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

(Rev. 149, 10-09-15)

Transmittals for Appendix W

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Regulations and Interpretive Guidelines for CAHs

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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 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. 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.

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 Agency 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.

- The regulatory authority for the photocopying of records and information during the survey is found at 42 CFR 489.53.

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

Surveyors assess the CAH's compliance with the CoP for all services, areas and locations in which the provider receives reimbursement for patient care services billed under its provider number.

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 routine CAH surveys are unannounced. Do not provide CAHs with advance notice of the survey.

Tasks in the Survey Protocol

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

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 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 facility 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.

Team Coordinator

Surveyors conduct the survey under the leadership of a team coordinator. The SA (or the RO for Federal teams) should designate this individual. The team coordinator is responsible for assuring that all survey preparation and survey activities are completed within the specified time frames 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 on-going communication among team members;
- Evaluating team progress;
- Coordinating daily team meetings;
- Coordinating any ongoing conferences 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; and
- Coordinating the preparation of the Form CMS-2567.

Task 1 - Off-Site Survey Preparation

General Objective

The objective of this task is to analyze information about the provider 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 provider (e.g., provider-based clinics, specialty units, services offered, etc.) require the addition of any specialty surveyors to the team. Information obtained about the provider 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 provider 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 Regional Office (RO); and

- Any additional information available about the facility (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 facility. 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 facility (if available);

- Preliminary team member assignments;

- Date, location and time team members will meet to enter the facility;

- The time for the daily team meetings; and

- Potential date and time of the exit conference.

Gather copies of 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;
- Letter of authorization to obtain facilities most recent accreditation survey, Exhibit 287; and
- Worksheets for swing bed and CAH distinct part rehabilitation and psychiatric units, Exhibit 288.

Task 2 - Entrance Activities

General Objectives

The objectives of this task are to explain the survey process to the provider 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. 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 provider number 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 facility will ensure that surveyors are able to obtain the photocopies of material, records, and other information as they are needed;

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

- 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 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 facility for obtaining this information;

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

- A copy of the facility's organizational chart;
- The names and addresses of all off-site locations operating under the same provider number;
- 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 facility's floor plan, indicating the location of patient care and treatment areas.

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

Facility Tours

Guided tours of the facility are not encouraged and should be avoided. A tour of a facility 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 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;
- 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 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.

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 provider's compliance with the Medicare Conditions of Participation 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 provider number and are considered a part of the CAH. 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. The depth of assessment of the CoP 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 should meet at least daily in order to assess the status of the survey, progress of completion of assigned tasks, areas of concern, and to identify areas for additional investigations. The team meetings should include an update by each surveyor that addresses findings and areas of concern that have been identified. 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.

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

- Maintain open and ongoing dialogue with the facility staff throughout the survey process. Conferences with facility staff may be held in order to inform them of survey findings. This affords facility 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.

- Surveyors should always maintain a professional working relationship with facility 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, 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. 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 facility is functioning as one integrated whole;
- Whether quality assurance (QA) is a facility-wide activity, incorporating every service and activity of the provider and whether every facility department and activity reports to, and receives reports from, the facility's central organized body managing the facility-wide QA program; and
- Storage, security, and confidentiality of medical records.

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

A surveyor must not examine patients by themselves, although in certain circumstances, in order to determine a patient's health status and whether safe and appropriate health care is being provided, especially to ensure a patient's welfare where he/she appears to be in immediate jeopardy, it is permissible and necessary to examine the patient. After

obtaining permission from the patient, the surveyor should request that a staff member of the facility examine the patient in the surveyor's presence. 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 facility 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 facility'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 facility's compliance with the CoP. 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 educational requirements, have had the necessary training required, and are licensed, if it is required;

- Credential files to determine if the facility 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 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.

Photocopies

Surveyors should make photocopies of all documents needed to support survey findings. The surveyor needs access to a photocopier where he/she can make his/her own photocopies of needed documents. If requested by the hospital, the surveyor should make the hospital 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-2/27/04 page 3" or "Patient # 6, progress note –2/17/04."

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

At this meeting, the surveyors will share their findings with the team, evaluate the evidence, and make team decisions regarding compliance with each requirement. Proceed sequentially through the requirements for each condition appropriate to the facility as they appear in regulation. For any issues of noncompliance, the team needs to reach a consensus. 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 facility noncompliance. The team should document their decisions, the substance of the evidence, and the numbers of patients impacted, in order to identify the extent of facility 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 hospital.

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 nature (how severe, how dangerous, how critical, etc.) and extent (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 nature and extent 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?
- 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?

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. 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 facility 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 facility 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 facility wishes to audio tape the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously. The surveyors should take one of the tapes at the conclusion of the conference. Videotaping is also permitted if it is not disruptive to the conference, and a copy is provided at the conclusion of the conference. It is at the sole discretion of the surveyor(s) to determine if videotaping is permitted.

General Principles

The following general principles apply when conducting an exit conference:

- The facility 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 facility staff during the survey, there should be few instances in which the facility 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 facility.

- 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 facility staff.

- State that the provider will have an opportunity to present new information after the exit conference for consideration after the survey.

C - Presentation of Findings

- Avoid referring to data tag numbers.

- Present the 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 facility is very good”). Stick to the facts. Do not rank findings. Treat requirements as equal as possible.

- 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 working days to the CAH.

- Explain that the Form CMS-2567 is the document disclosed to the public about the facility’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 facility’s plans for correction and timeframes, and it provides an opportunity for the facility to refute survey findings and furnish documentation that requirements are met.

- Inform the facility that a written plan of correction must be submitted to the survey agency within 10 calendar days following receipt of the written statement of deficiencies.

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

    - Corrective action to be taken for each individual affected by the deficient practice, including any system changes that must be made;

    - The position of the person who will monitor the corrective action and the frequency of monitoring;

    - Dates each corrective action 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.

- If the exit conference was audio or video taped, obtain a copy of the tape in its entirety before leaving the facility.

All team members should leave the facility together immediately following the exit conference. If the facility 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

When conducting a full survey of an accredited or unaccredited CAH that has swing bed approval, conduct a survey of the CAH swing-bed requirements found at 42 CFR Part 485.645. These requirements, as well as interpretive guidelines, are found in Appendix W of the State Operations Manual (SOM). The optional survey worksheet may be used.

Background

Swing-bed patients are CAH patients who are situated in the CAH but for whom the CAH is receiving reimbursement for 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 facility. 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 hospital when the reimbursement status changes, but moving to a different location is allowed. A 3-day qualifying stay for the same spell of illness in any hospital or CAH is required prior to admission to swing-bed status. The 3-day qualifying stay does not need to be from the same facility as the swing-bed admission.

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 18883 of the Act authorizes payment under Medicare for post-hospital SNF services provided by any CAH that meets certain requirements. By regulation, the Secretary has specified these requirements at 42 CFR § 485.645.

- 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.
- The CAH has not had a swing-bed approval terminated within two years previous to application; and
- The CAH meets the swing-bed CoP on Resident Rights; Admission, Transfer, and Discharge Rights; Resident Behavior and Facility Practices; Patients Activities; Social Services; Discharge Planning; Specialized Rehabilitative Services; and Dental Services.

Activities Conducted Prior to Swing-Bed Survey

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

- The hospital's swing-bed approval is in effect and has not been terminated within the two previous years.

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.

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.

Assess the CAH's compliance with the swing-bed requirements at 42 CFR §485.645 found in appendix W of the SOM. 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 two closed records for compliance with swing-bed requirements. In all cases, 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

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

Post-Survey Activities

The findings for swing-bed deficiencies must be documented on a separate Form CMS-2567, even though the swing-bed survey is being conducted simultaneously with the CAH survey.

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-0150

§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-0151

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§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-0152

§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-0153

§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-0154

§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-0160

(Rev. 143, Issued: 07-31-15, Effective: 07-31-15, Implementation: 07-31-15)

§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-0161

§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-0162

(Rev. 143, Issued: 07-31-15, Effective: 07-31-15, Implementation: 07-31-15)

§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-0165

(Rev. 143, Issued: 07-31-15, Effective: 07-31-15, Implementation: 07-31-15)

[§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-0166

(Rev. 32, Issued: 01-18-08, Effective: 09-07-07, Implementation: 09-07-07)

§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-0167

(Rev. 49, Issued: 06-12-09, Effective/Implementation: 06-12-09)

§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-0168

(Rev. 143, Issued: 07-31-15, Effective: 07-31-15, Implementation: 07-31-15)

[§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-0170

§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-0190

§485.616 Condition of Participation: Agreements

C-0191

§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-0192

§485.616(a)(1) Patient referral and transfer;

C-0193

§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-0194

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

C-0195

§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-0196

(Rev. 78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§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-0197

(Rev. 78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§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-0200

§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 met 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-0201

§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-0202

§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-0203

§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-0204

§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-0205

§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-0206

§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-0207

§485.618(d) Standard: Personnel

(1) Except as specified in paragraph (d)(2) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, or a nurse practitioner 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 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)(2)(ii) 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).

(3) The request, as specified in paragraph (d)(2)(ii) 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, or registered nurse (as allowed under (d)(2)) with emergency training or experience has been on call and available on site at the CAH within 30 or 60 minutes, as appropriate?

C-0209

§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-0210

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

C-0211

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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-0212

§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-0220

§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-0221

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§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-0222

§485.623(b) Standard: Maintenance

(Rev. 124, Issued: 10-10-14, Effective: 10-10-14, Implementation: 10-10-14)

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-0223

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

Interpretive Guidelines §485.623(b)(2)

The term trash refers to common garbage as well as biohazardous waste. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (i.e., EPA, OSHA, CDC, State environmental, health and safety regulations). The Radiology requirements address handling and storage of radioactive materials.

Survey Procedures §485.623(b)(2)

Verify that the CAH has developed and implemented policies for the proper storage and disposal of trash. Verify through observation that staff adhere to these policies and that the CAH has signage, as appropriate.

C-0224

§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-0225

§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-0226

(Rev. 99 Issued: 01-31-14, Effective: 01-31-14, Implementation: 01-31-14)

§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)

There must be proper ventilation in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);
- Pharmaceutical preparation areas (hoods, cabinets, etc.);
- Laboratory locations; and
- Anesthetizing locations. According to NFPA 99, anesthetizing locations are "Any area of a facility that has been designated to be used for the administration of nonflammable inhalation anesthetic agents in the course of examination or treatment, including the use of such agents for relative analgesia." NFPA 99 defines relative analgesia as "A state of sedation and partial block of pain perception produced in a patient by the inhalation of concentrations of nitrous oxide insufficient to produce loss of consciousness (conscious sedation)." (Note that this definition is applicable only for LSC purposes and does not supercede other guidance we have issued for other purposes concerning anesthesia and analgesia.)

There must be adequate lighting in all the patient care, food and medication preparation areas.

Temperature, humidity and airflow in anesthetizing locations must be maintained within acceptable standards to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort. Ventilation systems in anesthetizing locations must maintain relative humidity (RH) levels at 35 percent or greater unless a facility elects to use the CMS categorical waiver, which permits new and existing ventilation systems to operate at a RH of 20 percent or greater (see Appendix I, Section II for additional

information). Although not required, CMS recommends that facilities maintain the upper range of RH at 60 percent or less as excessive humidity is conducive to microbial growth and compromises the integrity of wrapped sterile instruments and supplies. Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the Facilities Guidelines Institute (FGI) should be incorporated into hospital policy.

The CAH must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).

