The CMS Hospital Conditions of Participation and Interpretive Guidelines
The CMS Hospital Conditions of Participation and Interpretive Guidelines
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Every hospital should have an up-to-date copy of the Centers for Medicare & Medicaid Services’ (CMS) *Conditions of Participation* (CoP) and *Interpretive Guidelines* (IG) because surveyors use them to guide inspections. Following such guidelines also helps to ensure full reimbursement. This document is also referred to as the *State Operations Manual* (*SOM*).

This book reproduces the CMS hospital CoPs and IGs verbatim. It includes CMS’ survey protocol guidelines, which includes a list of questions surveyors will ask and the policies they will look for during an on-site visit.

This book also reproduces the Emergency Medical Treatment and Active Labor Act (EMTALA) regulations, also reprinted verbatim. Medicare participating hospitals must meet these regulations, which require hospitals (including critical access hospitals) with emergency departments to provide a medical screening examination to any individual who comes to the emergency department and requests such an examination.

Our goal is to make it easier for you to understand the CoP requirements and have a successful survey and receive full reimbursement. We hope you will find this book to be an essential resource to help you comply with CMS regulations.

**Summary of recent changes**

This book contains two major documents—both appendixes of the *SOM* that apply to hospitals.

*Appendix A: Survey Protocol, Regulations, and Interpretive Guidelines for Hospitals*

This portion of the book is a government reprint of the CMS survey protocol and the CoP and IG regulations. This section includes all recent revisions from October 2008 and June 2009, which are summarized and listed below.
Summary of October 2008 changes

Appendix A is being revised to reflect amended regulations and survey and certification policy issuances concerning the Conditions of Participation for Hospitals, 42 CFR Part 482. It also contains new guidance related to the Patients’ Rights Final Rule, 42 CFR 482.13(e), (f), and (g), published in the Federal Register December 8, 2006 (71 FR 71378). In addition, regulatory text that appears in brackets was included in a previous tag, but is repeated for clarity and accuracy in representing the regulatory citation.

—CMS, Transmittal 37, October 17, 2008

These include changes to the following regulations:

§482.11 Condition of Participation: Compliance With Federal, State and Local Laws
§482.11(a)
§482.11(b)
§482.11(c)
§482.12 Condition of Participation: Governing Body
§482.12(a) Standard: Medical Staff
§482.12(b) Standard: Chief Executive Officer
§482.12(c) Standard: Care of Patients
§482.12(d) Standard: Institutional Plan and Budget
§482.12(e) Standard: Contracted Services
§482.12(f) Standard: Emergency Services
§482.13 Condition of Participation: Patient’s Rights
§482.13(e) Restraint or Seclusion
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§482.28 Condition of Participation: Food and Dietetic Services
§482.28(a) Standard: Organization
§482.28(b) Standard: Diets
§482.30 Condition of Participation: Utilization Review
§482.30(a) Standard: Applicability
§482.30(b) Standard: Composition of Utilization Review Committee
§482.30(c) Standard: Scope and Frequency of Review
§482.30(d) Standard: Determination Regarding Admissions or Continued Stays
§482.30(e) Standard: Extended Stay Review
§482.30(f) Standard: Review of Professional Services
§482.41 Condition of Participation: Physical Environment
§482.41(a) Standard: Buildings
§482.41(b) Standard: Life Safety From Fire
§482.41(c) Standard: Facilities
§482.42 Condition of Participation: Infection Control
§482.42(a) Standard: Organization and Policies
§482.42(b) Standard: Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services
§482.43 Condition of Participation: Discharge Planning
§482.43(a) Standard: Identification of Patients in Need of Discharge Planning
§482.43(b) Standard: Discharge Planning Evaluation
§482.43(c) Standard: Discharge Plan
§482.43(d) Standard: Transfer or Referral
§482.43(e) Standard: Reassessment
§482.45 Condition of Participation: Organ, Tissue, and Eye Procurement
§482.45(a) Standard: Organ Procurement Responsibilities
Summary of May 2010 changes

Revisions to Appendix A, “Survey Protocol, Regulations and Interpretive Guidelines for Hospitals.” This instruction updates and clarifies the guidance for the Anesthesia Services Condition of Participation and related standards.

