State Operations Manual
Appendix P - Survey Protocol for Long Term Care Facilities - Part I

(Rev. 106, 04-04-14)

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I. Introduction

(Rev. 106, Issued: 04-04-14, Effective: 04-04-14, Implementation: 04-04-14)

Skilled nursing facilities (SNFs) and nursing facilities (NFs) are required to be in compliance with the requirements at 42 CFR Part 483, Subpart B, to receive payment under the Medicare or Medicaid programs. To certify a SNF or NF, complete at least a:

- Life Safety Code (LSC) survey; and
- Standard Survey. There are two types of Standard Surveys, the Traditional Survey and the Quality Indicator Survey (QIS). CMS deems both as surveys of record to evaluate compliance of nursing homes with the requirements at 42 CFR 483.5-483.75:
    - The Traditional Survey, which uses Forms CMS-670, CMS-671, CMS-672, CMS-677, and CMS-801 through CMS-807 (see Exhibits 85, 86, and 88 thru 95); and
    - The QIS, which uses the QIS procedures and forms as contained in the QIS Surveyor Training Manual. CMS maintains the authority to identify those States that are permitted to use the QIS. Only CMS-approved training entities and training materials may be used by States to train their surveyors in the QIS. The QIS is used by a State Survey Agency only upon approval by CMS.

NOTE: CMS is in the process of a staged implementation of the QIS as a replacement for the current (Traditional) survey process. The QIS is a two-staged, computer-assisted survey process with Stage 1 consisting of both computer analysis of offsite data as well as data collected by surveyors onsite from observations, interviews, and record reviews of large computer-selected resident samples. Stage 2 consists of systematic surveyor investigations of triggered issues and residents using the Guidance to Surveyors as well as a set of investigative tools known as critical elements protocols. In addition to the Stage 1 and Stage 2 sample-based investigations, the QIS also contains several facility-level tasks that are unstaged and are completed either on every survey or when triggered as areas of concern.

reviews of large computer-selected resident samples. The information collected throughout Stage 1 is analyzed by computer to derive a set of approximately 160 Quality of Care Indicators (QCIs) that are

used to compare the facility being surveyed to national norms. QCIs that score beyond a statistical threshold are computer-selected for Stage 2 review, and the relevant residents are also computer selected. Stage 2 consists of systematic surveyor investigations of triggered issues and residents using a set of detailed investigative tools known as critical elements protocols. In addition to the Stage 1 and Stage 2 sample-based investigations, the QIS also contains several facility-level tasks that are unstaged and are completed either on every survey or when triggered as areas of concern.

During this period, as CMS conducts pilot implementation, CMS deems both the QIS and Traditional Survey as surveys-of-record to evaluate compliance of nursing homes with the requirements at 42 CFR 483.5-483.75.

Do not announce SNF/NF surveys to the facility. Conduct standard surveys and complete them on consecutive workdays, whenever possible. They may be conducted at any time including weekends, 24 hours a day. When standard surveys begin at times beyond the business hours of 8:00 a.m. to 6:00 p.m., or begin on a Saturday or Sunday, the entrance conference and initial tour should be modified in recognition of the residents' activity (e.g., sleep, religious services) and types and numbers of staff available upon entry.

Use the standard survey procedure discussed in this section for all standard surveys of SNFs and NFs, whether freestanding, distinct parts, or dually participating. For surveys of facilities predominantly serving short stay residents, modifications of offsite survey preparation and sampling procedures will be necessary.

NOTE: Do not use this process for surveys of intermediate care facilities for *individuals with intellectual disabilities* (ICFs/*IID*), swing-bed hospitals, or skilled nursing sections of hospitals that are not separately certified as SNF distinct parts. Survey Protocols and Interpretive Guidelines for these surveys are found in Appendix J (ICFs/*IID*) and Appendix T (swing-bed hospitals and hospitals with non-distinct part SNFs).

When the survey team suspects substandard quality of care (SQC), expand the standard (or abbreviated) survey sample as necessary to determine scope. If the existence of SQC is verified, then inform the Administrator that the facility has SQC and an extended (or partial extended) survey will be conducted.

Surveys

If a possible noncompliant situation related to any requirement is identified while conducting the information gathering tasks of the survey, investigate the situation to determine whether the facility is in compliance with the requirements.

Standard Survey

The QIS Standard Survey is composed of Tasks 1 – 9 and the Traditional Standard Survey is composed of Tasks 1 – 7. Both versions of the survey process are resident-centered, outcome-oriented inspections that rely on a case-mix stratified sample of residents to gather information about the facility's compliance with participation requirements. Outcomes include both actual and potential negative outcomes, as well as failure of a facility to help residents achieve their highest practicable level of well-being. Based on the specific procedures detailed in this Appendix, a standard survey assesses:

- Compliance with residents' rights and quality of life requirements;
- The accuracy of residents' comprehensive assessments and the adequacy of care plans based on these assessments;
- The quality of care and services furnished, as measured by indicators of medical, nursing, rehabilitative care and drug therapy, dietary and nutrition services, activities and social participation, sanitation and infection control; and
- The effectiveness of the physical environment to empower residents, accommodate resident needs, and maintain resident safety, including whether requested room variances meet health, safety, and quality of life needs for the affected residents.

Extended Survey

The extended survey is conducted after substandard quality of care is determined during a standard survey. If, based on performing the resident-centered tasks of the standard survey it is determined that the facility has provided substandard quality of care in 42 CFR 483.13, Resident Behavior and Facility Practices; 42 CFR 483.15, Quality of Life; and/or 42 CFR 483.25, Quality of Care, conduct an extended survey within 14 days after completion of the standard survey. (See Section II.A.2. for further information about the QIS extended survey and Section III for further information about the Traditional Extended Survey.

Abbreviated Standard Survey

This survey focuses on particular tasks that relate, for example, to complaints received or a change of ownership, management or director of nursing. The abbreviated standard survey does not cover all aspects covered in the standard survey, but rather concentrates on a particular area of concern(s). For example, an abbreviated standard survey may be conducted to substantiate a complaint. The survey team can expand the abbreviated standard survey to cover additional areas, or to a Traditional Standard Survey if, during the Abbreviated Standard Survey, evidence is found that warrants a more extensive

review. (See also Chapter 5 of this manual for additional administrative procedures related to complaints.) At this time, the QIS is not used to conduct an abbreviated standard survey. See §II.A.4. below for investigation of complaints during the QIS standard survey.

Partial Extended Survey

A partial extended survey is always conducted after substandard quality of care is found during an abbreviated standard survey or during a revisit, when substandard quality of care was not previously identified. If, based on performing the abbreviated standard survey or revisit it is determined that the facility has provided substandard quality of care in 42 CFR 483.13, Resident Behavior and Facility Practices; 42 CFR 483.15, Quality of Life; and/or 42 CFR 483.25, Quality of Care, conduct a partial extended survey. (See Section III for further information about the partial extended survey. At this time, the QIS is not used for partial extended surveys.)

Post-Survey Revisit (Follow-Up)

The post-survey revisit is an onsite visit intended to verify correction of deficiencies cited in a prior survey. See §2732 and Appendix P, Part I, Section VI, "Writing the Statement of Deficiencies." (See Section II.A.3. for further information about the QIS revisit and Section VI. for further information about the Traditional revisit.) If substandard quality of care is determined during a revisit, complete a partial extended survey, if a partial extended or extended survey had not been conducted as the result of the prior standard or abbreviated standard survey.

Initial Certification Survey

In a survey for initial certification of SNFs or NFs, perform the tasks of both the Traditional Standard and Extended Surveys. During the initial survey, focus both on residents and the structural requirements that relate to qualification standards and resident rights notification, whether or not problems are identified during the information gathering tasks. Gather additional information to verify compliance with every tag number. For example, during an initial survey, verify the qualifications of the social worker, dietitian, and activities professional. Also, review the rights notification statements on admissions contracts. Complete the "Statement of Deficiencies and Plan of Correction" (Form CMS-2567) in Exhibit 7.

Specialty Surveyors

All members of a survey team need not be onsite for the entire survey. Specialty surveyors participating in surveys (e.g., a pharmacist, physician, or registered dietitian) must be onsite during that portion of the survey dealing with their area of expertise. However, they must conduct that portion while the rest of the team is present. All members of the survey team should enter the facility at the same time, if possible. Before leaving the facility, at the completion of his/her portion of the survey, the specialty

surveyor must meet with the team or team coordinator to discuss his/her findings and to provide supporting documentation. The specialty surveyor should also share any information he/she obtained that may be useful to other team members. If he/she is not present at the information analysis for deficiency determination, the specialty surveyor should be available by telephone at that time and during the exit conference.
Team Communication

Throughout the survey process, the team (including specialty surveyors onsite at the time) should discuss among themselves, on a daily basis, observations made and information obtained in order to focus on the concerns of each team member, to facilitate information gathering and to facilitate decision making at the completion of the standard survey.

II. The Survey Process

II.A. - The Quality Indicators Survey (QIS)

The QIS survey is used as the survey-of-record only for states that have received CMS approval, and only by surveyors who have completed QIS training. Sections II.A.1.-4. below describe the use of the QIS for standard surveys, extended surveys, post-survey revisits, and complaint investigations.

