisfy this requirement.

Survey Procedures §485.635(a)(3)(i)

Verify that the CAH's healthcare policies identify and describe all healthcare services offered by the CAH, including services provided under arrangement or by agreement.

C-1012

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(a)(3) [The policies include the following:]

(ii) Policies and procedures for emergency medical services.

Interpretive Guidelines §485.635(a)(3)(ii)

The CAH's written patient care policies must include its policies and procedures for providing emergency services, addressing all of the requirements at 42 CFR 485.618. See the interpretive guidelines for §485.618.

Survey Procedures §485.635(a)(3)(ii)

Verify that written policies and procedures detail how the CAH plans to comply with the requirements of 42 CFR 485.618. Do the written policies and procedures address the following:

- How the CAH provides 24 hour emergency care to its patients?
- 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?
- What types of personnel are available to provide emergency services and what are their required onsite response times?

Do they address how the CAH coordinates with local emergency response systems?

C-1014

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(a)(3) [The policies include the following:]

(iii) 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.

Interpretive Guidelines §485.635(a)(3)(iii)

The written policies for the CAH's healthcare services must include guidelines, such as general instructions and protocols, for the medical management of patients' health

problems. The guidelines may include directly or reference protocols that are documented elsewhere for the treatment of medical conditions that are commonly presented in the CAH.

Because nurse practitioners, clinical nurse specialists, and physician assistants may play a large role in patient care at a CAH, the CAH's policies must 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. The CAH's policies must also address the circumstances under which patient referral outside the CAH should occur.

The policies must also address maintenance of medical records, consistent with the requirements at §485.638. See interpretive guidelines for §485.638.

The policies must also address the CAH's procedures for periodical review and evaluation of its services, consistent with the requirements of §485.641. See interpretive guidelines for §485.641.

Survey Procedures §485.635(a)(3)(iii)

Verify that the CAH's written patient care policies:

- Address the circumstances under which consultation with other CAH professional healthcare staff, or referral outside the CAH should occur;
- Address maintenance of medical records, in a manner consistent with the requirements at §485.638; and
- Address periodic evaluation of the CAH's healthcare services, in a manner consistent with the requirements at §485.641.

C-1016

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(a)(3) [The policies include the following:]

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must 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.

Interpretive Guidelines §485.635(a)(3)(iv)

The CAH must ensure that drugs and biologicals are managed in a manner that is safe and appropriate, and that its pharmacy system provides all drugs and biologicals prescribed by the CAH's practitioners in a timely manner for administration to its

patients.

The CAH's written patient care policies must include rules governing pharmacy services within the CAH. The CAH's rules may be in the form of pharmacy services policies and procedures. These CAH rules must address storage, handling, dispensing, and administration of drugs and biologicals within the CAH. The rules must be in accordance with accepted professional principles of pharmacy and medication administration practices. Accepted professional principles include compliance with applicable Federal and State law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations, including, but not limited to: U.S. Pharmacopeia (www.usp.org), the American Society of Health-System Pharmacists (http://www.ashp.org/), the Institute for Safe Medication Practices (http://www.ismp.org/default.asp), the National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org); the Institute for Healthcare Improvement (http://www.ihi.org/ihi); or the Infusion Nurses Society (http://www.ins1.org).

The CAH's rules must address the following:

- **Responsibility for pharmacy services**

  The CAH must identify the qualifications for and designate an individual who has overall responsibility for the CAH's pharmacy services, including development of the rules governing pharmacy services. The CAH and the responsible individual must ensure adherence to State law requirements governing who may perform pharmacy services as well as requirements for supervision of pharmacy staff. The CAH and responsible individual are also responsible for assuring that pharmacy practices adhere to accepted professional principles. The CAH is expected to be able to identify the sources of accepted professional pharmacy practices that it relies upon in developing the CAH's pharmacy rules, policies and procedures.

- **Storage of drugs and biologicals, including the location of storage areas, medication carts, and dispensing machines**

  Consistent with accepted professional principles, CAHs must demonstrate appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

- **Proper environmental conditions**

  Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for storage of drugs, the CAH is expected to follow the labeled conditions. CAHs must exercise caution in dispensing or using any drug or biological that is not labeled to indicate proper storage conditions or that may have been stored under inadequate conditions.

- **Security**

The CAH must have policies and procedures that are consistent with State and Federal law to address who is authorized access to the pharmacy or drug storage area. Drugs and biologicals must be stored in a secure manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional (for example, ambulatory infusion), they are generally considered secure. Areas restricted to authorized personnel only would generally be considered "secure areas."

CAHs are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff are actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked.

Medication carts, anesthesia carts, epidural carts and other non-automated medication carts containing drugs or biologicals (hereafter, all referred to as "carts") must be secured when not in use. A CAH's policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety.

If a cart containing drugs or biologicals is in use and unlocked, someone with authorized access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with State and Federal law and CAH policy is authorized access to the drugs and biologicals in the cart. That individual must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

- **Handling drugs and biologicals**

  "Handling" includes reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug's manufacturer. "Handling" also includes compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either CAH staff or a contracted pharmacy service. CAHs use many medications that need to be reconstituted, mixed or compounded. Whether furnishing the services via CAH staff or a contractor, the CAH is responsible for proper handling of drugs and biologicals.

  Except in emergencies or when not feasible (for example, when the product's stability is short), only the pharmacy performs reconstituting, mixing, admixing or compounding.

- **Compounding**

All compounding of medications used or dispensed by the CAH must be performed consistent with accepted professional principles applicable to both sterile and non-sterile compounding.

Compounded medications, whether non-sterile or sterile, may be subject to physical and chemical contamination and unintended variations in strength. Microbial contamination and bacterial endotoxins are particularly hazardous with respect to compounded medications that are intended to be sterile.

A CAH pharmacy must be administered in accordance with accepted professional principles, and therefore must be able to demonstrate how it assures that all sterile and non-sterile compounded preparations dispensed and/or administered to the CAH's patients are being compounded consistent with accepted professional standards to ensure safety. The CAH must be able to provide evidence that the CAH's standard operating procedures for compounding, if performed in-house, and for quality oversight of compounding, regardless of source, are consistent with accepted professional principles.

Compounding may take place in the CAH's pharmacy on-site and/or the CAH may obtain some or all of its compounded medications from external sources. Regardless of the source, if accepted standards for safe compounding are not met, compounded medications may contain less or more than the intended dose and/or may be chemically or microbiologically contaminated, with potentially serious adverse consequences for the patients who receive them.

Use of Outside Compounders (also known as Outsourcing Facilities)

The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an "outsourcing facility." The law defines an "outsourcing facility" as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA. Facilities that elect to register as outsourcing facilities:

- Must comply with the FDA's Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA's publishes the most current versions of its draft and final regulations and guidance related to compounding on its website: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Phar

macyCompounding/default.htm ;

- Will be inspected by FDA according to a risk-based schedule; and

- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

In a January 2014 letter to purchasers of compounded medications (available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that,"[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling."

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at: http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm

Note that these registered outsourcing facilities are also popularly referred to as "503B pharmacies."

- **Use of Compounding Pharmacies**

If a CAH obtains compounded medications from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the CAH must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

- Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?

Note that these types of compounding pharmacies are also popularly referred to as "503A pharmacies" and generally are subject to oversight only by their State pharmacy board.

For Information – Not Required/Not to be Cited

ASHP Research and Education Foundation™ "Outsourcing Sterile Products Preparation: Contractor Assessment Tool"

The ASHP Research and Education Foundation™ offers a tool that CAHs may find useful for assessing vendors that provide compounded sterile preparations. http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx and click on "Start using Sterile Products Outsourcing Tool now."

- **Dispensing drugs and biologicals**

  CAHs must comply with applicable State law that governs the qualifications, certification, or licensure of staff who dispense drugs and biologicals. There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery.

  Medications must be dispensed in a timely manner. The CAH must have a system that ensures medication orders get to the pharmacy promptly and medications are available for administration to patients when needed, including when the pharmacy is not open. Methods to accomplish this when the pharmacy is not open could include, but are not limited to, one or more of the following: automated dispensing units outside the pharmacy, night cabinets, contracted services after hours via telepharmacy contracting, on-call pharmacists, etc.

  Concerns, issues or questions pharmacy staff have about any medication order must be clarified with the prescribing practitioner or another practitioner responsible for the care of the patient before dispensing.

  A CAH may utilize a unit dose system, individual prescription, floor stock system or a combination of these systems, properly stored.

  - Automated Dispensing Cabinets (ADCs) for medications are a secure option for medication storage since they ensure locked storage of medications and allow for electronic tracking of controlled substances and other drugs. These cabinets often have embedded security features, such as login and password or biometric identification so that they can only by accessed by authorized personnel.

  - Policies and procedures must address who can access medications during after-hours.

For Information Only – Not Required/Not to be Cited

In addition to the required pharmacy policies and procedures above, a well-designed pharmacy service would have policies and procedures addressing medication safety practices such as:

- Implementation of a do-not-use abbreviation list. CAHs may wish to refer to lists offered by the Institute for Safe Medication Practices (http://www.ismp.org/tools/errorproneabbreviations.pdf) or The Joint Commission (http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf) ;

- A high alert drug list. CAHs may wish to refer to a high alert drug list offered by the Institute for Safe Medication Practices (https://www.ismp.org/tools/institutionalhighAlert.asp);

- For specific high alert medications designated by the CAH, having two health professionals independently check doses CAHs may wish to refer to guidance from the Institute for Safe Medication Practices concerning appropriate use of double-checks (http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=51);

- Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;

- Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit doses that have been repackaged by the pharmacy;

- The CAH consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system; and

- The American Society of Health-System Pharmacists (ASHP) recommends that floor stocks of medications should be limited to medications for emergency use and routinely used safe items (e.g. mouthwash, antiseptic solutions).

When utilizing automated dispensing cabinets (ADCs), the Institute for Safe Medication Practices recommendations include the following: (See: http://www.ismp.org/Newsletters/acutecare/articles/20090212.asp and http://www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf) Security processes are established to ensure adequate control of medications outside of the pharmacy and to reduce the potential for medication diversion from ADCs.

- Utilize biometric user identification or, at a minimum, change user passwords quarterly.

- Link the ADC to the pharmacy computer to allow for patient “profiling,” so that a pharmacist can review each medication order and screen it for safety before the drug is dispensed or accessed by the nurse or other healthcare professional.

- Limiting the availability of overrides to the ADC system.
- Limiting access to drugs based on the patients profile so to decrease medication selection errors.
- Store each medication and strength in an individual lidded ADC compartment that opens only when the specific medication is selected.
- Document the destruction of medication waste at the time of removal of the medication whenever possible. Record this waste via the ADC, and match the administered dose with ordered dose. Have a process to routinely review/reconcile the documented medication waste.
- Return all medications to a common secure one-way return bin that is maintained by pharmacy, not to an individual pocket or bin within the ADC.

- **Administration of drugs and biologicals to patients**

  CAHs must comply with applicable State law that governs the qualifications, certification, or licensure of staff who administer drugs and biologicals and must adhere to accepted standards of practice for medication administration. See the guidance for §485.635(d)(3) concerning medication administration by CAH nursing staff.

- **Record keeping for the receipt and disposition of all scheduled drugs**

  The U.S. Department of Justice Drug Enforcement Administration (DEA) classifies drugs that are controlled in accordance with the Controlled Substances Act into five "schedules", ranging from Schedule I substances, which have a high potential for abuse and no currently accepted medical use in treatment, to Schedule V substances, which have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. The CAH is required to accurately track the receipt and disposition of all scheduled drugs used in the CAH. Components of a record system for scheduled drugs would include:

  - Locked storage of scheduled drugs when not in use.
  - Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.
  - The record system tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer. This system provides

documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- Any discrepancies in count are reconciled promptly. The CAH is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

- **Ensuring that outdated, mislabeled, or otherwise unusable drugs are not used for patient care**

The CAH must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use. This would include drugs that are the subject of a manufacturer's recall.

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer's approved labeling.

A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available. The CAH must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer

For individual drug containers: each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD. In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.

If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date. and/or, if applicable, a BUD.

For Information Only

Certain provisions of the FDCA address the labeling of prescription drugs generally (e.g., section 503(b)(2) of the FDCA). Section 503B of the FDCA includes labeling requirements for drugs compounded by registered outsourcing facilities (see section 503B(a)(10)). Although CAHs are expected to comply with these requirements, surveyors conducting a Medicare survey do not assess compliance with other Federal law.

- **Assessing Adverse Drug Reactions & Medication Administration Errors**

In accordance with §485.635(a)(3)(v) the CAH must have a system for staff to report adverse drug reactions and medication administration errors. The pharmacy services is expected to assess all such reports to determine if problems or errors in pharmacy services caused or contributed to the adverse reaction or medication administration error. Where such problems or errors are identified, the CAH is expected to take effective action to address the identified issues.

Survey Procedures §485.635(a)(3)(iv)

- Has the CAH adopted pharmacy rules that were developed with the advice of the CAH's professional healthcare staff?

- Has the CAH identified the qualifications of and designated an individual who is responsible for developing and implementing the rules for the CAH's pharmacy services, consistent as applicable with State and Federal law?

    - Review the qualifications of the responsible individual to verify that they satisfy the CAH's written criteria.

- Ask CAH practitioners, nursing and pharmacy staff whether the CAH's pharmacy service dispenses prescribed drugs and biologicals in a timely manner. If there is evidence in medical records reviewed of late administration of prescribed medications, probe to determine whether delays are due to pharmacy dispensing delays.

- Ask the individual responsible for CAH pharmacy services what sources of accepted professional principles of pharmacy practice the CAH relies upon in developing and implementing its CAH pharmacy rules, policies and procedures. Is the source(s) a nationally recognized source?

- Are drugs and biologicals stored in a secure manner?

    - Are drugs stored in areas not accessible to unauthorized personnel?

    - When drugs or biologicals are kept in a patient care area during hours when patient care is not provided, are they locked up?

- Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.

- Determine if the CAH has a system that tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacturer.
  - Does this system provide documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs?

  - Review records of scheduled drugs over a recent time period. Is there evidence of discrepancies, and if so, of efforts by the CAH to reconcile and address the discrepancies?

  - Interview the person responsible for pharmacy services as well as other CAH staff to determine their understanding of the CAH's controlled drug policies.
- Verify that only a pharmacist or other personnel authorized in accordance with State and Federal law compound, label and dispense drugs or biologicals, regardless of whether the services are provided by CAH staff or under arrangement.

  - Interview pharmacy and CAH staff to determine how drugs and biologicals are dispensed;

  - Observe on-site dispensing operations;

  - Review records to see if drugs and biologicals are removed from the pharmacy by unauthorized personnel;

- Do the CAH's pharmacy rules address ADCs, if used within the CAH? Are the ADCs being used in the manner prescribed by the CAH's rules?

- Can the CAH demonstrate that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices?
  - Does the individual responsible for the pharmacy service, including compounding policies, practices and quality assurance within the CAH, and selecting and overseeing any external sources of compounded medications, have the expertise to conduct effective quality oversight?

  - Can the individual responsible for the pharmacy services explain the risk level(s) of the CSPs being produced in-house and/or obtained from external sources?

  - If any CSPs are produced in the CAH:
  - Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the CAH and/or to

assess how this is done by external source(s) of CSPs. Is there evidence that the BUDs are determined consistent with the CAH's rules, policies and procedures?

- Interview staff who engage in sterile and non-sterile compounding. Are they knowledgeable about applicable levels of aseptic practices?

- Ask the individual responsible for pharmacy services to demonstrate how the following are accomplished to ensure that sterile compounding practices are consistent with standards for the risk level(s) of CSPs being produced for/dispensed to CAH patients:

  - Verification of compounding accuracy and sterility.

  - Environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection;

  - Personnel training and competency assessment, including but not limited to accuracy/precision in identifying and measuring ingredients; cleansing and garbing; aseptic manipulation skills; environmental quality and disinfection; appropriate work practices within and adjacent to the direct compounding area; verification/calibration of equipment; sterilization; and post-production quality checks.

- Review the CAH's procedures for maintaining the quality of CSPs during storage, transport and dispensing. Are CSPs packaged in a manner to protect package integrity and sterility? How are CSP-specific requirements with respect to motion, light exposure, temperature and potentially hazardous contents addressed? How does the CAH ensure that such information is effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable?

- Review the pharmacy rules, policies and procedures for determining BUDs (for medications compounded in-house as well as from external sources).

  - Can the CAH demonstrate that the policies and procedures are consistent with or more stringent than the applicable *nationally accepted* standards?

  - Can it demonstrate that the pharmacy personnel assigned to determining BUDs when a manufacturer's instructions are not available have the expertise and technical support needed to properly conduct the assessments needed to make such determinations in a manner consistent with standards and hospital policies?

- Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the CAH and/or to assess how this is done by external source(s) of CSPs. Is there evidence that the

BUDs are determined consistent with the CAH's rules, policies and procedures?

- If the CAH obtains compounded products from an external source that is not an FDA registered outsourcing facility, can it demonstrate that it systematically evaluates and monitors whether these sources adhere to accepted professional principles for safe compounding?

- Does the CAH have a process for following up on adverse drug reactions and errors in medication administration reported by CAH staff in accordance with §485.635(a)(3)(v)? If any have been reported, did the CAH thoroughly assess and analyze them? Has the CAH taken effective preventive action to address identified issues?

- Spot-check the labels of individual drug containers to verify that they contain the following minimal information:
  - Each patient's individual drug container bears his/her full name and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date, and, when applicable, a BUD.

  - Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date, and, when applicable, a BUD.

- If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, expiration date, and, when applicable, a BUD.

- Spot-check patient-specific and floor stock medications to identify expired, mislabeled or unusable medications, including medications that are past their BUD.

C-1018

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(a)(3) [The policies include the following:]

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

Interpretive Guidelines §485.635(a)(3)(v)

CAH staff must report all drug (medication) administration errors and all adverse drug reactions. This required reporting includes two distinct steps in the reporting of drug (medication) administration errors and adverse drug reactions. The first and highest priority reporting relates to the care of the patient, at time of occurrence. The second reporting step is related to the CAH-wide Quality Assurance review as addressed in §485.641(b).

Medication administration error:

The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use." A medication administration error is one that occurs in the phase of the medication process where the drug actually enters the patient by one of various possible routes, e.g., orally, intravenously, etc.

- Adverse drug reaction:

  The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as "Any unexpected, unintended, undesired, or excessive response to a drug that:

  1. Requires discontinuing the drug (therapeutic or diagnostic)
  2. Requires changing the drug therapy
  3. Requires modifying the dose (except for minor dosage adjustments)
  4. Necessitates admission to a hospital
  5. Prolongs stay in a health care facility
  6. Necessitates supportive treatment
  7. Significantly complicates diagnosis
  8. Negatively affects prognosis, or
  9. Results in temporary or permanent harm, disability, or death.

  Consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs."

Patient Care

In the case of ADRs or medication administration errors that are not caught before they reach the patient, a "report" must be made to a practitioner responsible for the care of the patient.

For example, if a medication actually is administered to a patient when it should not be, or the wrong dose is administered, or the wrong route of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, then the medication administration error has reached the patient and must be reported to the responsible practitioner.

If, on the other hand the wrong dose of a drug is prepared for a patient, but a nurse catches this and does not give that dose to the patient, then a medication

administration error has occurred, but the error has not reached the patient, and thus does not need to be reported to the responsible practitioner.

Not every medication administration error that reaches the patient causes harm or has the potential to cause harm; it depends both on the drug and on the patient's condition.

In the case of all ADRs and any medication administration error that has harmed or has reached the patient and could potentially cause harm, the report to a practitioner must be made immediately after the staff identify the adverse reaction or (potentially) harmful error, to enable a timely assessment and intervention. The report must be made directly in a manner that confirms a practitioner received the report, for example, via a phone call. If the impact of the medication error that reached a patient is unknown, the error must be reported to a practitioner immediately. Documentation of the error or reaction, including notification to the practitioner, must be in the patient's medical record.

Medication administration errors that have reached the patient but result in no harm and do not have the potential to cause harm can be reported to a practitioner during usual working hours. For example, if an over-the counter analgesic dose is missed during the night shift, it can be reported first thing in the morning as no further intervention would be required by the practitioner. CAHs should provide clinical staff with expected guidance on how to respond to these situations.

Quality Assurance/Improvement Reporting:

Reduction of medication administration errors and ADRs may be facilitated by effective internal CAH reporting that can be used to assess vulnerabilities in the medication process and implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, the CAH must educate staff on medication administration errors and ADRs including the criteria for those errors and ADRs that are to be reported for quality assurance/improvement purposes, and how, to whom and when they should be reported.

Reporting for quality assurance/improvement purposes covers all identified medication errors, regardless of whether or not they reach the patient, and those ADRs meeting the criteria specified in the CAH's policies.

For Information Only - Not Required/Not to be Cited

To improve staff willingness to report medication errors and ADR incidents, CAHs are encouraged to adopt a non-punitive approach that focuses on system issues rather than individual health care professionals. A non-punitive approach is likely to encourage reporting by those who otherwise may fear retribution or CAH disciplinary action.

In addition to internal staff reporting, the CAH is expected to take other steps to identify medication administration errors and ADRs. Reliance solely on staff-generated incident reporting fails to identify the majority of adverse drug events. Proactive identification

includes observation of medication passes, concurrent and retrospective review of patient's clinical records, implementation of medication usage evaluations for high-alert drugs, and identification of indicator drugs that, when ordered, automatically generate a drug regimen review for a potential adverse drug event.

The CAH must assess the effectiveness of its internal reporting system to determine whether or not it is identifying as many medication errors and ADRs that would be expected for the size and scope of services provided by the CAH. In making such assessments the CAH could refer to established benchmarks or studies on error or ADR rates published in peer-reviewed journals.

For Information Only – Not Required/Not to be Cited

CAHs are encouraged to participate in state-wide and national patient safety organizations for reporting of drug administration errors, ADRs, and drug incompatibilities. National organizations include, but are not limited to, the FDA MedWatch Reporting Program and the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. These organizations, along with other patient safety organizations, collect and analyze data, identify trends, and provide feedback and recommendations to health care organizations to reduce the risk of medication related errors and events.

Survey Procedures §485.635(a)(3)(v)

- Assess whether the CAH ensures that medication administration errors and ADRs are reported to practitioners in a timely manner.
    - Are nursing staff familiar with the concepts of medication errors that do and do not reach the patient, as well as ADRs?
    - Ask nursing staff what they would do in the case of a medication administration error that reaches the patient or an adverse drug event.
    - Ask nursing staff if they can provide examples of cases where they needed to report an ADR. Is the report to the practitioner documented in the medical record?
    - Review records of medication errors and ADRs to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.
- Can the CAH demonstrate that it has a system for reporting/identifying ADRs and medication administration errors for quality assurance/improvement purposes?
- Interview CAH staff (nursing, pharmacy and medicine) to ascertain awareness of the

CAH's policy on reporting medication administration errors and ADRs for quality improvement purposes

- Does the CAH have evidence of training staff on reporting expectations?
- Does the CAH rely only upon internal staff incident reporting or does it use other methods to identify potential/actual medication errors and ADRs, as well?