Survey Procedures §485.623(b)(5)

- Verify that all food and medication preparation areas are well lighted.
- Verify that the CAH is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.
- Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on nationally-accepted sources such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally-recognized standard.
- Verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer.
- Verify that each anesthetizing location has temperature control mechanisms.
- Review the records for anesthetizing locations temperature and humidity to ensure levels are maintained.
- Review temperature and humidity maintenance records for anesthetizing locations to ensure, if monitoring determined temperature or humidity levels were not within acceptable parameters, the corrective actions were performed in a timely manner to achieve acceptable levels.

C-0227

§485.623(c) Standard: Emergency Procedures

The CAH assures the safety of patients in non-medical emergencies by--

(1) Training staff in handling emergencies, including prompt reporting of fires,

extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

Survey Procedures §485.623(c)(1)

- How does the CAH ensure that all personnel on its staff, including new additions to the staff, are trained to manage non-medical emergencies?
- Ask facility staff what they are supposed to do in case of an emergency such as a tornado or a blizzard.
- Review staff training documents and inservice records to validate training.
- Review the CAH'S written fire control plans to verify they contain the required provisions of the Life Safety Code or State law.
- Verify that CAH staff reported all fires as required to State officials.
- Interview staff throughout the facility to verify their knowledge of their responsibilities during a fire (this is usually done during the LSC survey, but health surveyors may also verify staff knowledge).

C-0228

§485.623(c)(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

Interpretive Guidelines §485.623(c)(2)

The CAH must comply with the applicable provisions of the Life Safety Code, National Fire Protection Amendments (NFPA) 101, 2000 Edition and applicable references such as NFPA-99: Health Care Facilities, for emergency lighting and emergency power.

Survey Procedures §485.623(c)(2)

Use the Life Safety Code Survey Report Form (CMS-2786) to evaluate compliance with this item.

C-0229

§485.623(c)(3) Providing for an emergency fuel and water supply; and

Interpretive Guidelines §485.623(c)(3)

The CAH must have a system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care. This

includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The CAH should consider nationally accepted references or calculations made by qualified staff when determining the need for at least water and gas. For example, one source for information on water is the Federal Emergency Management Agency (FEMA).

Emergency gases include fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the CAH uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.

The CAH should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community).

Survey Procedures §485.623(c)(3)

- Review the system used by CAH staff to determine the CAH'S emergency needs for gas and water. Verify that the system accounts for not only inpatients, but also staff and other persons who come to the CAH in need of care during emergencies.

- Determine the source of emergency gas and water, both the quantity of these supplies readily available at the CAH, and that are needed within a short time through additional deliveries.

- Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities, such as water and gas.

C-0230

§485.623(c)(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

Interpretive Guidelines §485.623(c)(4)

Assuring the safety and well being of patients would include developing and implementing appropriate **emergency preparedness** plans and capabilities. The CAH must develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations. The CAH must coordinate with Federal, State, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will ensure the safety and well being of patients. The following issues should be considered when developing the comprehensive emergency plans(s):

- Differences needed for each location where the certified CAH operates;
- The special needs of patient populations treated at the CAH (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);
- Security of patients and walk-in patients;
- Security of supplies from misappropriation;
- Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;
- Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);
- Communication among staff within the CAH itself;
- Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;
- Identification, availability and notification of personnel that are needed to implement and carry out the CAH'S emergency plans;
- Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;
- Provisions for gas, water, electricity supply if access is shut off to the community;
- Transfer or discharge of patients to home or other healthcare settings
- Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.

Survey Procedures §485.623(c)(4)

Verify that the CAH has developed and implemented a comprehensive plan to ensure the safety and well being of patients during local emergency situations.

C-0231

§485.623(d) Standard: Life Safety From Fire

(1) Except as otherwise provided in this section, the CAH must meet the applicable

provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capital Street NW, Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes. Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

Interpretive Guidelines §485.623(d)(1)

Medicare-participating CAHs, regardless of size or number of beds, must comply with the Hospital/healthcare Life Safety Code requirements for all inpatient care locations. CAH departments and locations such as emergency departments, outpatient care locations, etc. must comply with Hospital/healthcare Life Safety Code Requirements. Additionally, the CAH must be in compliance with all applicable codes referenced in the Life Safety Code, such as NFPA-99: Health Care Facilities.

This revision adopts the 2000 edition of the LSC and deletes provisions for the use of roller latches in the facility.

Survey Procedures §482.41(b)(1)

- There is a separate survey form, (CMS-2786) used by the Fire Authority surveyor to evaluate compliance with the Life Safety Code and a separate 1985 Life Safety Code Addendum to be used when surveying for compliance with the 1985 Life Safety Code. (Life Safety Code Guidelines and a copy of the 1985 Life Safety Code Addendum are contained in SOM Appendix I.)

- Survey the entire building occupied by the CAH unless there is a 2-hour firewall separating the space designated as the CAH from the remainder of the building. A 2-hour floor slab does not count; it must be a vertical firewall to constitute a separate building or part of a building.

C-0232

§485.623(d)(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

Interpretive Guidelines §485.623(d)(2)

This revision deletes "grandfathering" of older editions of the LSC and allows the use of

a State code if approved by CMS.

C-0233

§485.623(d)(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(d)(3)

Life Safety Code waivers may be recommended by the State survey agency but only CMS (at the regional office level) may grant those waivers for Medicare or Medicaid-participating CAHs.

Survey Procedures §485.623(d)(3)

Consideration, assessment and recommendation for waivers of specific Life Safety Code provisions are handled by the Fire Authority surveyor as part of the Life Safety Code survey process.

C-0234

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

Survey Procedures §485.623(d)(4)

Examine copies of inspection and approval reports from State and local fire control agencies.

C-0235

§485.623(d)(5) A critical access CAH must be in compliance with the following provisions beginning on March 13, 2006:

- **(i) Chapter 19.3.6.3.2 exception number 2.**
- **(ii) Chapter 19.2.9, Emergency Lighting.**

Interpretive Guidelines §485.623(d)(5)

§ 485.623(d)(1) states, “Chapter 19.3.6.3.2 exception number 2 of the adopted edition of the Life Safety Code does not apply to CAH.” The wording in § 485.623(d)(5) and § 485.623(d)(5)(i) when used together means that after March 13, 2006 a CAH may no longer continue to keep in service existing roller latches even when these roller latches have been demonstrating the ability to keep the door closed against 5lbf.

Medicare-participating CAHs must be in compliance with chapter 19.3.6.3.2 of the 2000 Edition of NFPA 101 beginning March 13, 2006. Exception number 2 of chapter 19.3.6.3.2 will not be allowed in Medicare-participating CAHs.

CAHs should develop plans for compliance with this requirement so that in all applicable locations roller latches have been replaced by positive latches prior to March 13, 2006.

Beginning March 13, 2006, Medicare-participating CAHs must be in compliance with Chapter 19.2.9 of the 2000 Edition of NFPA 101.

This section gives facilities until March 13, 2006, to replace roller latches and to replace 1 hour batteries with 1-1/2 hour batteries in emergency lighting systems that use batteries as power sources.

After March 13, 2006 a CAH with doors in service with roller latches or with emergency lighting systems with less than 1-1/2 hour batteries will not be in compliance and will be cited at 485.623(d)(1).

C-0240

§485.627 Condition of Participation: Organizational Structure

C-0241

§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-0242

§485.627(b) Standard: Disclosure

The CAH discloses the names and addresses of--

(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

Survey Procedures §485.627(b)(1)

- Review CAH policy for reporting changes of ownership.
- How does the CAH implement its policy or procedure for reporting changes in ownership to the State agency?

C-0243

§485.627(b)(2) The person principally responsible for the operation of the CAH; and

Survey Procedures §485.627(b)(2)

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

C-0244

§485.627(b)(3) The person responsible for medical direction

Survey Procedures §485.627(b)(3)

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

C-0250

§485.631 Condition of Participation: Staffing and Staff Responsibilities

C-0251

§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-0252

§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-0253

§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-0254

§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 physicians 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-0255

§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-0256

§485.631(b) Standard: Responsibilities of the Doctor of Medicine or Osteopathy

C-0257

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-0258

§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-0259

§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-0260

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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-0261

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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-0262

§485.631(c) Standard: Physician Assistant, Nurse Practitioner, and Clinical Nurse Specialist Responsibilities

C-0263

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-0264

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-0265

§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-0267

§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-0268

§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-0270

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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-0271

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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?

C-0272

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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 annually 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 annually 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 annually and indicated whether or not it recommended any changes?

C-0273

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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-0274

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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-0275

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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-0276

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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).

Note Re: US Pharmacopeia/National Formulary (USP/NF)

According to the Federal Food, Drug and Cosmetic Act (FCDA), the official compendia of the United States for excipients, drug substances, and drug products is the USP/NF. It is published every year in November by the United States Pharmacopeial Convention (http://www.usp.org/) and includes two supplements published in February and June.

The USP is a not-for-profit, non-governmental organization that since 1820 has established quality standards for, among other things, drug substances, drug products and compounded preparations. Congress established a role for USP standards in the adulteration provision of the 1906 Food and Drug Act. That role was expanded in the modern Food, Drug and Cosmetic Act (FDCA) beginning in 1938, with a role for USP compendial standards for naming and identity; strength, quality, and purity; and packaging and labeling, in both the adulteration and misbranding provisions of FDCA. (See, for example, §501(b) of the FDCA regarding compendial standards for strength, quality and purity, §502(g) for compendial standards for packaging and labeling). Under the FDCA, a drug with a name recognized in the USP/NF must comply with compendial identity standards, or be deemed adulterated, or misbranded, or both. To avoid being deemed adulterated, such drugs must also comply with compendial standards for strength, quality, and purity, unless labeled to show all respects in which the drug differs.

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. Absent the manufacturer's labeled conditions, USP indicates that storage of drugs and biologicals be done according to USP/NF, or the food chemicals codex (FCC) monograph requirements. 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 which are equivalent to or more stringent than those described in the compounding-related chapters in the USP/NF, which are recognized as authoritative standards regarding minimum standards of safe practice applicable to both sterile and non-sterile compounding.

  The definition of compounding as that term is used in the USP is found in USP Chapter <795> (USP <795>):

  "The preparation, mixing, assembling, altering, packaging and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

    - Preparation of drug dosage forms for both human and animal patients;

- Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients;

- Preparation of drugs or devices for the purposes of, or as incident to, research (clinical or academic), teaching or chemical analysis;

- Preparation of drugs and devices for prescriber's office use where permitted by federal and state law."

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 applicable standards for safe compounding are, at a minimum, the standards published in USP Chapters <795> ("Pharmaceutical Compounding – Nonsterile Preparations"), <797> ("Pharmaceutical Compounding – Sterile Preparations") and other relevant USP-NF Chapters. 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.

USP <797> outlines minimum standards of practice to be followed by all health care personnel in any setting when preparing, storing and transporting "compounded sterile preparations" (CSPs). Its stated objective is "to describe conditions and practices to prevent harm, including death, to patients that could result from…microbial contamination…excessive bacterial endotoxins…variability of intended strength of correct ingredients…unintended chemical and physical contaminants…and ingredients of inappropriate quality…." Contaminated CSPs are especially hazardous if administered into body cavities, the central nervous system, vascular system, eyes, joints, and/or used as baths for live organs and tissues. "All compounded dosage forms that must be sterile when they are administered to patients" are considered by USP <797> to be CSPs, including but not limited to:

- "Aqueous bronchial and nasal inhalations;

- Baths and soaks for live organs and tissues;

- Injections [and infusions];

- Irrigations for wounds and body cavities;

- Ophthalmic drops and ointments;

- Tissue implants."