1. The QIS Standard Survey

The QIS standard survey consists of the following Tasks (details are contained in the QIS Surveyor Training Manual, which is incorporated by reference):

Introduction

Task 1: Offsite Survey Preparation:

- Offsite Survey Preparation and Initial Sampling

Task 2: Onsite Preparatory Activities and Entrance Conference

- Prior to the Entrance Conference
- Entrance Conference
- Possible Off Hours Activities

Task 3: Initial Tour

- Tour

Task 4: Stage I Survey Tasks

- Finalize Sample Selection
    - Stage I Sample Selection Procedures
- Stage I Team Meetings (first meeting)
- Stage I Information Gathering
- Stage I Admission Sample Review
    - Medical Record Review
- Stage I Census Sample Review
    - Resident Interviews
    - Resident Unavailable for Interviews
    - Resident Observations
    - Staff Interviews
    - Medical Record Review
    - Family Interviews

Task 5: Non-Staged Survey Tasks

- Resident Council President/Representative Interview
- Dining Observation
- Kitchen/Food Service Observation
- Infection Control Policies and Practices
- Demand Billing Review
- Abuse Prohibition Review
- Quality Assessment and Assurance (QA&A Review)

Task 6: Transition From Stage I to Stage II

- Update the Resident Pool
- Review Completion of Stage I
- Review Surveyor-Initiated Residents and/or Care Areas
- Import All Data into the Primary Laptop
- Review the Relevant Findings Report
- Review the QCI Results Report

Task 7: Stage II Survey Tasks

- Introduction
- Team Meetings
- Stage II Sample Selection
    - Substituting Residents
    - Supplementing the Sample
- Staff Assignments
- Stage II Information Gathering
    - Stage II Critical Element Pathways
    - Medication Administration Observation and Unnecessary Drug Review
- Facility-Level Investigations
    - Environmental Observation
    - Resident Funds
    - Admission, Transfer, and Discharge Review
    - Sufficient Staff

Task 8: Analysis and Decision-Making: Integration of Information

- Integration of Facility-Level Information
- Integration of Critical Element Pathways
- Analysis of Information Gained
- Analysis of Scope and Severity and Team Decision-Making

Task 9: Exit Conference

- Exit Conference

2. The QIS Extended Survey

When the survey team is conducting a QIS standard survey and they have determined there is substandard quality of care, they will conduct QIS extended survey procedures. Substandard quality of care is defined as one or more deficiencies with scope/severity levels of F, H, I, J, K, or L in any of the following regulatory groupings:

- 42 CFR 483.13, Resident Behavior and Facility Practices;
- 42 CFR 483.15, Quality of Life; and/or
- 42 CFR 483.25, Quality of Care.

The purpose of the QIS extended survey is to gather further information (unless already gathered during the standard survey) concerning the facility's nursing and medical services and administration, in order to evaluate systemic issues with the facility's provision of services and management that may be non-complaint with the long term care requirements, and may have contributed to problems cited in the substandard quality of care deficiency(ies). When conducting the QIS extended survey, the survey team coordinator will surveyor-initiate all Tags within the following regulatory groupings into the QIS survey software: 42 CFR 483.30, Nursing Services; 42 CFR 483.40, Physician Services; and 42 CFR 483.75, Administration. There are no specific QIS forms to assist this review. The survey team shall document their findings about these Tags on Surveyor Notes Worksheets (Form CMS-807) and shall input their findings into the QIS software. If the QIS Staffing Review protocol was not already completed during the standard survey, the survey team will complete this protocol.

At the discretion of the State Survey Agency, the QIS extended survey can be conducted either:

- Prior to the exit conference, in which case the facility will be provided with findings from the standard and extended survey; or

- Subsequent to the standard survey, but no longer than 2 weeks after the completion of the standard survey, if the survey team is unable to complete the extended survey prior to the exit conference.

3. The QIS Post-Survey Revisit (Follow-up)

A QIS post-survey revisit is conducted in accordance with §7317 to confirm that the facility is in compliance and has the ability to remain in compliance. The purpose of the revisit is to reevaluate the specific care and services that were cited as noncompliant during the QIS standard and/or extended survey. The specific procedures for each revisit depend on the deficiencies that were cited during the QIS standard survey. Detailed procedures are found in the QIS Surveyor Training Manual. For each QIS revisit, the surveyor(s) will use portions of the QIS standard survey, only as applicable to their need to evaluate the facility's return to compliance for requirements cited as deficiencies. For all QIS revisits, the surveyor(s) will review offsite the Statement of Deficiencies and conduct a focused review of the summary information from the QIS standard survey. Once onsite, the surveyor(s) will ask the facility to provide a roster of residents. The surveyor(s) will use the QIS software as well as information from the QIS standard survey (such as residents investigated) to surveyor-initiate the Care Areas and/or Tags and residents to be investigated. The surveyor(s) will use Stage 2 Critical Element Pathways (CEs) protocols as applicable to the Tags that have been cited, or the general CE for aspects of care not covered by the other CEs. For example, if deficiencies were cited for pressure ulcers and medication errors, the surveyor(s) would use the pressure ulcer CE and the QIS Medication Administration and Unnecessary Drug Review form to conduct these investigations. The surveyor(s) will input findings into the QIS software and

proceed through QIS deficiency decision making, and scoring of scope and severity for any deficiencies that are cited.

4. The QIS Complaint Survey Procedures

The QIS is used for investigation of complaints during a QIS standard survey. The survey team coordinator will surveyor-select the complaint area(s) of concern and the resident(s) involved in the complaint and add them to the list of issues and residents evaluated during the QIS standard survey. The QIS Surveyor Training Manual contains further details concerning the manner in which these surveyor-selected concerns and issues are added to the standard survey for investigation, determination of whether they are substantiated or unsubstantiated, and conveying of findings into the CMS ASPEN data system.

At this time, the QIS is not used for investigation of complaints during an abbreviated standard survey. Surveyors should use the procedures contained in §VII.A. below for these investigations.

II.B. - The Traditional Survey

II.B.1 - Traditional Standard Survey Tasks

Task 1 - Offsite Survey Preparation

(Rev. 106, Issued: 04-04-14, Effective: 04-04-14, Implementation: 04-04-14)

A. General Objectives

The objectives of offsite survey preparation are to analyze various sources of information available about the facility in order to:

- Identify and pre-select concerns for Phase 1 of the survey, based on the Facility Quality Measure/Indicator Report (see description below at B.3.a.). This pre-selection is subject to amendment based on the results of the tour;

- Pre-select potential residents for Phase I of the survey based on the Resident Level Quality Measure/Indicator Reports (see description below at B.3.a.) This pre-selection is subject to amendment based on the results gathered during the tour, entrance conference, and facility Roster/Sample Matrix;

- Note concerns based on other sources of information listed below and note other potential residents who could be selected for the sample; and

- Determine if the areas of potential concerns or special features of the facility require the addition to the team of any specialty surveyors.

B. Information Sources for Offsite Survey Preparation

The following sources of information (1-8) are used during the offsite team meeting to focus the survey.

1. Quality Measure/Indicator Reports

QM/QIs are to be used as indicators of potential problems or concerns that warrant further investigation. They are not determinations of facility compliance with the long term care requirements. There are three QM/QI reports which should be downloaded from the State database:

- Facility Characteristics Report (Exhibit 268)

  This report provides demographic information about the resident population (in percentages) for a selected facility compared to all the facilities in the State. It includes information in the following domains: Gender, age, payment source, diagnostic characteristics, type of assessment, stability of conditions, and discharge potential.

- Facility Quality Measure/Indicator Report (Exhibit 269)

  This report provides facility status for each of the MDS-based QM/QIs (quality measures and quality indicators) as compared to State and national averages. Listed are the individual QM/QIs (grouped by domains). This report begins with a set of 12 domains and a total of 31 QM/QIs for the chronic (long stay) resident population, followed by three additional QM/QIs for the post-acute care (PAC) resident population. For each QM/QI, (reading across a row from left to right) are:

  - The numerator - the number of residents in the facility who have the condition;
  - The denominator - the number of residents in the facility who could have the condition;
  - The facility observed percentage of residents who have the condition;
  - The facility adjusted percentage of residents who have the condition;
  - The State average percentage of residents who have the condition;
  - The national average percentage of residents who have the condition; and

- The State percentile ranking of the facility on the QM/QI - a descriptor of how the facility compares (ranks) with other facilities in the state. The higher the percentile rank, the greater potential there is for a care concern in the facility.

- An asterisk is present in any row in which the facility flagged on a QM/QI, which means that the facility is at or above the 90th percentile; and any of the three sentinel event rows if any resident has the condition (see D. below for more information on sentinel events).

- Resident Level Quality Measure/Indicator Reports (Exhibit 270)

  The resident level reports are divided into Chronic Care and PAC samples, to correspond to the division of residents in the Facility Quality Measure/Indicator Report described above. Both reports provide resident-specific information generated using current records from the CMS Minimum Data Set (MDS) data base. An X appears in a QM/QI column for a resident who has that condition. If a QM/QI is risk adjusted, this X is in either the high or low risk subcolumn, indicating whether this resident was at high or low risk to develop the condition. The Chronic Care version contains the following columns for each long-stay resident, reading from left to right:

  - Resident identification number;

  - Resident name in alphabetical order;

  - MDS type of assessment (1 = admission, 2 = annual, 3 = significant change, 4 = significant correction, and 5 = quarterly);

  - Columns for each QM/QI for the chronic care resident in the same order and under the same domains as on the Facility Quality Measure/Indicator Report; and

  - A column that counts how many QM/QIs the resident triggered.

The PAC version contains the following columns for each PAC resident, reading from left to right:

- Resident identification number;

- Resident name in alphabetical order;

- Columns for the three PAC QM/QIs; and

- A column that counts how many QM/QIs the resident triggered.

NOTE: Resident-specific information in the Resident Level reports must be kept confidential in accordance with the Privacy Act. These reports are only for the use of the State agency, CMS representatives, and the facility.

2. Statements of Deficiencies (CMS-2567) and Statements of Isolated Deficiencies Which Cause No Actual Harm With Only Potential For Minimal Harm (Form A)

   Statements of deficiencies from the previous survey should be reviewed, along with the sample resident identifiers list. Review the specific information under each deficiency and note any special areas of concern. For example, a deficiency was cited for comprehensive care planning last year. Share with the team the specific care planning problems that were listed as the reasons for this deficiency. For resident-centered requirements, determine if any residents identified in the deficiency might be good candidates for the sample. For example, a deficiency was cited for abuse partly based on surveyor observation of a staff member striking a resident who was combative. Identify this resident by name and add the name to the Offsite Preparation Worksheet. During the Initial Tour, evaluate this resident for inclusion in the sample.