Ask the individual responsible for the QA program to demonstrate how the CAH determines if the number of medication administration errors and ADRs reported is consistent with the size and scope of services provided by the CAH.

- Review QA activities for medication administration errors and ADRs to determine if, upon analyses of the reports, potential corrective actions are identified and implemented, if appropriate.

C-1020

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(a)(3) [The policies include the following:]

(v*i*) Procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices*. All patient diets, including therapeutic diets, must be 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.*

Interpretive Guidelines §485.635(a)(3)(v*i*)

Guidance is pending and will be updated in future release.

Survey Procedures §485.635(a)(3)(vi)

Survey Procedures are pending and will be updated in future release.

C-1022

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(a)(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (a)(2) of this section and updated as necessary by the CAH.

Interpretive Guidelines §485.635(a)(4)

Guidance is pending and will be updated in future release.

Survey Procedures §485.635(a)(4)

Survey Procedures are pending and will be updated in future release.

C-1024

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(b) Standard: Patient Services

(1) General

(i) **The CAH provides those 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. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.**

Interpretive Guidelines §485.635(b)(1)(i)

This regulation addresses the minimum level of outpatient services (with the exception of emergency services – see §485.635(b)(4)) which a CAH must provide. Such services must be provided on-site at the CAH, but may be provided either by CAH staff or under an arrangement or contract. At a minimum, the CAH must provide those diagnostic and therapeutic services and supplies which are typically found in an ambulatory healthcare setting where patients first come into contact with the healthcare delivery system. The services required to be provided must, at a minimum, reflect the scope and complexity of services provided in a physician's office or in a hospital outpatient or emergency department that furnishes low intensity (i.e., less complex) services. Such services include, but are not limited to: taking a patient's medical history; conducting a physical examination of the patient; specimen collection, assessment of health status, and treatment for a variety of medical conditions. The extent of the CAH's outpatient services is expected to be sufficient to meet the needs of the patients it services for basic ambulatory care services. Further, the CAH's outpatient services must be integrated with its inpatient services.

For those outpatient services that fall only within the scope of practice of a physician or non-physician practitioner, in order to demonstrate compliance, a CAH physician or non-physician practitioner must be available to treat patients at the CAH when such outpatient services are provided. This requirement does not mean the CAH must have a practitioner physically present in the CAH 24 hours per day, seven days per week. See the discussion of required emergency services at §485.618(d) concerning required response times for a physician or non-physician practitioner to come to the CAH to provide medical care.

Survey Procedures §485.635(b)(1)(i)

- Does the CAH provide on-site outpatient services that are typical of those provided in a physician office or low intensity hospital outpatient or emergency department, including medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions?

- Determine that the outpatient services are integrated with the appropriate CAH inpatient services in accordance with the needs of the patient care provided.

- Verify that the types and number of qualified personnel are appropriate for the scope and complexity of the outpatient services offered. Review personnel files or contracts to verify current licensure, certifications and training of staff consistent with applicable State laws.

- Verify that equipment, staff and facilities are adequate to provide the outpatient services and are in accordance with acceptable standards of practice.

C-1026

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(b) [Standard: Patient Services

(1) General]

(ii) **The CAH furnishes acute care inpatient services.**

Interpretive Guidelines §485.635(b)(1)(ii)

In accordance with §485.620(b), CAHs are required to have an average annual per acute inpatient length of stay that does not exceed 96 hours. Accordingly, CAHs are expected to provide less complex inpatient services in order to comply with the length of stay requirement. Furthermore, for each Medicare beneficiary, the CAH is required in accordance with Medicare payment law and regulations to 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. However, while it may be true that CAHs generally are not expected to handle patients requiring complex, specialized inpatient services, such as those services provided by trauma centers, or cardiac surgery centers, CAHs should be able to handle a range of patient needs requiring inpatient admission. CMS does not believe it is in the best interest of patients for them to routinely be transferred to a more distant hospital if instead their care can be provided locally without compromising quality or the length of stay requirements (78 FR 50749). Accordingly, acute inpatient services must be furnished to patients who present to the CAH for treatment 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.

Given the resources of the CAH, the needs of the community it serves, and the variable nature of a CAH's inpatient census, a CAH may not be actively treating inpatients at all times. CAHs may experience significant seasonal variations in the inpatient occupancy rates as well as variations that are a function of the size of the community in which the CAH is located.

A CAH is not required to maintain a minimum average daily census of patients receiving inpatient acute care services or maintain a minimum number of beds that are to be used for inpatient services. However, in determining compliance with this requirement factors to be considered include, but are not limited to, the following:

- What is the volume of emergency services the CAH provides on average quarterly and annually?
- What is the number of certified inpatient beds in the CAH?
- Are there dedicated observation beds in the CAH? If so, how many compared to the number of inpatient beds?
- What is the average acute care occupancy rate for the CAH's inpatient beds quarterly and annually?
- What is the volume of acute inpatient admissions in the CAH quarterly and annually?
- What is the volume of patients placed in observation status in the CAH quarterly and annually?
- What is the percentage of emergency department patients admitted to the CAH as an inpatient versus transferred to a hospital quarterly and annually?
- What is the range, volume and complexity of outpatient services the CAH provides?

While there is no specific formula for determining the number of patients a CAH is expected to admit, surveyors must be alert to disproportionate relationships among the CAH's various services. For example, if a CAH has only 4 certified beds and an average of 3 acute care inpatients per month, but has 18 observation beds that have an annual occupancy rate of 85%, has an ED staffed by physicians 24/7 and sees 9,000 ED patients/year, offers extensive and complex outpatient services, such as chemotherapy, advanced diagnostic imaging, sleep lab services, and same day surgery, but transfers to another hospital from the ED almost all patients who need inpatient admission, then these inpatient services would not be reasonably proportional to the overall mix and volume of services offered by the CAH. Based on data published by the Agency for Healthcare Research and Quality (AHRQ), in 2008 approximately 8.3 percent of emergency department (ED) visits in a rural "hospital" resulted in an inpatient admission, compared

to 16 percent for non-rural hospital ED visits. Also, a higher percentage of rural ED patients were likely to be discharged – 91.7% compared to 84% for non-rural hospitals. The AHRQ rural hospital data included both hospitals and CAHs, with CAHs accounting for 51 percent of rural EDs. [1] Other published AHRQ data indicates that, in 2009, 3 percent of patients who lived in a rural area were transferred from the ED where they presented to a hospital, compared to 1.5 percent of all patients nationally who presented to an ED.[2]

Given that a CAH may offer fewer services than even the average rural hospital and is expected to achieve a 96-hour average length of stay or less, there is no expectation that every CAH is expected to admit 8 percent of its ED patients. This benchmark can, however, provide a useful starting point for assessing compliance.

- Generally, if a CAH admits at least 8 percent of its ED patients annually, it would be considered compliant with the requirement to provide inpatient services and surveyors do not have to investigate further.

- If a CAH admits less than 8 percent of its ED patients annually, this is **not** in and of itself evidence of noncompliance. More investigation is needed to assess compliance by determining whether the volume of activity and number of staff the CAH has for its ED, other outpatient, and inpatient services are reasonably related to each other. There can be great variation among CAHs in their volume and types of activities, despite their relative similarity in size, making a "one size fits all" formula inappropriate. Researchers in one State with 79 CAHs found that they averaged 3,851 ED visits annually, but that visits for individual CAHs ranged from a low of 389, or a little more than one patient per day, to a high of 14,425, or about 40 patients per day. CAHs in this State averaged 19,705 other types of outpatient visits annually, but again the range was very large, from a low of 89 to a high of 86,367 per year. For inpatient admissions the annual average was 836, ranging from a low of 100 to a high of 3,838[3]. Presentation of the data found in this State is not intended to provide benchmarks for CAHs in other States, but rather to emphasize the tremendous range in the volume of activity among CAHs, even within one State.

- A couple of extreme but illustrative examples are presented below to indicate the types of factors to be considered when assessing whether the CAH satisfies the requirement to provide inpatient services:

  - Example #1: A CAH has a very low volume of ED visits, such as 2 or fewer

[1] *Hines, A.L., Fraze, T., and Stocks, C. Emergency Department Visits in Rural and Non-Rural Community Hospitals, 2008. HCUP Statistical Brief #116. June 2011. Agency for Healthcare Research and Quality, Rockville, MD. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb116.pdf*
[2] *Kindermann, D, Mutter, R. and Pines, J.M. Emergency Department Transfers to Acute Care Facilities, 2009. HCUP Statistical Brief #155. May 2013. Agency for Healthcare Research and Quality, Rockville, MD. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb155.pdf*
[3] *Moscovice, I. and Casey, M. Rural-relevant Quality Measures for Critical Access Hospitals. June 27, 20211 PowerPoint presentation to the Minnesota Rural Health Conference. http://www.health.state.mn.us/divs/orhpc/conf/2011/presentations/2b.pdf*

patients per day on average, discharges over 90% of its annual ED patients, has a total professional health care staff that consists of one physician who spends a limited amount of time on-site, and one nurse practitioner who works days five days per week. In this case it would not be unreasonable for the CAH to admit a patient for acute inpatient services only occasionally and transfer a majority of those ED patients who require inpatient services to a hospital.

- Example #2: A CAH has 50 ED visits per day on average, 4 certified inpatient beds, 2 inpatient admissions per month on average (all elective surgery patients who started as outpatient cases), 10 dedicated observation beds and places about 2 ED patients per day in observation; transfers out to a neighboring hospital an average of 15 ED patients per week who require admission, has twenty physicians on staff, is performing an average of three thousand outpatient surgeries per year, provides outpatient chemotherapy, cardiology and advanced diagnostic imaging, and has a total of about 40,000 outpatient visits per year, not counting ED visits. This CAH's services are very skewed toward outpatient services, and the needs of its patient population for inpatient services do not appear to be met by the CAH. The CAH might arguably have the staff to provide a larger volume of inpatient services to many of the ED patients who require admission. The CAH would be expected to demonstrate to the surveyor why it could be reasonable for its inpatient capacity and admissions to be so disproportionately small compared to its outpatient services volume and capabilities, and in view of the needs of its ED patients for inpatient services. The surveyor would also review the medical records of a sample of ED patients transferred out to see if they required services the CAH's professional healthcare staff is not able to provide. (This case might also raise EMTALA issues related to on-call lists and appropriate transfers. See Appendix V)

- Example #3: A CAH has 25 ED visits per day, 25 certified beds, 23 of which, on average, are used for swing-bed services and are occupied by nursing home or skilled nursing facility residents. The CAH transfers out to a neighboring hospital an average of eight ED patients per week who require admission, and admits an average of one patient per month for acute inpatient services. The CAH has fifteen physicians on staff, is performing an average of 800 outpatient surgeries per year, provides outpatient chemotherapy, cardiology and advanced diagnostic imaging, and has a total of about 20,000 outpatient visits per year, not counting ED visits. In this situation the CAH's services are skewed towards outpatient and long-term care services and the needs of its patient population for inpatient services do not appear to be met by the CAH. The CAH would be expected to demonstrate to the surveyor why it could be reasonable for its inpatient acute care capacity and admissions to be so disproportionately small compared to its outpatient and long term care services and to the needs of its ED patients for inpatient services. The surveyor would also review the medical records of a sample of ED patients transferred out to see if they required services the CAH's professional healthcare staff is not able to provide. (This case might also raise EMTALA issues related to on-call lists and appropriate transfers. See Appendix V)

Survey Procedures §485.635(b)(1)(ii)

- Verify that the CAH is furnishing acute care inpatient services by reviewing data on the number of patients admitted over the prior year.

- Determine the percentage of ED visits that result in an admission to the CAH. If fewer than eight percent of ED visits lead to an inpatient admission, review data on transfers of ED patients, overall staffing, the volume and type of outpatient services offered, including observation services, and swing bed services to determine whether there is a reasonably proportionate relationship among the various services the CAH provides.

- Review a sample of records of the patients the CAH transferred and determine if the transfers were appropriate based on the services available at the CAH.

C-1028

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§485.635(b)(2) Laboratory Services

The CAH provides 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). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include the following:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones).

(ii) Hemoglobin or hematocrit.

(iii) Blood glucose.

(iv) Examination of stool specimens for occult blood.

(v) Pregnancy tests.

(vi) Primary culturing for transmittal to a certified laboratory.

Interpretive Guidelines §485.635(b)(2)

Laboratory services that must be provided on-site at the CAH's main campus are the tests specified in the regulation, which would be considered the minimum necessary for diagnosis and treatment of a patient:

- Chemical examination of urine by stick or tablet method or both (including urine ketones);

- Hemoglobin or hematocrit;
- Blood glucose;
- Examination of stool specimens for occult blood;
- Pregnancy tests; and
- Primary culturing for transmittal to a certified laboratory.

These services may be provided by CAH staff or under arrangement or agreement with a laboratory, or through a combination of CAH staff and a laboratory under arrangement. Laboratory services, whether provided directly by the CAH or under an arrangement with a laboratory contractor, must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter. Compliance with Part 493 is not assessed by CAH surveyors evaluating compliance with the CAH conditions of participation, but surveyors are expected to refer potential issues they may identify to the program responsible for CLIA certification.

Given that the CAH must provide emergency services 24 hours a day, 7 days a week, the CAH must determine which laboratory services are to be immediately available to meet the emergency needs of patients and how the services are to be provided. The emergency laboratory services available should reflect the scope and complexity of the CAH's emergency services operations.

The provision of laboratory services that exceed the minimum tests specified is optional. The scope and complexity of the CAH's laboratory service must be adequate to support the clinical services the CAH offers to patients. Additional laboratory services may be offered directly or through arrangement. The CAH should have a written description of all the laboratory services that it provides, including those delivered on routine and stat basis.

The laboratory must have written policies and procedures for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the CAH must comply with the requirements of the clinical records CoP at §485.638(a)(4)(ii).

Survey Procedures §485.635(b)(2)

- Ask the CAH to identify which laboratory services it offers. Are the required lab services provided at the CAH's main campus?
- Does the CAH have a CLIA certificate or waiver, as applicable, for all laboratory

tests performed in CAH facilities?

- Verify that the CAH has a procedure in place for obtaining tests that are needed but unavailable at the CAH laboratory.

- If the CAH refers specimens to another laboratory for testing, does the CAH have documentation that the referral laboratory is CLIA certified for the appropriate tests?

- Has the CAH identified laboratory services that must be available to support the emergency services the CAH provides? Ask the staff who furnish emergency services whether these laboratory services are available whenever they provide emergency services.

C-1030

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§485.635(b)(3) Radiology services. Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards.

Interpretive Guidelines §485.635(b)(3)

Radiologic services encompass many different modalities used for the purpose of medical imaging. Each type of technology gives different information about the area of the body being studied or treated, related to possible disease, injury, or the effectiveness of medical treatment. All the modalities use some form of radiation, such as ionizing radiation (radiography, computed tomography, fluoroscopy), which has enough energy to potentially cause damage to DNA, and other forms of radiation (ultrasound, magnetic resonance imaging) to view the human body in order to diagnose, monitor, or treat medical conditions.

Radiological services furnished by the CAH may be provided by CAH staff or under arrangement. The CAH must maintain and have available diagnostic radiological services to support the services the CAH provides to meet the needs of its patients. These services must be available at all times the CAH provides services, including emergency services. The CAH has the flexibility to choose the types and complexity of radiologic services offered. They may offer only a minimal set of services or a more complex range of services (including nuclear medicine).

All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered should be specified in writing and approved by the governing body (or responsible individual).

Acceptable standards of practice include maintaining compliance with appropriate

Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professions such as the American Medical Association, Radiological Society of North America, Alliance for Radiation Safety in Pediatric Imaging, American Society of Radiologic Technologists, American College of Cardiology, American College of Neurology, American College of Physicians, American College of Radiology, etc.

Qualified Radiologic Personnel

There must be written policies that are developed and approved by the governing body or responsible individual and are consistent with State law, that designate which personnel are qualified to use the radiological equipment and administer procedures.

When telemedicine is used to provide teleradiology services, radiologists who interpret radiological tests must satisfy the telemedicine privileging requirements §485.616(c)(3).

In addition to radiologists, there are other types of healthcare personnel who, depending on State law and the scope and complexity of the CAH's radiologic services, may be involved in the delivery of radiologic services in the CAH, including radiologic technologists and medical physicists. Radiologic technologists perform diagnostic imaging examinations and administer radiation therapy treatments. They are educated in anatomy, patient positioning, examination techniques, equipment protocols, radiation safety, radiation protection and basic patient care.

For Information Only – Not Required/Not to be Cited

Well-designed radiologic services include a medical physicist, who, in conjunction with the person responsible for radiologic services, performs or supervises the pertinent procedures necessary to assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result. The responsibilities of the medical physicist include: protection of the patient and others from potentially harmful or excessive radiation; establishment of adequate protocols to ensure accurate patient dosimetry; the measurement and characterization of radiation; the determination of delivered dose; advancement of procedures necessary to ensure image quality; development and direction of quality assurance programs; and assistance to other health care professionals in optimizing the balance between the beneficial and deleterious effects of radiation (www.aapm.org). CAHs are encouraged to involve a medical physicist in the calibration of the imaging equipment and monitoring of radiation dosage exposures.

Safety from Radiation Hazards

The CAH must adopt and implement policies and procedures that ensure safety from radiation hazards for patients and personnel. The CAH must implement and ensure

compliance with its established safety standards. The policies must address at least the following:

- Adequate radiation shielding for patients, personnel and facilities, which includes:
  - Shielding built into the CAH's physical plant, as appropriate;
  - Types of personal protective shielding to be used, under what circumstances, for patients, including high risk patients as identified in radiologic services policies and procedures, and CAH personnel;
  - Types of containers to be used for various radioactive materials, if applicable, when stored, in transport, in use, and when disposed;
  - Clear signage identifying hazardous radiation areas;
- Labeling of all radioactive materials, including waste, with clear identification of all material(s);
- Transportation of radioactive materials between locations within the CAH;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Periodic testing of equipment for radiation hazards;
- Periodic checking of staff regularly exposed to radiation for the level of radiation exposure, via exposure meters or badge tests;
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

Radiologic Equipment Maintenance

The CAH must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, and that problems identified are corrected in a timely manner. The CAH must ensure that equipment is inspected and maintained in accordance with Federal and State laws and regulations, as applicable, and the manufacturer's recommendations. The CAH must have a system in place to correct identified problems. The CAH must have evidence of its inspections and corrective actions.

Radiology Records

The CAH radiology records are to be treated in the same manner as any other part of a medical record. The medical records CoP at §485.638(a)(4)(ii) requires that the CAH

maintain reports of physical examinations, diagnostic and laboratory test results, and consultative findings.

Survey Procedures §485.635(b)(3)

- Interview the person responsible for radiologic services.
    - Ask what radiologic services the CAH offers at its main campus. At off-site locations ask how the CAH ensures patient needs for radiologic services are met, if applicable.
    - Ask how the CAH ensures that radiologic services are provided consistent with acceptable standards of practice.
- Safety:
    - Determine if the radiologic services staff is familiar with the policies and procedures related to safety.
    - Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the CAH.
    - Observe areas where radiologic testing is done and check for safety problems.
    - Verify that hazardous materials are clearly labeled. Review records to verify that they are tracked, handled and stored properly in a safe manner with the requisite containers.
        - Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.
- Equipment maintenance:
    - Review the inspection records to verify that periodic inspections and maintenance are conducted in accordance with the manufacturer's recommendations.
    - Determine whether any problems identified are properly corrected in a timely manner and the correction is maintained over time.
- Qualified Personnel:
    - Are studies interpreted only by qualified staff approved to do so by the CAH's governing body or responsible individual?
    - Determine which staff are using various pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine if they meet the qualifications for tasks they perform, as established

in the CAH's policies and consistent with state law.

- Ask staff to explain the protocol for the procedures/studies they administer. Ask to see the CAH's written protocols and verify that the staff is adhering to them.

C-1032

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§485.635(b)(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides medical services as a first response to common life-threatening injuries and acute illness.

Interpretive Guidelines §485.635(b)(4)

Emergency services must be provided by the CAH at the CAH campus either by CAH staff or by individuals providing services under arrangement or agreement. The individuals providing the services must have the ability to recognize a patient's need for emergency care at all times. The CAH must provide medically appropriate initial interventions, treatment and stabilization of any patient who requires emergency services.

Survey Procedures §485.635(b)(4)

The survey procedures for §485.618 apply.

C-1034

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(c) Standard: Services Provided Through Agreements or Arrangements

(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including

(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, the distant-site telemedicine entity is not required to be a Medicare-participating provider or supplier.

Interpretive Guidelines §485.635(c)(1)&(c)(5)

All agreements for providing health care services to the CAH's patients must be with a provider or supplier that participates in the Medicare program, except in the case of an agreement with a distant-site telemedicine entity for the provision of telemedicine services. The agreements should describe routine procedures (e.g., for obtaining outside laboratory tests); and there should be evidence in the agreement or arrangement that the governing body (or responsible individual) is responsible for these services provided

under agreement or arrangement. Individual agreements or arrangements should be revised when the nature and scope of services provided has changed.

The governing body (or responsible individual) has the responsibility for ensuring that CAH services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by CAH employees or indirectly by agreement or arrangement. The governing body must take actions through the CAH'S QA program to: assess the services furnished directly by CAH staff and those services provided under agreement or arrangement, identify quality and performance problems, implement appropriate corrective or improvement activities, and to ensure the monitoring and sustainability of those corrective or improvement activities.

Survey Procedures §485.635(c)(1)&(c)(5)

- Determine whether the CAH verifies that every entity providing health care services to the CAH's patients under an agreement participates in Medicare, with the exception of a distant-site telemedicine entity providing telemedicine services under an agreement or arrangement.

C-1036

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(c)(1) [The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—]

(i) Services of doctors of medicine or osteopathy;

§485.635(c)(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Interpretive Guidelines §485.635(c)(1)(i) & §485.635(c)(2)

In accordance with §485.631(a)(1), the CAH is required to have at least one doctor of medicine or osteopathy (MD or DO) on its staff who is responsible for the functions described in §485.631(b). CAHs are free to have additional MDs or DOs on staff, part- or full-time. MDs and DOs who have been credentialed and privileged to provide services on-site at the CAH are part of the CAH's professional healthcare staff, even if they are not at the CAH full-time; they would not be considered to be providing services under an arrangement and would not be covered by these regulatory provisions. These regulations also do not apply to MDs and DOs who provide telemedicine services to the CAH's patients, even when they are provided under arrangement. (See §485.616(c) and §485.635(c)(5) concerning telemedicine requirements.)