USP <797> specifies differing standards for the physical layout and structure of the locations in which compounding takes place as well as processes, precautions and quality assurance practices to be implemented during the preparation, transport and storage of CSPs. The standards differ in part based on the level of risk of microbial contamination of the CSP, and the risk level has implications for whether a CSP must be terminally sterilized before being dispensed and for how long a CSP may be stored before use. The risk categories and accompanying standards are based on specific criteria, including but not limited to factors such as:

- The structural design, environmental controls, air quality levels (based on International Organization for Standardization (ISO) standards for particulate matter in air) and air flow patterns in and surrounding the environment to which the contents of the CSP as well as the surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs are exposed.

- The sterility of the original ingredients and/or device(s) used in compounding, the number of containers that need to be entered, how many times they need to be entered, the nature and complexity of the manipulations and length of time required to prepare the CSP.

- Whether compounding personnel are appropriately garbed and gloved.

- Whether multiple doses of sterile products are pooled to produce a CSP that will be administered on more than one occasion or to more than one patient.

The goal of the USP <797> standards is to prevent and/or minimize the risk of microbial contamination of CSPs, whether by direct contact, exposure to particles in air generated by personnel or objects, or other mechanisms. A major concern is preventing contamination of "critical sites," which include "any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed or at risk of direct contact with air…moisture…or touch contamination."

USP <797> describes two basic structural designs for the physical layout and environmental controls intended to minimize airborne contamination of critical sites during preparation of CSPs. The risk level of the CSPs a facility can produce depends, in part, on which USP <797> environmental quality and control/facility design standards the CAH (or its vendor) is able to meet (low-risk level, medium-risk level and high-risk level are discussed here; see §485.635(d)(3) for a discussion of "immediate-use" CSPs):

- Some facilities may only prepare low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient, and administration must commence within the lesser of 12 hours of preparation or as recommended in the manufacturer's package insert. Such a facility would have a designated, demarcated room or space that is the "segregated compounding area (SCA)," which contains a device that provides unidirectional airflow of International Standards Organization (ISO) Class 5 air quality (quality class ranges from class 0, the most stringent, to class 9, the most relaxed). The SCA may not be in an area with unsealed openings/potential openings to high traffic locations, the outdoors and other proscribed environmental conditions, and the SCA area may not contain any materials or be the site of any activities unrelated to preparing low-risk CSPs.

- If a facility is preparing high- or medium-level risk CSPs or low-risk CSPs with a beyond-use date of greater than 12 hours, it must meet additional environmental design and monitoring/testing standards in the buffer and ante-areas.

- USP<797> contains separate standards for the safe compounding of hazardous medications (defined as "...if studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive toxicity, or harm to organs…"), radiopharmaceuticals and allergen extracts.

In addition, USP <797> includes standards for various processes, precautions and quality assurance practices required and recommended for the safe preparation of all risk levels of CSPs. These address issues such as:

- The responsibilities of compounding personnel and their supervisors to implement and maintain proper procedures and quality assurance checks.

- Issues specific to "immediate use" CSPs; single- and multiple-dose containers; CSPs containing hazardous drugs; radiopharmaceuticals; allergen extracts; and automated compounding devices used for parenteral nutrition compounding.

- Methods for sterilization, depyrogenation and for verifying compounding accuracy and sterility.

- Specifications for environmental quality and control, including but not limited to:

    - Specifications and related personnel training, including competency assessment and evaluation of skill in aseptically preparing CSPs using visual observation as well as bacterial sampling of glove fingertips and "media-fill testing" at specified intervals.

- Evaluation and monitoring/testing of the environment in which compounding takes place and, if applicable, the adjacent "ante-" and "buffer" areas, including facility layout, design, environmental controls, restricted access, air quality standards and testing, surface characteristics, furnishings, cleaning and disinfection procedures, and standards for personnel health, attire/cosmetics, cleansing/garbing/gloving, aseptic work practices, etc.

- Suggested standard operating procedures to protect the quality of the environment in which CSPs are prepared.

- Quality control related to ingredients, devices and equipment used in relation to CSPs.

- Quality checks to be performed before CSPs are dispensed or administered.

- Issues related to beyond-use dating and packaging, storage and transportation conditions for CSPs.

- Protecting dispensed and distributed CSPs.

- Patient education issues.

- Monitoring for and reporting adverse patient events related to CSPs.

- Requirements for a formal quality assurance program to be maintained by providers of CSPs.

For Information – Not Required/Not to be Cited

USP <797> Appendices I and III-V contain summaries and assessment tools that CAHs may find helpful. However, there is no requirement to use specific forms or materials as long as the CAH and/or its external sources of CSPs are implementing plans, procedures, testing and documentation consistent with applicable standards for safe compounding. These USP <797> suggested materials are referenced here only as examples:

- "Appendix I: Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required…and Recommended in USP Chapter <797>"
- "Appendix III: Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel"
- "Appendix IV: "Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel"

- "Appendix V: "Sample Form for Assessing Cleaning and Disinfection Procedures"

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/PharmacyCompounding/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:

- Ensuring that the CAH has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements, and can the CAH document that it obtains and reviews such data?

- 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. The policies and procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the United States Pharmacopeia-National Formulary (USP).[1]

According to Chapters <795> and <797> of the USP, the BUD must be safe for patients, and determined conservatively. The section in USP <797> entitled "Determining Beyond-Use Dates", which addresses sterile compounding, notes that "the truly valid evidence for predicting beyond-use dating can be obtained only through product-specific experimental studies." It provides an example of testing considered more appropriate for certain types of compounded sterile preparations (CSPs) such as "CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity…." It also provides examples of important issues that a pharmacist must be able to critically interpret and evaluate when consulting literature sources in the process of determining a BUD; and distinguishes between reviewing literature specific to a particular drug, composition, concentration of ingredients, fill volume, container, storage conditions and duration of use, etc., versus merely reviewing available publications or tables. The former is the preferred approach, while the latter results in a "theoretical BUD," which has an inherent likelihood of inaccuracy or error.

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,

[1] All references to "USP" herein are from: United States Pharmacopeial Convention. *USP on Compounding: A Guide for the Compounding Practitioner. Current with USP 37-NF32 through First Supplement.* Rockville, MD: United States Pharmacopeial Convention, 2014.

and expiration date. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD. It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., need-punctured), the USP standard is that the BUD is 28 days, unless otherwise specified by the manufacturer. 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 equivalent to or more stringent than the standards described in USP <795> and <797>?

  - 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 consistent with USP <795> and <797> (or equivalent/more stringent) standards?

  - 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? Can he or she demonstrate that the assigned risk levels are consistent with USP <797> or equivalent/more stringent standards?

  - 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 USP <797> or equivalent/more stringent 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 USP 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-0277

(Rev. 138, Issued: 04-07-15, Effective: 04- 07-15, Implementation: 04- 07-15)

§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-0278

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§485.635(a)(3) [The policies include the following:]

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

Interpretive Guidelines §485.635(a)(3)(vi)

This regulation requires the CAH to have a facility-wide system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel. The National Institute of Allergy and Infectious Diseases (NIAID) defines infectious disease as a disease caused by microbes that can be passed to or among humans by several methods. (http://www.niaid.nih.gov/topics/microbes/pages/glossary.aspx)

The Centers for Disease Control and Prevention (CDC) refers on its website to the following definition (from the state of New York) of a communicable disease: "an illness caused by an infectious agent or its toxins that occurs through the direct or indirect transmission of the infectious agent or its products from an infected individual or via an animal, vector or the inanimate environment to a susceptible animal or human host" (http://www.cdc.gov/tb/programs/laws/menu/definitions.htm).

A Healthcare-associated infection (HAI) is one that develops in a patient who is cared for in any setting where healthcare is delivered (e.g., acute care hospital, chronic care facility, ambulatory clinic, dialysis center, surgical center, home) and is related to receiving health care (i.e., was not incubating or present at the time healthcare was provided). According to the CDC, healthcare-associated infections, i.e., infections that patients acquire during the course of receiving treatment for other conditions within a healthcare setting, are one of the top ten leading causes of death in the United States. Based on a large sample of U.S. acute care hospitals, a CDC survey found that on any given day, about **1 in 25** hospital patients has at least one healthcare-associated infection. There were an estimated **722,000** HAIs in U.S acute care hospitals in 2011. About **75,000** hospital patients with HAIs died during their hospitalizations. More than half of all HAIs occurred outside of the intensive care unit.

The CAH must provide and maintain a sanitary environment to avoid sources and transmission of infections and communicable diseases. All areas of the CAH must be visibly clean and sanitary. This includes all CAH departments and off-site locations.

The CAH is expected to have a designated individual who is qualified by education and/or experience and who is responsible for the infection control program. This person must have education or experience in the principles and methods for infection prevention and control.

The CAH's program for prevention, control and investigation of infections and communicable diseases must be conducted in accordance with nationally recognized infection control practices or guidelines, as well as applicable regulations of other federal or state agencies. Examples of organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN).

The U.S. Occupational Health and Safety Administration (OSHA) also issues federal regulations applicable to infection control practices.

Special Challenges in Infection Control

- **Multi-Drug Resistant Organisms (MDROs)**

  The prevention and control of MDROs is a national priority - one that requires that all healthcare facilities and agencies assume responsibility and participate in community-wide control programs. MDROs are defined as microorganisms – predominantly bacteria – that are resistant to one or more classes of antimicrobial agents. A notable example is methicillin-resistant Staphylococcus aureus (MRSA), an MDRO pathogen which is transmitted within and between healthcare facilities, as well as in the community setting. Options for treating patients with MDRO infections are very limited, resulting in increased mortality, as well as increased length of stay and costs. During the last several decades the prevalence of MDROs in hospitals has increased steadily. CAHs are encouraged to have mechanisms in place for the early identification of patients with targeted MDROs prevalent in their CAH and community, and for the prevention of transmission of such MDROs. When ongoing transmission of targeted MDROs in the CAH is identified, the infection prevention and control program should use this event to identify potential breaches in infection control practice.

- **Ambulatory Care**

  The ambulatory care setting, including emergency departments and outpatient clinics, accounts for a growing number of patient health encounters. Ambulatory care settings present unique challenges for infection control, because patients remain in common areas for prolonged periods waiting to be seen by a healthcare professional or awaiting admission to the CAH, examination or treatment rooms are turned around quickly with limited cleaning, and infectious patients may not be recognized immediately. Furthermore, immuno-compromised patients may receive treatments in rooms among other patients who may be infectious.

  The CAH's infection prevention and control program must be designed with these ambulatory care setting challenges in mind. After assessing the likely level of risk in its various ambulatory care settings, including off-site settings, a CAH might identify particular settings, such as the emergency department, where it would be appropriate to employ measures for screening individuals with potentially communicable diseases during their initial patient encounter, and taking appropriate control measures for those individuals who may present risk for the transmission of infectious agents by the airborne or droplet route. For example, when potentially infectious individuals are identified, prevention measures should include prompt physical separation wherever possible, implementation of respiratory hygiene/cough etiquette protocols, and/or appropriate isolation precautions based on the routes of transmission of the suspected infection.

- **Communicable Disease Outbreaks**

  Community-wide outbreaks of communicable diseases (such as measles, SARS, or influenza) present many of the same issues and require many of the same considerations and strategies as other CAH infectious disease threats. If a communicable disease outbreak occurs, an understanding of the epidemiology, modes of transmission, and clinical course of the disease is essential for responding to and managing the event. Among the infection control issues that may need to be addressed are:

  - Preventing transmission among patients, healthcare personnel, and visitors;
  - Identifying persons who may be infected and exposed;
  - Providing treatment or prophylaxis to large numbers of people; and
  - Logistics issues (staff, medical supplies, resupply, continued operations, and capacity).