3. OSCAR Report 3, History Facility Profile, and OSCAR Report 4, Full Facility Profile from CMS' OSCAR Computer System

   (Refer to Exhibit 96 for sample copies of Reports 3 and 4.) Report 3 contains the compliance history of the facility over the past 4 surveys. Use it to determine if the facility has patterns of repeat deficiencies in particular tags or related tags. This report also lists the dates of any complaint investigations and Federal monitoring surveys during the 4-year time period.

   Report 4 contains information provided by the facility during the previous survey on the Resident Census (Form CMS-672). This report compares facility population characteristics with State, CMS region, and national averages.

4. Results of Complaint Investigations

   Review information from both complaints investigated since the previous standard survey and complaints filed with the survey agency, but not yet investigated. Note resident and staff names related to the complaints and note patterns of problems relating to specific wings or shifts.

5. Information about Waivers or Variances

   If the facility has, or has requested any staffing waiver or room variances, note these for onsite review. The team will determine onsite if these should be granted, continued, or revoked due to a negative effect on resident care or quality of life.

6. Information from the State Ombudsman Office

   Note any potential areas of concern reported by the ombudsman office and note resident names reported as potential sample residents, residents for closed record review, or family members for family interviews and the reasons for their recommendation by the ombudsman.

7. Preadmission Screening and Resident Review Reports (PASRR)

   Some States may have formal mechanisms to share with the survey agency the results of PASRR screens for residents with mental illness or *intellectual disabilities*. If this information is available, evaluate if there are any potential concerns and note names of residents for possible inclusion in the sample.

8. Other Pertinent Information

   At times, the survey agency may be aware of special potential areas of concern that were reported in the news media or through other sources. Evaluate this information to determine if there are potential areas of concern that should be investigated onsite.

C. Team Coordinator Responsibilities

The team coordinator and/or designee is responsible for completing the following tasks:

1. Contact the ombudsman office in accordance with the policy developed between the State survey agency and State ombudsman agency. The purposes of this contact are to notify the ombudsman of the proposed day of entrance into the facility and to obtain any information the ombudsman wishes to share with the survey team. Ascertain whether the ombudsman will be available if residents participating in the group or individual interviews wish her/him to be present.

2. Obtain all information sources listed in B. above for presentation at the offsite team meeting. (See Section B. for descriptive information about these reports.) They are as follows:

   - Specified QI/QM Reports:

     - Facility Characteristics Report;

     - Facility Quality Measure/Indicator Report; and

     - The two resident level reports:

- Resident Level Quality Measure/Indicator Report: Chronic Care Sample; and

- Resident Level Quality Measure/Indicator Report: Post Acute Care Sample

NOTE: It is important that the QM/QI reports be generated as close to the date of survey as possible, preferably no more than a few days prior to the survey.

- Form CMS-2567 and Statement of Isolated Deficiencies Which Cause No Actual Harm With Only Potential For Minimal Harm;
- Standard OSCAR Report 3 and 4;
- Results of complaint investigations;
- Information about waivers or variances;
- Information from the State Ombudsman office;
- Preadmission Screening and Resident Review Reports; and
- Other pertinent information.

3. Complete the following additional duties:

- Copy and distribute to the team the facility's floor plan if the team is unfamiliar with the facility's layout;
- Make extra copies of the OSCAR Reports 3 and 4, and the QM/QI reports to be given to the facility's administrator;
- Obtain an extra copy of the group interview worksheet (see Form CMS-806B, Exhibit 94) to give to the council president.

D. Offsite Survey Preparation Team Meeting

Present copies of the information obtained to the survey team members for review at a team meeting offsite. The team must prepare for the survey offsite, so that they are ready to begin the Entrance Conference and Initial Tour immediately after they enter the facility. The team should:

1. Review the Facility Characteristics Report to note the facility's demographics. This report can be used to identify whether the facility's population is unusual,

e.g., high prevalence of young or male residents, high prevalence of residents with psychiatric diagnosis, high percentage of significant change assessments, etc.;

2. Use a copy of the Roster/Sample Matrix (Form CMS-802, Exhibit 90) to highlight concerns the team identifies for Phase 1 of the survey, and to list residents pre-selected and the QM/QI conditions for which each was selected. Mark the offsite block on this form to distinguish it from the Phase 1 version that will be completed in Task 4, "Sample Selection;"

   The Facility Quality Measure/Indicator Report divides the QM/QIs into a set for the chronic care residents, followed by three post acute measures, which are based on MDS information for short-stay residents. The three PAC QM/QI items include two that are the same topics as the chronic care residents (13.2, Short-stay residents who had moderate to severe pain, and 13.3, Short-stay residents with pressure ulcers) and one unique item (13.1, Short-stay residents with delirium). Use this report to select concerns based on the following:

   - Any sentinel health event QM/QI that is flagged. For the chronic care sample, a "sentinel health event" is a QM/QI that represents a significant occurrence that should be selected as a concern, even if it applies to only one or a few residents. The sentinel event QM/QIs are 5.4, Prevalence of fecal impaction, 7.3, Prevalence of dehydration, and 12.2, Low-risk residents with pressure ulcers. This means that even if one resident has any of these conditions, this QM/QI will flag and the care area must be selected as a concern and the resident with the problem must be selected for the sample. If there are multiple residents who flag on a sentinel event QM/QI, it is not necessary to select all of them;

   - Any other QM/QI that is flagged at the 90th percentile; and

   - Any unflagged QM/QI in which the facility is at the 75th percentile or greater.

   For the items that are duplicated between the chronic care and PAC residents (pain and pressure ulcers), note whether the area of concern was selected based on only chronic or PAC samples, or both. The survey team may also wish to select as concerns any other QM/QIs that are of interest to them because they are related to QM/QIs that have been selected.

3. Begin selection of potential residents for the Phase 1 survey sample with the chronic care sample residents to represent the concerns that have been selected, including selecting residents who have sentinel event QM/QI conditions; if multiple residents have a sentinel event QM/QI condition, it is not necessary to select all of them. Use Table 1 in this section and the number of the total resident census to determine the sample size for the Phase 1 sample. Pre-select a few more

residents (3-5) than the actual number that will be required for Phase 1 sample since some selected residents may no longer be available. Most if not all residents from the PAC sample are likely to have been discharged. The survey team may use this sample of residents from which to select potential closed records for review. (If some PAC residents that triggered a selected QM/QI are still at the facility, the team may select some of these residents in order to investigate issues of concern).

- In any facility in which the team has noted concerns with weight loss, dehydration, and/or pressure sores, select approximately one-half of the pre-selected sample as residents who have one or more of these conditions. For the condition of hydration, select a resident who has flagged for the sentinel event QM/QI 7.3 (Prevalence of dehydration) and residents may be selected who have any of the following related QM/QI conditions: 5.4 – Prevalence of fecal impaction; 6.1, - Residents with a urinary tract infection; 7.1 – Residents who lose too much weight; 7.2 – Prevalence of tube feeding; and 9.1 – Residents whose need for help with daily activities has increased. The best residents to select will be those who also have multiple care areas that have been selected as concerns. For any facility in which these concerns were not identified, the team should still select some residents who have these QM/QI conditions, if any, on the Resident Level Quality Measure/Indicator Reports, but this need not be 50% of the Phase 1 sample size.

- For the remaining half of the Phase 1 preliminary sample, select residents to represent the remaining areas of concern.

NOTE: If there are no other QM/QIs that have been selected as concerns, the team may select residents based on other sources of information, e.g., complaints or a report from the ombudsman, or may wait to select the remaining Phase 1 residents based on Initial Tour findings.

If the average length of stay for the facility's population is less than 14 days, there may be little information available. Pre-selection of QM/QI-based concerns and/or the full sample may not be possible. Selection of some or all concerns and residents may need to be totally conducted onsite.

- The survey team should be alert to inconsistencies on the Facility Quality Measure/Indicator Report that may indicate facility error in completing and/or transmitting its Minimum Data Set (MDS) records, or a problem with State's software or CMS' database. The following are some possible indicators of data quality problems:

    - The denominator for QM/QIs that use "all residents" substantially exceeds or is substantially smaller than the facility bed size;

- The number of residents with a QM/QI condition, i.e., the numerator, exceeds the resident population; or,

- The numerator for a particular QM/QI is zero although other information sources indicate otherwise. For example, the QM/QI report shows zero residents in restraints, but the ombudsman notified the team that she/he verified complaints about restraints. The most common reason for this type of inconsistency is incorrect MDS coding by the facility.

If these or other potential accuracy concerns are noted, the team should add resident assessment accuracy as a concern for the survey.

NOTE: This review need not be done for "short-stay" facilities, which will often have unusual values in the numerator and denominator due to rapid turnover of residents.

The Facility Quality Measure/Indicator Report is generated using the current MDS records in the State database at the time the report was generated. However, it excludes residents who have only an initial MDS record in the system. This was done so that the report reflects the care residents have received while residing in the facility, as opposed to the conditions of residents at the time of admission to the facility. The Resident Level reports are calculated using the most recently transmitted MDS record, e.g., annual, significant change, quarterly, or initial MDS record. Differences could be seen between the Facility Quality Measure/Indicator Report and the Resident Level reports since the former does not use the admission MDS data. For example, a Resident Level report may indicate a resident had a catheter but the Facility Quality Measure/Indicator Report might show a "0." This is not an accuracy problem, it only reflects the use of different data to generate each report.

4. Review the OSCAR reports after the review of the QM/QI reports to add corroborative information to the QM/QI information, e.g., a pattern of repeat deficiencies in a requirement related to a flagged QM/QI, and/or to point out areas of large discrepancies between the QM/QI numerators and the OSCAR Reports, e.g., the OSCAR 4 report lists the facility as having triple the average number of residents in restraints, but the QM/QI for restraints shows the facility has less restraints than most facilities). The team coordinator may wish to discuss such discrepancies with the administrator on entrance to determine the reason for them.

   Relate information between Reports 3 and 4 such as a pattern of repeat deficiencies in range of motion and a lower than average percentage of residents receiving rehabilitative services. Also, note any special resident characteristics not contained in the QM/QI reports.