—CMS, Transmittal 59, May 21, 2010

Standards that were recently revised include:

§482.52/Condition of Participation Anesthesia Services/Tag A-1000
§482.52(a)/Standard: Organization and Staffing/Tag A-1001
§482.52(b)/Standard: Delivery of Services/Tag A-1002
§482.52(b)(1)/Standard: Pre-anesthesia Evaluation/Tag A-1003
§482.52(b)(2)/Standard: Intraoperative Anesthesia Record/Tag A 1004
§482.52(b)(3)/Standard: Post-anesthesia Evaluation/Tag A-1005

All sets of revisions are italicized in the text so you can identify changes easily.

Appendix V: Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency

This document includes CMS’ EMTALA Investigative Procedures and Interpretive Guidelines. It includes the most recent revisions, including those made in May 2009, which are italicized in the text for easy use.

Revisions to EMTALA Interpretive Guidelines are about on-call and community plan—you can see in italics where all the changes were made. Some of the topics addressed were patients
being sent home with false labor and minors being brought to the emergency department, preempting state EMTALA laws (i.e., rules regarding parental consent). Every emergency department should be aware of the changes to the guidelines. Staff members should be educated on an ongoing basis on the EMTALA regulations.

Summary of May 2009 changes

Appendix V, Survey Protocol, Regulations and Interpretive Guidelines for the Emergency Medical Treatment and Labor Act (EMTALA) is updated to include information previously released via the Survey and Certification Memoranda issued to State Survey Agency Directors from April 22, 2005, through March 6, 2009.

— CMS, Transmittal 46, May 29, 2005

Standards that were recently revised include:

§489.20(l) Tag A-2400/C-2400
§489.20(m) Tag A-2401/C-2401
§489.20(q) Tag A-2402/C-2402
§489.20(r) Tag A-2403/C-2403
§489.20(r)(2) Tag A-2404/C-2404
§489.20(r)(3) Tag A-2405/C-2405
§489.24(a) Applicability of Provisions of this Section/§489.24(b) & (c)/Tag A-2406/C-2406
§489.24(a)(2) Non-applicability of Provisions of this Section/Tag A-2406/C-2406
§489.24(d)(1)-(3) Necessary Stabilizing Treatment for Emergency Medical Conditions/Tag A-2407/C-2407
§489.24(d)(4) Delay in Examination or Treatment/Tag A-2408/C-2408
§489.24(d)(5) Refusal to Consent to Transfer/Tag A-2408/C-2408
§489.24(e) Restricting Transfer Until the Individual is Stabilized/Tag A-2409/C-2409
§489.24(e)(3) Tag A-2410/C-2410
§489.24(f) Recipient Hospital Responsibilities/Tag A-2411/C-2411
§489.24(j) Availability of On-call Physicians

Revisions are italicized in the text.

How to track updates

CMS provides the following instructions for tracking updates on the CMS Web site under Regulations and Guidance (www.cms.hhs.gov):
The CMS Hospital Conditions of Participation and Interpretive Guidelines

- Each appendix is a separate file that can be accessed directly from the SOM Appendixes Table of Contents, as applicable.

- The appendixes are in PDF format, which is the format generally used in the SOM to display files. Click on the red button in the Download column to download a copy of any available file in PDF format.

- To return to this page after opening a PDF file on your desktop, use your browser’s “back” button, because closing the file usually will also close most browsers.

The following is a list of several CMS Web site pages and instructions on how they are of use:

- For tracking updates, refer to the CMS State Survey and Certification Web site page, located at www.cms.hhs.gov/SurveyCertificationGenInfo. Everyone should go in once a month and check for updates here. Save this page as a favorite and appoint someone in your facility who is responsible for doing the monthly checks. This page contains CMS survey and certification memoranda, guidance, clarifications, and instructions to state survey agencies and CMS regional offices. It is searchable by date and keyword.