  Widespread pandemics present special challenges for CAH staffing, supplies, resupply, etc. CAHs should work with local, State, and Federal public health agencies to identify likely communicable disease threats and develop appropriate preparedness and response strategies.

- **Bioterrorism**

  CAH facilities would confront a set of issues similar to naturally occurring communicable disease threats when dealing with a suspected bioterrorism event. The required response is likely to differ based on whether exposure is a result of a biological release or person-to-person transmission. A variety of sources offer guidance for the management of persons exposed to likely agents of bioterrorism, including Federal agency websites (e.g., http://www.ahrq.gov/prep; http://www.usamriid.army.mil/ ; http://www.bt.cdc.gov). Because of the many similarities between man-made and naturally occurring threats, an all-hazards approach to developing emergency response plans is preferred, and CAHs are encouraged to work with their State and local emergency response agencies to develop their plans.

Surveillance & Corrective Action

In order to prevent, control and investigate infections and communicable diseases, the CAH's program must include an active surveillance component that covers both CAH patients and personnel working in the hospital. Surveillance includes infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions.

The CAH must conduct surveillance on a facility-wide basis in order to identify infectious risks or communicable disease problems at any particular location. This does

not imply "total hospital surveillance," but it does mean that CAHs must have reliable sampling or other mechanisms in place to permit identifying and monitoring infections and communicable diseases occurring throughout the CAH. The CAH must document its surveillance activities, including the measures selected for monitoring, and collection and analysis methods. Surveillance activities must be conducted in accordance with recognized infection control surveillance practices, such as, for example, those utilized by the CDC's National Healthcare Safety Net (NHSN).

The CAH must develop and implement appropriate infection control interventions to address issues identified through its detection activities, and then monitor the effectiveness of interventions through further data collection and analysis.

Sanitary environment

Prevention of infections includes the proper maintenance of a sanitary environment.

The CAH must provide and maintain a sanitary environment to avoid sources and transmission of infections and communicable diseases. All areas of the CAH must be visibly clean and sanitary. This includes all CAH units and off-site locations. The infection prevention and control program must include appropriate monitoring of housekeeping, maintenance (including repair, renovation and construction activities), and other activities to ensure that the CAH maintains a sanitary environment. Examples of areas to monitor would include: food storage, preparation, serving and dish rooms, refrigerators, ice machines, air handlers, autoclave rooms, venting systems, inpatient rooms, treatment areas, labs, waste handling, surgical areas, supply storage, equipment cleaning, etc. Failure to maintain a clean environment would also be a deficiency related to §485.623(b)(4), which requires the CAH to maintain clean and orderly premises.

Mitigation of Risks

The CAH must have policies and procedures in place to mitigate the risks that contribute to healthcare-associated infections. They must incorporate infection control techniques and standard precautions including, but not limited to:

- Hand Hygiene
- Respiratory Hygiene/Cough Etiquette
- Use of Transmission-Based Precautions such as: contact precautions, droplet precautions, and airborne precautions
- Use of personal protective equipment (PPE) for healthcare personnel such as gloves, gowns, masks, and respirators
- Safe work practices to prevent healthcare worker exposure to bloodborne pathogens, such as safety needles and safety engineered sharps devices

- Safe medication preparation and administration practices including, but not limited to:

  - Routine preparation of injectable medications takes place in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed;

  - Proper hand hygiene before handling medications;

  - Always disinfecting a rubber septum with alcohol prior to piercing it;

  - Always using aseptic technique when preparing and administering injections;

  - Never entering a vial with a used syringe or needle;

  - Never administering medications from the same syringe to more than one patient, even if the needle is changed;

  - Recognizing that. after a syringe or needle has been used to enter or connect to a patient's IV it is contaminated and must not be used on another patient or to enter a medication vial;

  - Never using medications labeled as single-dose or single-use for more than one patient. This includes ampoules, bags, and bottles of intravenous solutions. Exception: It is permissible to use medications that have been **repackaged** from a previously unopened single-dose container if the repackaging has been done by a pharmacy in a manner consistent with USP/NP Chapter <797> standards, and if the repackaged medications have subsequently been stored consistent with USP <797> and the manufacturer's package insert, provided that each repackaged dose is used for a single patient.

  - If multi-dose vials are used for more than one patient, they must not be kept or accessed in the immediate patient treatment area. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could then lead to infections in subsequent patients. If a multi-dose vial enters the immediate patient treatment area, it must be dedicated to that patient only and discarded after use.

  - Never using bags or bottles of intravenous solution as a common source of supply for more than one patient

  - Wearing a surgical mask when placing a catheter or injecting material into the spinal canal or subdural space

  - Never using insulin pens and other medication cartridges and syringes

intended for single-patient-use only for more than one person

- Other safe care practices, including, but not limited to:
  - Never using the same fingerstick device for more than one person
  - Avoiding sharing blood glucose meters if possible. If they must be shared, the device must be cleaned and disinfected after every use, per manufacturer's instructions. If the manufacturer does not specify how the device should be cleaned and disinfected, it must not be shared.
  - Policies to ensure that reusable patient care equipment is cleaned and reprocessed appropriately before use on another patient

The CAH must train staff on infection control policies and practices pertinent to the staff's responsibilities and activities. For example, the CAH is expected to provide role-specific education on proper hand hygiene, standard and transmission-based precautions, asepsis, sterilization, disinfection, food sanitation, housekeeping, linen care, medical and infectious waste disposal, injection safety, separation of clean from dirty, as well as other means for limiting the spread of infections.

The CAH is also expected to provide education to patients and their visiting family members/caregivers, when applicable, about precautions to take to prevent infections.

The CAH is expected to monitor compliance with all policies, procedures, protocols, and other infection control program requirements and to conduct program evaluation and revision of the program, when indicated.

Survey Procedures §485.635(a)(3)(vi)

- Verify that the CAH has designated a qualified individual to be responsible for the infection control program.
- Can the responsible individual demonstrate that the CAH's program adheres to nationally recognized practices or guidelines?
- Is the environment sanitary throughout the CAH?
- Do CAH staff employ standard precautions appropriately?
- Do CAH staff employ safe infection control practices for preparing and administering medications?
- Does the CAH perform active surveillance to identify infections?
- Can the responsible individual demonstrate how staff compliance with infection control program requirements is assessed and what corrective actions are taken?

- Can the responsible individual demonstrate that infection control incidents, problems, and trends are analyzed and that corrective actions are taken and further assessed?

- Is there evidence of training of staff in infection control practices pertinent to their roles?

C-0279

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§485.635(a)(3) [The policies include the following:]

> **(vii) Procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §483.25(i) of this chapter is met with respect to inpatients receiving post hospital SNF care.**

Interpretive Guidelines §485.635(a)(3)(vii)

The dietary services must be organized, directed and staffed in such a manner to ensure that the nutritional needs of inpatients are met in accordance with practitioners' orders and recognized dietary practices. The CAH must designate a qualified individual who is responsible for dietary services. The designated individual must be qualified based on education, experience, specialized training, and, if required by State law, licensed, certified, or registered by the State.

If the CAH provides swing-bed services, then it must also comply with the following requirement for resident nutrition:

> 483.25(i): Nutrition. Based on a resident's comprehensive assessment, the facility must ensure that a resident—
>
> (1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and
>
> (2) Receives a therapeutic diet when there is a nutritional problem.

Each CAH inpatient (including residents) must have their nutritional needs met in a manner that is consistent with recognized dietary practices.

For Information Only – Not Required/Not to be Cited

Although not required by the explicit language of the regulation, CMS recommends that the CAH also ensure it meets the nutritional needs of those patients in observation status whose stay is sufficiently long that they must be fed.

According to the U.S. Department of Agriculture's (USDA) Food and Nutrition Center, the nationally recognized source for recommended dietary intakes allowances is the Institute of Medicine Food and Nutrition Board's Dietary Reference Intakes (DRIs), which are designed to provide recommended nutrient intakes for use in a variety of settings. The DRIs are a set of four reference values:

- Recommended Dietary Allowance (RDA) is the average daily dietary intake of a nutrient that is sufficient to meet the requirement of nearly all (97-98%) healthy persons.

- Adequate Intake (AI) for a nutrient is similar to the Estimated Safe and Adequate Daily Dietary Intake (ESADDI) and is only established when an RDA cannot be determined. Therefore a nutrient either has an RDA or an AI. The AI is based on observed intakes of the nutrient by a group of healthy persons.

- Tolerable Upper Intake Level (UL) is the highest daily intake of a nutrient that is likely to pose no risks of toxicity for almost all individuals. As intake above the UL increases, risk increases.

- Estimated Average Requirement (EAR) is the amount of a nutrient that is estimated to meet the requirement of half of all healthy individuals in the population.

USDA provides access to an interactive DRI tool and DRI tables at http://fnic.nal.usda.gov/dietary-guidance/dietary-reference-intakes

Meeting individual patient nutritional needs may include the use of therapeutic diets. Therapeutic diets refer to a diet ordered as part of the patient's treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium), or to provide mechanically altered food when indicated.

Patients must be assessed for their risk for nutritional deficiencies or need for therapeutic diets and/or other nutritional supplementation. The care plan for patients identified as having specialized nutritional needs must address those needs as well as monitoring of their dietary intake and nutritional status. The methods and frequency of monitoring intake and nutritional status to be used must also be identified in the patient's care plan and could include one or more of the following, as well as other methods:

- Patient weight (BMI, unintended weight loss or gain)
- Intake and output
- Lab values

Examples of patients who may require a comprehensive nutritional assessment include:

- Patients whose medical condition, surgical intervention, or physical status

interferes with their ability to ingest, digest or absorb nutrients;

- Patients whose diagnosis or presenting signs/symptoms indicates a risk for malnutrition, (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc.);

- Patients whose medical condition can be adversely affected by their nutritional intake and thus require a special diet (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc.);

- All patients requiring artificial nutrition by any means (e.g., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition).

All inpatients' diets, including therapeutic diets, must be provided in accordance with orders from a practitioner responsible for the care of the patient.

CAHs may choose, when permitted under State law, to designate qualified dietitians or qualified nutrition professionals as practitioners with diet-ordering privileges. In many cases State law determines what criteria an individual must satisfy in order to be a "qualified dietician;" State law may define the term to mean a "registered dietician" registered with a private organization, the Commission on Dietetic Registration, or State law may impose different or additional requirements. Terms such as "nutritionists," "nutrition professionals," "certified clinical nutritionists," and "certified nutrition specialists" are also used to refer to individuals who are not dieticians, but who may also be qualified under State law to order patient diets. It is the responsibility of the hospital to ensure that individuals are qualified under State law before appointing them to the medical staff or granting them privileges to order diets.

A CAH may provide dietary services under arrangement with a food vendor, but the CAH retains responsibility for ensuring that all dietary services meet the regulatory requirements.

Survey Procedures §485.635(a)(3)(vii)

- Verify that the individual responsible for dietary services is qualified based on education, experience, specialized training, and, if required by State law, is licensed, certified, or registered by the State.

- Ask the responsible individual to demonstrate how the CAH uses DRIs in its menus to meet the nutritional needs of patients.

- From the sample of inpatient and swing-bed patient records, identify if patients were assessed using a screening mechanism for the risk of malnutrition and nutritional complications.