NOTE: Both the OSCAR reports and the QM/QI reports can alert surveyors to the acuity and characteristics of the facility's residents at the time the information for these reports was determined. This information may not represent the current condition of residents in the facility at the time of the survey. Keep in mind that the OSCAR information is approximately 1 year old, and the QM/QI information may be from 2-6 months old. Resident characteristics that were reported by the facility during the last survey may have changed significantly and may be the source of some discrepancies between OSCAR and QM/QI information.

5. Review all other sources of information and record additional information on the Offsite Preparation Worksheet (Form CMS-801, Exhibit 89), for example, residents' names for possible inclusion in the Phase 2 sample based on non-QM/QI sources of information (B. 2 through 8 above), special features of the facility, or special resident populations. Identify any outstanding complaints needing investigation. At this meeting, establish preliminary surveyor assignments and projections of which days team members will enter early and/or stay late to make observations of resident care and quality of life.

Task 2 - Entrance Conference/Onsite Preparatory Activities

(Rev. 26; Issued: 08-17-07; Effective/Implementation Dates: 08-17-07)

A. Entrance Conference

1. The team coordinator informs the facility's administrator about the survey and introduces team members.

2. After the introduction to the administrator, the other team members should proceed to the initial tour (Task 3), while the team coordinator conducts the entrance conference.

3. The team coordinator should:

   - Request a copy of the actual working schedules for licensed and registered nursing staff for this time period by the end of the tour or earlier if possible.

   - Inform facility staff that the survey team will be communicating with them throughout the survey and will ask for facility assistance when needed. (See §2713.A for further information about facility staff accompanying surveyors.) Advise them that they have the opportunity to provide the team with any information that would clarify an issue brought to their attention.

   - Explain the survey process and answer any questions from facility staff.

- Give the Administrator copies of the QM/QI reports and the OSCAR 3 and 4 reports that are being used for the survey. Briefly explain these reports and how they were used by the survey team in Task 1. If there are discrepancies between the OSCAR information and the QM/QI Facility Characteristics report, ask the administrator, or person designated by the administrator, to explain the discrepancies.

- Ask the administrator to describe any special features of the facility's care and treatment programs, organization, and resident case-mix. For example, does the facility have a special care unit for residents with dementia? Are residents with heavy care needs placed in particular units? If so, which ones?

- Ask the administrator if the facility utilizes paid feeding assistants. If yes, request further information about how and where the paid feeding assistants receive their training. Determine whether the training for the paid feeding assistant was provided through a State-approved training program by qualified professionals as defined by State law, with a minimum of 8 hours of training.

- Request the names of staff (including agency staff) who have successfully completed training for paid feeding assistants, and who are currently assisting selected residents with eating meals and/or snacks;

  NOTE: Paid feeding assistants must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN). Therefore, if a facility has a nursing waiver, that facility cannot use paid feeding assistants when a licensed nurse is not available.

- Inform the administrator that there will be interviews with individual residents, groups of residents, family members, friends, and legal representatives, and that these interviews are conducted privately, unless the interviewees request the presence of a staff member. Ask the administrator to ensure that there are times during the survey when residents can contact the survey team without facility staff present and without having to ask facility staff to leave or to allow access to the team.

- Determine through interview with the administrator if the facility has a functioning QA&A committee. Determine:

  - Which staff participate on the committee;

  - Who leads the committee;

  - How often the committee meets; and

  - With whom should the survey team discuss QA&A concerns.

- Ask the administrator to provide the following information within 1 hour of the conclusion of the entrance conference (or later at the survey team's option):

    1. List of key facility personnel and their locations, e.g., the Administrator; directors of finance, nursing services, social services, and activities; dietitian or food supervisor; rehabilitation services staff; charge nurses; pharmacy consultant; plant engineer; housekeeping supervisor; persons responsible for infection control and quality assurance; health information management professional; and the medical director;

    2. A copy of the written information that is provided to residents regarding their rights;

    3. Meal times, dining locations, copies of all menus, including therapeutic menus that will be served for the duration of the survey;

    4. Medication pass times (by unit, if variable);

    5. List of admissions during the past month, and a list of residents transferred or discharged during the past 3 months with destinations;

    6. A copy of the facility's layout, indicating the location of nurses' stations, individual resident rooms, and common areas, if not obtained in Task 1;

    7. A copy of the facility admission contract(s) for all residents, i.e., Medicare, Medicaid, other payment sources;

    8. Facility policies and procedures to prohibit and investigate allegations of abuse and the name of a person the administrator designates to answer questions about what the facility does to prevent abuse. (See Task 5G, Abuse Prohibition Review, for further information);

    9. Evidence that the facility, on a routine basis, monitors accidents and other incidents, records these in the clinical or other record; and has in place a system to prevent and/or minimize further accidents and incidents;

       NOTE: At the discretion of the facility, this evidence could include or be a record of accident and incident reports.

    10. The names of any residents age 55 and under; and

11. The names of any residents who communicate with non-oral communication devices, sign language, or who speak a language other than the dominant language of the facility.

- Ask the facility to complete, to the best of their ability, the Roster/Sample Matrix (Form CMS-802), including all residents on bed-hold, by the end of the initial tour, or to provide this information in some other format, e.g., computer-generated list.

NOTE: This is an important source of resident information, which is crucial for the team to have for their sample selection meetings. Stress to the facility that this form should be completed first and given to the team coordinator by the end of the initial tour. After the Roster/Sample Matrix is delivered to the team, the facility may make modifications for accuracy or add additional information within 24 hours.

- Ask the facility to provide the following within 24 hours of the Entrance Conference:

    1. A completed Long Term Care Facility Application for Medicare and Medicaid (Form CMS-671), (see Exhibit 85) and a Resident Census and Conditions of Residents (Form CMS-672), (See Exhibit 86); and

    2. A list of Medicare residents who requested demand bills in the last 6 months (SNFs or dually-participating SNF/NFs only).

- Also, ask the administrator the following questions:

    1. Which, if any, rooms have less square footage than required? Do you have a variance in effect and are you prepared to continue to request a variance for any such rooms? (F458)

    2. Which, if any, rooms are occupied by more than four residents? Do you have a variance in effect and are you prepared to continue to request a variance for any such rooms? (F457)

    3. Is there at least one window to the outside in each room? (F461)

    4. Which, if any, bedrooms are not at or above ground level? (F461)

    5. Do all bedrooms have access to an exit corridor? (F459)

    6. What are the procedures to ensure water is available to essential areas when there is a loss of normal supply? (F466)

NOTE: If the survey is commencing at times beyond the business hours of 8:00 a.m. to 6:00 p.m., or on a Saturday or Sunday, once onsite, announce the survey, ascertain who is in charge, ask the person to notify the administrator that a survey has begun. Modify the entrance conference in accordance with staff available and complete the task and the onsite preparatory activity as appropriate within the context of the survey.

4. For any survey conducted outside of the influenza season (October 1-March 31), obtain the name of the staff person who is responsible for coordinating and implementing the facility's immunization program to request a list of current residents who were in the facility during the previous influenza season, October 1 to March 31.

B. Onsite Preparatory Activities

1. In areas easily observable by residents and visitors, post, or ask the facility to post, signs announcing that a survey is being performed and that surveyors are available to meet with residents in private.

2. The team coordinator or designee should contact the resident council president after the Entrance Conference to introduce her/himself and to announce the survey. Provide the president with a copy of the group interview questions. Request the assistance of the president for arranging the group interview and to solicit any comments or concerns. Ask the council president for permission to review council minutes for the past 3 months (see Task 5D, Section 3B, for further information). If there is not an active resident council, or if the council does not have officers, ask for a list of residents who attend group meetings, if any, and select a resident representative to assist in arranging the group interview. If the ombudsman has indicated interest in attending the group interview, ask the president if that is acceptable to the group; if it is, notify the ombudsman of the time/place of the meeting.

3. The team coordinator, the surveyor assigned to conduct the group interview, or a designee should arrange for date, time and private meeting space for the interview. Advise the facility staff that non-interviewable residents are not part of this meeting. (See Task 5D for further guidance.)

Task 3 - Initial Tour

A. General Objectives

The Initial Tour is designed to:

- Provide an initial review of the facility, the residents, and the staff;

- Obtain an initial evaluation of the environment of the facility, including the facility kitchen; and

- Confirm or invalidate the pre-selected concerns, if any, and add concerns discovered onsite.

B. General Procedures

The initial tour is used to gather information about concerns which have been pre-selected; new concerns discovered onsite; and whether residents pre-selected for the Phase 1 sample offsite are still present in the facility. In addition, attempt to meet and talk with as many residents as possible during the tour in order to identify other candidates for the sample, to get an initial overview of facility care and services, to observe staff/resident interactions; and to evaluate the impact of the facility environment on the residents. The tour also includes a first brief look at the facility's kitchen.

Document tour information, on either the Roster/Sample Matrix (Form CMS-802 or the Surveyor Notes Worksheet (Form CMS-807). Document any concerns regarding the general environment on the General Observations of the Facility Worksheet, (Form CMS-803) or Surveyor Notes Worksheets, (Form CMS-807). (See Task 5A for further information.) Surveyors may also document notes on the facility's Roster/Sample Matrix or other list of residents provided by the facility. Document any concerns noted in the brief tour of the facility kitchen on the Kitchen/Food Service Observation worksheet (Form CMS-804, Exhibit 92). (See Task 5B for information regarding observations to make during this brief tour.)

C. Protocol

Surveyors should tour individually as assigned by the team coordinator. It is desirable for team members to have a facility staff person who is familiar with the residents accompany them during the tour to answer questions and provide introductions to residents or family. However, do not delay the beginning of the Initial Tour if facility staff are not available. Begin the tour as soon as possible after entering the facility.

NOTE: When standard surveys begin at times beyond the business hours of 8:00 a.m. to 6:00 p.m., or begin on a Saturday or Sunday, the initial tour will need to be modified in recognition of the residents' activity, e.g., sleep, religious services, and types and numbers of staff available upon entry. The tour may focus on specific care and quality of life issues, e.g., restraint use, meal service, use of foam or paper meal service products rather than regular dinnerware, adherence to the planned menu; sufficiency of staff; whether enteral/parenteral fluids are being administered as ordered; whether incontinent residents are being checked, toileted, changed; etc., as appropriate. The tour should not be delayed for lack of staff to accompany the surveyor and/or survey team.