Under §485.635(c)(1)(i) & §485.635(c)(2), the CAH must have policies and procedures for referring patients it discharges who need additional specialized MD or DO services

not available at the CAH. The policies and procedures must at a minimum identify the services for which the CAH has referral arrangements or agreements, as well as the information to be provided to referred patients. MDs and DOs to whom the CAH refers its patients must participate in Medicare.

The CAH is not required to have referral arrangements in writing, but if it does not, then it must be able to document that patients it has referred to an outside MD or DO have been offered appointments and treatment.

Survey Procedures §485.635(c)(1)(i) & §485.635(c)(2)

- Verify that the CAH has arrangements with one or more MDs or DOs for referral of discharged CAH patients who need medical services not available at the CAH.

- Are the referral arrangements in writing? If not, can the CAH document that patients referred to an outside MD or DO have been offered appointments and treatment?

- Does the CAH have policies and procedures addressing referral of discharged patients? Are the CAH's practitioners and staff who handle the discharge of patients familiar with these policies and procedures?

C-1038

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(c)(1) [The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—]

> **(ii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and**

§485.635(c)(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Interpretive Guidelines §485.635(c)(1)(ii) & §485.635(c)(2)

In accordance with §485.635(b)(2), the CAH is required to furnish, either directly by the CAH staff, under arrangement or agreement, or through a combination of CAH staff and a laboratory under arrangement 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). These services must be provided on-site at the CAH and may be provided either by CAH staff or under an arrangement with a laboratory. The CAH is also free to provide additional laboratory services on-site, beyond the minimum required services. The provision at §485.635(c)(1)(ii) does not apply to laboratory services provided on-site.

Instead, this provision addresses the requirement for the CAH to have an arrangement or agreement, as appropriate, with a laboratory that can provide additional or specialized clinical laboratory services that are not available at the CAH. The arrangement or agreement may provide either for the CAH to draw the specimens to be examined and send them to the outside laboratory. The CAH is not required to have a written agreement or arrangement, but if it does not, it is expected to be able to document that an outside laboratory to which it sends specimens provides the CAH with test results.

Laboratories that provide additional diagnostic and clinical laboratory services to a CAH under agreement or arrangement must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter. The CAH is expected to have evidence of the outside laboratory to which it refers patients holding a current CLIA certificate or waiver.

The CAH must have policies and procedures for additional or specialized laboratory services provided under arrangement or agreement which address at least the following: the specific laboratory services provided under arrangement; and the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Likewise, although the CAH is expected to provide radiology services in accordance with §485.635(b)(3), it is also expected to have an arrangement or agreement, as appropriate, with other providers or suppliers of diagnostic imaging services, including advanced diagnostic imaging services, such as magnetic resonance imaging, computed tomography, etc. The CAH is not required to have a written agreement or arrangement, but if it does not, it is expected to be able to document that an outside diagnostic imaging facility to which it sends patients provides the CAH with the resulting studies and reports.

Patient diagnostic imaging studies and reports, laboratory results and all other laboratory clinical patient records must be included in the patient's medical record and meet all requirements at §485.638(a)(4)(ii).

Survey Procedures §485.635(c)(1)(ii) & §485.635(c)(2)

- Verify that the CAH has an agreement or arrangement with an outside laboratory and an outside diagnostic imaging facility for services not provided in the CAH.

- Ask the CAH how it ensures that the laboratory with which it has an agreement or arrangement holds the necessary CLIA certification.
- 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?

- 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?

C-1040

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(c)(1) [The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—]

(iii) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

Interpretive Guidelines §485.635(c)(1)(iii)

If the CAH does not provide all food and other services required to meet the nutritional needs of the CAH's inpatients using CAH staff, then the CAH must provide these services under an agreement or arrangement.

The CAH must assure that dietary services provided under an agreement or arrangement are provided in accordance with the CAH's policies adopted as required by §485.635(a)(3)(vii). Unless the CAH is a grandfathered co-located CAH (see §485.610(e)(1)) that has an arrangement with the co-located facility to provide food services to the CAH's inpatients, it is expected that the CAH's vendor provides dietary services on-site at the CAH in order to meet the needs of the CAH's inpatients. Surveyors assess compliance with the requirements of §485.635(a)(3)(vii) in the same manner, regardless of whether the services are provided by CAH staff or a vendor. In the case of a grandfathered co-located CAH that obtains food services from the co-located facility, surveyors must assess the food service operations in the co-located facility as part of the CAH survey.

Survey Procedures §485.635(c)(1)(iii)

- Verify that the CAH has an agreement or arrangement with a vendor to provide dietary services to inpatients if the CAH does not use its own staff to provide these services.

C-1042

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(c)(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

Interpretive Guidelines §485.635(c)(3)

The CAH must maintain a list of all patient care services furnished by the CAH through arrangements or agreements. The list must be updated each time a contracted service is

added or removed. For each service the list must 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.

Survey Procedures §485.635(c)(3)

- Review the list of contracted services and verify that it contains all required information.
- Ask the CAH for evidence that the list is updated whenever there are changes.
- Ask various CAH staff during the course of the survey whether they work directly for the CAH or some other entity; check that services provided by staff employed by outside entities are on the list of contracted services.

C-1044

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(c)(4) The person principally responsible for the operation of the CAH under
§485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

(ii) 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.

Interpretive Guidelines §485.635(c)(4)

The person principally responsible for the operation of the CAH, in accordance with §485.627(b)(2), i.e., the CAH's Chief Executive Officer (CEO), is responsible for the operation of all patient care services furnished at the CAH. This includes services provided directly by CAH staff and services provided by the CAH under arrangement or agreement. It includes not only care provided directly to patients, but also services related to patient care, such as environmental cleaning, instrument cleaning and

sterilization, laundry, pharmacy services, laboratory services, etc. (This requirement for the CEO to be responsible does not relieve the CAH's governing body of its ultimate responsibility for the CAH's total operation in those CAHs where there are both a governing body and a CEO.)

The CEO must take actions to assure that all services furnished by the CAH through a contractor comply with the applicable requirements of the CAH's CoPs. When assessing compliance of a service provided by a contractor with the CoPs, deficiencies cited under other CoPs warrant a citation of this requirement, because the CEO has failed to assure that the contractor provides services in a manner that allows the CAH to comply with the CoPs.

Survey Procedures §485.635(c)(4)(i)

- Ask the CAH's CEO to demonstrate how he or she provides oversight of all contracted services related to patient care.

- Ask for specific examples of how the CEO assures that services furnished in the CAH comply with the CoPs (e.g., policies and procedures, by-laws, etc.) that the individual responsible for its operations is responsible for all services provided through arrangements or agreements.

C-1046

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(d) Standard: Nursing Services

Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

Interpretive Guidelines §485.635(d) & (d)(1)

In order to meet the needs of patients, nursing services must be a well-organized service of the CAH. The CAH designates an individual who is responsible for nursing services, including development of policies and procedures for nursing services. The designated individual is generally expected to be a registered nurse. Various titles may be used for the responsible nurse leader may have (e.g., director of nursing services, nurse executive, chief nursing officer, or nurse manager). The nurse leader is responsible for the overall management and evaluation of nursing care in the CAH, including, but not limited to:

- Development and maintenance of nursing policies and procedures;

- Supervision of nursing staff, either directly, or, depending on the size of the CAH, indirectly through other nursing managers; and

- Ongoing review and analysis of the quality of nursing care.

As required at §485.631(a)(5), the CAH must have a registered nurse, clinical nurse specialist, or licensed practical nurse on duty whenever the CAH has one or more inpatients (including patients in a swing bed receiving long term care services).

The CAH must also ensure that, for outpatient nursing services, appropriate nursing staff are available in accordance with State law and CAH policy.

For both inpatient and outpatient services there must be sufficient numbers of supervisory and non-supervisory nursing personnel with the appropriate education, experience, licensure (as applicable), competence and specialized qualifications to respond to the nursing needs of the patient population of each CAH department or nursing unit. Staffing schedules must be reviewed and revised as necessary to meet patient care needs and to make adjustments for nursing staff absenteeism.

The CAH must have a procedure for assigning and coordinating the nursing care for every CAH patient. A registered nurse must either provide directly, or assign to other staff, the required nursing care for each CAH patient, including patients receiving swing bed services. The RN making the assignment must consider the specialized qualifications and competence of the CAH's available nursing staff in order to meet patients' nursing care needs. Nursing care duties may be assigned to appropriate personnel, such as a licensed practical nurse, nursing assistant or nurse's aide, so long as such assignment is consistent with state law and the individual has the qualifications and competence to perform the assigned tasks.

The CAH must ensure that all CAH nursing staff are adequately trained and oriented, aware of CAH nursing policies and procedures, supervised, and that their clinical activities are evaluated. If temporary outside agency nurses are employed to address temporary nurse staffing needs, determine how are these nurses oriented and supervised. (**NOTE:** Regular nursing services may be provided under arrangement instead of using CAH employees, but in this case the CAH is responsible for the ongoing training and supervision of these regular nursing staff.)

Survey Procedures §485.635(d)(1)

- Determine whether an RN has been designated responsible for nursing services at the CAH.

- Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Sources of information to use in the evaluation of the nursing services are: staffing schedules, nursing care plans for inpatients, credentialing and training files (including contracted staff), and QA activities and reports.

- Interview the registered nurse responsible for nursing services and ask the following--
    - How are the nursing needs of patients determined? Who makes this determination?
    - How are staff assigned to provide nursing care to patients?
    - How does the CAH ensure that care provided meets the needs of each patient?
    - How are staff trained and oriented? If temporary outside agency nurses are used, how are they oriented and supervised?
- Review nursing assignments in one or more inpatient units, the emergency department, and one other outpatient department. Did an RN make the assignments? Was the complexity of patient care needs and the competence and specialized qualifications of the nursing staff taken into consideration?
- Review written staffing schedules; do they adhere to the CAH's policies and procedures for staffing levels and types of nursing personnel?
- Verify that there is supervision of personnel performance and nursing care for each nursing unit.
- If there are temporary agency nurses providing services, interview one or more to determine if they are familiar with the nursing policies and procedures of the unit or department where they are working.
- Review personnel files to determine that nursing staff have required licenses and competencies.

C-1048

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(d)(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.
Interpretive Guidelines §485.635(d)(2)

The nursing care of each patient of the CAH must be supervised by a registered nurse or a physician assistant where permitted by State law. Even where permitted under State law, a CAH is not required to have nursing care supervised by a physician assistant. This is simply an option for the CAH.

For inpatients, including patients receiving long term care services in swing beds, evaluation of their nursing care includes evaluating the care for each patient upon admission and, when appropriate, on an ongoing basis in accordance with accepted

standards of nursing practice and CAH policy. Evaluation would include assessing the patient's care needs, patient's health status/conditioning, as well as the patient's response to interventions.

Nursing care plans are not developed for outpatients, so the focus of the evaluation would be on adherence to generally acceptable standards of nursing care practice, including requirements at §485.635(d)(3) for medication administration.

Survey Procedures §485.635(d)(2)

- Determine that a registered nurse (or physician assistant where permitted by State law and CAH policy) supervises and evaluates the nursing care for each patient.

- Interview one or more registered nurses (or physician assistants, if applicable) who supervise and evaluate the nursing care for CAH patients.

C-1049

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(d)(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

Interpretive Guidelines §485.635(d)(3)

As required at §485.635(a)(3)(iv), the CAH must have written policies and procedures for the administration of all drugs and biologicals that adhere to accepted standards of practice and Federal and State laws. In accordance with §485.635(d)(3), all medication administration must be consistent with accepted standards of practice, as well as Federal and State laws. Examples of nationally recognized organizations with expertise in medication administration include, but are not limited to:

- National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org);
- Institute for Healthcare Improvement (http://www.ihi.org/ihi);

- U.S. Pharmacopeia (www.usp.org);

- Institute for Safe Medication Practices, which offers guidelines specifically on timely medication administration, which can be found at: www.ismp.org/Newsletters/acutecare/articles/20110113.asp;

- Infusion Nurses Society (http://www.ins1.org).

In addition, the Centers for Disease Control and Prevention (CDC) publishes evidenced-

based practice guidelines and recommendations on medication preparation and administration practices, designed to reduce the risk of infection associated with these activities.

Who May Administer Medications?

Drugs and biologicals, including intravenous (IV) medications, must be administered by, or under the supervision of, an MD or DO; an RN, or, where permitted by State law, a PA. Other personnel, such as LPN's, may administer medications when permitted by State law and CAH policy, so long as they are supervised by an MD, DO, RN or, where permitted by State law, a PA. The CAH's written policies must delineate the categories of clinical staff authorized to administer medication at the CAH.

Medication Orders

Drugs and biologicals, including intravenous (IV) medications, may only be administered in accordance with orders written and signed by a practitioner who is authorized by CAH policy, and in accordance with State law, to write orders and who is responsible for the care of the patient as specified under §485.631(b)(1)(iii).

Accepted standards of practice

Based on accepted standards of practice for medication administration, the CAH must assure compliance with the following requirements concerning:

- Minimum content of medication orders;
- Policies and procedures for verbal and standing orders;
- Self-administration of medications, if the CAH permits this;
- Training;
- Basic Safe Practices;
- Timing of Medication Administration;
- Assessment/Monitoring of Patients Receiving Medications;
- Intravenous (IV) medications; and
- Documentation

Content of the medication order

In accordance with accepted standards of practice, the minimum elements that must be present in orders for all drugs and biologicals to ensure safe preparation and

administration include:

- Name of patient;
- Age and weight of patient, to facilitate dose calculation when applicable. Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the CAH's policies. (**NOTE:** Dose calculations are based on metric weight (kg, or g for newborns). If a CAH permits practitioners to record weight in either pounds or using metric weight, the opportunity for error increases, since some orders would require conversion while others would not. Accordingly, CAHs must specify a uniform approach to be used by prescribing practitioners. For example, a CAH could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric);
- Date and time of the order;
- Drug name;
- Exact strength or concentration, when applicable;
- Dose, frequency, and route;
- Dose calculation requirements, when applicable;
- Quantity and/or duration, when applicable;
- Specific instructions for use, when applicable; and
- Name of the prescriber.

Verbal and Standing Orders

Although the regulation requires medication administration be based on a written, signed order, this does not preclude the CAH from using:

- Verbal orders; or
- Standing orders.

In the case of both verbal and standing orders, a practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact. The CAH must adopt policies and procedures regarding verbal and standing orders. (**NOTE:** CAHs that have a distinct part psychiatric and/or rehabilitation unit must follow the hospital CoPs for all services provided in those units, including the hospital requirements for verbal and standing orders.)

For verbal orders, CAH policies must, at a minimum, address the following:

- Describe situations in which verbal orders may be used, as well as limitations or prohibitions on their use;
- Provide a mechanism to establish the identity and authority of the practitioner issuing a verbal order;
- List the elements required for inclusion in the verbal order process;
- Establish protocols for clear and effective communication and verification of verbal orders. CMS expects nationally accepted read-back verification practice to be implemented for every verbal order;
- Identify the categories of clinical staff who are authorized to receive and act upon a verbal order; and
- Provide for prompt documentation in the medical record of the receipt of a verbal order.

For standing orders, CAH policies must, at a minimum, address the following:

- The process by which a standing order is developed; approved; monitored; evaluated and updated when needed;
- For each standing order, which staff may initiate it and under what circumstances; (under no circumstances may a CAH use standing orders in a manner that requires any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders); and
- The requirements for subsequent authentication by a practitioner responsible for the care of the patient.

For Information Only – Not Required/Not to Be Cited

Verbal Orders

CAHs are encouraged to minimize the use of verbal orders as much as possible and not permit their use merely as a convenience to practitioners. Verbal orders carry a higher risk of miscommunication and error and thus should only be used when necessary. With the increasing use of Electronic Health Records and Computerized Physician Order Entry systems, the need for verbal orders is expected to decline.

Standing Orders

There is no standard definition of a "standing order" in the healthcare community, but the terms "pre-printed standing orders," "electronic standing orders," "order sets," and "protocols for patient orders" are various ways in which the term "standing orders" has been applied. The lack of a standard definition for these terms and their interchangeable and indistinct use by health care facilities professionals may result in confusion

CAHs are encouraged to focus on those situations where their use of "standing orders" permits treatment that is outside the scope of practice of a non-practitioner, such as a nurse, to be initiated by the non-practitioner without a prior specific order from a practitioner responsible for the care of the patient. Such treatment is typically initiated when a patient's condition meets certain pre-defined clinical criteria. For example, standing orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practical for a nurse to obtain either a written, authenticated order or a verbal order from a practitioner prior to the provision of care.

Appropriate use of standing orders can contribute to patient safety and quality of care by promoting consistency of care, based on objective evidence. Much of the evidence on the effectiveness of standing orders has been narrowly focused on aspects of their use by Rapid Response Teams addressing inpatient emergencies. However, standing orders may also be appropriate in other clinical circumstances, including, but not limited to:

- Protocols for triaging and initiating required screening examinations and stabilizing treatment for emergency department patients presenting with symptoms suggestive of acute asthma, myocardial infarction, stroke, etc. (This does not relieve a CAH of its obligations under the Emergency Medical Treatment and Labor Act (EMTALA) to have qualified medical personnel complete required screening and, when applicable, provide stabilizing treatment in a timely manner.)

- Post-operative recovery areas.

- Timely provision of immunizations, such as certain immunizations for newborns, for which there are clearly established and nationally recognized guidelines.

CAHs are encouraged to address at least the following in their standing orders policies and procedures:

- Review and approval of each standing order by a multi-disciplinary team that includes the following individuals or their designees: the MD/DO providing medical direction and the individuals designated responsible for nursing and pharmacy services.

- The CAH should be able to document that the standing order is consistent with nationally recognized and evidence-based guidelines. This does not mean that there must be a template standing order available in national guidelines which the CAH copies, but rather that the content of each standing order the CAH uses is consistent with nationally recognized, evidence-based guidelines for providing care.

Clear, specific criteria in the protocol for the order for authorized non-practitioners to initiate the execution of the order, for example, the specific clinical situations, patient conditions, or diagnoses by which initiation of the order would be justified.

- Instructions that the clinical staff receive on the conditions and criteria for using standing orders as well as any individual staff responsibilities associated with the initiation and execution of standing orders.

- At least annual review of each standing order as well as a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions based on changes in nationally recognized, evidence-based guidelines. Among other things, reviews should consider:

- Whether there have been any preventable adverse patient events resulting from the use of the standing order, and if so, whether changes in the order would reduce the likelihood of future similar adverse events. The review would not be expected to address adverse events that are a likely outcome of the course of patient's disease or injury, even if the order was applied to that patient, unless there is concern that use of the standing order exacerbated the patient's condition; and

- Whether a standing order has been initiated and executed in a manner consistent with the order's protocol, and if not, whether the protocol needs revision and/or staff need more training in the correct procedures.

Self-Administration of Medications

The CAH may choose to allow practitioners to write orders allowing patients to self-administer CAH-issued drugs and biologicals or drugs the patient has brought from home into the CAH for use during their stay, e.g., an insulin pen for a diabetic patient. If the CAH does permit this, it must develop policies and procedures for self-administration of drugs by patients or their informal caregivers.

Training

Medication administration education and training is typically included in the CAH's orientation or other continuing education programs for nursing staff and other authorized healthcare personnel. Training or continuing education topics regarding medication

administration may include but are not limited to the following:

- Safe handling and preparation of drugs, biologicals, and IV 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.

Policies and procedures must address the required components of the training and if the training provided during CAH orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.

Basic safe practices for medication administration

The CAH's policies and procedures must reflect accepted standards of practice that require the following be confirmed prior to each administration of medication (often referred to as the "five rights" of medication administration practice):

- Right patient: the patient's identity— acceptable patient identifiers include, but are not limited to: the patient's full name; an identification number assigned by the CAH; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the CAH's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.
- Right medication: the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;
- Right dose: the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);
- Right route: the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient; and
- Right time: the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

NOTE: The "5 rights" focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering;

administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the "5 rights" of medication administration, for example when there has been a prescribing or a dispensing error. CAHs are also expected to comply with requirements for pharmacy services at §485.635(a)(3)(iv), using a systems approach to all components of the medication process.

For Information – Not Required/Not to be Cited

Recent literature* identifies up to nine "rights" of medication administration including:

- Right patient
- Right drug
- Right route
- Right time
- Right dose
- Right documentation
- Right action (appropriate reason)
- Right form
- Right response

However, other sources refer to 8 or 10 "rights, and some of these topics, such as right action, appear to involve prescribing and/or dispensing. Accordingly, there does not (yet) appear to be consensus about expanding beyond the 5 "rights."

*Reference: Elliott, M. and Lis, Y. (2010). The Nine Rights of Medication Administration: An Overview. British Journal of Nursing, Vol. 19, 5, 300-305.

CAHs are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly.

Timing of Medication Administration

Appropriate timing of medication administration must take into account the complex nature and variability among medications; the indications for which they are prescribed; the clinical situations in which they are administered; and the needs of the patients receiving them. The chemical properties, mechanism of action, or therapeutic goals of some medications require administration at the exact time prescribed, or within a narrow window of its prescribed scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However, the therapeutic effect of many other medications is uncompromised by a much broader window of time for administration. Consequently, the application of a uniform required window of time

before or after the scheduled time for the administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize nursing care activities appropriately. This could also result in staff work-arounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, CAH policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration. The policies and procedures must address at least the following:

- Medications **not eligible** for scheduled dosing times;
- Medications **eligible for** scheduled dosing times;
- Administration of eligible medications outside of their scheduled dosing times and windows; and
- Evaluation of medication administration timing policies, including adherence to them.

Medications or categories of medication not eligible for scheduled dosing times

The policies and procedures must identify medications or categories of medication which are not eligible for scheduled dosing times, either in general or in specific clinical applications. These are medications that require exact or precise timing of administration, based on diagnosis type, treatment requirements, or therapeutic goals. The policies and procedures must reflect consideration of factors including, but not limited to, the pharmacokinetics of the prescribed medication; specific clinical applications; and patient risk factors. Examples of medications that CAHs may choose to identify as not eligible for scheduled dosing times may include, but are not limited to:

- Stat doses (immediate);
- First time or loading doses (initial large dose of a drug given to bring blood, tissue or fluid levels to an effective concentration quickly);
- One-time doses; doses specifically timed for procedures;
- Time-sequenced doses; doses timed for serum drug levels;
- Investigational drugs; or
- Drugs prescribed on an as needed basis (PRN doses).