- Among patients who were assessed as having special nutritional needs, were dietary orders reflecting the assessment written and implemented?

- Is/was their dietary intake and nutritional status being monitored, as appropriate? If the CAH has swing bed patients, verify that it has documentation of maintaining acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible;

- Verify that all inpatient diets are prescribed by a practitioner(s) responsible for the care of the patient. If the State and the CAH permit dieticians or other nutrition professionals to order diets, has the CAH verified that they meet any requirements for licensure or certification under State law?

C-0280

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-0281

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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. [2] 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.[3]

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[4]. 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

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[2] *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*

[3] *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*

[4] *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*

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 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-0282

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-0283

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-0284

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-0285

(Rev. 78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§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-0287

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-0288

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-0289

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-0291

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-0292

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-0294

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-0296

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

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-0297

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

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[5]:

  - Snoring or history of sleep apnea
  - No recent opioid use or first-time use of IV opioids
  - Increased opioid dose requirement or opioid habituation

[5] *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*

- 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 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[6]. See the blue box below for information on sedation assessment methods.

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	X	X	X	X	X	X

[6] *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 Drug/Syringe Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours						
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., adverse change in sedation score) Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
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[7]. 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.

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[7] *The 2011 National Blood Collection and Utilization Survey Report. Retrieved September 27,2013 from http://www.hhs.gov/ash/bloodsafety/2011-nbcus.pdf*

Survey Procedures §485.635(d)(3)

- 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-0298

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

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-0299

(Rev. 138, Issued: 04-07-15, Effective: 04-07-15, Implementation: 04-07-15)

§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-1000

(Rev. 75, Issued: 12-02-11, Effective: 12-02-11, Implementation: 12-02-11)

§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-1001

(Rev. 75, Issued: 12-02-11, Effective: 12-02-11, Implementation: 12-02-11)

§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-1002

(Rev. 75, Issued: 12-02-11, Effective: 12-02-11, Implementation: 12-02-11)

§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-0300

§485.638 Condition of Participation: Clinical Records

C-0301

§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-0302

§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-0303

§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-0304

§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-0305

§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-0306

§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-0307

§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 identify 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-0308

§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-0309

§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-0310

§485.638(b)(3) The patient's written consent is required for release of information not required by law.

C-0311

§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-0320

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§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-0321

§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-0322

§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-0323

§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-0324

§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-0325

§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-0326

§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.

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-0344

§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-0345

§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-0346

§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-0347

§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-0348

§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-0349

§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-0350

§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 care services, appropriate progress notes, discharge summary, and subsequent admission orders to swing-bed status regardless of whether the patient stays in the same facility or transfers to another facility. If the patient does not change facilities, the same chart can be utilized but the swing-bed section of the chart must be separate with appropriate admission orders, progress notes, and supporting documents.

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.

Medicare reimbursement requires a 3-day qualifying stay in any CAH or CAH prior to admission to a swing-bed. The swing-bed stay must fall within the same spell of illness as the qualifying stay. This requirement does not apply to patients who are not receiving Medicare reimbursement.

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.

C-0351

§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, and the number of beds used at any time for acute care inpatient services does not exceed 15 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.

C-0352

§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-0355

§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-0360

§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:

(1) Resident rights (§483.10(b)(3) through (b)(6), (d), (e), (h), (i), (j)(1)(vii) and (viii), (1), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§483.12(a) of this chapter).

(3) Resident behavior and facility practices (§483.13 of this chapter).

(4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (k), and (l) 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).

(7) Specialized rehabilitative services (§483.45 of this chapter).

(8) Dental services (§483.55 of this chapter).

(9) Nutrition (§483.25(i) of this chapter).

C-0361

§483.10 Resident Rights

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:

§483.10(a) Exercise of Rights

(1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.

(3) 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 are exercised by the person appointed under State law to act on the resident's behalf.

(4) In the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by State law.

§483.10(b) Notice of Rights and Services

(1) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. The facility must also provide the resident with the notice (if any) of the State developed under section 1919(e)(6) of the Act. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, must be acknowledged in writing;

(2) The resident or his or her legal representative has the right--

> **(i) Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and**
>
> **(ii) After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and 2 working days advance notice to the facility.**

(3) The resident has 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;

Interpretive Guidelines §483.10(b)

The intent of this requirement is to assure that each resident knows his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, during the resident's stay, and when the facility's rules changes. A facility must promote the exercise of rights for all residents, including those who face barriers

such as communication problems, hearing problems and cognition limits. These rights include the resident's right to:

- Be informed about what rights and responsibilities the resident has (§483.10(b)(3 through 6));
- Choose a MD/DO (§483.10(d));
- Participate in decisions about treatment and care planning (§483.10(d));
- Have privacy and confidentiality (§483.10(e));
- Work or not work (§483.10(h));
- Have privacy in sending and receiving mail (§483.10(i));
- Visit and be visited by others from outside the facility (§483.10(j)(1)(vii and viii));
- Retain and use personal possessions (§483.10(l));
- Share a room with a spouse (§483.10(m)).

"**Total health status**" includes functional status, medical care, nursing care, nutritional status, rehabilitation and restorative potential, activities potential, cognitive status, oral health status, psychosocial status, and sensory and physical impairments. Information on health status must be presented in language that the resident can understand.

Communicating with the resident in language that the resident can understand includes minimizing the use of technical words, providing interpreters for non-English speaking residents, using sign language when needed, or other interventions, as appropriate.

Survey Procedures §483.10(b)

- Look for on-going efforts on the part of facility staff to keep residents informed.
- Look for evidence that information is communicated in a manner that is understandable to residents.
- Is information available when it is most useful to the residents such as when they are expressing concerns, raising questions, and on an on-going basis?
- Is there evidence in the medical record that the patient was informed of his rights, including the right to accept or refuse medical or surgical treatment?

C-0362

§483.10(b)(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph 8 of this section; and

Interpretive Guidelines §483.10(b)(4)

"**Treatment**" is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms.

"**Experimental research**" is defined as development and testing of clinical treatments, such as an investigational drug or therapy that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research.

"**Advance directive**" means a written instruction, such as living will or durable power of attorney for health care, recognized under state law, relating to the provisions of health care when the individual is incapacitated.

A resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes.

The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining resident permission.

Survey Procedures §483.10(b)(4)

If the facility participates in any experimental research involving residents, does it have an Institutional Review Board or other committee that reviews and approves research protocols? The requirement at §483.75(c) Relationship to Other HHC Regulations may apply, see 45 CFR Part 46, Protection of Human Subjects of Research). "Although these regulations at §483.75(c) are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds."

C-0363

§483.10(b)(5) The facility must--

> **(i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, 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 resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.

(6) 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 or by the facility's per diem rate.

Interpretive Guidelines: §483.10(b)(5-6)

If Medicare or Medicaid does not make payment for services, the provider must fully inform the resident of any related charges both at the time of admission and prior to the time that changes will occur in their bills.

Listed below are general categories and examples of items and services that the facility may charge to resident funds, if they are requested and agreed to by a resident.

- Telephone;
- Television/radio for personal use;
- Personal comfort items including smoking materials, notions, novelties, and confection;
- Cosmetic and grooming items and services in excess of those for which payment is made;
- Personal clothing;
- Personal reading matter;
- Gifts purchased on behalf of a resident;
- Flowers and plants;
- Social events and entertainment offered outside the scope of the activities program;
- Non-covered special care services such as privately hired nurses or aides;

- Private room, except when therapeutically required, for example, isolation for infection control;

- Specially prepared or alternative food requested;

NOTE: 42 CFR §483.10(b)(8), containing advance directive requirements, guidelines, procedures and probes, is contained below.

§483.10(b)(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, facility may give advance directive information 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. The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

"Advance directive" means a written instruction, such as a living will or durable power of attorney for health care recognized under State law, relating to the provision of health care when the individual is incapacitated.

Interpretive Guidelines §483.10(b)(8)

This provision applies to residents admitted on or after December 1, 1991. The regulation at 42 CFR §489.102 specifies that at the time of admission of an adult resident, the facility must:

- Maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care;

- Provide written information concerning his or her rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives;

- Document in the resident's medical record whether or not the individual 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;

- Ensure compliance with requirements of State law regarding advance directives;

- Provide for educating staff regarding the facility's policies and procedures on advance directives; and

- Provide for community education regarding issues concerning advance directives.

The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is also not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive, and state law allows the provider to conscientiously object.

The sum total of the community education efforts must include a summary of the state law, the rights of residents to formulate advance directives, and the facility's implementation policies regarding advance directives. Video and audiotapes may be used in conducting the community education effort. Individual education programs do not have to address all the requirements if it would be inappropriate for a particular audience.

Survey Procedures §483.10(b)(8)

Review the records of sampled residents admitted on or after December 1, 1991, for facility compliance with advance directive notice requirements.

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

- Determine to what extent the facility provides education for the community regarding individual rights under State law to formulate advance directives.

C-0364

§483.10(d) Free Choice

The resident has the right to--

(1) Choose a personal attending MD/DO;

Interpretive Guidelines §483.10(d)(1)

The right to choose a personal MD/DO does not mean that the MD/DO must serve the resident. If the MD/DO of the resident's choosing fails to fulfill a given requirement, such as frequency of MD/DO visits, the facility will have the right, after informing the resident, to seek alternate MD/DO participation to assure provision of appropriate and adequate care and treatment. A facility may not place barriers in the way of residents choosing their own MD/DO. If a resident does not have a MD/DO, or if the resident's MD/DO becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his/her choice in finding another MD/DO. A resident can choose his/her own MD/DO, but cannot have a MD/DO who does not have swing-bed admitting privileges.

The requirement for free choice is met if a resident is allowed to choose a personal MD/DO from among those who have practice privileges.

C-0365

§483.10(d)(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being; and

Interpretive Guidelines §483.10(d)(2)

"Informed in advance" means that the resident receives information necessary to make a health care decision. The information should include his/her medical condition, changes in his/her medical condition, the benefits and reasonable risks of the recommended treatment, and reasonable alternatives. If there are any financial costs to the resident in the treatment options, they should be disclosed in advance and in writing to the resident prior to his/her decision.

C-0366

§483.10(d)(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.

Interpretive Guidelines §483.10(d)(3)

"Participates in planning care and treatment" means that the resident is afforded the opportunity to select from alternative treatments, to the level of his ability to understand. This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment. The resident has the right to participate in care planning and to refuse treatment.

Survey Procedures §483.10(d)(3)

- Look for evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes.

- If there appears to be a conflict between a resident's right and the resident's health or safety, determine if the facility attempted to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident may participate.

- If a resident whose ability to make decisions about care and treatment is impaired, was he kept informed and consulted on personal preferences to the level of his ability to understand?

C-0367

§483.10(e) Privacy and Confidentiality

The resident has the right to personal privacy and confidentiality of his or her personal and clinical 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) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;

(3) The resident's right to refuse release of personal and clinical records does not apply when--

(i) The resident is transferred to another health care institution; or

(ii) Record release is required by law.

Interpretive Guidelines §483.10(e)

"**Right to personal privacy**" means that the resident has the right to privacy with whomever the resident wishes to be private and that this privacy should include both visual and auditory privacy. Private space may be created flexibly and need not be dedicated solely for visitation purposes.

For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents.

Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services.

Survey Procedures §483.10(e)

Document any instances where you observe a resident's privacy being violated. Completely document how the resident's privacy was violated.