Phase 1-- Pre-selected Concerns and Potential Residents:

During the tour, determine whether each resident pre-selected offsite for the Phase 1 sample is still there. Determine which, if any, of the pre-selected Phase 1 sample residents are interviewable residents who can be selected to participate in a Quality of Life Assessment Resident Interview or Group Interview. (See Task 5D.) This can be accomplished by talking with residents and asking questions. Examples of questions that can be asked are: What is your name? What are you planning to do today?

NOTE: Do not rely solely on the information that the facility provides concerning which residents are interviewable. The survey team should determine the residents who are able to participate in a Quality of Life Assessment interview.

If possible, determine if there are family members of non-interviewable residents in the pre-selected Phase 1 sample who can be selected for a Quality of Life Assessment family interview. Also note other non-interviewable residents among the facility population whose family members could be selected for interviews;

Observations of All Residents During the Tour

Ask staff to identify those residents who have no family or significant others. The team may include one or more of these residents in the Phase 2 sample for investigation of quality of life issues.

Have staff identify newly admitted residents, i.e., who have been admitted within the past 14 days, for possible inclusion in the sample for investigation of decline or deterioration that may have occurred before all MDS, other resident assessment information, and care planning is completed.

Have staff identify any residents for whom transfer or discharge is planned within the next 30 days.

Note residents who are interviewable or who have special factors, as listed in Task 4. When on the Initial Tour, observe and document possible quality of care and quality of life concerns in addition to those pre-selected offsite. If observed concerns involve specific residents, note the resident's name and room number on the worksheet, and the date/time when describing the observed concern. Include the details of the observation in documentation, including any effects on the residents involved.

Conduct a brief initial observation of the kitchen. (See Task 5B for further information).

While on tour, identify the licensed and registered nursing staff who are currently on duty. At the end of the tour, compare the observed staff with the duty roster the facility is to provide. If there are discrepancies between the duty roster and the staff observed onsite,

ask the person in charge to explain the discrepancies. This information will be used in Task 6 to determine if the facility is compliant with the requirements for licensed and registered nursing staff at 42 CFR 483.30(a)(2), F353 and 42 CFR 483.30(b)(1), F354.

During the tour focus on the following:

- Quality of Life

    1. Resident grooming and dress, including appropriate footwear;

    2. Staff - resident interaction related to residents' dignity; privacy and care needs, including staff availability and responsiveness to residents' requests for assistance;

    3. The way staff talk to residents, the nature and manner of interactions, and whether residents are spoken to when care is given; and

    4. Scheduled activities taking place and appropriateness to the residents.

- Emotional and behavioral conduct of the residents and the reactions and interventions by the staff:

    1. Resident behaviors such as crying out, disrobing, agitation, rocking, pacing; and

    2. The manner in which these behaviors are being addressed by staff, including nature and manner of staff interactions, response time, staff availability, and staff means of dealing with residents who are experiencing catastrophic reactions. (See "Abuse Prohibition Investigative Protocol" in Task 5G for a definition of catastrophic reaction.)

- Care issues, how care is provided, and prevalence of special care needs

    1. Skin conditions, e.g., excessive dryness, wetness;

    2. Skin tears, bruising, or evidence of fractures that warrant investigation;

    3. Dehydration risk factors including availability of water for most residents, and other indicators or factors, e.g., the amount and color of urine in tubing and collection bags, dependence on staff, the presence of strong urinary odors, and resident complaints of dry mouth and lips;

    4. Clinical signs such as edema, emaciation and contractures;

5. Functional risk factors such as poor positioning and use of physical restraints;

6. Side effects of antipsychotic drug use such as tardive dyskinesia, e.g., lip, tongue or other involuntary abnormal movements;

7. Presence or prevalence (numbers) of infections including antibiotic resistant strains of bacteria (e.g., Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomycin Resistant Enterococcus (VRE), Clostridium Difficile (C-Diff) or other infections: Urinary tract infections, draining wounds, eye infections, skin rashes (especially if spreading, undiagnosed, and/or not responding to treatment), respiratory infections, gastroenteritis including diarrhea, etc.

8. Pressure sores, old scars from pressure sores or evidence of surgical repair of pressure sores;

9. Amputation;

10. Significant weight loss;

11. Feeding tubes and/or improper positioning while feeding is infusing; and

12. Ventilators, oxygen, or intravenous therapies.

- Impact of the facility environment and safety issues:

    1. Infection control practices, e.g., handwashing, glove use, and isolation procedures);

    2. Functional and clean equipment, including kitchen equipment;

    3. Presentation and maintenance of a homelike and clean environment; and

    4. Availability, use, and maintenance of assistive devices.

NOTE: If the initial tour is being conducted during a mealtime, include an initial brief observation of the dining areas. Note if there are any concerns with meal service, quality of life, positioning, sufficient space, etc.

Task 4 - Sample Selection

(Rev. 106, Issued: 04-04-14, Effective: 04-04-14, Implementation: 04-04-14)

A. General Objective

The objective of this task is to select a case-mix stratified sample (see Special Factors to Consider in Sample Selection below for further information) of facility residents based on QM/QIs and other offsite and onsite sources of information in order to assess compliance with the resident-centered long term care requirements.

B. General Procedures

- The Phase 1 sample is pre-selected during Task 1, "Offsite Survey Preparation," based on QM/QIs and other areas of concern. The pre-selected sample is reviewed during the sample selection meeting and residents are retained for the sample unless they are discharged, or the survey team has another reason to substitute, e.g., to select interviewable residents. Each team member is assigned a certain number of residents, completing all facets of review that have been selected including any quality of life assessment protocols selected for these residents.

- The Phase 2 sample is selected onsite, part way through the survey when surveyors have collected enough information to determine the focus of the remainder of the survey. The Phase 2 sample residents are selected to represent new concerns and/or to continue further investigation of Phase 1 concerns when Phase 1 reviews proved inconclusive or when necessary to determine scope of a problem. It is statutorily required that the sample in each facility be case-mix stratified in order to capture both interviewable and non-interviewable residents as well as residents from both heavy and light care categories.

NOTE: If the team is conducting sample selection during meal time, delay or interrupt this task to conduct brief observations of the dining areas. Note if there are any concerns with meal service, quality of life, positioning, sufficient space, etc.

C. Definitions

- Interviewable Resident --This is a resident who has sufficient memory and comprehension to be able to answer coherently the majority of questions contained in the Resident Interview. These residents can make day-to-day decisions in a fairly consistent and organized manner.

- Comprehensive Review -- For Task 5C, "Resident Review," this includes observations, interviews, and record reviews for all care areas for the sampled residents, as applicable.

- Focused Review -- For Task 5C, "Resident Review," this includes the following:

    - For Phase 1: Observations, interviews and record reviews concerning all highlighted areas of concern and all unhighlighted areas pertinent to the resident; and

- For Phase 2: Observations, interviews and record review for all highlighted areas of concern pertinent to the resident.

- Closed Record Review -- For Task 5C, "Resident Review," this includes a record review of residents' care issues and transfer and discharge.

- Roster/Sample Matrix -- This worksheet, (Exhibit 265, Form CMS-802), is used by the survey team during Offsite Survey Preparation, and at the Phase 1 and Phase 2 Sample Selection meetings to note areas of concern for the survey, and to select residents for the sample. There are separate sets of instructions for the use of this form by the survey team and the facility. (See these instructions at Exhibits 266 and 267.

D. Protocol

1. Phase 1 - Sample Selection

The Phase 1 sample is pre-selected during Task 1, Offsite Survey Preparation, based on the facility's QM/QIs of concern. (See Task 1 for further information.) Final Phase 1 sample selection occurs after the tour is completed and the facility has provided the completed Roster/Sample Matrix (Form CMS-802, Exhibit 265), or provided this information in some other format, e.g., computer-generated list. However, do not delay Phase 1 sample selection if the facility's Roster/Sample Matrix has not arrived. The team will complete the sample selection for Phase 1 by performing the following tasks:

NOTE: For facilities with a population of "short-stay" residents, the team may not have been able to pre-select concerns or potential sampled residents. In that instance, Phase 1 sample selection will occur during this task.

- First determine if any pre-selected concerns should be dropped due to the QM/QI data not representing the conditions of current residents. For example, there was a pre-selected QM/QI concern with residents with tube feedings, but the tour has verified there are no residents in the facility who are receiving tube feedings. Note new concerns and determine if some pre-selected residents can be evaluated for the new concerns as well as those originally selected.

- Review the Roster/Sample Matrix provided by the facility and compare it to the findings from the tour to determine if there is a reason to substitute another resident for any of the residents from the Offsite sample. A pre-selected resident who is no longer in the facility can be considered for the closed record review. The team may substitute other residents for those pre-selected, if necessary. They can select either from the QM/QI reports, the tour, or the facility's Roster/Sample Matrix.

If any resident is substituted for a pre-selected resident, record a short explanation on the Offsite Roster/Sample Matrix next to that person's name, e.g., "discharged."