The policies and procedures must ensure timely administration of such medications. In addition they must specify if the policy for the administration of these medications will be applied throughout the CAH or only for specific CAH units or specific clinical

situations or types of diagnoses.

Medications eligible for scheduled dosing times

Medications eligible for scheduled dosing times are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc. The goal of this scheduling is to achieve and maintain therapeutic blood levels of the prescribed medication over a period of time.

Medication administration policies and procedures typically establish standardized dosing times for the administration of all 'scheduled' medications. For example, medications prescribed for BID (twice a day) administration might, under a given CAH's policies and procedures, be scheduled to be administered at 8am and 8pm. Another CAH might choose to schedule BID medications at 7:30 am and 7:30 pm. Use of these standardized times facilitates the medication administration process, e.g., by providing to the CAH's pharmacy that morning doses of all BID drugs must be dispensed and delivered to patient units in time for the scheduled administration. For the nursing staff, the scheduled administration time might prompt prioritization of additional activities that may be required, in the case of particular drugs, such as vital sign assessment or the collection and review of blood work, to ensure safe and timely medication administration.

Policies and procedures for medications eligible for scheduled dosing times must also address: first dose medications, including parameters within which nursing staff are allowed to use their own judgment regarding the timing of the first and subsequent doses, which may fall between scheduled dosing times; retiming of missed or omitted doses; medications that will not follow scheduled dosing times; and patient units that are not subject to following the scheduled dosing times.

Time-critical scheduled medications

Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect. Accordingly, scheduled medications identified under the CAH's policies and procedures as time-critical must be administered within thirty minutes before or after their scheduled dosing time, for a total window of one hour.

It is possible for a given medication to be time- critical for some patients, due to diagnosis, clinical situation, various risk factors, or therapeutic intent, but not time-critical for other patients. Therefore, CAH policies and procedures must address the process for determining whether specific scheduled medications are always time-critical, or only under certain circumstances, and how staff involved in medication administration will know when a scheduled medication is time-critical. Examples of time-critical scheduled medications/medication types may include, but are not limited to:

- Antibiotics;

- Anticoagulants;
- Insulin;
- Anticonvulsants;
- Immunosuppressive agents;
- Pain medication (non-IV);
- Medications prescribed for administration within a specified period of time of the medication order;
- Medications that must be administered apart from other medications for optimal therapeutic effect; or
- Medications prescribed more frequently than every 4 hours.

Non-time-critical scheduled medications

Non-time critical scheduled medications are those for which a longer or shorter interval of time since the prior dose does not significantly change the medication's therapeutic effect or otherwise cause harm. For such medications greater flexibility in the timing of their administration is permissible. Specifically:

- Medications prescribed for daily, weekly or monthly administration may be within two hours before or after the scheduled dosing time, for a total window that does not exceed four hours.
- Medications prescribed more frequently than daily but no more frequently than every four hours may be administered within one hour before or after the scheduled dosing time, for a total window that does not exceed two hours.

Missed or late administration of medications

The CAH's policies and procedures must address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time. This includes doses which may have been missed due to the patient being temporarily away from the nursing unit, for example, for tests or procedures; patient refusal; patient inability to take the medication; problems related to medication availability; or other reasons that result in missed or late dose administration. Likewise, policies and procedures must also outline guidelines for the administration and timing of new medications which are initiated between standardized dosing times.

These policies and procedures must identify parameters within which nursing staff are allowed to use their own judgment regarding the rescheduling of missed or late doses and when notification of the practitioner responsible for the care of the patient is required prior doing so. In either case, errors in the administration of medication must be reported

internally as required at §485.635(a)(1)(v).

Evaluation of medication administration timing policies

CAHs must periodically evaluate their medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration. Medication errors related to the timing of medication administration must be tracked and analyzed to determine their causes. Based on the results of the evaluations of the policies and the medication administration errors, the CAH must consider whether there is a need to revise the policies and procedures governing medication administration timing.

Assessment/Monitoring of Patients Receiving Medications

Observing the effects medications have on the patient is part of the multi-faceted medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse effects and timely initiation of appropriate corrective action. Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;

- Physical signs and clinical symptoms relevant to the patient's medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.

Certain types of medications – "high alert medications" - are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients

For Information – Not Required/Not to be Cited

The Institute for Safe Medication Practices (ISMP) makes available a list of high alert medications, which it defines as those medications that bear a heightened risk of causing significant patient harm when they are used in error. The current list may be found at:
http://www.ismp.org/Tools/highAlertMedicationLists.asp

In addition, certain factors place some patients at greater risk for adverse effects of medication. Factors including, but not limited to, age, altered liver and kidney function, a history of sleep apnea, patient weight (obesity may increase apnea or smaller patients

may be more sensitive to dose levels of medications), asthma, history of smoking, drug-drug interactions, and first-time medication use may contribute to increased risk.

Consideration of patient risk factors as well as the risks inherent in a medication must be taken into account when determining the type and frequency of monitoring. Further, to enhance continuity of care/safe medication administration, it is essential to communicate all relevant information regarding patients' medication risk factors and monitoring requirements during hand-offs of the patient to other clinical staff, such as when patients are moved from a nursing for tests, during shift report at change of shift, etc. This would apply to hand-offs involving not only to nursing staff, but also to any other types of staff who administer medications, e.g., respiratory therapists.

Adverse patient reactions, such as anaphylaxis or opioid-induced respiratory depression, require timely and appropriate intervention, per established CAH protocols.

An example of vigilant post-medication administration monitoring in the case of a high-alert medication where patient factors may increase risk would be regularly checking vital signs, oxygen level via pulse oximetry, and sedation levels of a post-surgical patient who is receiving pain medication via a patient controlled analgesia (PCA) pump. Narcotic medications, such as opioids, are often used to control pain but also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. Timely assessment and appropriate monitoring is essential in all parts of the CAH in which opioids are administered, to permit intervention to counteract respiratory depression should it occur. (See also the discussion below for intravenous medications.)

As part of the monitoring process, staff are expected to include the patient's reports of his/her experience of the medication's effects. Further, when monitoring requires awakening the patient in order to assess effects of the medications, the patient and/or the patient's representative must be educated about this aspect of the monitoring process. In addition, CAHs are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

CAH policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the CAH's requirements for the method(s) of communication.

IV Medications & Blood Transfusions

Many of the medications included in the high-alert categories are administered intravenously. CAH policies and procedures for IV medications must address at least the following:

Vascular Access Route

Patients may require a form of vascular access to deliver blood or medications, either venous or arterial, based on the desired treatment plan. Safe administration of blood transfusions and IV medications includes the correct choice of vascular access. IV medications, such as fluids, antibiotics, and chemotherapy, may require specific types of access, such as peripheral or central catheters versus implanted port devices, based on the medication's chemical properties or safety concerns. Hospital policies and procedures must address which medications can be given intravenously via what type of access.

Other Patient Safety Practices

In addition to the basic safe practices that apply to all medication administration, there are additional safe practices specific to IV medication administration that require consideration, including but not limited to, the following:

- Tracing invasive lines and tubes prior to administration to ensure the medication is to be administered via the proper route (for example, peripheral catheter versus epidural catheter connections);

- Avoiding forcing connections when the equipment offers clear resistance;

  - Verifying proper programming of infusion devices (concentrations, flow rate, dose rate).

Monitoring patients receiving IV medications

To the extent that IV medications have a more rapid effect on the body, it is important that staff administering medications via IV understand each medication and its monitoring requirements. Policies and procedures for IV medication administration must address appropriate IV medication monitoring requirements, including assessment of patients for risk factors that would influence the type and frequency of monitoring.

For example: a 50 year old patient with a history of renal failure is receiving IV vancomycin to treat a wound infection. The CAH policy for IV antibiotics, including vancomycin, requires the patient's kidney function to be monitored daily with blood draws. Based on review of the lab results, a practitioner responsible for the care of the patient would be expected to determine on a timely basis whether or not the antibiotic dose needs to be adjusted to protect kidney function or prevent drug toxicity while achieving the desired therapeutic effects. Staff administering the medication would be expected to review the lab results as well, and to raise with a practitioner responsible for the care of the patient any concerns they might have about whether an adjustment in the medication is needed.

CAH policies and procedures related to monitoring patients receiving IV medications are expected to address, but are not limited to, the following:

- **Monitoring for Fluid & Electrolyte Balance**

Whenever IV medications and blood transfusions are administered, the patient may become at risk for fluid and electrolyte imbalance. Policies and procedures must address monitoring and treatment for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications.

- **Monitoring Patients Receiving High-alert Medications, Including IV Opioids**

  Policies and procedures related to IV medication administration must address those medications the CAH has identified as high-alert medications and the monitoring requirements for patients receiving such drugs intravenously.

  At a minimum, if the CAH provides surgical services, it is expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients.

  Opioids are a class of medication used frequently to treat pain. The sedating effects of opioids make it difficult at times to properly assess the patient's level of sedation. It can be erroneously assumed that patients are asleep when they are actually exhibiting progressive symptoms of respiratory compromise - somnolence, decreased respiratory rate, and decrease in oxygen levels. These symptoms, if unrecognized, can progress to respiratory depression and even death.

  In addition to those patient characteristics that affect risk of adverse effects from medication discussed above, other factors placing patients receiving IV opioids at higher risk for oversedation and respiratory depression include, but are not limited to[4]:

  - Snoring or history of sleep apnea
  - No recent opioid use or first-time use of IV opioids
  - Increased opioid dose requirement or opioid habituation
  - Longer length of time receiving general anesthesia during surgery
  - Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other central nervous system depressants
  - Preexisting pulmonary or cardiac disease
  - Thoracic or other surgical incisions that may impair breathing

Of particular concern are patients receiving IV opioids post-operatively. The effects

[4] *Jarzyna D., Junquist C., Pasero C., et al. American Society for Pain Management Nursing - Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression. Pain Management Nursing, Vol 12, No. 3 (September), 2011: pp 118-145*

of IV opioids in post-operative patients must be monitored vigilantly via serial assessments of pain, respiratory status, and sedation levels.

CAHs that provide surgical services must have policies and procedures related to the use of high-alert medications, including IV opioids for post-operative patients. Policies and procedures must address, at a minimum, the process for patient risk assessment, including who conducts the assessments, and, based on the results of the assessment, monitoring frequency and duration, what is to be monitored, and monitoring methods. The policies and procedures must also address whether and under what circumstances practitioners prescribing IV opioids are allowed to establish protocols for IV opioid administration and monitoring that differ from the CAH's policies and procedures.

The frequency of the serial assessments and duration of the monitoring timeframe for post-operative patients receiving IV opioids must be determined based on at least the following considerations:

- Patient risk for adverse events;
- Opioid dosing frequency and IV delivery method. (push or patient-controlled analgesia (PCA));
- Duration of IV opioid therapy.

Regardless of the above factors, at a minimum monitoring must include the following:

- Vital signs (blood pressure, temperature, pulse, respiratory rate);
- Pain level;
- Respiratory status;
- Sedation level; sedation levels are important indicators for the clinical effects of opioids. Sedation is a useful assessment parameter to observe the effects of opioids since sedation typically precedes respiratory depression[5]. See the blue box below for information on sedation assessment methods.

[5] *Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013*

For Information – Not Required/Not to be Cited

In addition to assessing risk for respiratory depression, the Institute for Safe Medication Practices recommends hospitals use a standard sedation scale when assessing patients receiving PCA. Scales such as the Richmond Agitation Sedation Scale, Pasero, Ramsey, or Glasgow Coma Scale are useful in assessing sedation.

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

In addition to vigilant nursing assessment at appropriate intervals, CAHs may choose to use technology to support effective monitoring of patients' respiratory rate and oxygen levels.

For additional information regarding recommendations of expert organizations on post-operative opioid monitoring, including technology-supported monitoring, see blue boxes below. The practices described in the blue boxes below are not required under the regulations.

The assessment and monitoring process must be explained to the patient and/or the patient's representative, to communicate the rationale for vigilant monitoring, including that it might be necessary to awaken the patient in order to assess effects of the medications. In addition, CAHs are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

For Information – Not Required/Not to be Cited
Institute for Safe Medication Practices Guidelines for PCA Monitoring

Assessment of Opioid Tolerance	Vital Signs	Pain	Sedation	Respiratory		
				Rate	Quality	SPO_2* &/or $ETCO_2$**
Baseline Assessment before PCA	X	X	X	X	X	X
PCA Initiation or Change in Drug/Syringe Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
PCA Dose Change or Bolus Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Adverse Event or Patient Deterioration (e.g.,	X	X	X	X	X	X

adverse change in sedation score) Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours						
Hand-offs/Shift Change	X	X	X	X	X	X
Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013 ISMP adapted these recommendations from the San Diego Patient Safety Council * SPO_2: Saturation of peripheral oxygen via pulse oximetry ** $ETCO_2$: End-tidal carbon dioxide via capnography						

For Information – Not Required/Not to be Cited
Anesthesia Patient Safety Foundation

- *APSF calls for every patient receiving postoperative opioid analgesics to be managed based on the following clinical considerations*:*
    - *Individualize the dose and infusion rate of opioid while considering the unique aspects of each patient's history and physical status.*
    - *Make continuous monitoring of oxygenation (pulse oximetry) the routine rather than the exception.*
    - *Assess the need for supplemental oxygen, especially if pulse oximetry or intermittent nurse assessment are the only methods of identifying progressive hypoventilation.*
    - *When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.*

APSF also has issued a video on opioid induced ventilatory impairment: http://apsf.org/resources_video4.php

**Stoelting, RK.,Weinger MB. Dangers of postoperative opioids: Is there a Cure? APSF Newsletter 2009;24:2.*

For Information – Not Required/Not to be Cited
The Patient Safety Movement Foundation

PSMF recommends all patients receiving IV opioids have continuous measure-through motion and low perfusion pulse oximetry, and that patients on supplemental oxygen also have continuous respiration rate monitoring. It also calls for the monitoring system to be linked with a notification system to clinical staff who can respond immediately. It calls for an escalation protocol so that if a staff person does not acknowledge the alert in 60 seconds a second person will be notified.

The Patient Safety Movement Foundation - Actionable Patient Safety Solution (APSS) #1: Failure to Rescue: Post-Operative Respiratory Depression. January 13, 2013

Adverse patient reactions to IV medications require timely and appropriate intervention, per established protocols.

IV Blood Administration Procedures

According to the U.S. Department of Health and Human Services, 13,785,000 units of whole blood and red blood cells were transfused in the United States in 2011[6]. The collection, testing, preparation, and storage of blood and blood components are regulated by the Food and Drug Administration. Blood transfusions can be life-saving. However, they are not without risk of harm to patients. Transfusion reactions and/or errors can be fatal.

In addition to the safe practices and other safety considerations that apply to all IV medication administration, policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to:

- Confirming the following prior to each blood transfusion:

  - the patient's identity
  - verification of the right blood product for the right patient

  The standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation.

- Requirements for patient monitoring, including frequency and documentation of monitoring

- How to identify, treat, and report any adverse reactions the patient may experience during or related to transfusion.

Documentation

Note that documentation of medication administration is addressed in the Medical Records CoP at §485.638(a)(4)(iii). This regulation requires that the record contain: "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, progress notes describing the patient's response to treatment…." Documentation is expected to occur after actual administration of the drugs or biologicals to the patient; advance documentation is not only inappropriate, but may result in medication errors. Proper documentation of medication administration actions taken and their outcomes is essential for planning and delivering future care of the patient. See the guidance for the various parts of §485.638 concerning documentation in the medical record. Deficiencies in documentation would be cited under the Clinical Records regulation.

Survey Procedures §485.635(d)(3)

[6] *The 2011 National Blood Collection and Utilization Survey Report. Retrieved September 27,2013 from http://www.hhs.gov/ash/bloodsafety/2011-nbcus.pdf*

- Ask the person responsible for nursing services what type of personnel administer drugs and biologicals, including IVs. Are they practicing within their permitted scope?

    - If anyone other than an MD/DO, RN or PA administers drugs or biologicals, are they supervised by an RN or, if permitted under State law and CAH policy, a PA?

    - Verify that nursing staff administering drugs have completed training consistent with CAH training policy.

    - Review a sample of medication orders and determine if they contain the required elements:

    - Determine if orders are legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible for the care of the patient.

    - Was the administration of the medication consistent with the order, i.e., the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the hospital's policies and procedures? Check that the practitioner's order was still in force at the time the drug was administered.

    - Ask nursing staff if the CAH permits verbal orders and, if so, what the policy is for a verbal order. If staff are unaware of any policy, or if their description of a policy suggests it is incomplete or inconsistent with accepted standards of practice, ask to see the written policy.

    - Ask nursing staff whether they initiate medications in accordance with standing orders. Are they familiar with the hospital's policies and procedures for using standing orders? Are they following the policies and procedures? Ask to see the protocol for a standing order used by nursing staff, and ask nursing staff to explain how their practice conforms to the protocol.

        - Determine whether all standing orders which were initiated by a nurse were authenticated by an authorized practitioner.

    - Ask nursing staff if the CAH permits patient self-administration of medications.

        - If yes, does the CAH have policies and procedures addressing this?

        - Is there an order from a practitioner responsible for the care of the patient permitting self-administration of medications, either issued by the CAH or brought from home?

- Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed.
    - Is the patient's identity confirmed prior to medication administration?
    - Are procedures to assure the correct medication, dose, and route followed?
    - Are drugs administered in accordance with the hospital's established policies and procedures for timely medication administration?
    - Does the nurse remain with the patient until medication is taken, unless they are permitted to self-administer?
- Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?
- Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?
    - Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?
- Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.
    - Are they able to identify time-critical and non-time-critical scheduled medications? Medications not eligible for scheduled dosing times?
    - Are they able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies?
- Interview nursing staff who administer IV medications and blood transfusions. Are staff knowledgeable with respect to:
    - Venipuncture techniques;
    - Safe medication administration practices, including general practices applying to all types of medications and practices concerning IV tubing and infusion pumps;
    - Maintaining fluid and electrolyte balance;
    - Patient assessment for risk related to IV medications and appropriate monitoring;

    - Early detection and intervention for IV opioid-induced respiratory depression in post-operative patients;
    - With respect to blood transfusions:
        - Blood components;
    - Process for verification of the right blood product for the right patient; and
    - Transfusion reactions: identification, treatment, and reporting requirements.
- If able, observe blood transfusion and IV medication administration to assess staff adherence to accepted standards of practice.
    - Were safe medication administration practices used?
    - Was the transfused patient correctly identified and matched to the correct blood product prior to administration?
    - Was the appropriate access used for IV medications?
    - Were appropriate steps taken with regard to IV tubing and infusion pumps?
    - Are patients being monitored post-infusion for adverse reactions?
- If staff appear to not be following accepted standards of practice for patient risk assessment related to IV medications, particularly opioids, and appropriate monitoring of patients receiving IV medications and/or blood transfusions, review policies and procedures for IV medication administration and blood transfusion to determine if they address safe practices considerations.

C-1050

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(d)(4) A nursing care plan must be developed and kept current for each inpatient.

Interpretive Guidelines §485.635(d)(4)

There must be a nursing care plan for every CAH inpatient. Nursing care planning starts upon admission. It includes planning the patient's care while in the CAH as well as planning for transfer to a hospital, to a post-acute care facility or for discharge. A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis). The assessment considers the patient's treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge

planning. The plan develops appropriate nursing interventions in response to the identified nursing care needs. One resource for information about nursing care plans is The American Nurses Association http://www.nursingworld.org/EspeciallyforYou/StudentNurses/Thenursingprocess.aspx.

The nursing care plan is kept current by ongoing assessments of the patient's needs and of the patient's response to interventions, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's clinical record and must comply with the clinical records requirements at §485.638.

CAHs have the flexibility of developing the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. This method may serve to promote communication among disciplines and reinforce an integrated, multi-faceted approach to a patient's care, resulting in better patient outcomes. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote the collaboration between members of the patient's health care team.

Survey Procedures §485.635(d)(4)

Select a representative sample of nursing care plans based on the number of inpatient records reviewed.

- Are the care plans created as soon as possible after admission for each patient?
- Are the care plans based on the nurse's assessment of the individual patient?
- Is there evidence that the care plans are reviewed on an ongoing basis?
- Is there evidence that the nursing care plan is revised as needed and is there documentation of nursing reassessment?
- Verify that there is evidence that the nursing care plans have been implemented.

C-1052

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(e) Standard: Rehabilitation Therapy Services

Physical therapy, occupational therapy, and speech-language therapy pathology services furnished at the CAH, if provided, are provided by staff qualified under State law, and consistent with the requirements for therapy services in §409.17 of this subpart.

Interpretive Guidelines §485.635(e)

Rehabilitation services are optional CAH services. If a CAH provides any rehabilitative services to its patients, either directly or under arrangement or agreement, either inpatient

or outpatient, the services must be provided by staff qualified under State law, and consistent with the requirements for therapy services in §409.17. Rehabilitation services services can be initiated only upon the order of a practitioner responsible for the care of the patient. Physical therapy, occupational therapy, or speech-language pathology must be furnished in accordance with the regulation at 42 CFR 409.17, which specifies the following rehabilitation services plan of care requirements:

- Establishment of the plan: "The plan must be established before treatment begins by one of the following: (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; (5) An occupational therapist furnishing the occupational therapy services."

- Content of the plan: "The plan: (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."

- Changes in the plan: "Any changes in the plan are implemented in accordance with the provider's policies and procedures."

Also in accordance with 42 CFR 409.17, rehabilitation services must be provided by qualified physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists who meet the personnel qualifications defined in 42 CFR 484.4. CAHs must have policies and procedures consistent with State law.

Rehabilitation services must be provided according to national standards of practice as established by professional organizations such as, but not limited to, the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association.

Survey Procedures §485.635(e)

If the CAH provides rehabilitation services:

- Review clinical records of patients who received rehabilitation services. Determine whether the required care plan was developed and implemented.

- Review employee personnel files to verify the rehabilitation service providers (i.e., physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists) have the necessary education, experience, training, and documented competencies to provide rehabilitation services.

- Ask the CAH what national standards of rehabilitation practice provide the basis

for its rehabilitation services. Is there supporting documentation?

C-1054

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(f) Standard: Patient visitation rights. A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation….