Documentation Example: Resident #12 left without gown or bed covers and unattended on 2B Corridor at 3:30 p.m. February 25, 2001. Identify the responsible party, if possible.

C-0368

(Rev. 110, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

§483.10(h) Work

The resident has the right to--

(1) Refuse to perform services for the facility;

(2) Perform services for the facility, if he or she chooses, when--

(i) The facility has documented the need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care.

Interpretive Guidelines §483.10(h)

All resident work, whether of a voluntary or paid nature, must be part of the plan of care. A resident's desire for work is subject to medical appropriateness. As part of the plan of care, the resident must agree to a therapeutic work assignment. The resident also has the right to refuse such treatment at any time that he or she wishes. At the time of

development or review of the plan, voluntary or paid work can be negotiated.

The "**prevailing rate**" is the wage paid to workers in the community surrounding the facility for the same type, quality, and quantity of work requiring comparable skills.

Survey Procedures §483.10(h)

- Are residents engaged in work (e.g., doing housekeeping, doing laundry, preparing meals)?
- Pay special attention to the possible work activities of residents with intellectual disabilities or mental illness.
- If a resident is performing work, determine whether it is voluntary, and whether it is described in the plan of care. Is the work mutually agreed upon between the resident and the treatment team?

C-0369

§483.10(i) Mail

The resident has the right to privacy in written communications, including the right to--

(1) Send and promptly receive mail that is unopened; and

(2) Have access to stationery, postage, and writing implements at the resident's own expense.

Interpretive Guidelines §483.10(i)

"**Promptly**" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours of regularly scheduled postal delivery and pickup service.

C-0370

§483.10(j) Access and Visitation Rights

(1) The resident has the right and the facility must provide immediate access to any resident by the following:

> **(vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and**

(viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

Interpretive Guidelines §483.10(j)(1)(vii)-(viii)

The facility may set reasonable hours for visitation.

If it would violate the rights of a roommate to have visitors in the resident's room, the facility must establish alternate areas in the facility for visiting. These areas could include the chapel, a suitable office area, a dining room, or a porch or patio area.

C-0371

§483.10(l) Personal Property

The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

Interpretive Guidelines §483.10(l)

The intent of this regulation is to encourage residents to bring personal possessions into the facility, as space, safety considerations and fire code permits. All residents' possessions must be treated with respect and safeguarded.

The facility has the right to limit personal property due to space limitations in the facility or for safety considerations.

Survey Procedures §483.10(l)

If residents' rooms have few personal possessions, ask residents and families if--

- They are encouraged to have and to use personal items;
- Their personal property is safe in the facility.

C-0372

§483.10(m) Married Couples

The resident has 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.

Interpretive Guidelines §483.10(m)

The requirement means that when a room is available for a married couple to share, the facility must permit them to share it if they choose.

C-0373

§483.12 Admission, Transfer and Discharge Rights

§483.12(a) Transfer and Discharge

(1) Definition: 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.

Interpretive Guidelines §483.12(a)(1)

The intent of the regulation on transfer and discharge provisions is to significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility to prevent dumping of high care or difficult residents. This requirement applies to transfer or discharges that are initiated by the facility, not by the resident.

C-0374

§483.12(a)(2) Transfer and discharge requirements. The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless--

(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(ii) 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;

(iii) The safety of individuals in the facility is endangered;

(iv) The health of individuals in the facility would otherwise be endangered;

(v) 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. 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

(vi) The facility ceases to operate.

Interpretive Guidelines §483.12(a)(2)

If transfer is due to a significant change in the resident's condition, the facility must conduct the appropriate assessment, prior to any transfer or discharge to determine if a new care plan would allow the facility to meet the resident's needs.

If the significant change in the resident's condition is an emergency, immediate transfer should be arranged.

Survey Procedures §483.12(a)(2)

During closed record review, determine the reasons for transfer/discharge.

- Do records document accurate assessments and attempts through care planning to address the resident's needs through multidisciplinary interventions, accommodation of individual needs, and attention to the resident's customary routine?

- Did the resident's MD/DO document the record if the resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization) or the resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility?

- Did a MD/DO document the record if residents were transferred because the health of individuals in the facility is endangered?

- Do the records of residents who are transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary?

- If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident's MD/DO justify why the facility could not meet the needs of this resident.

C-0376

§483.12(a)(3) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by--

(i) The resident's MD/DO when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and

(ii) A MD/DO when transfer or discharge is necessary under paragraph

(a)(2)(iv) of this section.

Interpretive Guidelines §483.12(a)(3)

A physician extender may complete documentation of the transfer/discharge unless prohibited by State law or facility policy.

C-0377

§483.12(a)(4) Notice before transfer. Before a facility transfers or discharges a resident, the facility must--

(i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

(ii) Record the reasons in the resident's clinical record; and

(iii) Include in the notice the items described in paragraph (a)(6) of this section.

C-0378

§483.12(a)(5) Timing of the notice.

(i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice may be made as soon as practicable before transfer or discharge when--

(A) The safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or

(E) A resident has not resided in the facility for 30 days.

C-0379

§483.12(a)(6) Contents of the notice. The written notice specified in paragraph (a)(4) 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 that the resident has the right to appeal the action to the State;

(v) The name, address and telephone number of the State long term care ombudsman;

(vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and

(vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

C-0380

§483.12(a)(7) Orientation for transfer or discharge. A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

Interpretive Guidelines §483.12(a)(7)

"**Sufficient preparation**" means the facility informs the resident where he or she is going and assures safe transportation. The facility should actively involve the resident and the resident's family in selecting the new residence. Some examples of orientation may include trial visits by the resident to a new location; working with family; and orienting staff in the receiving facility to the resident's daily patterns.

Survey Procedures §483.12(a)(7)

During resident reviews, check social service notes to see if appropriate referrals have been made and, if necessary, if resident counseling has occurred.

C-0381

§483.13 Resident Behavior and Facility Practices

§483.13(a) Restraints

The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

Interpretive Guidelines §483.13(a)

The intent of this requirement is for each person to reach his/her highest practicable well being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

"**Physical restraints**" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily and that restricts freedom of movement or normal access to one's body.

"**Chemical Restraint**" is defined as a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms.

"**Discipline**" is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

"**Convenience**" is defined as any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident's best interest.

Medical symptoms that would warrant the use of restraints should be reflected in the comprehensive assessment and care planning. The facility must engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities).

Survey Procedures §483.13(a)

- Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints.

- Determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated.

- Did the team institute measures in the care plan to address reversal of any decline in health status?

- Determine the intended use of any restraints. Was the use for convenience or discipline?

C-0382

§483.13(b) Abuse

The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

Interpretive Guidelines §483.13(b)

The intent of this regulation is to assure that each resident is free from abuse, corporal punishment, and involuntary seclusion. The facility is responsible for preventing abuse, but also for those practices and omissions, neglect and misappropriation of property, which if left unchecked, lead to abuse.

Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals.

"**Abuse**" is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish.

"**Verbal abuse**" is defined as any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; and saying things to frighten a resident, such as telling a resident that she will never be able to see her family again.

"**Sexual abuse**" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.

"**Physical abuse**" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment and restraints.

"**Mental abuse**" includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation.

"**Involuntary seclusion**" is defined as separation of a resident from other residents or from his or her room or confinement to his or her room (with or without roommates)

against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.

Survey Procedures §483.13(b)

- Offsite, pre-survey review of complaints can focus the survey team's on-site review of actual incidents and predisposing factors to abuse or neglect and misappropriation of property.

- Report and record **any** instances where the survey team **observes** an abusive incident. Completely document who committed the abusive act, the nature of the abuse, and where and when it occurred. Ensure that the facility addresses that incident immediately.

- If the survey team's observations and resident's responses signal the presence of abuse, determine how the facility prevents and reports abusive behavior.

- If a resident is being temporarily separated from other residents, for less than 24 hours, as an emergency short-term intervention, answer these questions:

    - What are the symptoms that led to the consideration of the separation?

    - Are these symptoms caused by failure to:

        - Meet individual needs;

        - Provide meaningful activities;

        - Manipulate the resident's environment?

    - Can the cause(s) be removed?

    - If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation?

    - Does the facility use the separation for the least amount of time?

    - To what extent has the resident, surrogate or representative participated in care planning and made an informed choice about separation?

    - Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives?

- If residents are temporarily separated in secured units, staff should carry keys to these units at all times.

- If the purpose of the unit is to provide specialized care for residents who are cognitively impaired (through a program of therapeutic activities designed to enable residents to attain and maintain the highest practicable physical, mental or psychosocial well-being) then placement in the unit is not in violation of resident rights, as long as the resident's individual care plan indicates the need for the stated purpose and services provided in the unit and the resident, surrogate, or representative has participated in the placement decision.

C-0383

§483.13(c) Staff Treatment of Residents

The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

(1) The facility must--

(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

Interpretive Guidelines §483.13(c)

The intent of this regulation is to assure that the facility has in place an effective system that prevents mistreatment, neglect and abuse of residents, and misappropriation of resident's property.

"**Misappropriation of resident's property**" is defined as the patterned or deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

C-0384

§483.13(c)(1)(ii) Not employ individuals who have been--

(A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or
(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and

(iii) Report 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 to the State nurse aide registry or licensing authorities.

(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

(3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

Interpretive Guidelines §483.13(c)(1-4)

The intent of this regulation is to prevent employment of individuals who have been convicted of abusing, neglecting, or mistreating individuals in a health care related setting.

In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility should check all staff references and make reasonable efforts to uncover information about any past criminal prosecutions.

"Found guilty...by a court of law" applies to situations where the defendant pleads guilty, is found guilty, or pleads nolo contendere.

"**Finding**" is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents or misappropriation of their property.

Any facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law must have his or her name entered into the nurse aide registry, or reported to the licensing authority, as appropriate.

Survey Procedures §483.13(c)(1-4)

During Sample Selection--

- If the team has identified a problem in mistreatment, neglect or abuse of residents or misappropriation of their property, then request--
    - A copy of the facility's policies and procedures regarding abuse

prevention: Note particularly the extent to which those policies concern the areas uncovered through complaints and/or previous survey;

  - Reports of action(s) by a court of law against employees;
  - Reports of alleged violations involving mistreatment, neglect, abuse, injuries of unknown source, and misappropriation of resident's property;
  - Reports of the results of these investigations; and
  - Records of corrective actions taken.

- Spot check employment applications for questions about convictions or mistreatment, neglect or abuse of residents, or misappropriation of their property. Determine if applicants have answered these questions and if affirmative answers had resulted in rejections of employment candidates.

- Contact the State Nurse Aide Registry or Board of Nursing, as appropriate. Determine if applicants with a finding concerning mistreatment, neglect, and abuse of residents or misappropriation of their property have been rejected.

- Ask for the results of any in-house investigations of mistreatment, neglect, or abuse of residents, misappropriation of their property, or injuries of unknown sources.

  - Was the administrator notified of the incident and when?
  - Did investigations begin promptly after the report of the problem?
  - Is there a record of statements or interviews of the resident, suspect (if one is identified), any eyewitnesses and any circumstantial witnesses?
  - Was relevant documentation reviewed and preserved (e.g., dated dressing which was not changed when treatment recorded change)?
  - Was the alleged victim examined promptly (if injury was suspected) and the finding documented in the report?
  - What steps were taken to protect the alleged victim from further abuse (particularly where no suspect has been identified)?
  - What actions were taken as a result of the investigation?
  - What corrective action was taken, including informing the nurse aide registry, State licensure authorities, and other agencies (e.g., long-term care ombudsman; adult protective services; Medicaid fraud and abuse unit)?