- Check "Phase 1" on the copy of the Roster/Sample Matrix that will be used to denote the resident sample for Phase 1 of the survey.
    - Highlight the column for each identified concern for Phase 1.
    - Use Table 1 in this section and the number of the total resident census to determine the number of comprehensive and focused reviews, number of closed records, number of resident and family interviews, and the minimum number of residents who have conditions of weight loss, hydration risk and/or pressure sores, i.e., the WHP group. The number in the WHP column represents the minimum total of residents who must be selected for the Phase 1 sample to represent any or all of these conditions. For example, in a facility with 96 residents, out of 12 residents selected for the Phase 1 sample, a minimum of 6 will be those who have any of the conditions mentioned above, if any of these 3 QM/QIs were selected as concerns.
    - Use the unnumbered blocks to the right of Resident Name to fill in the total number of residents in each sub-sample for the entire survey as listed in Table 1. For example, in a facility with a census of 100, the total number of individual interviews is 5. Enter that number in the small block below that title.
    - All residents selected for comprehensive reviews are selected by the team during the Phase 1 sample selection. Residents selected for focused reviews, closed record reviews, individual and family interviews may be selected during Phase 1 or Phase 2 sample selection.
    - Each resident the team selects is entered on the worksheet. Note the following about each resident:
        - Resident number and room number;
        - Surveyor assigned to complete the resident review and any quality of life assessment protocols (Resident Interview or Family Interview) that are selected for the resident;
        - Check any columns that pertain to this resident, whether or not they are highlighted as concerns for Phase 1. Each resident will be reviewed for each checked area, not just those that are highlighted; and

- If there is anything about this resident that the team decides to investigate that is not one of the numbered columns on the worksheet, use a blank column at the far right to write the item that will be assessed and check that column for that resident. For example, if the team wants to assess ventilator use for a particular resident, write "ventilator" in one of the blank columns and make a check mark in that column for that resident.

2. Phase 2 Sample Selection

Part way through the survey, after the team has obtained enough information to decide what concerns need further investigation, the team meets to determine the areas of concern, if any, for Phase 2 of the survey and to select the remaining sample. It is not necessary to complete all the reviews of all residents in Phase 1 before this meeting. Determine which Phase 1 concerns are ruled out as these do not need to be carried over into Phase 2 sample selection.

- Select concerns for Phase 2 based on the following:
  - Initial concerns noted during Offsite Survey Preparation or the Initial Tour that have not yet been reviewed;
  - Currently un-reviewed concerns that are related to those under investigation, e.g., adding residents who have had falls based on results of the Phase 1 discovery of a problem with use of psychoactive drugs; and
  - Current concerns for which the information gathered is inconclusive.
- Select residents for the Phase 2 sample based on the following:
  - The statute requires selection of a "case mix stratified" sample (but not for each phase of the sample selection, just for the total sample). This stratification is defined by CMS as including residents who are interviewable and non-interviewable, and as including residents who require heavy and light care. It is important that at least one resident in the sample represent each of these categories. The requirements of the sample selection procedures make it necessary for survey teams to select interviewable and non-interviewable residents in order to complete the Task 5D, Quality of Life Assessment Interviews, so those categories of case-mix stratification will be automatically filled by complying with the sample selection procedures. At the beginning of the Phase 2 sample selection meeting, the team should review the Phase 1 sample to determine if at least one heavy care and one light care resident has been selected to fulfill this portion of the case mix stratification requirement. If not, it is a priority to ensure that if either heavy or light care residents are missing

from the Phase 1 sample, that at least one is selected from the missing category in Phase 2.

- Select residents who represent one or more of the areas of concern the team has selected for Phase 2 of the survey.

- If no residents have been selected for the Phase 1 sample for hydration, and if any residents are seen during Phase 1 of the survey who appear to have risk factors for dehydration, e.g., such as residents who are dependent on staff for activities of daily living, are immobile, receive tube feedings, or have dementias in which the resident no longer recognizes thirst, select at least one of these residents at risk and review the care area of dehydration.

- During Phase 2 sample selection, a clean copy of the Sample/Matrix worksheet is used as follows:

  - Check "Phase 2" on the copy of the Roster/Sample Matrix that will be used to denote the resident sample for Phase 2 of the survey;

  - Highlight the column for each identified concern for Phase 2;

  - Each resident the team selects is entered on the worksheet. Note the following about each resident:

    - Resident number and room number;

    - Surveyor assigned to complete the resident review and any quality of life assessment protocols (Resident Interview, or Family Interview) that are selected for the resident;

    - Checkmarks are made only in the highlighted columns and these residents will be reviewed for these concerns, and any other concerns that are discovered during this review;

    - Be sure that residents are selected to complete the required number of resident interviews, family interviews, and closed record reviews.

- If there are no outstanding areas of concern and the team has already selected interviewable, non-interviewable, heavy care and light care residents, then select remaining residents to represent any of the following, in no particular order:

  - An area of concern on the worksheet that has not been highlighted, but which the team has determined should be assessed;

- Living units that are unrepresented; and
- Special factors below that have not been reviewed.

NOTE: When selecting the sample in a facility in which there are no outstanding areas of concern, each resident will be reviewed for at least one area on the Roster/Sample Matrix that has not yet been reviewed.

3. Special Factors to Consider in Sample Selection

Residents must be selected for both the Phase 1 and Phase 2 samples as representatives of concerns to be investigated and to fulfill the case mix stratified sample requirement. If during sample selection, many more residents are identified than can be selected to represent the concerns of interest, consider the factors below in determining which residents to select:

- New admissions, especially if admitted during the previous 14 days. Even though the Resident Assessment Instrument (RAI) is not required to be completed for these residents, the facility must plan care from the first day of each resident's admission;
- Residents most at risk of neglect and abuse, i.e., residents who have dementia; no or infrequent visitors, psychosocial, interactive, and/or behavioral dysfunction; or residents who are bedfast and totally dependent on care;
- Residents in rooms in which variances have been granted for room size or number of beds in room;
- Residents receiving hospice services;
- Residents with end-stage renal disease;
- Residents under the age of 55;
- Residents with mental illness or *intellectual disabilities*; and
- Residents who communicate with non-oral communication devices, sign language, or who speak a language other than the dominant language of the facility.

4. Other Phase 2 Tasks

- If there are any concerns about residents' funds, check that the amount of the surety bond is at least equal to the amount of residents' funds the facility is managing as of the most recent quarter.

- If concerns have been identified in the area of infection control, review policies and procedures including a focus on what preventative infection control practices the facility has in place. For example, does the facility administer the influenza vaccine yearly to its residents, and administer pneumococcal vaccine to new residents as appropriate (does facility evaluate whether new residents have received the pneumococcal vaccine within the last 5 years)?

- Complete Task 5F Quality Assessment Assurance Review.

- If the group interview has not yet occurred, discuss what special concerns to ask of the group.

- If the facility has or has requested a nurse staffing waiver, review the requirements at 42 CFR 483.30.

- Review the Resident Census and Condition of Residents (Form CMS-672) that the facility has completed. Note any new areas of concern and determine if there appears to be large discrepancies between what is recorded by the facility and what the team has observed. For example, the team has noted 13 residents with pressure sores and the facility has listed 3. If there are large discrepancies, ask the facility to verify their totals. Answer questions F146 - F148 on the Resident Census.

- If the team has identified quality of care problems during Phase 1 of the survey, use the investigative protocol at Task 5C: Nursing Services, Sufficient Staffing to gather information and (at Task 6) to determine compliance with the following requirement: 42 CFR 483.30(a), F353 Nursing services, Sufficient Staff. If problems with staffing have been discovered early in Phase 1, this protocol can begin in Phase 1.

5. Substituting Residents

If the team has found it necessary during the survey to remove a resident from the sample, e.g., a resident refused to complete the interview, replace this resident with another who best fulfills the reasons the first person was selected. For example, the resident who was removed had been selected because he/she was in restraints and had a pressure sore. Attempt to select another resident who meets both of these criteria. In Phase 1, the substituted resident should be selected from the pre-selected list of residents which was determined offsite, if possible, or from other information gained during the survey. Make the substitution as early in the survey as feasible. Note on the Roster/Sample Matrix that the new resident was substituted for resident #___, and briefly give the reason the first resident was dropped.

6. Supplementary Sample

If sampled residents are found not to provide enough information to make deficiency determinations concerning specific requirements under review, or to determine if there is "substandard quality of care" (see Task 6 for further information), supplement the sample with residents who represent the areas of concern under investigation. Focus review for these residents only on the concern under investigation and any other concerns that are discovered during this review. Add the names of these residents to the Phase 2 Sample Matrix worksheet, checking the relevant categories. Use the Resident Review Worksheet to complete these investigations.

Table 1 - Survey Procedures for Long Term Care Facilities - Resident Sample Selection

Survey Procedures for Long Term Care Facilities
Resident Sample Selection

Resident Census	Phase 1/ Phase 2	Compre-hensive Reviews *	Focused Reviews *	Closed Rec. Reviews *	Res./ Family Interviews	W, H, P Group **
1 - 4	All / 0	2	2	0	1/1	All
5 - 10	3 / 2	2	2	1	1 / 1	2
11 - 20	5 / 3	2	5	1	2 / 2	3
21 - 40	6 / 4	2	7	1	3 / 2	3
41 - 44	7 / 4	2	8	1	3 / 2	4
45 - 48	7 / 5	2	9	1	3 / 2	4
49 - 52	8 / 5	3	9	1	4 / 2	4
53 - 56	8 / 6	3	9	2	4 / 2	4
57 - 75	9 / 6	4	9	2	4 / 2	5
76 / 80	10 / 6	4	9	3	4 / 2	5
81 - 85	10 / 7	4	10	3	4 / 2	5
86 - 90	11 / 7	4	11	3	4 / 2	6
91 - 95	11 / 8	4	12	3	4 / 2	6
96 - 100	12 / 8	5	12	3	5 / 2	6
101 - 105	13 / 8	5	13	3	5 / 2	7
106 - 110	13 / 9	5	14	3	5 / 2	7
111 - 115	14 / 9	5	15	3	5 / 2	7
116 - 160	14 / 10	5	16	3	5 / 2	7
161 - 166	15 / 10	5	17	3	5 / 2	8
167 - 173	16 / 10	5	18	3	5 / 2	8
174 - 180	16 / 11	5	19	3	5 / 2	8
181 - 186	17 / 11	5	20	3	5 / 2	9
187 - 193	17 / 12	5	21	3	5 / 2	9
194 - 299	18 / 12	5	22	3	5 / 2	9
300 - 400	18 / 12	5	22	3	6 / 3	9
401 -	18 / 12	5	22	3	7 / 3	9

* Comprehensive reviews plus focused reviews plus closed record reviews added together equals the total sample size (Phase 1 plus Phase 2).