Interpretive Guidelines §485.635(f)

Visitation plays an important role in the care of hospital patients, including CAHs. An article published in 2004 in the Journal of the American Medical Association (Berwick, D.M., and Kotagal, M.: "Restricted visiting hours in ICUs: time to change." JAMA. 2004; Vol. 292, pp. 736-737) discusses the health and safety benefits of open visitation for patients, families, and intensive care unit (ICU) staff and debunks some of the myths surrounding the issue (physiologic stress for the patient; barriers to provision of care; exhaustion of family and friends). The article ultimately concluded that "available evidence indicates that hazards and problems regarding open visitation are generally overstated and manageable," and that such visitation policies "do not harm patients but rather may help them by providing a support system and shaping a more familiar environment" as they "engender trust in families, creating a better working relationship between hospital staff and family members." CAHs that unnecessarily restrict patient visitation often miss an opportunity to gain valuable patient information from those who may know the patient best with respect to the patient's medical history, conditions, medications, and allergies, particularly if the patient has difficulties with recall or articulation, or is totally unable to recall or articulate this vital personal information. Many times visitors who may know the patient best act as an intermediary for the patient, helping to communicate the patient's needs to CAH staff.

Although visitation policies are generally considered to relate to visitors of inpatients, "visitors" also play a role for outpatients who wish to have a support person present during their outpatient visit. For example, a same-day surgery patient may wish to have a support person present during the pre-operative patient preparation or post-operative recovery. Or an outpatient clinic patient may wish to have a support person present during their examination by a physician. Accordingly, CAH visitation policies must address both the inpatient and outpatient settings.
CAHs are required to develop and implement written policies and procedures that address the patient's right to have visitors. If the CAH's policy establishes restrictions or limitations on visitation, such restrictions/limitations must be clinically necessary. Furthermore, the CAH's policy must include the reasons for any restrictions/limitations. The right of a patient to have visitors may be limited or restricted when visitation would

interfere with the care of the patient and/or the care of other patients. The regulation permits CAHs some flexibility, so that health care professionals may exercise their best clinical judgment when determining when visitation is, and is not, appropriate. Best clinical judgment takes into account all aspects of patient health and safety, including the benefits of visitation on a patient's care as well as potential negative impacts that visitors may have on other patients in the CAH.

Broad examples of clinically reasonable bases for a CAH to impose restrictions or limitations on visitors might include (but are not limited to) when:

- there may be infection control issues;
- visitation may interfere with the care of other patients;
- the CAH is aware that there is an existing court order restricting contact;
- visitors engage in disruptive, threatening, or violent behavior of any kind;
- the patient or patient's roommate needs rest or privacy;
- in the case of an inpatient substance abuse treatment program, there are protocols limiting visitation; and
- the patient is undergoing care interventions. However, while there may be valid reasons for limiting visitation during a care intervention, we encourage CAHs to try to accommodate the needs of any patient who requests that at least one visitor be allowed to remain in the room to provide support and comfort at such times.

It may also be reasonable to limit the number of visitors for any one patient during a specific period of time, as well as to establish minimum age requirements for child visitors. However, when a CAH adopts policies that limit or restrict patients' visitation rights, the burden of proof is upon the CAH to demonstrate that the visitation restriction is reasonably necessary to provide safe care.

CAHs are expected to provide a clear explanation in their written policy of the clinical rationale for any visitation restrictions or limitations reflected in that policy. CAHs are not required, however, to delineate each specific clinical reason for policies limiting or restricting visitation, given that it is not possible to anticipate every instance that may give rise to a clinically appropriate rationale for a restriction or limitation. If visitation policies differ by type of unit, e.g., separate policies for intensive care units, or for newborn nurseries, the CAH policy must address the clinical rationale for this differentiation explicitly.

The CAH's policies and procedures are expected to address how CAH staff who play a role in facilitating or controlling visitor access to patients will be trained so as to assure appropriate implementation of the visitation policies and procedures and avoidance of unnecessary restrictions or limitations on patients' visitation rights.

Survey Procedures §485.635(f)

- Verify that the CAH has written policies and procedures that address the right of patients to have visitors.

- Review the policy to determine if there are limitations or restrictions on visitation. If there are, does the policy explain the clinical rationale for the restrictions or limitations? Is the rationale clear and reasonably related to clinical concerns?

- 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?

- 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?

C-1056

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(f) Standard: Patient visitation rights. A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible.

(2) Inform each patient (or support person, where appropriate) 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.

Interpretive Guidelines §482.635(f)(1)&(2)

CAHs are required to inform each patient (or the patient's support person, where appropriate) of his/her visitation rights. A patient's "support person" does not necessarily have to be the same person as the patient's representative designated under an advance directive who is legally responsible for making medical decisions on the patient's behalf. A patient's support person could be a family member, friend, or other individual who supports the patient during the course of the CAH stay. Not only may the support person visit the patient, but he or she may also exercise a patient's visitation rights on behalf of the patient with respect to other visitors, when the patient is unable to do so. CAHs must accept a patient's designation, orally or in writing, of an individual as the patient's support person.

When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no advance directive designating a representative on file, and an individual provides an advance directive designating an individual as the patient's support person, (it is not necessary for the document to use this exact term), the CAH must accept this designation, provide the required notice of the patient's visitation rights, and allow the individual to exercise the patient's visitation rights on the patient's behalf.

When a patient is incapacitated or otherwise unable to communicate his or her wishes and no one has presented an advance directive designating them as the patient's support person, but an individual asserts that he or she, as the patient's spouse, domestic partner (including a same-sex domestic partner), parent or other family member, friend, or otherwise, is the patient's support person, the CAH is expected to accept this assertion, without demanding supporting documentation, provide the required notice of the patient's visitation rights, and allow the individual to exercise the patient's visitation rights on the patient's behalf. However, if more than one individual claims to be the patient's support person, it would not be inappropriate for the CAH to ask each individual for documentation supporting his/her claim to be the patient's support person.

- CAHs are expected to adopt 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.

- A refusal by the CAH of an individual's request to be treated as the patient's support person with respect to visitation rights must be documented in the patient's medical record must, along with the specific basis for the refusal.

The required notice of the patient's visitation rights must be provided, whenever possible, before the CAH provides patient care. The notice to patients must be in writing in a language or manner that the patient (or the patient's support person) can understand. This is consistent with the guidance related to Title VI of the Civil Rights Act of 1964 issued by the Department of Health and Human Services - "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons" (August 8, 2003, 68 FR 47311). In accordance with §485.608(a), CAHs are expected to comply with Title VI and may use this guidance to assist the CAH in ensuring patient's rights information is provided in a language and manner that the patient understands. Surveyors do not assess compliance with this guidance on limited English proficiency, but may refer concerns about possible noncompliance to the Office of Civil Rights in the applicable Department of Health and Human Services Regional Office.

The required visitation rights notice must address any clinically necessary or reasonable limitations or restrictions imposed by CAH policy on visitation rights, providing the clinical reasons for such limitations/restrictions, including how they are aimed at protecting the health and safety of all patients. The information must be sufficiently detailed to allow a patient (or the patient's support person) to determine what the

visitation hours are and what restrictions, if any, apply to that patient's visitation rights.

The notice must also inform the patient (or the patient's support person, where appropriate) of the patient's right to:

- Consent to receive visitors he or she has designated, either orally or in writing, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend;

- Receive the visitors he or she has designated, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend; and

- Withdraw or deny his/her consent to receive specific visitors, either orally or in writing.

The medical record must contain documentation that the required notice was provided to the patient or, if appropriate, the patient's support person.

Survey Procedures §485.635(f)(1) & (2)

- Determine whether the CAH's visitation policies and procedures require providing notice of the patient's visitation rights to each patient or, if appropriate, to a patient's support person and/or, as applicable, the patient's representative .

- Review the CAH's standard notice of visitation rights. Does it clearly explain the:

    - CAH's visitation policy, including any limitations or restrictions, such as visiting hours, numbers of visitors, or unit-specific restrictions, etc., and the clinical rationale for such limitations or restrictions?

    - right of the patient to have designated visitors, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and the right to withdraw or deny consent to visitation?

- Review a sample of medical records to determine if there is documentation that the required notice was provided and if it was provided in advance of care, unless circumstances made this not feasible.

- Ask the CAH to identify how the required notice is provided. Ask staff responsible for providing the notice how they accomplish this. Ask the staff if they are familiar with the concept of a patient's "support person" and what it means.

- Ask a sample of current CAH patients or patients' support persons (where

appropriate) whether they were provided notice of their right to have visitors. Ask if they were able to have visitors when they wanted to. If not, verify whether the restriction/limitation on visitors was addressed in the CAH's visitation policies and notice, or was inappropriate.

- Ask a sample of current CAH patients or patients' support persons (where appropriate) whether the CAH did not limit some or all visitors, contrary to the patient's wishes.

C-1058

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.635(f) Standard: Patient visitation rights. A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

Interpretive Guidelines §485.635(f)(3)&(4)

The CAH's visitation policies and procedures may not use the race, color, national origin, religion, sex, gender identity, sexual orientation, or disability of either the patient (or the patient's support person, where appropriate) or the patient's visitors (including individuals seeking to visit the patient) as a basis for limiting, restricting, or otherwise denying visitation privileges.

The CAH's policies and procedures must ensure that all visitors (including individuals seeking to visit the patient) enjoy full and equal visitation privileges, consistent with the preferences the patient (or, where appropriate, the patient's support person) has expressed concerning visitors. In other words, it is permissible for the patient (or the patient's support person, where appropriate) to limit the visiting privileges of his/her visitors, including providing for more limited visiting privileges for some visitors than those for others. But it is not permissible for the CAH, on its own, to differentiate among visitors without any clinically necessary or reasonable basis. This includes visitors designated by the patient who have characteristics not addressed specifically in §485.635(f)(3), when those characteristics do not reasonably relate to a clinically reasonable basis for limiting or denying visitation. For example, it would not be appropriate to prohibit a designated visitor based on that individual's style of dress, unless there was a clinically reasonable basis for doing so.

The CAH is responsible for ensuring that CAH staff treat all individuals seeking to visit patients equally, consistent with the preferences of the patient (or, where appropriate, the patient's support person) and do not use the race, color, national origin, religion, sex, gender identity, sexual orientation, or disability of either the patient (or the patient's support person, where appropriate) or the patient's visitors (including individuals seeking to visit the patient)as a basis for limiting, restricting, or otherwise denying visitation privileges. CAHs are expected to educate all staff who play a role in facilitating or controlling visitors on the CAH's visitation policies and procedures, and are responsible for ensuring that staff implement the CAH's policies correctly. CAHs are urged to develop culturally competent training programs designed to address the range of patients served by the CAH.

Survey Procedures §485.635(f)(3)&(4)

- Review the CAH's visitation policies and procedures to determine whether they restrict, limit, or otherwise deny visitation to individuals on a prohibited basis.

- Ask the CAH how it educates staff to assure that visitation policies are implemented in a non-discriminatory manner.

- Ask CAH staff who play a role in facilitating or controlling visitors to discuss their understanding of the circumstances under which visitors may be subject to restrictions/limitations. Are the restrictions/limitations appropriately based on the CAH's clinically-based policies?

- Ask CAH patients (or patients' support persons, where appropriate) whether the CAH has limited visitors against their wishes? If yes, verify whether the restriction/limitation on visitors was addressed in the CAH's visitation policies and in the patient notice, and whether it was appropriately based on a clinical rationale rather than impermissible discrimination.

C-1100

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638 Condition of Participation: Clinical Records

C-1102

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(a) Standard: Records System

(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

Interpretive Guidelines §485.638(a)(1)

The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. The medical record system must correctly identify the author of every medical record entry. The medical record system must protect the security of all medical record entries. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security and protection of the records.

The CAH must have a system in place that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of the entry, that the entry is accurate, and that he/she takes responsibility for accuracy of the entry.

If the CAH uses computer entries there must be security system in place to ensure the integrity of the record system, to ensure that the author of each entry is correctly identified, to ensure that record entries are not altered or lost, that limits access to medical records to only authorized persons, and ensures that records are not released to unauthorized individuals. For the purposes of this regulation, electronic signatures comply with those medical record entries that include a requirements for a signature.

There should be a current list of authenticated signatures, as well as a list of computer codes and signature stamps (when used for authorship purposes) that have been authorized by the governing body and are protected by adequate safeguards. CAH policies and procedures should provide for appropriate sanctions for unauthorized or improper use of computer codes or signature stamps.

The CAH must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the CAH. A unit record for both inpatients and outpatients may be used; however, when two different systems are used they must be appropriately cross referenced. When a patient reimbursement status changes from acute care services to swing bed services, a single medical record may be used for both stays as long as the record is sectioned separately. Both sections must include admission and discharge orders, progress notes, nursing notes, graphics, laboratory support documents, any other pertinent documents, and discharge summaries.
The medical record must be properly filed and retained. The CAH must have a medical recording system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the CAH within the past 6 years.

The medical record must be accessible. The CAH must 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 accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.

Survey Procedures §485.638(a)(1)

- Verify that a medical record is maintained for each person receiving care.
- Verify that written procedures ensure the integrity of authentication and protect the security of patient records.
- Verify that medical records are stored and maintained in locations where the records are secure, with protection from damage, flood, fire, theft, etc., and limits access to only authorized individuals.
- Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed.
- Verify that there is an established system that addresses at least the following activities of the medical records services:
    - Timely processing and retrieval of records;
    - Protecting the confidentiality of medical information;
    - Compiling and retrieval of data of quality assurance activities.
- Verify that the system policies and procedures are reviewed and revised as needed.
- Verify that the CAH employs adequate medical record personnel who possess adequate education, skills, qualifications and experience to ensure the CAH complies with requirements of the medical records regulations and other appropriate Federal and State laws and regulations.
- Are medical records promptly completed in accordance with State law and CAH policy?
- Select a sample of past patients of the CAH (inpatient and/or outpatient). Request those patient's medical records. Can the CAH promptly retrieve those records?

C-1104

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(a)(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

Interpretive Guidelines §485.638(a)(2)

All medical records must be accurately written. The CAH must ensure that all medical records accurately and completely document all orders, test results, evaluations, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

Survey Procedures §485.638(a)(2)

For CAH surveys that are conducted after the initial certification survey, examine a sample of records using an adequate sample size to evaluate the scope of services provided. In a very small CAH, look at all inpatient and outpatients records, if appropriate.

C-1106

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(a)(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

Interpretive Guidelines §485.638(a)(3)

The CAH must have one unified medical record service with a department head that has been appointed by the governing body (or responsible individual). The director of medical records must have responsibility for all medical records to include both inpatient and outpatient records.

Survey Procedures §485.638(a)(3)

- Verify that the CAH employs adequate medical record personnel.
- Review the organizational structure and policy statements and interview the person responsible for the service to ascertain that the medical records service is structured appropriately to meet the needs of the CAH and the patients.

C-1110

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(a)(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable--

> **(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;**

Interpretive Guidelines §485.638(a)(4)(i)

The medical record must include evidence of properly executed informed consent forms for any procedures or surgical procedures specified by the medical staff, or by Federal or State law, if applicable, that require written patient consent.

Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment.

A properly executed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedures(s);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent;
- Name/signature of person who explained the procedure to the patient or guardian.

The medical record must contain information such as progress and nursing notes, documentation, records, reports, recordings, test results, assessments etc. to:

- Justify admission;
- Support the diagnosis;
- Describe the patient's progress;
- Describe the patient's response to medications; and
- Describe the patient's response to services such as interventions, care, treatments, etc.

The medical record must contain complete information/documentation regarding medical history, assessment of the health status and health care needs of the patient, and a summary of the episode, disposition, and instructions to the patient. This information and documentation is contained in a discharge summary.

A discharge summary discusses the outcome of the CAH stay, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post CAH appointment, how post CAH patient care needs are to be met, and any plans for post-CAH care by providers such as swing-bed services, home health, hospice, nursing

homes, or assisted living. A discharge summary is required following any CAH acute care stay prior to and following a swing-bed admission and discharge.

The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and CAH policy, who admitted the patient is responsible for the patient during the patient's stay in the CAH. This responsibility would include developing and entering the discharge summary.

The MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and physician assistants to the extent recognized under State law or a State's regulatory mechanism. The MD/DO may also delegate writing the discharge summary to another MD/DO who is familiar with the patient.

Survey Procedures §485.638(a)(4)(i)

- Verify that the medical staff have specified which procedures or treatments require a written informed consent.
- Verify that medical records contain consent forms for all procedures or treatment that are required by CAH policy.
- Verify that consent forms are properly executed.
- Examine a sample of patient records and/or facility records of requests for information contained in patient records to determine if there are signed and dated consent forms, when required, medical history, health status and care needs assessment, and discharge summary in each record, as needed.
- Review of sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and CAH policy. The sample should be at least 10 percent of the average daily census, as appropriate.

C-1114

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(a)(4)(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

Interpretive Guidelines §485.638(a)(4)(ii)

All or part of the history and physical exam (H & P) may be delegated to other practitioners in accordance with State law and CAH policy, but the MD/DO must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P.

Survey Procedures §485.638(a)(4)(ii)

- Determine that the bylaws require a physical examination and medical history be done for each patient.

- For sampled records, does the appropriate practitioner sign reports of physical examinations, diagnostic and laboratory test results, and consultative findings?

C-1116

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(a)(4)(iii) 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, progress notes describing the patient's response to treatment; and

Interpretive Guidelines §485.638(a)(4)(iii)

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record. In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.

The medical record must contain:

- All practitioner's orders (properly authenticated);

- All nursing notes;

- All reports of treatment (including complications and CAH-acquired infections);

- All medication records (including unfavorable reactions to drugs);

- All radiology reports;

- All laboratory reports;

- All vital signs; and

- All other information necessary to monitor the patient's condition.

All medical records must be promptly completed. Every medical record must be 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.

Survey Procedures §485.638(a)(4)(iii)

- Verify that the patient records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports and other information necessary to monitor the patient's condition.

- Is necessary information included in patient records in a prompt manner so that health care staff involved in the care of the patient have access to the information necessary to monitor the patient's condition?

C-1118

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(a)(4)(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

Interpretive Guidelines §485.635(a)(4)(iv)

Entries in the medical record may be made only by individuals as specified in CAH and medical staff policies. All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code.

When rubber stamps are authorized, the individual whose signature the stamp represents shall place 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. There shall be no delegation to another individual.

A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The CAH must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable.

The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of physical examination, such information shall be appropriately authenticated by the responsible MD/DO. Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations.

All entries in the medical record must be authenticated.

Authentication would include at a minimum:

- The CAH has a method to establish the identity of the author of each entry. This

would include verification of the author of faxed orders/entries or computer entries.

- The author takes a specific action to verify that the entry is his/her entry or that he/she is responsible for the entry, that the entry is accurate.

- The timing of the entry is noted and correct.

Timing documents the time and date of each entry (orders, reports, notes etc.). Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries are necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or time lines of various signs, symptoms, or events. There must be a specific action by the author to indicate that the entry is, in fact, verified and accurate. Failure to disapprove an entry within a specific time period is not acceptable as authentication.

A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.

Survey Procedures §485.635(a)(4)(iv)

- Verify that entries are authenticated.

- Verify that the department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification.

- Verify that computer or other code signatures are authorized by the CAH'S governing body and that a list of these codes is maintained under adequate safeguards by the CAH administration.

- Verify that the CAH'S policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes.

- Examine the CAH'S policies and procedures for using the system, and determine if documents are being authenticated after transcription.

- For sampled records, are there dated and authenticated signatures by appropriate MD/DOs and/or mid-level practitioners, as needed?

C-1120

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(b) Standard: Protection of Record Information

(1) The CAH maintains the confidentially of record information and provides safeguards against loss, destruction, or unauthorized use.

Interpretive Guidelines §485.638(b)(1)

The CAH has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. CAH staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.

Survey Procedures §485.638(b)(1)

- Verify that only authorized persons are permitted access to records maintained by the medical records department.

- Verify that the CAH has 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.

- Verify that medical records are 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.

- Verify that copies of medical records are 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.

- Verify that precautions are taken to prevent unauthorized persons from gaining access to or altering patient records.

- Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

C-1122
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(b)(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

Interpretive Guidelines §485.638(b)(2)

The CAH'S patient record system must ensure the security of patient records. The CAH must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the CAH and outpatients in outpatient clinics.

Survey Procedures §485.638(b)(2)

- Observe the CAH'S security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurses stations, or on counters where an unauthorized person could gain access to patient records?

- If the CAH uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?

- Verify that the CAH has policies and procedures for the use and release of records and that these policies and procedures are enforced.

C-1124
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(b)(3) The patient's written consent is required for release of information not required by law.

C-1126
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.638(c) Standard: Retention of Records

The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

Interpretive Guidelines §485.638(c)

Medical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks. The CAH must be able to 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.

In accordance with Federal and State law and regulations, certain medical records may have retention requirements that exceed 6 years (for example: FDA, OSHA, EPA).

Survey Procedures §485.638(c)

Determine that records are retained for at least 6 years, or more if required by State or local laws.

C-1140

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.639 Condition of Participation: Surgical Services.

If a CAH provides surgical services, surgical procedures must be 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.

Interpretive Guidelines §485.639

The provision of surgical services is an optional CAH service. However, if a CAH provides surgical services to its patients, the services must be organized and staffed in such a manner to ensure the health and safety of patients. Surgical services that are performed in a safe manner would be performed in accordance with acceptable standards of practice. In accordance with acceptable standards of practice includes maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of periOperative Registered Nurses, Association for Professionals in Infection Control and Epidemiology, etc.) Additionally, the CAH'S outpatient surgical services must be integrated with the CAH's inpatient surgical services.

When the CAH offers surgical services, the CAH must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the surgical services offered by the CAH in accordance with acceptable standards of practice.

The scope of surgical services provided by the CAH should be defined in writing and approved by the governing body or responsible individual.

Supervision in the OR

The operating room must be supervised by an experienced staff member authorized by State law. The supervisor's experience could include education, background working in

surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The CAH should address its required qualifications for the supervisor of the CAH'S operating rooms in its policies. If the CAH utilizes LPN or operating room technicians as "scrub nurses," those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care, as required in State law.

Policies and Procedures

Policies governing surgical care should contain:

- Aseptic surveillance and practice, including scrub techniques
- Identification of infected and non-infected cases
- Housekeeping requirements/procedures
- Patient care requirements
    - Preoperative work-up
    - Patient consents and releases
    - Clinical procedures
    - Safety practices
    - Patient identification procedures
- Duties of scrub and circulating nurse
- Safety practices
- The requirement to conduct surgical counts in accordance with accepted standards of practice
- Scheduling of patients for surgery
- Personnel policies unique to the OR
- Resuscitative techniques
- DNR status
- Care of surgical specimens
- Malignant hyperthermia

- Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignments.