C-0385

§483.15(f) Activities

(1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(2) The activities program must be directed by a qualified professional who--

(i) Is a qualified therapeutic recreation specialist or an activities professional who--

(A) Is licensed or registered, if applicable, by the State in which practicing; and

(B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or

(iii) Is a qualified occupational therapist or occupational therapy assistant; or

(iv) Has completed a training course approved by the State.

Interpretive Guidelines §483.15(f)

A "**recognized accrediting body**" refers to those organizations or associations recognized as such by certified therapeutic recreation specialists or certified activity professionals or registered occupational therapists.

The activities program should be multi-faceted and reflect individual resident's needs on their care plan. Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers, and visitors.

In a Critical Access Hospital, the services at §483.15(f) may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

Survey Procedures §483.15(f)

- Observe individual, group and bedside activities.
    - Are residents who are confined or choose to remain in their rooms provided with suitable in-room activities (e.g., music, reading, visits with individuals who share their interests)? Do any facility staff members assist the resident with activities?
    - If residents sit for long periods of time with no apparently meaningful activities, is the cause:
        - The resident's choice;
        - Failure of any staff or volunteers either to inform residents when activities are occurring or to encourage resident involvement in activities;
        - Lack of assistance with ambulation;
    - Lack of sufficient supplies and/or staff to facilitate attendance and participation in the activity programs; or
    - Program design that fails to reflect the interests or ability levels of residents, such as activities that are too complex?
    - For residents selected for review, determine to what extent the activities resident's assessment.
    - Review the activity calendar for the month prior to the survey to determine if the formal activity program:
        - Reflects the schedules, choices and rights of the residents;
        - Offers activities at hours convenient to the residents (e.g., morning, afternoon, some evenings and weekends);
        - Reflects the cultural and religious interests of the resident population; and
        - Would appeal to both men and women and all age groups living in the facility.
    - Review clinical records and activity attendance records of residents to determine if:
        - Activities reflect individual resident history indicated by the comprehensive assessment;

- Care plans address activities that are appropriate for each resident based on the comprehensive assessment;
- Activities occur as planned; and
- Outcomes/responses to activities interventions are identified in the progress notes of each resident.

o If there are problems with provision of activities, determine if qualified staff provide these service.

C-0386

§483.15(g) Social Services

(1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(2) A facility with more than 120 beds must employ a qualified social worker on a full-time basis.

(3) Qualifications of social worker. A qualified social worker is an individual with--

(i) A bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and

(ii) One year of supervised social work experience in a health care setting working directly with individuals.

Interpretive Guidelines §483.15(g)

The intent of this regulation is to assure that all facilities provide for the medically-related social services needs of each resident. This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services. A qualified social worker need not personally provide all of these services. It is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate discipline.

"**Medically-related social services**" means services provided by the facility's staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services could include:

- Making arrangements for obtaining needed adaptive equipment, clothing, and personal items;

- Maintaining contact with family (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning;

- Assisting staff to inform residents and those they designate about the resident's health status and health care choices;

- Making referrals and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation);

- Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements);

- Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities);

- Providing or arranging provision of needed counseling services;

- Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions;

- Finding options that meet the physical and emotional needs of each resident;

- Meeting the needs of residents who are grieving; and

- Assisting residents with dental/denture care, podiatric care; eye care; hearing services, and obtaining equipment for mobility or assistive eating devices.

Where the Medicaid State Plan does not cover needed services, facilities are still required to attempt to obtain these services.

Survey Procedures §483.15(g)

For residents selected for review:

- How do facility staff implement social services interventions to assist the resident in meeting treatment goals?

- How do staff that are responsible for social work monitor the resident's progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly?

- How does the care plan link goals to psychosocial functioning/well being?
- Has the staff responsible for social work established and maintained relationships with the resident's family or legal representative?
- What attempts does the facility make to access services for Medicaid recipients when a Medicaid State Plan does not cover those services?
- Look for evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality.

C-0388

§483.20 Resident Assessment

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

(b) Comprehensive assessment.

(1) Resident assessment instrument. A facility must make a comprehensive assessment of a resident's needs. 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 potential.

(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.

(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 non-licensed direct care staff members on all shifts.

Interpretive Guidelines §483.20(b)(1)

The intent of this regulation is to provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status. The facility is expected to use resident observation and communication as the primary source of information when completing the assessment. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's MD/DO, family members, or outside consultants and review of the resident's record.

C-0389

§483.20(b)(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.)

Interpretive Guidelines §483.20(b)(2)

The intent of this regulation is to assess residents in a timely manner.

"**Admission**" to the facility is defined as an initial stay or a return stay (not a readmission) in the facility. A "return stay" applies to those residents who are discharged without expectation that they will return to the facility, but who do return to the facility.

A "**readmission**" is an expected return to the facility following a temporary absence for hospitalization, off-site visit or therapeutic leave.

Items in (b)(2) of this section would include comprehensive assessments of a resident which were done within 14 days of admission; within 14 days of a significant change in the resident's physical or mental condition; or done on an annual review. These assessments need to be in the final discharge summary.

C-0390

§483.20(b)(2)(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 inter-disciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

Interpretive Guidelines §483.20(b)(2)(ii)-(iii)

A "**significant change**" may include, but is not limited to, any of the following, or may be determined by a MD/DO's decision if uncertainty exists.

- Deterioration in two of more activities of daily living (ADLs), or any combination of deterioration in two or more areas of ADLs, communication, or cognitive abilities that appear permanent. For example, pronounced deterioration in function and communication following a stroke.

- Loss of ability to ambulate freely or to use hands to grasp small objects to feed or groom oneself, such as spoon, toothbrush, or comb. Temporary loss of ability, such as during an acute illness, is not included.

- Deterioration in behavior or mood, to the point where daily problems arise or relationships have become problematic and staff conclude that these changes in the resident's psychosocial status are not likely to improve without staff intervention.

- Deterioration in a resident's health status, where this change places the resident's life in danger (e.g., stroke, heart disease, metastatic cancer); where the change is associated with a serious clinical complication (e.g., initial development of a stage III pressure sore, prolonged delirious state, or recurrent decline in level of consciousness); or change that is associated with an initial diagnosis of a condition that is likely to affect the resident's physical, mental, or psychosocial well-being over a prolonged period of time (e.g., Alzheimer's disease or diabetes); or the onset of significant, unplanned weight loss (5% in the last 30 days, 10% in the last 180 days).

C-0395

§483.20(k) Comprehensive Care Plans

(1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment. The 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 §483.25; and

(ii) Any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).

Interpretive Guidelines §483.20(k)(1)

An interdisciplinary team, in conjunction with the resident, resident's family, surrogate, or representative, as appropriate, should develop quantifiable objectives for the highest level of functioning the resident may be expected to attain, based on the comprehensive assessment. The care plan must reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to follow resident progress. Facilities may, for some residents, need to prioritize needed care. This should be noted in the clinical record or on the plan of care.

The requirements reflect the facility's responsibility to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well being, in accordance with the comprehensive assessment and plan of care.

However, in some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record.

Survey Procedures §483.20(k)(1)

- Does the care plan address the needs, strengths and preferences identified in the comprehensive assessment?
- Is the care plan oriented toward preventing avoidable declines in functioning or functional levels?
- How does the care plan attempt to manage risk factors?
- Does the care plan build on resident strengths?
- Do treatment objectives have measurable outcomes?
- Does the care plan reflect standards of current professional practice?
- Corroborate information regarding the resident's goals and wishes for treatment in the plan of care by interviewing residents; especially those identified as refusing treatment.
- Determine whether the facility has provided adequate information to the resident so that the resident was able to make an informed choice regarding treatment.
- If the resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem?

C-0396

§483.20(k)(2) A comprehensive care plan must be--

(i) Developed within 7 days after the completion of the comprehensive assessment;

(ii) Prepared by an interdisciplinary team, that includes the attending MD/DO, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

(iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

Interpretive Guidelines §483.20(k)(2)

"**Interdisciplinary**" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident. It does not mean that every goal

must have an interdisciplinary approach. The mechanics of how the interdisciplinary team meets its responsibilities in developing an interdisciplinary care plan (e.g., a face-to-face meeting, teleconference, written communication) are at the discretion of the facility.

The MD/DO must participate as part of the interdisciplinary team, and may arrange with the facility for alternative methods, other than attendance at care planning conferences, of providing his/her input, such as one-to-one discussions and conference calls.

The resident has the right to refuse specific treatments and to select among treatment options before the care plan is instituted. The facility should encourage residents, surrogates, and representatives to participate in care planning, including encouraging attendance at care planning conferences if they so desire.

Survey Procedures §483.20(k)(2)

- Was interdisciplinary expertise utilized to develop a plan to improve the resident's functional abilities?
    - For example, did an occupational therapist design needed adaptive equipment or a speech therapist provide techniques to improve swallowing ability?
    - Do the dietitian and the speech therapist determine, for example, the optimum textures and consistency for the resident's food that provide both a nutritionally adequate diet and effectively use oropharyngeal capabilities of the resident?
    - Is there evidence of MD/DO involvement in development of the care plan (e.g., presence at care planning meetings, conversations with team members concerning the care plan, conference calls)?
- In what ways does staff involve residents and families, surrogate, and/or representatives in care planning?
- Does staff make an effort to schedule care plan meetings at the best time of the day for residents and their families?
- Do facility staff attempt to make the process understandable to the resident/family?
- Is the care plan evaluated and revised as the resident's status changes?
- Ask in your resident interviews, "Have you had concerns or questions about your care and brought them to the attention of facility staff?" If yes, "What happened as a result?"

C-0397

§483.20(k)(3) The services provided or arranged by the facility must--

(i) Meet professional standards of quality; and

Interpretive Guidelines §483.20(k)(3)(i)

The intent of this regulation is to assure that persons providing services are qualified to do so, that the resident's plan of care is implemented, and that those services provided meet professional standards of quality and are provided by appropriate qualified persons (e.g., licensed, certified).

"**Professional standards of quality**" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes might also be found in clinical literature.

Survey Procedures §483.20(k)(3)(i)

Question those practices that have a negative outcome or have a potential negative outcome.

- Do nurses notify MD/DOs, as appropriate, and show evidence of discussions of acute medical problems?
- Are residents with acute conditions promptly hospitalized, as appropriate?
- Are there errors in medication administration?
- Is there evidence of assessment and care planning sufficient to meet the needs of newly admitted residents, prior to completion of the first comprehensive assessment and care plan?
- Are MD/DOs' orders carried out, unless otherwise indicated by an advanced directive?
- Can staff describe the care, services and expected outcomes of the care they provide?

C-0398

§483.20(k)(3)(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

C-0399

§483.20(l) Discharge Summary

When the facility anticipates discharge a resident must have a discharge summary that includes--

(1) A recapitulation of the resident's stay;

(2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and

(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

Interpretive Guidelines §483.20(l)

The intent of this regulation is to ensure appropriate discharge planning and communication of necessary information to the continuing care provider.

"**Post discharge plan of care**" means the discharge planning process that includes assessing continuing care needs and developing a plan designed to ensure that the individual's needs will be met after discharge from the facility into the community.

When the facility "**anticipates discharge**" the discharge is not an emergency discharge (e.g., hospitalization for an acute condition) and is not due to the resident's death.