** For any survey in which there are identified concerns in the areas of (W) unintended weight loss, (H) hydration, and/or (P) pressure sores, this is the minimum total of residents who must be selected for the Phase 1 sample to represent any or all of these conditions

Task 5 - Information Gathering

(Rev. 22, Issued: 12-15-06, Effective/Implementation: 12-18-06)

Task 5 provides an organized, systematic, and consistent method of gathering information necessary to make decisions concerning whether the facility has met the requirements reviewed during the Standard Survey.

Task 5 includes the following sub-tasks:

5A General Observations of the Facility: Assessment of the environment of the facility affecting the resident's life, health and safety;

5B Kitchen/Food Service Observations: Assessment of the facility's food storage, preparation and service;

5C Resident Review: An integrated, holistic assessment of the sampled residents which includes the assessment of: drug therapies, the quality of life of the resident as affected by his/her room environment and daily interactions with staff, and assessment of those pertinent care concerns identified for each sampled resident by the survey team. Closed record reviews and dining observations are integrated into the resident review;

5D Quality of Life Assessment: Assessment of residents' quality of life through individual interviews, a group interview, family interviews, and observations of residents who are non-interviewable;

5E Medication Pass and Pharmacy Services: An assessment of the pharmaceutical services provided in the facility, including the provision of the medication pass observation; the application of the medication error detection methodology; the provision of services by a licensed pharmacist; and facility procedures and processes in place regarding the acquiring, receiving, dispensing and administering medications, use of controlled medications, and medication access and storage.

5F Quality Assessment and Assurance Review: An assessment of the facility's Quality Assessment and Assurance program to determine if the facility identifies and addresses specific care and quality issues and implements a program to resolve those issues; and

5G Abuse Prohibition Review: A determination of whether the facility has developed and operationalized policies and procedures designed to protect residents from abuse, neglect, involuntary seclusion, and misappropriation of their property. This includes policies and procedures for hiring practices, training and ongoing

supervision for employees and volunteers who provide services, and the reporting and investigation of allegations and occurrences that may indicate abuse.

Use survey worksheets and Guidance to Surveyors, also known as the Interpretive Guidelines, for each of the sub-tasks and requirements reviewed in Task 5. While these sub-tasks are discrete information gathering activities, there are a number of things to take into consideration during Task 5.

A. General Procedures

As appropriate, use the interpretations, definitions, probes, and procedures provided in the Guidance to Surveyors to guide the investigation and to help determine whether, based on the investigation and findings, the facility has met the requirements.

Worksheet documentation should be resident-centered, as appropriate. For example, if the lack of a reading light near the resident's bedroom chair is being documented, also note that this resident has said he/she prefers to read in his/her chair, and that the light over the chair is inadequate.

Relate to the requirements and provide clear evidence, as appropriate, of the facility's failure to meet a requirement. As information is collected, keep in mind that the information written on the worksheet will be used by the team to determine if there are any deficiencies, and, if so, the degree of severity and scope. Make documentation specific enough so that these decisions can be made. Include information about how the faulty facility practice affected residents, the number of residents affected, and the number of residents at risk. This documentation will be used both to make deficiency determinations and to categorize deficiencies for severity and scope. The Guidance to Surveyors assists in gathering information in order to determine whether the facility has met the requirements. For example, the facility has care plan objectives which are measurable. If the resident does not meet her/his goals, does the documentation reflect how the lack of implementation of the care plan and/or lack of quarterly assessments prevents the resident from reaching her/his goals?

In conducting the survey, use the worksheets in conjunction with the survey procedures and Guidance to Surveyors. When investigating a concern, note the tag number listed on the worksheet for that requirement and use the Guidance to Surveyors for that tag to direct the investigation.

Devote as much time as possible during the survey to performing observations and conducting formal and informal interviews. Limit record reviews to obtaining specific information, i.e., look at what is needed, not the whole record.

The information gathering tasks are interrelated. Information acquired while doing observations and interviews will direct the record review. Likewise, information obtained while doing the record review may help direct what observations or interviews are

needed. Acquire the information that is necessary to make deficiency decisions in Task 6 using the survey worksheets and corresponding Guidance to Surveyors for each of the sub-tasks in Task 5.

Regardless of the task, be alert at all times to the surrounding care environment and activities. For example, while conducting the dining observations of sampled residents and the medication pass observation, observe the environment and residents, e.g., care being given, staff interactions with residents, and infection control practices.

The team should meet on a daily basis to share information, e.g., findings to date, areas of concern, any changes needed in the focus of the survey. These meetings include discussions of concerns observed, possible requirements to which those problems relate, and strategies for gathering additional information to determine whether the facility is meeting the requirements.

Throughout the survey, discuss observations, as appropriate, with team members, facility staff, residents, family members, and the ombudsman. Maintain an open and ongoing dialogue with the facility throughout the survey process. This gives the facility the opportunity to provide additional information in considering any alternative explanations before making deficiency decisions. This, however, does not mean that every negative observation is reported on a daily basis, e.g., at a nightly conference. Moreover, if the negative observation relates to a routine that needs to be monitored over time to determine whether a deficiency exists, wait until a trend has been established before notifying the facility of the problem. If it has been verified through observation and record review that a resident's condition has declined, start the investigation to determine if this decline was avoidable or unavoidable by asking a knowledgeable facility staff member, such as the nurse or other professional staff member charged with responsibility for the resident's care, to provide documentation in the resident's chart that provides the reasons for why they believe this decline occurred. Use this information to guide the investigation, but use professional judgment and team approach to determine if a deficient practice has occurred.

In conducting the tasks of the Standard Survey, situations may be identified to indicate that the facility may not be meeting a requirement not routinely reviewed in the Standard Survey.

Investigate this further. For example, residents at the council meeting say that they have not had a visit from a physician (or extender) for several months. This would lead to an investigation of facility compliance with the requirements for frequency of physician visits.

Verify information and observations in terms of credibility and reliability. If the credibility or reliability of information is doubted, validate that information or gather additional information before using it to make a compliance decision.

B. Observations

The objectives of the observational portion of information gathering are to gather resident-specific information for the residents included in the sample, and also, to be alert to the provision of care, staff-resident interactions, and quality of life for all residents.

C. Informal and Formal Interviews

The objectives of interviews are to:

- Collect information;
- Verify and validate information obtained from other survey procedures; and
- Provide the opportunity for all interested parties to provide what they believe is pertinent information.

Interview residents, staff, family, ombudsman, family council representatives, and other appropriate persons. Informal interviews are conducted throughout the duration of the information gathering tasks of the survey. Formal structured interviews are also done as part of the Quality of Life Assessment protocols. Use the information obtained from interviews to assist in deciding what additional observations and record review information is necessary. Avoid asking leading questions, but use the Guidance to Surveyors for specific requirements to focus questions and determine the significance of the answers.

In general, the individual who provides information during an interview will not be identified as providing that information. However, it is possible that their identity may be revealed if a deficiency is cited based in whole or part on their information, and that deficiency citation is appealed.

If residents appear reticent in providing information or express concern about retaliation:

- Verify that residents have information on whom to contact in the event they become the objects of retaliation by the facility; and
- With the resident's permission, notify the ombudsman of the resident's concerns.

D. Record Review

The objectives of the record review are to:

- Acquire information to direct initial and/or additional observations and interviews;

- Provide a picture of the current status of the resident as assessed by the facility; and

- Evaluate assessments, plans of care, and outcomes of care interventions for residents included in the sample. Record review of RAI information, care planning, implementation of the care plan, and evaluation of care is one facet of the resident review which determines if there has been a decline, improvement, or maintenance in identified focus areas.

  NOTE: Do not spend excessive time gathering and recording information from the record. Use the record review to obtain information necessary to validate and/or clarify information obtained through observation and interviews. Ask facility staff to assist in finding any information that has not been found or that requires validation.

E. Determining Citations of Past Noncompliance at the Time of the Current Survey

During information gathering, findings of past noncompliance may be identified. Before considering a citation of past noncompliance with a specific regulatory tag, surveyors must determine if current compliance with the specific regulatory tag exists. Similar to verifying correction of current noncompliance on a revisit, surveyors should use a variety of methods to determine whether correction of the past noncompliance occurred and continues. This may include, but is not limited to, the following:

- Interviews with facility staff, such as the administrator, nursing staff, social services staff, medical director, quality assessment and assurance committee members, and/or other facility staff, as indicated, to determine what procedures, systems, structures, and processes have been changed.

- Reviewing through observation, interview, and record review, how the facility identified and implemented interventions to address the noncompliance. Examples of interventions may include, but are not limited to:

  - The facility's review, revision, or development of policies and/or procedures to address the areas of concerns;

  - The provision and use of new equipment, as necessary;

  - The provision of staff training required to assure ongoing compliance for the implementation and use of new and/or revised policies, procedures, and/or equipment, especially with new and/or temporary staff;

  - The provision of additional staffing, changes in assignments or deployment of staff, as needed; and

- The provision of a monitoring mechanism to assure that the changes made are being supervised, evaluated, and reinforced by responsible facility staff.

- Evaluating whether the facility has a functioning quality assessment and assurance committee, whose responsibilities include the identification of quality issues; providing timely response to ascertain the cause; implementing corrective action; implementing monitoring mechanisms in place to assure continued correction and revision of approaches as necessary to eliminate the potential risk of occurrence to other residents and to assure continued compliance.

A citation of past noncompliance must meet all of the criteria described in section H of Task 6 below.

Sub-Task 5A - General Observations of the Facility

(Rev. 22, Issued: 12-15-06, Effective/Implementation: 12-18-06)

A. General Objective

The general objective of this task is to observe physical features in the facility's environment that affect residents' quality of life, health, and safety. Use the General Observations of the Facility worksheet (Form CMS-803, Exhibit 91) to complete this task.

B. General Procedures

During the Initial Tour, each surveyor should note and document any concerns in resident rooms and the general environment. Any concerns should be investigated and followed up either through the resident review for sampled residents or during the General Observation task. During the remainder of the survey, one surveyor is assigned to complete the General Observation of the Facility worksheet (Form CMS-803). This surveyor assures that all items on this worksheet are completed. Each surveyor who completes a medication pass observation should review medication storage on the assigned units and provide information regarding that review to the assigned surveyor responsible for the completion of Form CMS-803. All surveyors should share any additional concerns regarding the environment with the surveyor assigned to complete the worksheet. Begin observations as soon as possible after entering the facility, normally after introductions at the entrance conference.