- Sterilization and disinfection procedures

- Acceptable operating room attire

- Handling infections and biomedical/medical waste

Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Pre-Operative History and Physical (H & P)

A complete history and physical must be conducted in accordance with acceptable standards of practice, and the written document placed on the medical record, prior to surgery. All or part of the H & P may be delegated to other practitioners in accordance with State law and CAH policy, but the surgeon must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant, meeting these criteria, may perform the H & P.

In all circumstances, when an H & P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H & P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. The note should include at a minimum critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc.

Informed Consent

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;

- Name of CAH;

- Name of procedure(s);

- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);

- Signature of patient or legal guardian;

- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent; and
- Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments. Informed consent must be given despite a patient's anxiety or indecisiveness.

The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information needed in order to consent to a procedure or treatment.

An informed consent would include at least: an explanation of the nature and purpose of the proposed procedures, risks and consequences of the procedures, risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful, and alternative methods of treatment (if any) and their associated risks and benefits. Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out.

Post-Operative Care/Recovery

Adequate provisions for immediate post-operative care means:

- Post operative care must be in accordance with acceptable standards of practice.
- The post-operative care area or recovery room is a separate area of the CAH. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-

operative check before transferring the patient from the recovery room should include some of the following:

  - Level of activity
  - Respirations
  - Blood pressure
  - Level of consciousness
  - Patient color

- If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by an RN in the patient's room.

Operating Room Register

The register should include at least the following information:

- Patient's name
- Patient's CAH identification number
- Date of the operation
- Inclusive or total time of the operation
- Name of the surgeon and any assistant(s)
- Name of nursing personnel (scrub and circulating)
- Type of anesthesia used and name of person administering it
- Operation performed
- Pre and post-op diagnosis
- Age of patient

Operative Report

The operative report would include at least:

- Name and CAH identification number of the patient;

- Date and times of the surgery;
- Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);
- Pre-operative and post-operative diagnosis;
- Name of the specific surgical procedure(s) performed;
- Type of anesthesia administered;
- Complications, if any;
- A description of techniques, findings, and tissues removed or altered;
- Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and
- Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

Survey Procedures §485.639

- Inspect all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:
    - That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;
    - The conformance to aseptic and sterile technique by all individuals in the surgical area;
    - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;
    - That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical attire, that surgical attire is designed for maximum skin and hair coverage;
    - That equipment is available for rapid and routine sterilization of operating room materials and that equipment is monitored, inspected, tested, and maintained by the CAH'S biomedical equipment program; and
    - That sterilized materials are packaged, handled, labeled, and stored in a

manner that ensures sterility e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.

- Review the CAH'S organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.

- If LPNs and surgical technologists (STs) are performing circulating duties, verify that they do so in accordance with applicable State laws and approved medical staff policies and procedures.

- Verify in situations where LPNs and STs are permitted to circulate that a qualified RN supervisor is immediately available to respond to emergencies.

- Review policies and procedures, to ascertain whether they contain the minimum policies specified in the interpretive guidelines.

- Review a sample of medical records of surgical patients to determine if a complete history and physical examination by a surgeon is completed prior to surgery, except in an emergency, and in accordance with the methodology described above.

- Review a sample of medical records of surgical patients to verify that they contain consent forms. Ascertain that the completed forms contain at least the information specified in the interpretive guidelines.

- Check to determine that the operating room suite has available the items listed.

    - On-call system

    - Cardiac monitor

    - Resuscitator

    - Defibrillator

    - Aspirator (suction equipment)

    - Tracheotomy set (a cricothyroidotomy set is not a substitute)

- Verify that all equipment is working and, as applicable, in compliance with the CAH'S biomedical equipment inspection, testing, and maintenance program.

- Verify that the CAH has provisions for post-operative care.
- Determine that there are policies and procedures that govern the recovery room

area.

- Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.

- Review a sample of medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

C-1142

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.639(a) Standard: Designation of Qualified Practitioners

The CAH designates 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. Surgery is performed only 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.

Interpretive Guidelines §485.639(a)

Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must be retained in these area/locations.

The CAH must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the CAH'S QA program, credentialing process, the practitioner's adherence to CAH policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The CAH must specify the surgical privileges for each practitioner that performs surgical

tasks. This would include practitioners such as MD/DOs, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is in the same OR in line of sight) be delineated in that practitioner's surgical privileges and included on the surgical roster.

When practitioners whose scope of practice for conducting surgical procedures requires the supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted surgical privileges in accordance with those criteria established by the governing body (or responsible individual), and who is working within the scope of those granted and documented privileges.

Survey Procedures §485.639(a)

- Review the CAH'S method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance.

- Determine that a current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done.

- Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

C-1144

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.639(b) Standard: Anesthetic Risk and Evaluation

(1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

Interpretive Guidelines §485.639(b)

The pre-anesthesia evaluation must be performed prior to inpatient or outpatient surgery. The pre-anesthesia evaluation must be performed by an individual qualified to administer anesthesia. The pre-operative anesthetic evaluation should include:

- Notation of anesthesia risk
- Anesthesia, drug and allergy history
- Any potential anesthesia problems identified
- Patient's condition prior to induction of anesthesia

The post-anesthesia follow-up report must be written on all inpatients and outpatients prior to discharge from surgery and anesthesia services. The post-anesthesia evaluation must be written by the individual who is qualified to administer the anesthesia. An MD/DO may delegate the post-anesthesia assessment and the writing of the post-anesthesia follow-up report to practitioners qualified to administer anesthesia in accordance with State law and CAH policy. When delegation of the post-anesthesia follow-up report is permitted, the medical staff must address its delegation requirements and methods in its bylaws. The post-anesthesia follow-up report must be documented in the patient's medical record, whether the patient is an inpatient or outpatient of the CAH, and must include at a minimum:

- Cardiopulmonary status;
- Level of consciousness;
- Any follow-up care and/or observations; and
- Any complications occurring during post-anesthesia recovery.

Survey Procedures §485.639(b)

- Review records to determine that each patient has a pre-anesthesia evaluation by an individual qualified to administer anesthesia. The evaluation must be performed prior to surgery.
- Review medical records to determine that a post-anesthesia follow-up report is written for each patient receiving anesthesia services, by the individual who administered the anesthesia prior to discharge from anesthesia services. Documentation should include those items specified in interpretive guidelines.

C-1145

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.639(c) Standard: Administration of Anesthesia

The CAH designates 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.

(1) Anesthesia must be administered by only--

(i)A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

Interpretive Guidelines §485.639(c)(1)

The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The CAH must specify the anesthesia privileges for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and CAH policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

A dentist, oral surgeon, or podiatrist may administer anesthesia in accordance with State law, their scope of practice and CAH policy. The anesthesia privileges of each practitioner must be specified. Anesthesia privileges are granted in accordance with the practitioner's scope of practice, State law, the individual competencies of the practitioner and the practitioner's compliance with the CAH'S credentialing criteria.

When a CAH permits operating practitioners to supervise CRNA administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of procedures they may supervise. A CRNA may administer anesthesia when under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (unless

supervision is exempted in accordance with §485.639(e)). An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist who is immediately available if needed. Available to immediately intervene includes at a minimum, that the supervising anesthesiologist or operating practitioner, as applicable, is:

- Physically located within the operative suite or in the labor and delivery unit; and
- Is prepared to immediately conduct hands-on intervention if needed; and
- Is not engaged in activities that could prevent the supervising practitioner from being able to immediately intervene and conduct hands-on interventions if needed

Survey Procedures §485.639(c)(1)

- Review the qualifications of individuals authorized to deliver anesthesia.
- Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

C-1147
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.639(c)(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

C-1149
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.639(d) Standard: Discharge

All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

Interpretive Guidelines §485.639(d)

Any exceptions to this requirement must be made by the attending practitioner and annotated on the clinical record.

Survey Procedures §485.639(d)

Verify that the CAH has policies and procedures in place to govern discharge procedures and instructions.

C-1150

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.639(e) Standard: State Exemption

(1) A CAH may be exempted from the requirement for MD/DO supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter 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. The letter from the Governor must attest 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.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.640 Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs

The CAH must 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. The programs must 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. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in coordination with the facility-wide quality assessment and performance improvement (QAPI) program.

Interpretive Guidelines §485.640

Guidance is pending and will be updated in future release.

Survey Procedures §485.640

Survey Procedures are pending and will be updated in future release.

C-1204

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.640(a) Standard: Infection prevention and control program organization and policies.

The CAH must 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 and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

Interpretive Guidelines §485.640(a)(1)
Guidance is pending and will be updated in future release.

Survey Procedures §485.640(a)(1)

Survey Procedures are pending and will be updated in future release.

C-1206
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.640(a)(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings;

Interpretive Guidelines §485.640(a)(2)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(a)(2)

Survey Procedures are pending and will be updated in future release.

C-1208
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.640(a)(3) The infection prevention and control includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and

Interpretive Guidelines §485.640(a)(3)
Guidance is pending and will be updated in future release.

Survey Procedures §485.640(a)(3)

Survey Procedures are pending and will be updated in future release.

C-1210

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.640(a)(4) The infection prevention and control program reflects the scope and complexity of the CAH services provided.

Interpretive Guidelines §485.640(a)(4)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(a)(4)

Survey Procedures are pending and will be updated in future release.

C-1225

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.640(c) Standard: Leadership responsibilities

(1) The governing body, or responsible individual, must ensure all of the following:

(i) Systems are in place and 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.

Interpretive Guidelines §485.640(c)(1)(i)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(1)(i)

Survey Procedures are pending and will be updated in future release.

C-1229

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[(c) Standard: Leadership responsibilities]

§485.640(c)(1)(ii) 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.

Interpretive Guidelines §485.640(c)(1)(ii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(1)(ii)

Survey Procedures are pending and will be updated in future release.

C-1231

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.640(c) Standard: Leadership responsibilities]

(2) The infection prevention and control professional(s) is responsible for:

(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

Interpretive Guidelines §485.640(c)(2)(i)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(i)

Survey Procedures are pending and will be updated in future release.

C-1235

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.640(c) Standard: Leadership responsibilities

(2) The infection prevention and control professional(s) is responsible for:]

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

Interpretive Guidelines §485.640(c)(2)(ii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(ii)

Survey Procedures are pending and will be updated in future release.

C-1237

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.640(c) Standard: Leadership responsibilities

(2) The infection prevention and control professional(s) is responsible for:]

(iii) Communication and collaboration with the CAH's QAPI program on infection prevention and control issues.

Interpretive Guidelines §485.640(c)(2)(iii)
Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(iii)

Survey Procedures are pending and will be updated in future release.

C-1239

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.640(c) Standard: Leadership responsibilities

(2) The infection prevention and control professional(s) is responsible for:]

(iv) 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.

Interpretive Guidelines §485.640(c)(2)(iv)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(iv)

Survey Procedures are pending and will be updated in future release.

C-1240

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.640(c) Standard: Leadership responsibilities

(2) The infection prevention and control professional(s) is responsible for:]

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by CAH personnel.

Interpretive Guidelines §485.640(c)(2)(v)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(v)

Survey Procedures are pending and will be updated in future release.

C-1242

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.640(c) Standard: Leadership responsibilities

(2) The infection prevention and control professional(s) is responsible for:]

(vi) Communication and collaboration with the antibiotic stewardship program.

Interpretive Guidelines §485.640(c)(2)(vi)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(vi)

Survey Procedures are pending and will be updated in future release.

C-1244

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.640(c) Standard: Leadership responsibilities]

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

Interpretive Guidelines §485.640(c)(3)(i)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(3)(i)

Survey Procedures are pending and will be updated in future release.

C-1246

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.640(c) Standard: Leadership responsibilities

(3) The leader(s) of the antibiotic stewardship program is responsible for:]

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

Interpretive Guidelines §485.640(c)(3)(ii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(3)(ii)

Survey Procedures are pending and will be updated in future release.

C-1248

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.640(c) Standard: Leadership responsibilities

(3) The leader(s) of the antibiotic stewardship program is responsible for:]

(iii) 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.

Interpretive Guidelines §485.640(c)(3)(iii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(3)(iii)

Survey Procedures are pending and will be updated in future release.

C-1250

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[§485.640(c) Standard: Leadership responsibilities

(3) The leader(s) of the antibiotic stewardship program is responsible for:]

(iv) 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.

Interpretive Guidelines §485.640(c)(3)(iv)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(3)(iv)

Survey Procedures are pending and will be updated in future release.

C-0330

§485.641 Condition of Participation: Periodic Evaluation and Quality Assurance Review

Interpretive Guidelines §485.641

While conducting the survey, a surveyor may identify a patient care practice or other CAH practice with which the surveyor is unfamiliar. Health care and CAH practice are continually changing due to new laws, regulations and standards of practice. In order for the surveyor to determine compliance with the CAH CoP, the surveyor should interview appropriate CAH staff to gather additional information, such as:

- Tell me about this practice.
- Is the practice a requirement or standard of practice?
- What is your source for this requirement, activity or standard of practice?
- Show me your source material for this practice.

If the CAH produces a law, regulation, or standard of practice from a nationally recognized organization, evaluate whether the CAH'S policies and procedures reflect the law, regulation, or standard of practice. Then, evaluate whether the CAH'S actual practice reflects their policies and procedures, as well as the law, regulation or standard of practice.

C-0331

§485.641(a) Standard: Periodic Evaluation

(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of--

Survey Procedures §485.641(a)(1)

- How is information obtained to be included in the periodic evaluation?
- How does the CAH conduct the periodic evaluation?
- Who is responsible for conducting the periodic evaluation?

C-0332

§485.641(a)(1)(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

Survey Procedures §485.641(a)(1)(i)

How does the CAH ensure that the yearly program evaluation includes a review of all CAH services, the number of patients served and the volume of services provided?

C-0333

§485.641(a)(1)(ii) A representative sample of both active and closed clinical records; and

Interpretive Guidelines §485.641(a)(1)(ii)

"A representative sample of both active and closed clinical records" means not less than 10 percent of both active and closed patient records.

Survey Procedures §485.641(a)(1)(ii)

- Who is responsible for the review of both active and closed clinical records?
- How are records selected and reviewed in the periodic evaluation?
- How does the evaluation process ensure that the sample of records is representative of services furnished?
- What criteria are utilized in the review of both active and closed records?

C-0334

§485.641(a)(1)(iii) The CAH'S health care policies.

Survey Procedures §485.641(a)(1)(iii)

What evidence demonstrates that the health care policies of the CAH are evaluated, reviewed and/or revised as part of the annual program evaluation?

C-0335

§485.641(a)(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

Survey Procedures §485.641(a)(2)

- How does the CAH use the results of the yearly program evaluation?
- Were policies, procedures and /or facility practices added, deleted or revised as a result of the yearly program evaluation if needed?

C-0336

§485.641(b) Standard: Quality Assurance

The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that--

Interpretive Guidelines §485.641(b)

There is nothing in this requirement to preclude a CAH from obtaining QA through arrangement. Whether the CAH has a freestanding QA program or QA by arrangement, all of the requirements for QA must be met. If a CAH chooses to have a freestanding QA program, the QA program should be facility wide, including all departments and all services provided under contact. For services provided to the CAH under contract, there should be established channels of communication between the contractor and CAH staff.

"An effective quality assurance program" means a QA program that includes:

- Ongoing monitoring and data collection;
- Problem prevention, identification and data analysis;
- Identification of corrective actions;
- Implementation of corrective actions;
- Evaluation of corrective actions; and
- Measures to improve quality on a continuous basis.

Survey Procedures §485.641(b)

Review a copy of the CAH QA plan and other documentation regarding QA activities, (e.g., meeting notes from QA committees, reports produced by the QA director and/or QA committees, if designated, and follow-up communication relative to corrective actions) to become familiar with the scope, methodology and organization of the CAH QA program.

C-0337

§485.641(b)(1) All patient care services and other services affecting patient health and safety, are evaluated;

Survey Procedures §485.641(b)(1)

- Who is responsible to evaluate CAH patient care services?
- How are patient care services evaluated?
- What other services are evaluated?

- How does the CAH ensure quality assurance data is provided to the medical staff and governing body?

C-0338

§485.641(b)(2) Nosocomial infections and medication therapy are evaluated;

Survey Procedures §485.641(b)(2)

- What methodology does the CAH use to evaluate nosocomial infections and medications therapy?

- Review committee meeting minutes for current issues or projects, etc.

C-0339

§485.641(b)(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

Survey Procedures §485.641(b)(3)

- How does the CAH ensure that a doctor of medicine or osteopathy evaluates the quality of care provided by mid-level practitioners in the CAH?

- How is clinical performance of mid-level practitioners evaluated?

- What evidence demonstrates that there is an ongoing evaluation of care provided by mid-level practitioners (e.g., reports, periodic written evaluation, QA meeting notes)?

- How does the reviewing MD/DO inform the CAH if he/she determines that there are problems relative to the diagnosis and treatment provided by mid-level practitioners?

- What follow-up actions are called for in the QA plan?

C-0340

(Rev. 78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§485.641(b)(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by--

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity;

(iii) One other appropriate and qualified entity identified in the State rural health care plan;

(iv) 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 hospital, the distant-site hospital; or

(v) 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 paragraphs (b)(4)(i) through (iii)of this section;

Interpretive Guidelines §485.641(b)(4)

All CAHs must, as a part of their quality assurance program, have an arrangement with an outside entity to review the appropriateness of the diagnosis and treatment provided by each MD/DO providing services to the CAH's patients. This includes MDs and DOs providing telemedicine services to the CAH's patients from a distant-site hospital or distant-site telemedicine entity. (See §485.616(c) for more information about requirements for telemedicine services.

Some CAHs may prefer to conduct their own internal review in addition to the outside review; this is neither prohibited nor required under the regulation. The regulation does not specify the frequency of the outside review, since a quality assurance program is ongoing in nature. The CAH and the outside entity must reach a mutual agreement on the extent and frequency of the outside review.

Entities eligible to provide this outside review include, for MDs and DOs who provide services on-site at the CAH, a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; or another appropriate and qualified entity identified in the State's Rural Health Plan to perform this function.

In the case of MDs or DOs who provide telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site hospital, the distant-site hospital is the outside entity responsible for reviewing the quality of care provided by these physicians.

In the case of MDs or DOs who provide telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, the outside entity responsible for reviewing the quality of care provided by these physicians include a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; another appropriate and

qualified entity identified in the State's Rural Health Plan to perform this function; or a distant-site hospital with which the CAH has an agreement for provision of telemedicine services.

Survey Procedures §485.641 (b)(4)

- Is there evidence that the CAH has an agreement for outside review of the quality of care provided on-site (i.e., not including telemedicine services) by the CAH's MDs and DOs with at least one of the following: a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; or another appropriate and qualified entity identified in the State's Rural Health Plan?

- If the CAH has one or more agreements for the provision of telemedicine services to CAH patients by a distant-site hospital(s), does each such agreement include a provision for the distant-site hospital to conduct the required outside review of the quality of telemedicine services provided by the MDs and DOs covered by the agreement?

- If the CAH has one or more agreements for the provision of telemedicine services to CAH patients by a distant-site telemedicine entity, does the CAH have an agreement for outside review of the quality of telemedicine services provided by the MDs and DOs covered under the agreement? Is the outside review agreement with at least one of the following: a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; another appropriate and qualified entity identified in the State's Rural Health Plan; or a distant-site hospital with which the CAH has an agreement for telemedicine services?

- Can the CAH provide examples of any reviews of the quality and appropriateness of diagnosis and treatment of the CAHs MDs and DOs conducted by an eligible outside entity in the prior 12 – 24 months?

C-0341

§485.641(b)(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

C-0342

§485.641(b)(5)(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

Survey Procedures §485.641(b)(5)(ii)

- How does the CAH ensure that proper remedial actions are taken to correct deficiencies identified in the quality assurance program?

- Who is responsible for implementing remedial actions to correct deficiencies identified by the quality assurance program?

C-0343

§485.641(b)(5)(iii) The CAH documents the outcome of all remedial action.

Survey Procedures §485.641(b)(5)(iii)

How does the CAH document the outcome of any remedial action?

C-1400

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.642 Condition of Participation: Discharge Planning

A Critical Access Hospital (CAH) must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from the CAH to post-discharge care, and reduce the factors leading to preventable CAH and hospital readmissions.

Interpretive Guidelines §485.642

Guidance is pending and will be updated in future release.

Survey Procedures §485.642

Survey Procedures are pending and will be updated in future release.

C-1404

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(a) Standard: Discharge planning process.

The CAH's discharge planning process must 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 and must 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.

Interpretive Guidelines §485.642(a)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)

Survey Procedures are pending and will be updated in future release.

C-1406

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(1) Any discharge planning evaluation must be 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.

Interpretive Guidelines §485.642(a)(1)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(1)
Survey Procedures are pending and will be updated in future release.

C-1408

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) A discharge planning evaluation must 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, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

Interpretive Guidelines §485.642(a)(2)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(2)

Survey Procedures are pending and will be updated in future release.

C-1410

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

Interpretive Guidelines §485.642(a)(3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(3)

Survey Procedures are pending and will be updated in future release.

C-1412

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(4) Upon the request of a patient's physician, the CAH must arrange for the development and initial implementation of a discharge plan for the patient.

Interpretive Guidelines §485.642(a)(4)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(4)
Survey Procedures are pending and will be updated in future release.

C-1417

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(5) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

Interpretive Guidelines §485.642(a)(5)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(5)

Survey Procedures are pending and will be updated in future release.

C-1420

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(6) The CAH's discharge planning process must require regular reevaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

Interpretive Guidelines §485.642(a)(6)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(6)

Survey Procedures are pending and will be updated in future release.

C-1422

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(7) The CAH must assess its discharge planning process on a regular basis. The assessment must 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.

Interpretive Guidelines §485.642(a)(7)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(7)

Survey Procedures are pending and will be updated in future release.

C-1425

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(8) The CAH must 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. The CAH must 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.

Interpretive Guidelines §485.642(a)(8)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(8)

Survey Procedures are pending and will be updated in future release.

C-1430

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(b) Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information. The CAH must 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, postdischarge 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.

Interpretive Guidelines §485.642(b)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(b)

Survey Procedures are pending and will be updated in future release.

C-1500

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.643 Condition of Participation: Organ, Tissue, and Eye Procurement

The CAH must have and implement written protocols that:
Interpretive Guidelines §485.643

The CAH must have written policies and procedures to address its organ procurement responsibilities.

C-1503

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.643(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, 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. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for 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;

Interpretive Guidelines §485.643(a)

The CAH must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following:

- The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the CAH;
- Includes a definition of "imminent death";
- Includes a definition of "timely notification";

- Addresses the OPO's responsibility to determine medical suitability for organ donation;

- Specifies 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);

- Provides 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;

- Ensures 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;

- Permits 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;
- Includes 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

- The interventions the CAH will utilize to maintain potential organ donor patients so that the patient organs remain viable.