- The CMS Transmittals page also provides information on important issues (www.cms.hhs.gov/transmittals). According to the CMS Web site, program transmittals are used to communicate new or changed policies and/or procedures that are being incorporated into a specific CMS program manual. The cover page (or transmittal page) summarizes the new and changed material, specifying what has been changed.

- In general, if you are working in a hospital setting, another good place to check for updates includes the CMS’ Hospital Center page, which can be found at www.cms.hhs.gov/center/hospital.asp. A quick check of recent updates to this page show that most of the announcements this year have been related to payment systems, but other, more accreditation-related changes are also announced here.

- The EMTALA page should also be checked. This page can be found at www.cms.hhs.gov/EMTALA. On this page, you will find changes and updates to regulations, manuals, and appendixes, and links back to transmittals related to EMTALA and EMTALA survey and certification letters. There is also a series of links with related and helpful material.
State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

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(Rev. 47, 06-05-09)

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Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines

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§482.12 Condition of Participation: Governing Body
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§482.24 Condition of Participation: Medical Record Services
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§482.24(b) Standard: Form and Retention of Record

§482.24(c) *Standard: Content of Record*

§482.25 Condition of Participation: Pharmaceutical Services
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Survey Protocol

Introduction

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

Hospitals 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 hospital survey is to determine if the hospital is in compliance with the CoP set forth at 42 CFR Part 482. Also, where appropriate, the hospital must be in compliance with the PPS exclusionary criteria at 42 CFR 412.20 Subpart B and the swing-bed requirements at 42 CFR 482.66.

Certification of hospital compliance with the CoP is accomplished through observations, interviews, and document/record reviews. The survey process focuses on a hospital’s performance of patient-focused and organizational functions and processes. The hospital 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 hospitals are found at 42 CFR Part 482.

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

- Should an individual or entity (hospital) refuse to allow immediate access upon reasonable request to either a State Agency or CMS surveyor, the Office of the Inspector General (OIG) may exclude the hospital from participation in all Federal healthcare 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(a)(13).

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

Surveyors assess the hospital’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. This may include weekends and times outside of normal 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 hospital surveys are unannounced. Do not provide hospitals 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 hospital.
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 Hospital Services

The modules for PPS-exempt units (psychiatric and rehabilitation), psychiatric hospitals, rehabilitation hospitals and swing-bed hospitals are attached to this document. The survey team is expected to use all the modules that apply to the hospital being surveyed. For example, if the hospital has swing-beds, a PPS excluded rehabilitation unit, and a PPS excluded psychiatric unit, the team will use those three modules in addition to this protocol to conduct the survey. If the hospital is a rehabilitation hospital, the team will use the rehabilitation hospital module in addition to this protocol to conduct the survey. If the hospital is a psychiatric hospital and if the survey team will be assessing the hospital’s compliance with both the hospital CoPs and psychiatric hospital special conditions, the team will use the psychiatric hospital module in addition to this protocol to conduct the survey.

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 mid-size hospital would include two-four surveyors who will be at the facility for 3 or more days. Each hospital survey team should include at least one RN with hospital 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.
Training for Hospital Surveyors

Hospital surveyors should have the necessary training and experience to conduct a hospital survey. Attendance at a Basic Hospital Surveyor Training Course is suggested. New surveyors may accompany the team as part of their training prior to completing the Basic Hospital Surveyor Training Course.