"**Adjust to his or her living environment**" means that the post discharge plan should describe the resident's and family's preferences for care, how the resident and family will access these services, and how care should be coordinated if continuing treatment involves multiple care givers. It should identify specific resident needs after discharge such as personal care, sterile dressings, and physical therapy, as well as describe resident/care giver education needs to ensure the resident/care giver is able to meet care needs after discharge.

Survey Procedures §483.20(l)

- Does the discharge summary have information pertinent to continuing care for the resident?

- Is there evidence of discharge planning in the records of discharged residents who had an anticipated discharge or those residents to be discharged shortly (e.g., in the next 7-14 days)?

- Do discharge plans address necessary post discharge care?
- Has the facility aided the resident and his/her family in locating and coordinating post discharge services?
- What types of pre-discharge preparation and education has the facility provided the resident and his/her family?

C-0400

§483.25(i) Nutrition

Based on a resident's comprehensive assessment, the facility must ensure that a resident:

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

Interpretive Guidelines §483.25(i)(1)

Parameters of nutritional status that are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels).

Weight: Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of weight loss or gain should consider the loss or gain in light of the individual's former life style as well as the current diagnosis.

C-0401

§483.25(i)(2) Receives a therapeutic diet when there is a nutritional problem.

Interpretive Guidelines §483.25(i)(2)

Suggested parameters for evaluating significance of unplanned and undesired weight loss are:

Interval	Significant Loss	Severe Loss
1 month	5%	Greater than 5%
3 months	7.5%	Greater than 7.5%

6 months	10%	Greater than 10%

The following formula determines percentage of loss:

% of body weight loss = (usual weight - actual weight x 100) divided by usual weight

In evaluating weight loss, consider the resident's usual weight through adult life; the assessment of potential for weight loss; and care plan for weight management. Also, was the resident on a calorie restricted diet, or if newly admitted and obese, and on a normal diet, are fewer calories provided than prior to admission? Was the resident edematous when initially weighed, and with treatment, no longer has edema? Has the resident refused food?

Suggested laboratory values are:

Albumin >60 yr.: 3.4 - 4.8 g/dl (good for examining marginal protein depletion) Plasma Transferrin >60 yr.:180 - 380 g/dl. (Rises with iron deficiency anemia. More persistent indicator of protein status.)

Hemoglobin	Males	14-17 g/dl
	Females:	12-15 g/dl
Hematocrit	Males:	41 - 53
	Females	36 - 46
Potassium	3.5 - 5.0 mEq/L	
Magnesium	1.3 - 2.0 mEq/L	

Some laboratories may have different "normals." Determine range for the specific laboratory. Because some healthy elderly people have abnormal laboratory values, and because abnormal values can be expected in some disease processes, do not expect laboratory values to be within normal ranges for all residents. Consider abnormal values in conjunction with the resident's clinical condition and baseline normal values.

NOTE: There is no requirement that facilities order the tests referenced above.

Clinical Observations: Potential indicators of malnutrition are pale skin, dull eyes, swollen lips, swollen gums, and swollen and/or dry tongue with scarlet or magenta hue, poor skin turgor, cachexia, bilateral edema, and muscle wasting.

Risk factors for malnutrition are--

- Drug therapy that may contribute to nutritional deficiencies such as--
    - Cardiac glycosides;
    - Diuretics;

    - Anti-inflammatory drugs;
    - Antacids (antacid overuse);
    - Laxatives (laxative overuse);
    - Psychotropic drug overuse;
    - Anticonvulsants;
    - Antineoplastic drugs;
    - Phenothiazines;
    - Oral hypoglycemics;
- Poor oral health status or hygiene, eyesight, motor coordination, or taste alterations;
- Depression or dementia;
- Therapeutic or mechanically altered diet;
- Lack of access to culturally acceptable foods;
- Slow eating pace resulting in food becoming unpalatable, or in staff removing the tray before resident has finished eating; and
- Cancer.

Clinical conditions demonstrating that the maintenance of acceptable nutritional status may not be possible include, but are not limited to--

- Refusal to eat and refusal of other methods of nourishment;
- Advanced disease (i.e., cancer, malabsorption syndrome);
- Increased nutritional/caloric needs associated with pressure sores and wound healing (e.g., fractures, burns);
- Radiation or chemotherapy;
- Kidney disease, alcohol/drug abuse, chronic blood loss, hyperthyroidism;
- Gastrointestinal surgery; and

- Prolonged nausea, vomiting, diarrhea not relieved by treatment given according to accepted standards of practice.

"Therapeutic diet" means a diet ordered by a MD/DO as part of treatment for a disease or clinical condition, to eliminate or decrease certain substances in the diet, (e.g., sodium) or to increase certain substances in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet).

Survey Procedures §483.25(i)(2)

Determine if residents selected for a comprehensive review, or focused review as appropriate, have maintained acceptable parameters of nutritional status. Where indicated by the resident's medical status, have clinically appropriate therapeutic diets been prescribed?

For sampled residents whose nutritional status is inadequate, do clinical conditions demonstrate that maintenance of inadequate nutritional status was unavoidable--

- Did the facility identify factors that put the resident at risk for malnutrition?

- What routine preventive measures and care did the resident receive to address unique risk factors for malnutrition (e.g., provision of an adequate diet with supplements or modifications as indicated by nutrient needs)?

- Were staff responsibilities for maintaining nutritional status clear, including monitoring the amount of food the resident is eating at each meal and offering substitutes?

- Was this care provided consistently?

- Were individual goals of the plan of care periodically evaluated and if not met, were alternative approaches considered or attempted?

C-0402

(Rev. 110, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

§483.45 Specialized Rehabilitative Services

§483.45(a) Provision of Services

If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and intellectual disabilities, are required in the resident's comprehensive plan of care, the facility must--

(1) Provide the required services; or

(2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.

Interpretive Guidelines §483.45(a)

The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psychosocial well being.

Specialized rehabilitative services are considered a facility service and are included within the scope of facility services. They must be provided to residents who need them even when the services are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services.

A facility is not obligated to provide **specialized rehabilitative services** if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the service from an outside resource.

For a resident with mental illness (MI) or intellectual disabilities (ID) to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self determination as possible. Specialized services for mental illness or intellectual disabilities refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the nursing facility (NF) because the overall level of NF services is not as intense as necessary to meet the individual's needs.

"Mental health **rehabilitative services** for MI and ID" refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has intellectual disabilities. These services are necessary regardless of whether or not they require additional services to be provided for or arranged by the State as specialized services.

Mental health rehabilitative services for MI and ID may include, but are not limited to—

- Consistent implementation during the resident's daily routine and across settings, of systematic plans that are designed to change inappropriate behaviors;

- Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness;

- Provision of a structured environment for those individuals who are determined to

need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal);

- Development, maintenance and consistent implementation across settings of those programs designed to teach individuals the daily living skills they need to be more independent and self determining including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, mental health education, money management, and maintenance of the living environment;

- Crisis intervention services;

- Individual, group, and family psychotherapy;

- Development of appropriate personal support networks; and

- Formal behavior modification progress.

Survey Procedures §483.45(a)

Determine the extent of follow through with the comprehensive care plan. Verify from the chart that the resident is receiving frequency and type of therapy as outlined in the care plan.

1. Physical Therapy

- What did the facility do to improve the resident's muscle strength? The resident's balance?

- What did the facility do to determine if an assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function?

- If the resident has an assistive device, is he/she encouraged to use it on a regular basis?

- What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)?

- What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk of pressure ulcer occurrence?

2. Occupational Therapy

- What did the facility do to decrease the amount of assistance needed to

perform a task?

- What did the facility do to decrease behavioral symptoms?
- What did the facility do to improve gross and fine motor coordination?
- What did the facility do to improve sensory awareness, visual-spatial awareness, and body integration?
- What did the facility do to improve memory, problem solving, attention span, and the ability to recognize safety hazards?

3. Speech, Language Pathology

- What did the facility do to improve auditory comprehension?
- What did the facility do to improve speech production?
- What did the facility do to improve expressive behavior?
- What did the facility do to improve the functional abilities of residents with moderate to severe hearing loss who have received an audiology evaluation?
- For the resident who cannot speak, did the facility assess for a communication board or an alternate means of communication?

4. Rehabilitative Services For MI And ID

- What did the facility do to decrease incidents of inappropriate behaviors, for individuals with ID, or behavioral symptoms for persons with MI? To increase appropriate behavior?
- What did the facility do to identify and treat the underlying factors behind tendencies toward isolation and withdrawal?
- What did the facility do to develop and maintain necessary daily living skills?
- How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or ID?
- Questions to ask individuals with MI or ID--
    - Who do you talk to when you have a problem or need something?
    - What do you do when you feel happy? Sad? Can’t sleep at night?

- In what activities are you involved, and how often?

C-0403

(Rev. 110, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

§483.45(b) Qualifications

Specialized rehabilitative services must be provided under the written order of a MD/DO by qualified personnel.

Interpretive Guidelines §483.45(b)

A qualified professional provides specialized rehabilitative services for individuals under a MD/DO's order. Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative aides will follow to maintain functional and physical status.

"**Qualified personnel**" means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws. Health rehabilitative services for MI and ID must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only be licensed or credentialed personnel.

Survey Procedures §483.45(b)

- Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff.

- Determine from the care plan and record that qualified personnel provide rehabilitative services under the written order of a MD/DO. If a problem in a resident's rehabilitative care is identified that is related to the qualifications of the care providers, it might be necessary to validate the care provider's qualifications.

- If the facility does not employ professional staff who have experience working directly with or designing training or treatment programs to meet the needs of individuals with MI or ID, how has the facility arranged for the necessary direct or staff training services to be provided?

C-0404

§483.55 Dental Services

The facility must assist residents in obtaining routine and 24-hour emergency dental

care.

Interpretive Guidelines §483.55

This requirement makes the facility directly responsible for the dental care needs of its residents. The facility must ensure that a dentist is available for residents. It can satisfy this requirement by employing a staff dentist or having a contract/arrangement with a dentist to provide services.

For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services. Medicaid residents may not be charged.

For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well being.

C-0405

§483.55(a) Skilled Nursing Facilities

A facility--

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, routine and emergency dental services to meet the needs of each resident;

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

Interpretive Guidelines §483.55(a)(1-2)

"**Routine dental services**" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).

"**Emergency dental services**" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity that requires immediate attention.

"**Prompt referral**" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at

replacing the dentures.

C-0406

§483.55(a)(3) Must if necessary, assist the resident--

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(4) Promptly refer residents with lost or damaged dentures to a dentist.

Survey Procedures §483.55(a)(3-4)

- Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them?
- Are residents missing teeth and may be in need of dentures?
- Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?
- Are resident's dentures intact? Properly fitted?

NOTE: §483.55(b) Nursing Facilities does not usually apply to Medicare reimbursed swing-bed residents because Medicare swing-bed residents receive skilled nursing care comparable to services provided in a SNF not a NF. If a swing-bed resident is a NF level patient, apply standard §483.55(b) as appropriate.

C-0407

§483.55(b) Nursing Facilities

The facility

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident:

(i) Routine dental service (to the extent covered under the State plan); and

(ii) Emergency dental services;

Interpretive Guidelines §483.55(b)(1)

"**Routine dental services**" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning,

fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).

"**Emergency dental services**" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity that requires immediate attention.

"**Prompt referral**" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

C-0408

§483.55(b)(2) Must, if necessary, assist the resident--

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(3) Must promptly refer residents with lost or damaged dentures to a dentist.

Survey Procedures §483.55(b)(2-3)

- Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them?
- Are residents missing teeth and may be in need of dentures?
- Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?
- Are resident's dentures intact? Properly fitted?

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
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