CAHs must notify the OPO of every death or imminent death in the CAH. When death is imminent, the CAH must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The CAH should have a written policy, developed in coordination with the OPO and approved by the CAH'S medical staff and governing body, to define "imminent death." The definition for "imminent death" should strike a balance between the needs of the OPO and the needs of the CAH'S care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures. Collaboration between OPOs and CAHs will create a partnership that furthers donation, while respecting the perspective of CAH staff.

The definition for "imminent death" might include a patient with severe, acute brain injury who:

- Requires mechanical ventilation;

- Is in an intensive care unit (ICU) or emergency department; **AND**

- Has clinical findings consistent with a Glascow Coma Score that is less than or equal to a mutually-agreed-upon threshold; **or**

- MD/DOs are evaluating a diagnosis of brain death; **or**

- An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

CAHs and their OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glasgow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the CAH'S OPO or organizations such as the Association of Organ Procurement Organizations.

Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.
The definition agreed to by the CAH and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each CAH.

CAHs may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one CAH to another, it is the receiving CAH'S responsibility to notify the OPO.

"**Timely notification**" means a CAH must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a CAH must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the CAH does not consider an individual who is not on a ventilator to be a potential donor, the CAH must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a CAH to an OPO is timely if it is made:

- As soon as it is anticipated a patient will meet the criteria for imminent death agreed to by the OPO and CAH or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the CAH (ideally, within one hour); **AND**

- Prior to the withdrawal of any life sustaining therapies (i.e., medical **or** pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor. Timely

assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), ensures that the family is approached only if the patient is medically suitable for organ donation, and ensures that an OPO representative is available to collaborate with the CAH staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for 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.

Survey Procedures §485.643(a)

- Review the CAH'S written agreement with the OPO to verify that it addresses all required information.
- Verify that the CAH'S governing body has approved the CAH'S organ procurement policies.
- Review a sample of death records to verify that the CAH has implemented its organ procurement policies.
- Interview the staff to verify that they are aware of the CAH'S policies and procedures for organ, tissue and eye procurement.
- Verify that the organ, tissue and eye donation program is integrated into the CAH'S QA program.

C-1505

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.643(b) Incorporate 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;

Interpretive Guidelines §485.643(b)

The CAH must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every CAH death and should notify the tissue bank chosen by the CAH about potential tissue and eye donors.

It is not necessary for a CAH to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; not is it necessary for a

CAH to have a separate agreement with an eye bank if its OPO provides eye procurement services. The CAH is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes."

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the CAH. The CAH may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures §485.643(b)

Verify that the CAH has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all individuals who have died in the CAH. The agreement must also 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.

C-1507

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.643(c) 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. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is 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;

Interpretive Guidelines §485.643(c)

It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options.

Ideally, the OPO and the CAH will decide together how and by whom the family will be approached.

The individual designated by the CAH to initiate the request to the family must be a designated requestor.

A "**designated requestor**" is defined as a CAH-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community. If possible, the OPO representative and a designated requestor should approach the family together.

The CAH must ensure that any "designated requestor" for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families.

Survey Procedures §485.643(c)

- Verify that the CAH ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate.
- Review training schedules and personnel files to verify that all designated requestors have completed the required training.
- How does the CAH ensure that only designated requestors are approaching families to ask them to donate?

C-1509

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.643(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the family of potential donors;

Interpretive Guidelines §485.643(d)

Using discretion does not mean a judgment can be made by the CAH that certain families should not be approached about donation. CAHs should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The staff's perception that a family's grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family.

All potential donor families must be approached and informed of their donation rights.

Survey Procedures §485.643(d)

- Interview a CAH-designated requestor regarding approaches to donation requests.
- Review the designated requestor training program to verify that it addresses the use of discretion.
- Review the facility complaint file for any relevant complaints.

C-1511

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.643(e) Ensure that the CAH works 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.

§485.643(f) For purpose of these standards, the term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

Interpretive Guidelines §485.643(e)

Appropriate staff, including all patient care staff, must be trained regarding donation issues and how to work with the OPO, tissue bank and eye bank. Those CAH staff who may have to contact or work with the OPO, tissue bank and eye bank staff, must have appropriate training on donation issues including their duties and roles.

The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:

- Consent process;
- Importance of using discretion and sensitivity when approaching families;
- Role of the designated requestor;
- Transplantation and donation, including pediatrics, if appropriate;
- Quality improvement activities; and
- Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the CAH'S QA program.

CAHs must cooperate with OPOs, tissue banks and eye banks in regularly/periodically reviewing death records. This means that a CAH must develop policies and procedures which permit the OPO, tissue bank and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the CAH'S donor potential, ensure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the CAH, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.

The CAH must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintain the viability of their organs. The CAH must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

Survey Procedures §485.643(e)

- Review inservice training schedules and attendance sheets.
- 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?
- Verify by review of policies and records that the CAH works with the OPO, tissue bank, and eye bank in reviewing death records.
- Verify that the effectiveness of any protocols and policies is monitored as part of the CAH'S quality improvement program.
- Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.
- Determine how confidentiality is ensured.
- Verify that there are policies and procedures in place to ensure coordination between the facility staff and the OPO staff in maintaining the potential donor.
- Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.

C-1600

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645 Special Requirements for CAH Providers of Long-Term Care Services ("Swing-Beds").

A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-CAH SNF care, as specified in §409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

Interpretive Guidelines §485.645

The swing-bed concept allows a CAH to use their beds interchangeably for either acute-care or post-acute care. A "swing-bed" is a change in reimbursement status. The patient swings from receiving acute-care services and reimbursement to receiving skilled nursing (SNF) services and reimbursement.

Medicare allows a CAH to operate swing-beds through the issuance of a "swing-bed approval." If the facility fails to meet the swing-bed requirements, and the facility does not develop and implement an accepted plan of correction, the facility loses the approval

to operate swing-beds and receive swing-bed reimbursement. The facility does not go on a termination track. If the CAH continues to meet the CoP for the provider type, it continues to operate but loses swing-bed approval.

Swing-beds need not be located in a special section of the CAH. The patient need not change locations in the facility merely because his/her status changes unless the facility requires it.

The change in status from acute care to swing-bed status can occur within one facility or the patient can be transferred from another facility for swing-bed admission.
There must be discharge orders from acute inpatient care services and subsequent admission orders for swing-bed services, the same as if the patient had been transferred to a separately certified skilled nursing facility. The same clinical record may be used for a swing-bed patient, but it must include discharge orders from acute care and admission orders to swing-bed services, and the swing-bed services (which may be SNF or NF level services) must be clearly delineated within the clinical record.

There is no length of stay restriction for any CAH swing-bed patient. There is no Medicare requirement to place a swing-bed patient in a nursing home and there are no requirements for transfer agreements between CAHs and nursing homes. While there is no length of stay limit for patients in swing-bed status, the intended use for swing beds is for a transitional time period to allow the patient to fully recover to return home or while awaiting placement into a nursing facility. The CAH should document in the patient's medical record efforts made for nursing facility placement.

Medicare coverage rules require that, in order to be eligible for coverage of post-hospital swing-bed care, a beneficiary must have a qualifying 3-day inpatient stay in a participating or qualified hospital or participating CAH prior to admission to a swing-bed.

There is no requirement for a CAH to use the MDS form for recording the patient assessment or for nursing care planning.

Swing-bed patients receive a SNF level of care, and the CAH is reimbursed for providing a SNF level of care, however swing-bed patients are not SNF patients. Swing-bed patients in CAHs are considered to be patients of the CAH.

NOTE: Swing-beds must not be confused with beds in a skilled nursing facility (SNF) or nursing facility (NF), including a distinct part SNF/NF, that shares the same building/campus as the CAH but is a separately certified provider with its own Medicare provider agreement.

C-1602

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(a) Eligibility

A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under §485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

Interpretive Guidelines §485.645(a) Eligibility

CAHs seeking swing-bed approval are screened prior to survey for their eligibility for swing-beds. However, the CMS RO makes the determination whether the CAH has satisfied the eligibility criteria, regardless of whether the SA or AO, as applicable, recommends approval of swing-bed status (this responsibility may not be delegated to the SA).

The eligibility criteria at 42 CFR 485.645(a) requires:

- The CAH has a Medicare provider agreement;
- An initial CAH applicant may seek swing-bed approval. If the CAH applicant meets all Federal Requirements for participation, including those for swing-bed approval, the CAH applicant's approval for swing-bed services will be effective with the CAH's effective date of Medicare participation;

C-1604

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(b) Facilities Participating as Rural Primary Care Hospitals (RPCHs) on September 30, 1997

These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a hospital that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions, and limitations that were applicable at the time these approvals were granted..

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

C-1606
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(c) Payment

Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with §413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in §413.114 of this chapter.

C-1608
(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(d) SNF Services.

The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

§485.645(d)(1) Resident Rights (§483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2) *and* (4), (f)(4)(ii) *and* (iii), (g)(8) and (17), (g)(18) introductory text, (h) of this chapter).

- **§483.10(b)(7) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident devolve to and are exercised by the resident representative appointed under State law to act on the resident's behalf. The court-appointed resident representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law.**

- **§483.10(c) Planning and implementing care. The resident has the right to be informed of, and participate in, his or her treatment, including:**

  (1) The right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.

- **§483.10(c)(2)(iii) The right to be informed, in advance, of changes to the plan of care.**

- **§483.10(c)(6) The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive.**

- **§483.10(d) Choice of attending physician. The resident has the right to choose his or her attending physician.**

  (1) The physician must be licensed to practice, and

(2) If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in paragraphs (d)(4) and (5) of this section to assure provision of appropriate and adequate care and treatment.

(3) The facility must ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals responsible for his or her care.

(4) The facility must inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet requirements specified in this part and the facility seeks alternate physician participation to assure provision of appropriate and adequate care and treatment. The facility must discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.

(5) If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.

- **§483.10(e)(2) The right to retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.**

- **§483.10(e)(4) The right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.**

- **§483.10(f)(4)(ii) The facility must provide immediate access to a resident by immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time;**

- **§483.10(f)(4)(iii) The facility must provide immediate access to a resident by others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent at any time;**

- **§483.10(g)(8) The resident has the right to send and receive mail, and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service, including the right to:**

  (i) Privacy of such communications consistent with this section; and

(ii) Access to stationery, postage, and writing implements at the resident's own expense.

- **§483.10(g)(17) The facility must—**

  (i) Inform each Medicaid-eligible resident, in writing, at the time of admission to the nursing facility and when the resident becomes eligible for Medicaid of—

  (A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

  (B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

  (ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in §483.10(g)(17)(i)(A) and (B) of this section.

- **§483.10(g)(18)[introductory text only] The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/Medicaid or by the facility's per diem rate.**

- **§483.10(h) Privacy and confidentiality. The resident has a right to personal privacy and confidentiality of his or her personal and medical records.**

  (1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.

  (2) The facility must respect the residents right to personal privacy, including the right to privacy in his or her oral (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.

  (3) The resident has a right to secure and confidential personal and medical records.

(i) The resident has the right to refuse the release of personal and medical records except as provided at §483.70(i)(2) or other applicable federal or state laws.

(ii) The facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.

Interpretive Guidelines §485.645(d)(1)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(1)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1610

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(d)(2) Admission, Transfer and Discharge Rights (§483.5 definition of transfer & discharge, §483.15(c)(1), (c)(2), (c)(3), (c)(4), (c)(5), (c)(7), (c)(8), and (c)(9) of this chapter).

- **§483.5 definition of transfer & discharge: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.**

- **§483.15(c)(1) Transfer and discharge—(1) Facility requirements—**

  (i) The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

  (A) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

  (B) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

  (C) The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;

  (D) The health of individuals in the facility would otherwise be endangered;

(E) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. Non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(F) The facility ceases to operate.

(ii) The facility may not transfer or discharge the resident while the appeal is pending, pursuant to §431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to §431.220(a)(3) of this chapter, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. The facility must document the danger that failure to transfer or discharge would pose.

- **§483.15(c)(2) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (c)(1)(i)(A) through (F) of this section, the facility must ensure that the transfer or discharge is documented in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider.**

(i) Documentation in the resident's medical record must include:

(A) The basis for the transfer per paragraph (c)(1)(i) of this section.

(B) In the case of paragraph (c)(1)(i)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).

(ii) The documentation required by paragraph (c)(2)(i) of this section must be made by—

(A) The resident's physician when transfer or discharge is necessary under paragraph (c)(1)(A) or (B) of this section; and

(B) A physician when transfer or discharge is necessary under paragraph (c)(1)(i)(C) or (D) of this section.

(iii) Information provided to the receiving provider must include a minimum of the following:

(A) Contact information of the practitioner responsible for the care of the resident

(B) Resident representative information including contact information.

(C) Advance Directive information.

(D) All special instructions or precautions for ongoing care, as appropriate.

(E) Comprehensive care plan goals,

(F) All other necessary information, including a copy of the resident's discharge summary, consistent with §483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

- **§483.15(c)(3) Notice before transfer. Before a facility transfers or discharges a resident, the facility must—**

  (i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

  (ii) Record the reasons for the transfer or discharge in the resident's medical record in accordance with paragraph (c)(2) of this section; and

  (iii)Include in the notice the items described in paragraph (c)(5) of this section.

- **§483.15(c)(4) Timing of the notice.**

  (i) Except as specified in paragraphs (c)(4)(ii) and (8) of this section, the notice of transfer or discharge required under this section must be made by the facility at least 30 days before the resident is transferred or discharged.

  (ii)Notice must be made as soon as practicable before transfer or discharge when—

(A) The safety of individuals in the facility would be endangered under paragraph (c)(1)(i)(C) of this section;
(B) The health of individuals in the facility would be endangered, under paragraph (c)(1)(i)(D) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (c)(1)(i)(B) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (c)(1)(i)(A) of this section; or

(E) A resident has not resided in the facility for 30 days.

- **§483.15(c)(5) Contents of the notice. The written notice specified in paragraph (c)(3) of this section must include the following:**

  (i) The reason for transfer or discharge;

  (ii) The effective date of transfer or discharge;

  (iii) The location to which the resident is transferred or discharged;

  (iv) A statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request;

  (v) The name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman;

  (vi) For nursing facility residents with intellectual and developmental disabilities or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106-402, codified at 42 U.S.C. 15001 et seq.); and

  (vii) For nursing facility residents with a mental disorder or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act.

- **§483.15(c)(7) Orientation for transfer or discharge. A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand.**

- **§483.15(c)(8) Notice in advance of facility closure. In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives, as well as the plan for the transfer and adequate relocation of the residents, as required at §483.70(l).**

- **§483.15(c)(9) Room changes in a composite distinct part. Room changes in a facility that is a composite distinct part (as defined in §483.5) are subject to the requirements of §483.10(e)(7) and must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.**

Interpretive Guidelines §485.645(d)(2)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(2)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1612

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(d)(3) Freedom from abuse, neglect and exploitation (§483.12(a)(1), (a)(2), (a)(3)(i), (a)(3)(ii), (a)(4), (b)(1), (b)(2), (c)(1), (c)(2), (c)(3), and (c)(4) of this chapter).

- **§483.12(a)(1) Freedom from abuse, neglect, and exploitation. The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.(a) The facility must—**(1) **Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;**

- **§483.12(a)(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least**

amount of time and document ongoing re-evaluation of the need for restraints.

- **§483.12(a)(3) Not employ or otherwise engage individuals who—**

  (i) Have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law;

  (ii) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of their property.

- **§483.12(a)(4) Report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.**

- **§483.12(b) The facility must develop and implement written policies and procedures that:**

  (1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property,

  (2) Establish policies and procedures to investigate any such allegations,

- **§483.12(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:**

  (1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

  (2) Have evidence that all alleged violations are thoroughly investigated.

  (3) Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.

  (4) Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working

days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

Interpretive Guidelines §485.645(d)(3)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(3)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1616

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(d)(*4*) Social Services (§483.40(d) of this chapter).

- **§483.40(d) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.**

Interpretive Guidelines §485.645(d)(*4*)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(*4*)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1620

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(d)(*5*) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), and §483.21(b) and (c)(2) of this chapter), except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter).

- **§483.20(b) Comprehensive assessments—**

  (1) Resident assessment instrument. A facility must make a comprehensive assessment of a resident's needs, strengths, goals, life history and preferences, using the resident assessment instrument (RAI) specified by CMS. The assessment must include at least the following:
  (i) Identification and demographic information.

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.

(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

(xi) Dental and nutritional status.

(xii) Skin condition.

(xiii) Activity pursuit.

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge planning.

(xvii) Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the Minimum Data Set (MDS).

(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

(2) When required. Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2) (i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs.

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or

mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)

(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

- **§483.21(b) Comprehensive care plans.**

(1) The facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with the resident rights set forth at §483.10(c)(2) and §483.10(c)(3), that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The comprehensive care plan must describe the following:

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.24, §483.25, or §483.40; and

(ii) Any services that would otherwise be required under §483.24, §483.25, or §483.40 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(c)(6).

(1) Any specialized services or specialized rehabilitative services the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.

(2) In consultation with the resident and the resident's representative(s)—

(A) The resident's goals for admission and desired outcomes.

(B) The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.

(C) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in paragraph (c) of this section.

(2) A comprehensive care plan must be—

(i) Developed within 7 days after completion of the comprehensive assessment.

(ii) Prepared by an interdisciplinary team, that includes but is not limited to-

(A) The attending physician.

(B) A registered nurse with responsibility for the resident.

(C) A nurse aide with responsibility for the resident.

(D) A member of food and nutrition services staff.

(E) To the extent practicable, the participation of the resident and the resident's representative(s). An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan.

(F) Other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident.

(iii) Reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments.

(3) The services provided or arranged by the facility, as outlined by the comprehensive care plan, must—

(i) Meet professional standards of quality.
(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(iii) Be culturally-competent and trauma-informed.

- **§483.21(c)(2) Discharge summary. When the facility anticipates discharge a resident must have a discharge summary that includes, but is not limited to, the following:**

  (i) A recapitulation of the resident's stay that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results.

  (ii) A final summary of the resident's status to include items in paragraph (b)(1) of §483.20, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or resident's representative.

  (iii) Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter).

  (iv) A post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative(s), which will assist the resident to adjust to his or her new living environment. The post-discharge plan of care must indicate where the individual plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services.

Interpretive Guidelines §485.645(d)(*5*)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(*5*)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

***NOTE:** The CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter). Also, note that CAHs are not required to complete the PASARR. **However, if a patient had a PASARR completed by a facility that was required to do so prior to admission into a CAH swing bed, the recommendations from the PASARR should be included in the CAHs comprehensive treatment plan for the patient.**

C-1622

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(d)(*6*) Specialized Rehabilitative Services (§483.65 of this chapter).

- **§483.65 (a) Provision of services. If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for a mental disorder and intellectual disability or services of a lesser intensity as set forth at §483.120(c), are required in the resident's comprehensive plan of care, the facility must—**

  (1) Provide the required services; or

  (2) In accordance with §483.70(g), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Act.

  (b) Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

Interpretive Guidelines §485.645(d)(*6*)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(*6*)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1624

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(d)(*7*) Dental Services (§483.55*(a)(2), (3), (4), and (5) and (b)* of this chapter).

- **§483.55 Dental services. The facility must assist residents in obtaining routine and 24-hour emergency dental care.**

  (a) Skilled nursing facilities. A facility-

  (2) May charge a Medicare resident an additional amount for routine and emergency dental services;

  (3) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;

(4) Must if necessary or if requested, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dental services location; and

(5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

(b) Nursing facilities. The facility-

(1) Must provide or obtain from an outside resource, in accordance with §483.70(g), the following dental services to meet the needs of each resident:

(i) Routine dental services (to the extent covered under the State plan); and

(ii) Emergency dental services;

(2) Must, if necessary or if requested, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dental services locations;

(3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay;

(4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and

(5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.

Interpretive Guidelines §485.645(d)(*7*)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(*7*)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1626

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.645(d)(*8*) Nutrition (§483.25(g)(1) and (g)(2) of this chapter).

- **§483.25(g) Assisted nutrition and hydration. (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). Based on a resident's comprehensive assessment, the facility must ensure that a resident—**

  (1) Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;

  (2) Is offered sufficient fluid intake to maintain proper hydration and health.

Interpretive Guidelines §485.645(d)(*8*)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(*8*)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

Refer to Appendix A of the State Operations Manual (SOM) for Critical Access Hospital Distinct Part Unit interpretive guidelines and survey procedures.

C-0500

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.647 (1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of

§412.27 of Part 412 of this chapter for excluded psychiatric units.

C-0501

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.647 (b)(1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).

(3) The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.

C-0504

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ... §412.25(a)(2) through (f) of Part 412 ...]

Basis for exclusion (§412.25(a)(2)):

" In order to be excluded from the prospective payment systems ... a psychiatric ... unit must meet the following requirements:

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients."

C-0505

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

" In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements:]

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

C-0506

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the hospital."

C-0507

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(5) Meet all applicable State licensure laws."

C-0508

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(6) Have utilization review standards applicable for the type of care offered in the unit."

C-0509

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds."

C-0510

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(8) Be serviced by the same fiscal intermediary as the hospital."

C-0511

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(9) Be treated as a separate cost center for cost finding and apportionment purposes."

C-0512

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...
Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(10) Use an accounting system that properly allocates costs."

C-0513

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(11) Maintain adequate statistical data to support the basis of allocation."

C-0514

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(12) Report its cost in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital."

C-0515

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date."

C-0516

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)).]

Changes in the size of excluded units. Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change. The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit. A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting period. Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

C-0519

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Changes in the status of hospital units (§412.25(c)):

["For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period. "

C-0520

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the status of hospital units (§412.25(c)):]

"For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period."

C-0521

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Number of excluded units (§412.25(d)):

"Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems."

C-0522

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)):

"(1) For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital."

C-0523

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)):]

"(2) Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite

facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period.

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of State-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997."

C-0524

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(2)):

"(ii) The satellite facility independently complies with-

(A) For a rehabilitation unit, the requirements under §412.23(b)(2); or

(B) For a psychiatric unit, the requirements under §412.27(a)."

C-0525

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)).]

"(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods … it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located."

C-0526

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

C-0527

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)).

" (iii) The satellite facility meets all of the following requirements:]

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located."

C-0528

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part."

C-0529

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(E) It is treated as a separate cost center of the hospital unit of which it is a part."

C-0530

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation."

C-0531

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part."

§412.25 (e)(2)(iv) Effective for cost reporting periods beginning on or after October 1, 2019, the requirements of paragraph (e)(2)(iii)(A) of this section do not apply to a satellite facility of a unit that is part of a hospital excluded from the prospective payment systems specified in §412.1(a)(1) that does not furnish services in a building also used by another hospital that is not excluded from the prospective payment systems specified in §412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in §412.1(a)(1).