Team Coordinator

The survey is conducted under the leadership of a team coordinator. The SA (or the RO for Federal teams) should designate the team coordinator. The team coordinator is responsible for assuring that all survey preparation and survey activities are completed within the specified 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 hospital or tasks for the survey;
- Facilitating time management;
- Encouraging on-going communication among team members;
- Evaluating team progress and coordinating daily team meetings;
- Coordinating any ongoing conferences with hospital leadership (as determined appropriate by the circumstances and SA/RO policy) and providing on-going feedback, as appropriate, to hospital 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, remote locations, satellites, specialty units, PPS-exempt 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), such as the facility’s ownership, the type(s) of services offered, any prospective payment system (PPS) exclusion(s), whether the facility is a provider of swing-bed services, and the number, type and location of any off-site locations;

- 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 hospital’s Web site, any media reports about the hospital, etc).

**Off-Site Survey Preparation Team Meeting**

The team should prepare for the survey offsite 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 so a surveyor can update the Medicare database 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:

• Medicare Hospital CoP and Interpretive Guidelines (Appendix A);
• Survey protocol and modules;
• Immediate Jeopardy (Appendix Q);
• Responsibilities of Medicare Participating Hospitals in Emergency Cases (Appendix V);
• Hospital Swing-Bed Regulations and Interpretive Guidelines (Appendix T);
• Hospital/CAH Medicare Database Worksheet, Exhibit 286;
• Exhibit 287, Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey; and
• Worksheets for swing-bed, PPS exclusions, and restraint/seclusion death reporting.

Task 2 - Entrance Activities

General Objectives

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

General Procedures

Arrival

The entire survey team should enter the hospital 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 onsite 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 hospital 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 hospital administrative staff that is 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, the general area that each will be responsible for, and the various documents that they may request;
- Clarify that all hospital areas and locations, departments, and patient care settings under the hospital provider number may be surveyed, including any contracted patient care activities or patient services located on hospital campuses or hospital provider based locations;
- 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 preliminary date and time for the exit conference.

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

- A location (e.g., conference room) where the team may meet privately during the survey;
- A telephone for team communications, preferably in the team meeting location;
• A list of current inpatients, providing each patient’s name, room number, diagnosis(es), admission date, age, attending physician, and other significant information as it applies to that patient. The team coordinator will explain to the hospital 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 hospital’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 complete the Hospital/CAH Medicare Database Worksheet that will be used to update the provider’s file in the Medicare database. The worksheet may not be given to hospital personnel for completion.

**Hospital Tours**

Guided tours of the hospital are not encouraged and should be avoided. While a tour of a small facility may take place in less than one-man hour, a tour of a large 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. Do not delay the continuation of the survey process waiting for information from the provider, but adjust survey activities as necessary. During the on-site team meeting, team members should:
• Review the scope of hospital services;

• Identify hospital locations to be surveyed, including any off-site locations;

• Add survey protocol modules and 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 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 hospital and select patients who represent a cross-section of the patient population and the services provided. Patient logs (ER, OB, OR, restraint, etc) may be used in conjunction with the patient list to assure the sample is reflective of the scope of services provided by the hospital.

Whenever possible and appropriate, select patients who are in the facility during the time of survey (i.e., open records). Open records allow surveyors to conduct a patient-focused survey and enable surveyors to validate the information obtained through record reviews with observations and patient and staff interviews. There may be situations where closed records are needed to supplement the open records reviewed (e.g., too few open records, complaint investigation, etc), surveyors should use their professional judgment in these situations and select sample that will enable them to make compliance determinations. If it is necessary to remove a patient from the sample during the survey, (e.g., the patient refuses to participate in an interview), replace the patient with another who fits a similar profile. This should be done as soon as possible in the survey.

Select the number of patient records for review based on the facility’s average daily census. The sample should be at least 10 percent of the average daily census, but not fewer than 30 inpatient records. For small general hospitals (this reduction does not apply to surgical or other specialty hospitals) with an average daily census of 20 patients or less, the sample should not be fewer than 20 inpatient records, provided that number of records is adequate to determine compliance. Within the sample, select at least one patient from each nursing unit (e.g., med/surg, ICU, OB, pediatrics, specialty units, etc). In addition to the inpatient sample, select a sample of outpatients in order to determine compliance in outpatient departments, services, and locations. The sample size may be expanded as needed to assess the hospital’s compliance with the CoP.
If a complaint is being investigated during the survey, include patients who have been identified as part of the complaint in the sample. Issues or concerns identified through complaints may be an area of focus when selecting the patient sample.