C-0532

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(3)):

"Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999."

C-0533

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(4)):

" In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility-

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes."

C-0534

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(5)&(6)):

"(5) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (e)(3) of this section-

(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility

subject to the provisions of paragraph (b)(2) of this section, without affecting the provisions of paragraph (e)(3) of this section; and

(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of this section, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.

(6) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003."

C-0535

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Changes in classification (§412.25(f)):

"For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period."

§412.25(g) CAH units not meeting applicable requirements. If a psychiatric or rehabilitation unit of a CAH does not meet the requirements of §485.647 with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of §485.647.

C-0547

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"In order to be excluded from the prospective payment system as specified in §412.1(a)(1), and paid under the prospective payment system as specified in §412.1(a)(2), a psychiatric unit must meet the following requirements:

(a) Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the Fourth Edition, Text Revision of the American Psychiatric Association's Diagnostic and Statistical Manual, or in Chapter Five ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification."

C-0548

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"In order to be excluded from the prospective payment system ... a psychiatric unit must meet the following requirements:]

(b) Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and therapeutic activities."

C-0549

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"In order to be excluded from the prospective payment system ... a psychiatric unit must meet the following requirements:]

(c) Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit."

C-0550

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):]

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.

(i) Identification data must include the inpatient's legal status."

C-0551

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.]

(ii) A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses."

C-0552

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.]

(iii) The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both."

C-0553

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.]

(iv) The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history."

C-0554

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.]

(v) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination."

C-0555

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c) (2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-

(i) Be completed within 60 hours of admission."

C-0556

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(ii) Include a medical history."

C-0557

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(iii) Contain a record of mental status."

C-0558

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(iv) Note the onset of illness and the circumstances leading to admission."

C-0559

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(v) describe attitudes and behavior."

C-0560

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(vi) Estimate intellectual functioning, memory functioning, and orientation."

C-0561

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(vii) Include an inventory of the inpatient's assets in descriptive, not interpretative fashion."

C-0562

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan.

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis."

C-0563

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):
"(c)(3) Treatment plan.

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] short-term and long-term goals."

C-0564

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] the specific treatment modalities utilized."

C-0565

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan.

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] the responsibilities of each member of the treatment team."

C-0566

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out."

C-0567

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan]

(ii) The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included."

C-0568

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient."

C-0569

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by ...] a nurse."

C-0570

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by ...] a social worker."

C-0571

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by ...] others significantly involved in active treatment modalities, when appropriate."

C-0572

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress.] ...The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter."

C-0573

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress.] ...progress notes must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan."

C-0574

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(5) Discharge planning and discharge summary. The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit ..."

C-0575

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(5) Discharge planning and discharge summary. The record of each patient who has been discharged must have ...] recommendations from appropriate services concerning follow-up or aftercare ..."

C-0576

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(5) Discharge planning and discharge summary. The record of each patient who has been discharged must have ...] a brief summary of the patient's condition on discharge."

C-0577

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning ..."

C-0578

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):
"...A psychiatric unit must ...]

(d)(1) Personnel. The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to-

(i) evaluate inpatients;

(ii) formulate written, individualized, comprehensive treatment plans;

(iii) provide active treatment measures; and

(iv) engage in discharge planning."

C-0579

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(2) Director of inpatient psychiatric services: Medical staff. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program."

C-0580

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(2) Director of inpatient psychiatric services: Medical staff.]

...The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services."

C-0581

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(2) Director of inpatient psychiatric services: Medical staff.]

(i) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry."

C-0582

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(2) Director of inpatient psychiatric services: Medical staff.]

(ii) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff."

C-0583

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(3) Nursing services. The unit must have a qualified director of psychiatric nursing services ..."

C-0584

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units. Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

...In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient."

C-0585

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

(i) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill."

C-0586

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

...The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished."

C-0587

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

(ii) The staffing pattern must ensure the availability of a registered nurse 24 hours each day..."

C-0588

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services ....]

(ii) ...There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program."

C-0589

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(4) Psychological services. The unit must provide or have available psychological services to meet the needs of the inpatients ...."

C-0590

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(4) Psychological services.]

...The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures."

C-0591

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(5) Social services. There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished ..."

C-0592

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(5) Social services.]

...The social services must be furnished in accordance with accepted standards of practice and established policies and procedures ..."

C-0593

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(5) Social services.]

...Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital."

C-0594

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(6) Therapeutic activities. The unit must provide a therapeutic activities program."

C-0595

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(6) Therapeutic activities. The unit must provide a therapeutic activities program.]

(i) The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning."

C-0596

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(6) Therapeutic activities. The unit must provide a therapeutic activities program.]

(ii) The number of qualified therapeutic activities therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program."

C-0700

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.647(a)(2) If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

C-0701

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§485.647(b)(1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).

(3) The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.

C-0704

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Basis for exclusion (§412.25(a)(2)):

"In order to be excluded from the prospective payment systems ... a rehabilitation unit must meet the following requirements:

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients."

C-0705

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(3):

"In order to be excluded from the prospective payment systems ... a rehabilitation unit must meet the following requirements:]

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

C-0706

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(4)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the hospital."

C-0707

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(5)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(5) Meet all applicable State licensure laws."

C-0708

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(6)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(6) Have utilization review standards applicable for the type of care offered in the unit."

C-0709

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(7)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds."

C-0710

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(8)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(8) Be serviced by the same fiscal intermediary as the hospital."

C-0711

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(9)):
"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(9) Be treated as a separate cost center for cost finding and apportionment purposes."

C-0712

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(10)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(10) Use an accounting system that properly allocates costs."

C-0713

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(11)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(11) Maintain adequate statistical data to support the basis of allocation."

C-0714

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(12)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(12) Report its cost in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital."

C-0715

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(13)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, be fully equipped and staffed and capable of providing hospital inpatient rehabilitation care, regardless of whether there are any inpatients in the unit on that date."

C-0716

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)).]

"(b) Changes in the size of excluded units. Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change. The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit. A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting period. Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility or because of catastrophic events such as fires, floods, earthquakes, or tornadoes."

C-0719

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the status of hospital units (§412.25(c)(1)):

"For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period. "

C-0720

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the status of hospital units (§412.25(c)(2)):

"For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if he hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period."

C-0721

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Number of excluded units (§412.25(d)):

"Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems."

C-0722

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(1)):

"(1) For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital."

C-0723

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(i)).]

"(2) Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period.

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's on the last day of the unit's last cost reporting period beginning before October 1, 1997."

C-0724

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(ii)(A)(B)).]

"(ii) The satellite facility independently complies with-

(A) For a rehabilitation unit, the requirements under §412.23(b)(2); or

(B) For a psychiatric unit, the requirements under §412.27(a)."

C-0725

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(A)).]

"(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods … it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located."

C-0726

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(B)):

"(iii) The satellite facility meets all of the following requirements:]

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

C-0727

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(C)):

"(iii) The satellite facility meets all of the following requirements:]

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located."

C-0728

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(D)):

"(iii) The satellite facility meets all of the following requirements:]

(D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part."

C-0729

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(E)):

"(iii) The satellite facility meets all of the following requirements:]

(E) It is treated as a separate cost center of the hospital unit of which it is a part."

C-0730

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(F)):

"(iii) The satellite facility meets all of the following requirements:]

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation."

C-0731

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(G)):

"(iii) The satellite facility meets all of the following requirements:]

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part."

Satellite facilities (§412.25(e)(2)(iv)):

"(iv) Effective for cost reporting periods … the requirements of paragraph (e)(2)(iii)(A) of this section do not apply to a satellite facility of a unit that is part of a hospital excluded from the prospective payment systems specified in §412.1(a)(1) that does not furnish services in a building also used by another hospital that is not excluded from the prospective payment systems specified in §412.1(a)(1), or in one or more entire

buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in §412.1(a)(1)."

C-0732

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(3)):

"Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999."

C-0733

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(4)):

"In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility-

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes."

C-0734

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(5)&(6)):

"(5) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (e)(3) of this section-

(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of this section, without affecting the provisions of paragraph (e)(3) of this section; and

(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of this section, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.

(6) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003."

C-0735

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in classification (§412.25(f)):

"For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period."

C-0747

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

Excluded rehabilitation units: Additional requirements (§412.29):

"To be excluded from the prospective payment systems described in §412.1(a)(1) and to be paid under the prospective payment system specified in §412.1(a)(3), a rehabilitation unit must meet the following requirements:

(a) Have (or be part of a hospital that has) a provider agreement under part 489 of this chapter to participate as a hospital.

C-0748

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29).]

"...A rehabilitation unit must ...

(b) Except in the case of a "new" IRF or "new" IRF beds, as defined in paragraph (c) of this section, an IRF must show that, during its most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the Medicare contractor), it served an inpatient population that meets the following criteria:

(1) For cost reporting periods beginning on or after July 1, 2004, and before July 1, 2005, the IRF served an inpatient population of whom at least 50 percent, and for cost reporting periods beginning on or after July 1, 2005, the IRF served an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified at paragraph (b)(2) of this section. A patient with a comorbidity, as defined at §412.602 of this part, may be included in the inpatient population that counts toward the required applicable percentage if—

(i) The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in paragraph (b)(2) of this section;

(ii) The patient has a comorbidity that falls in one of the conditions specified in paragraph (b)(2) of this section; and

(iii) The comorbidity has caused significant decline in functional ability in the individual that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under subpart P of this part and that cannot be appropriately performed in another care setting covered under this title.

(2) List of conditions.

(i) Stroke.

(ii) Spinal cord injury.

(iii) Congenital deformity.
(iv) Amputation.

(v) Major multiple trauma.

(vi) Fracture of femur (hip fracture).

(vii) Brain injury.

(viii) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.

(ix) Burns.

(x) Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(xi) Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(xii) Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

(xiii) Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:

(A) The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.

(B) The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.

(C) The patient is age 85 or older at the time of admission to the IRF.

C-0749

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(c) In the case of new IRFs (as defined in paragraph (c)(1) of this section) or new IRF beds (as defined in paragraph (c)(2)of this section), the IRF must provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b) of this section. This written certification will apply until the end of the IRF's first full 12-month cost reporting period or, in the case of new IRF beds, until the end of the cost reporting period during which the new beds are added to the IRF.

C-0750

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(c) In the case of new IRFs (as defined in paragraph (c)(1) of this section) or new IRF beds (as defined in paragraph (c)(2)of this section), the IRF must provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b) of this section. This written certification will apply until the end of the IRF's first full 12-month cost reporting period or, in the case of new IRF beds, until the end of the cost reporting period during which the new beds are added to the IRF.]

(1) New IRFs. An IRF hospital or IRF unit is considered new if it has not been paid under the IRF PPS in subpart P of this part for at least 5 calendar years. A new IRF will be considered new from the point that it first participates in Medicare as an IRF until the end of its first full 12-month cost reporting period.

(2) New IRF beds. Any IRF beds that are added to an existing IRF must meet all applicable State Certificate of Need and State licensure laws. New IRF beds may be added one time at any point during a cost reporting period and will be considered new for the rest of that cost reporting period. A full 12-month cost reporting period must elapse between the delicensing or decertification of IRF beds in an IRF hospital or IRF unit and the addition of new IRF beds to that IRF hospital or IRF unit. Before an IRF can add new beds, it must receive written approval from the appropriate CMS RO, so that the CMS RO can verify that a full 12-month cost reporting period has elapsed since the IRF has had beds delicensed or decertified. New IRF beds are included in the compliance review calculations under paragraph (b) of this section from the time that they are added to the IRF.

C-0751

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(c) In the case of new IRFs (as defined in paragraph (c)(1) of this section) or new IRF beds (as defined in paragraph (c)(2)of this section), the IRF must provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b) of this section. This written certification will apply until the end of the IRF's first full 12-month cost reporting period or, in the case of new IRF beds, until the end of the cost reporting period during which the new beds are added to the IRF.]

(3) Change of ownership or leasing. An IRF hospital or IRF unit that undergoes a change of ownership or leasing, as defined in §489.18 of this chapter, retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the change of ownership or leasing if the new owner(s) of the IRF accept assignment of the previous owners' Medicare provider agreement and the IRF continues to meet all of the requirements for payment under the IRF prospective payment system. If the new owner(s) do not accept assignment of the previous owners' Medicare provider agreement, the IRF is considered to be voluntarily terminated and the new owner(s) may re-apply to participate in the Medicare program. If the IRF does not continue to meet all of the requirements for payment under the IRF prospective payment system, then the IRF loses its excluded status and is paid according to the prospective payment systems described in §412.1(a)(1).

(4) Mergers. If an IRF hospital (or a hospital with an IRF unit) merges with another hospital and the owner(s) of the merged hospital accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the merger, as long as the IRF hospital or IRF unit continues to meet all of the requirements for payment under the IRF prospective payment system. If the owner(s) of the merged hospital do not accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit is considered voluntarily terminated and the owner(s) of the merged hospital may reapply to the Medicare program to operate a new IRF.

C-0752

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(d) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program. This procedure must ensure that the preadmission screening for each Medicare Part A Fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.

C-0753

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(e) Have in effect a procedure to ensure that patients receive close medical supervision…

C-0754

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(e) Have in effect a procedure to ensure that patients receive close medical supervision…] as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.

C-0755

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(f) Furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services.

C-0756

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(g) Have a director of rehabilitation who—

(1) Provides services to the IRF hospital and its inpatients on a full-time basis or, in the case of a rehabilitation unit, at least 20 hours per week;

(2) Is a doctor of medicine or osteopathy;

(3) Is licensed under State law to practice medicine or surgery; and

(4) Has had, after completing a one-year hospital internship, at least 2 years of training or experience in the medical-management of inpatients requiring rehabilitation services.

C-0757

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(h) Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

C-0758

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(i) Use a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans, and that team conferences are held at least once per week to determine the appropriateness of treatment.

(j) Retroactive adjustments. If a new IRF (or new beds that are added to an existing IRF) are excluded from the prospective payment systems specified in §412.1(a)(1) and paid under the prospective payment system specified in §412.1(a)(3) for a cost reporting period under paragraph (c) of this section, but the inpatient population actually treated during that period does not meet the requirements of paragraph (b) of this section, we adjust payments to the IRF retroactively in accordance with the provisions in §412.130.

Refer to Appendix V of the State Operations Manual (SOM) for Critical Access Hospital Emergency Medical Treatment and Labor Act (EMTALA) interpretive guidelines and survey procedures.

C-2400

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[The provider agrees,] in the case of a hospital as defined in §489.24(b), to comply with §489.24.

C-2401

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[The provider agrees,] in the case of a hospital as defined in §489.24(b), to report to CMS or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of §489.24(e).

C-2402

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[The provider agrees,] in the case of a hospital as defined in §489.24(b), to post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital (e.g., critical access hospital) participates in the Medicaid program under a State plan approved under Title XIX.

C-2403

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[The provider agrees,] in the case of a hospital as defined in §489.24(b), (including both the transferring and receiving hospitals), to maintain medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of transfer.

C-2404

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§489.20(r)(2)
[The hospital (including both the transferring and receiving hospitals), must maintain] a list of physicians who are on call for duty after the initial examination to provide further evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition.

§489.24(j)(1)
Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

§489.24(j)(2)(i)
The hospital must have written policies and procedures in place to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control.

§489.24(j)(2)(ii)
The hospital must have written policies and procedures in place to provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

C-2405

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

[The provider agrees,] in the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain a central log on each individual who comes to the emergency department, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

§489.24 The provisions of this regulation apply to all hospitals that participate in Medicare and provide emergency services.

C-2406

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

Applicability of provisions of this section.

(1) In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) "comes to the emergency department", as defined in paragraph (b) of this section, the hospital must (i) provide an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of §482.55 of this chapter concerning emergency services personnel and direction; and

(b) If an emergency medical condition is determined to exist, provide any necessary stabilizing treatment, as defined in paragraph (d) of this section, or an appropriate transfer as defined in paragraph (e) of this section. If the hospital admits the individual as an inpatient for further treatment, the hospital's obligation under this section ends, as specified in paragraph (d)(2) of this section.

(2) Nonapplicability of provisions of this section.
Sanctions under this section for inappropriate transfer during a national emergency or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act. A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a public health emergency, as provided for by section 1135(e)(1)(B) of the Act.

(c) Use of Dedicated Emergency Department for Nonemergency Services
If an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an emergency medical condition.

C-2407

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(1) General. Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the

hospital determines that the individual has an emergency medical condition, the hospital must provide either-

(i) within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition.

(ii) For for transfer of the individual to another medical facility in accordance with paragraph (e) of this section.

(2) Exception: Application to inpatients.

(i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual

(ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.

(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(3) Refusal to consent to treatment.

A hospital meets the requirements of paragraph (d)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

C-2408

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(4) Delay in treatment.

(i) A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (d)(1) of this section in order to inquire about the individual's method of payment or insurance status.

(ii)A participating hospital may not seek, or direct an individual to seek, authorization from the individual's insurance company for screening or stabilization services to be furnished by a hospital, physician, or nonphysician practitioner to an individual until after the hospital has provided the appropriate medical screening examination required under paragraph (a) of this section, and initiated any further medical examination and treatment that may be required to stabilize the emergency medical condition under paragraph (d)(1) of this section.

(iii) An emergency physician or nonphysician practitioner is not precluded from contacting the individual's physician at any time to seek advice regarding the individual's medical history and needs that may be relevant to the medical treatment and screening of the patient, as long as this consultation does not inappropriately delay services required under paragraph (a) or paragraphs (d)(1) and (d)(2) of this section.

Hospitals may follow reasonable registration processes for individuals for whom examination or treatment is required by this section, including asking whether an individual is insured and, if so, what that insurance is, as long as that inquiry does not delay screening or treatment. Reasonable registration processes may not unduly discourage individuals from remaining for further evaluation.

A hospital meets the requirements of paragraph (d)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (e) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) does not consent to the transfer. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf). The written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

C-2409

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(1) General

If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless –

(i) The transfer is an appropriate transfer (within the meaning of paragraph (e)(2) of this section); and
(ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer.

The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer.

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its bylaws or rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

(2) A transfer to another medical facility will be appropriate only in those cases in which –

(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(ii) The receiving facility

(A) Has available space and qualified personnel for the treatment of the individual; and

(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment.

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (e)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (g) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

C-2410

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (e)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.

C-2411

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers, which, for purposes of this subpart, means hospitals meeting the requirements of referral centers found at §412.96 of this chapter) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual. This requirement applies to any participating hospital with specialized capabilities, regardless of whether the hospital has a dedicated emergency department.

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
R200SOMA	02/21/2020	Revisions to the State Operations Manual (SOM) Appendix A - Hospitals, Appendix AA – Psychiatric Hospitals, Appendix B – Home Health Agency, Appendix D - Portable X-Ray, Appendix G - Rural Health Clinics/Federally Qualified Health Centers, Appendix H- End Stage Renal Disease Facilities (ESRD), Appendix K – Comprehensive Outpatient Rehabilitation Facility, Appendix L - Ambulatory Surgical Centers, Appendix M – Hospice, Appendix U - Religious Nonmedical Healthcare Institutions, Appendix W - Critical Access Hospitals (CAHs), Appendix X - Organ Transplant Program and Appendix Z - Emergency Preparedness	02/21/2020	N/A
R183SOMA	10/12/2018	Revisions to Medicare State Operations Manual (SOM) Table of Contents, Medicare SOM Appendix, SOM Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, SOM Appendix T- Regulations and Interpretive Guidelines for Swing Beds in Hospitals, SOM Appendix W- Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs.	10/12/2018	N/A
R165SOM	12/16/2016	Revisions to State Operations Manual (SOM) Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs	12/16/2016	N/A
R163SOM	10/14/2016	Revisions to State Operations Manual (SOM) Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs	10/14/2016	N/A
R149SOM	10/09/2015	State Operations Manual (SOM) for All Types of Providers and Suppliers Subject to Certification	10/09/2015	N/A
R143SOM	07/31/2015	Revisions to State Operations Manual (SOM) Chapter 2, The Certification Process and Appendix W, Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs	07/31/2015	N/A

R138SOM	04/07/2015	Revisions to State Operations Manual (SOM), Appendix W, I for Critical Access Hospitals	04/07/2015	N/A
R124SOM	10/10/2014	Revisions to State Operations Manual (SOM), Appendix W, Interpretive Guidelines for Critical Access Hospitals	10/10/2014	N/A
R110SOM	04/11/2014	State Operations Manual (SOM) Appendix W Revisions For Intermediate Care Facilities For Individuals With Intellectual Disabilities (ICF/IID)	04/11/2014	N/A
R99SOM	01/31/2014	Revised State Operations Manual (SOM) Appendices A, I, L, and W	01/31/2014	N/A
R95SOM	12/12/2013	Revised Appendix A, Interpretive Guidelines for Hospitals, Appendix L, Interpretive Guidelines for Ambulatory Surgical Centers and Appendix W, Interpretive Guidelines for Critical Access Hospitals	06/07/2013	N/A
R90SOM	08/30/2013	State Operations Manual, Chapter 2, Section 2256A,CAH Distance Criteria	08/30/2013	N/A
R89SOM	08/30/2013	Revised State Operations Manual (SOM) Appendices A, I, L, and W – Rescinded and replaced by Transmittal 99	08/30/2013	N/A
R84SOM	06/07/2013	Revised Appendix A, Interpretive Guidelines for Hospitals, Appendix L, Interpretive Guidelines for Ambulatory Surgical Centers and Appendix W, Interpretive Guidelines for Critical Access Hospitals – Rescinded and replaced by Transmittal 95	06/07/2013	N/A
R78SOM	12/22/2011	Revised Appendix A, Interpretive Guidelines for Hospitals and Appendix W, Interpretive Guidelines for Critical Access Hospitals(CAH)	12/22/2011	N/A
R75SOM	12/02/2011	Revised Appendix A, Interpretive Guidelines for Hospitals and Appendix W, Interpretive Guidelines for Critical Access Hospitals(CAH)	12/02/2011	N/A
R49SOM	06/12/2009	New Critical Access Hospital (CAH) Requirements Under 42 CFR 485.610(e) Related to CAH Co-location and CAH Provider-based Locations	06/12/2009	N/A
R34SOM	04/04/2008	Revision to Appendix W, “Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs)”	04/04/2008	N/A

R32SOM	01/18/2008	Revisions to Chapter 2, “Critical Access Hospitals (CAHs) and Appendix W, “Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs”	09/2007	N/A
R01SOM	05/21/2004	Initial Release of Pub 100-07	N/A	N/A