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 hospital there must be enough inpatients currently in the hospital and patient records (open and closed) for surveyors to determine whether the hospital can demonstrate compliance with all the applicable CoP. 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 hospital satisfies all the standards within each CoP including any CoP applying to optional services offered by the hospital. Utilize the same sample size and selection methods as previously discussed.

**Task 3 - Information Gathering/Investigation**

**General Objective**

The objective of this task is to determine the hospital’s compliance with the Medicare CoP through observations, interviews, and document 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, remote locations, satellites, 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

Survey Locations

For hospitals with either no or a small number of off-campus provider-based locations, survey all departments, services, and locations that bill for services under the hospital’s provider number and are considered part of the hospital.

For hospitals with many provider-based locations survey:

- All hospital departments and services at the primary hospital campus and on the campuses of other remote locations of the hospital;
- All satellite locations of the hospital;
- All inpatient care locations of the hospital;
- All out-patient surgery locations of the hospital;
- All locations where complex out-patient care is provided by the hospital; and
- Select a sample of each type of other services provided at additional provider-based locations.

On any Medicare hospital survey, contracted patient care activities or patient services (such as dietary services, treatment services, diagnostic services, etc.) located on hospital campuses or hospital provider based locations should be surveyed as part of the hospital for compliance with the conditions of participation.

During the Survey

- 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. Expand the survey activities as necessary.

- The SA and surveyors have discretion whether to allow, or to refuse to allow, facility personnel to accompany the surveyors during a survey. 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 hospital 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 hospital 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 hospital 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, as far as care being given, 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 assessment and performance improvement (QAPI) 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 QAPI 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.

Surveyors must not examine patients by themselves, although in certain circumstances, in order to determine a patient’s health status and whether 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 patient rights, 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 hospital 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 hospital 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 possible;

- 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 hospital 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; and

• Contracts, if applicable, to determine if patient care, governing body, QAPI, and other CoP requirements are included.

**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 their 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 “hospital restraint policy- 2/17/04 page 3” or “Patient # 6, progress note- 2/17/04.”

**Completion of Hospital/CAH Medicare Database Worksheet**

Arrange an interview with 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 hospital’s services, locations, and staffing by Medicare surveyors during hospital surveys. The worksheet will be completed by the surveyors using observation, staff interviews, and document review. The worksheet will not be given to hospital staff to complete. The worksheet is used to collect information that will later be entered into the Medicare database. During the interview 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 hospital meets the Conditions of Participation found at 42 CFR Part 482 and, as appropriate, the PPS exclusionary criteria at 42 CFR Part 412 Subpart B, and the swing-bed requirements at 42 CFR 482.66. 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, 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 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 non compliance 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 state, “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 the 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 with requirements in a single standard or several standards within the condition, or with requirements 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.

When a deficient practice (noncompliance) is determined to have taken place prior to the survey and the hospital states that it has corrected the deficient practice/issue (noncompliance), 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 hospital implemented the corrective intervention(s) or action(s)?

• Has the hospital taken a QAPI 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 hospital 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 hospital 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 hospital. Citing noncompliance at a level below the noted degree and manner of the noncompliance does not ensure that the hospital will develop acceptable plans of correction and implement corrective actions, and does not depict accurately whether the care provided adversely affects the health and safety of patients; and 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. Video taping 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 video taping is permitted.

General Principles

The following general principles apply when conducting an exit conference:

- The facility determines which hospital 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 reference 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.
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.

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.

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.
Closure

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

- 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; and

  - 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 Federal 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,” following the “Principles of Documentation”;
- 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);
- Completion of “Hospital Restraint/Seclusion Death Reporting Worksheet,” as appropriate;
- Compilation of documents for the provider file;
- Signed Authority by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey is forwarded to RO; and
- 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.