During Task 5A, review the condition of the environment, e.g., cleanliness, sanitation, presence or absence of pests, accident hazards, functioning of equipment, and the proper and safe storage of drugs, biologicals, housekeeping compounds and equipment. (See Form CMS-803 worksheet for specific areas to review.)

C. Making Observations

The focus in Task 5A is on quality of life and environmental health and safety indicators in areas of the facility that would be visited or used by residents. However, some non-resident areas should also be reviewed due to their potential negative effect on residents, e.g., utility rooms.

Document thoroughly at the time of observations. If additional documentation space is needed, use the Surveyor Notes Worksheet Form CMS-807.

Plan to observe the facility's environment at different times during the survey, e.g., first and second shift, common areas when in use by residents.

Share any concerns with the team coordinator and other team members to determine the possible need to gather additional information.

Sub-Task 5B - Kitchen/Food Service Observation

A. General Objective

The general objective of the Kitchen/Food Service Observation is to determine if the facility is storing, preparing, distributing, and serving food according to 42 CFR 483.35(h)(2) to prevent food borne illness.

B. General Procedures

One surveyor is assigned to conduct the Kitchen/Food service observation.

> **NOTE**: The surveyor assigned to complete this task should begin the task with a brief visit to the kitchen as part of the initial tour, in order to observe the sanitation practices and cleanliness of the kitchen. Observe whether potentially hazardous foods have been left on counter tops or steam table and/or being prepared, the manner in which foods are being thawed, the cleanliness, sanitary practices, and appearance of kitchen staff, e.g., appropriate attire, hair restraints.

Use the Kitchen/Food Service Observation worksheet to direct observations of food storage, food preparation, and food service/sanitation. (See Kitchen/Food Service Observation worksheet (Form CMS-804, Exhibit 92) for specific areas to review).

In addition to completion of the Form CMS-804, also evaluate:

- The availability of food in relation to the number of residents; and
- Whether food being prepared is consistent with the written, planned menu.

NOTE: During team meetings, if surveyors, during the Dining Observation portion of the Resident Review, identified any concerns, such as the provision of meals that are not consistent in quality (such as color and texture of vegetables or meats, the preparation and presentation of mechanically altered foods); complaints regarding taste or texture of food and foods with an "off" or bad odor; or residents being at nutritional risk, including high prevalence of residents with unintended weight loss; then the surveyor assigned to Task 5(b) should review the following as appropriate.

Direct observations to the tray line and kitchen to determine:

- If recipes are available and consistent with the menu and followed by employees;
- If appropriate equipment is available and used to prepare and serve foods;
- If the food is being held for more than 30 minutes prior to food service, e.g., in the steam table, oven, refrigerator rather than freezer for frozen foods, etc.; and
- If cooked leftovers used during food preparation were stored and used within the appropriate time frames, and reheated to at least 165 degrees F.

Sub-Task 5C - Resident Review

(Rev. 42: Issued: 04-24-09; Effective/Implementation Date: 04-24-09)

A. General Objectives

The general objectives of the Resident Review are to determine:

- How resident outcomes and the resident's quality of life are related to the provision of care by the facility;
- If the care provided by the facility has enabled residents to reach or maintain their highest practicable physical, mental, and psychosocial well-being;
- If residents are assisted to have the best quality of life that is possible. The review will include aspects of the environment, staff interactions, and provision of services that affect sampled residents in their daily lives;
- If the facility has properly assessed its residents through the completion of the Resident Assessment Instrument (RAI), including accurate coding and transmitting of the Minimum Data Set (MDS) and has properly assessed care needs, conducted proper care planning, implemented the plan and evaluated care provided to the residents; and

- If there are additional areas of concern that need to be investigated in Phase II of the survey.

B. General Procedures

The team coordinator assigns specific residents in the sample to surveyors.

One surveyor should conduct the entire Resident Review for an assigned resident. If the resident has been chosen for a Quality of Life Assessment protocol (Task 5D), this same surveyor should also complete that protocol. If a surveyor has not passed the Surveyor Minimum Qualifications Test (SMQT) or if the complexity of a resident's care requires expertise of more than one discipline, surveyors should work jointly to complete the review. A surveyor must successfully complete the SMQT to survey independently.

To facilitate the Resident Review, ask the charge nurse for schedules of the following, as appropriate:

1. Meals;

2. Medications;

3. Activities;

4. Tube feedings and special treatments;

5. Specialized rehabilitation therapies; and

6. Physician visits or visits of other health professionals such as dentists, podiatrists, or nurse practitioners.

For all sampled residents except closed records, parts A, B, and C (Resident Room Review, Daily Life Review, and Assessment of Drug Therapies) on the Resident Review Worksheet (Exhibit 93) are completed. The difference between the two reviews is that the focus of the part D Care Review is more extensive for Comprehensive Reviews. Determine, as appropriate, if there has been a decline, maintenance or improvement of the resident in the identified focused care areas and/or Activities of Daily Living (ADL) functioning. If there has been a lack of improvement or a decline, determine if the decline or lack of improvement was avoidable or unavoidable.

C. Comprehensive Care Review

A Comprehensive Review includes observations, interviews, and a record review. After observing and talking with the resident, the surveyor conducts a comprehensive review, which includes the following:

- A check of specific items on the MDS for accurate coding of the resident's condition. The specific items to be checked will be based on QM/QIs identified for the resident on the Resident Level Summary. At least 2 of the QM/QIs identified for the resident must be matched against the QM/QI definitions (see Exhibit 270) and against evidence other than the MDS to verify that the resident's condition is accurately recorded in the MDS. What is being verified is that the resident's condition was accurately assessed at the time the MDS was completed;

- An overall review of the facility's completion of the RAI process including their:

    - Use of the Resident Assessment Protocols (RAPs);

    - Evaluation of assessment information not covered by the RAPs;

    - Identification of risks and causes of resident conditions;

    - Completion of the RAP Summary;

    - Development of a care plan that meets the identified needs of the resident;

- A review of the implementation of the care plan and resident response;

- A review of the relationship of the resident's drug regimen to the resident's condition (see the description of procedures for completing part C below);

- A thorough review of any of the following conditions that apply to the resident: weight loss, dehydration, pressure sores. This review is completed using the investigative protocols found below as a guide. (NOTE: All the residents selected for comprehensive reviews should have one or more of these concerns checked on the QM/QI reports [unless there are no residents with these concerns in the facility]); and

- An evaluation of the resident's dining experience (see Dining Observation Protocol below).

D. Focused Care Review Phase 1

This focused review includes observations, interviews, and a record review. This review focuses on care areas that were checked for the resident on the Resident Level Summary and any additional care items checked by the team as pertinent to the resident, e.g., all areas that are checked on the Roster/Sample Matrix by the team for the resident are reviewed, whether or not they have been highlighted as concerns for the survey. The dining observation is done for a resident if the resident has any checkmarks related to dining or the investigating team member has any concerns about the resident related to dining, e.g., such as weight loss.

The Phase 1 focused care review includes all care areas the team has checked for the resident: a review of the MDS, the facility's use of the RAPs, care planning, implementation of the care plan, and the resident's response to the care provided.

E. Focused Care Review Phase 2

This focused review includes observations, interviews and a record review, which concentrates only on those areas of concern for which the team requires additional information. For example, if the team needs additional information concerning facility compliance with the requirements for tube feeding, review only those RAI areas related to tube feeding; make observations of nutritional status, complications, and techniques of tube feeding, and interview residents, family and staff concerning related areas.

F. Closed Record Review

This includes a record review of the resident's care issues and transfer and discharge requirements. It may be possible to select some or all of the closed records from the preselected list of residents for the Phase 1 sample, if any of these preselected residents were noted onsite to be discharged or deceased.

Assess quality of care and quality of life requirements that relate to the identified care areas for the sampled resident. While assessing these, note and investigate concerns with any other requirements.

G. Conducting the Resident Review

The Resident Review consists of 4 main sections: Resident Room Review, Daily Life Review, Assessment of Drug Therapies, and Care Review. See Resident Review Worksheet and instructions (Form CMS-805, Exhibit 93) for specific areas to review.

1. Section A - The Resident Room Review assesses aspects of accommodation of needs, environmental quality, and quality of life in the resident's room. Through observations and interviews, evaluate how the resident's environment affects his/her quality of life.

2. Section B - The Daily Life Review is a review of the resident's daily quality of life, especially in the areas of staff responsiveness to resident grooming and other needs, staff interactions, choices, and activities. Through ongoing observations and interviews, evaluate the resident's daily life routines and interactions with staff.

3. Section C - The Assessment of Drug Therapies is a review of the medications the resident is receiving to evaluate whether the effectiveness of the therapeutic regimen, including all drugs that may play a significant role in the resident's

everyday life, is being monitored and assessed. Record the information on the Resident Review Worksheet, Form CMS-805. Review and record, as pertinent, all non-prescription and prescription medications taken by the resident during the past 7 days. In addition follow the guidance in Appendix PP, Tag F329 for the determination of unnecessary medications.

4. Section D -- The care review is an assessment of those quality of care areas (see 42 CFR 483.25) that are pertinent to the sampled resident. The survey team, through use of the Roster/Sample Matrix, determines what care areas will be reviewed for each sampled resident. Additional areas for evaluation may be identified during the review.

   There are a designated number of comprehensive, focused and closed record care reviews completed, depending on the size of the sample.

H. Care Observations and Interviews -- Make resident observations and conduct interviews, which include those factors or care areas as determined by the Roster/Sample Matrix. For example, if the resident was chosen because he/she is receiving tube feedings, observe the care and the outcomes of the interventions, facility monitoring and assessment, and nutritional needs/adequacy related to tube feeding.

Complete the following tasks:

- Observe the resident and caregivers during care and treatments, at meals, and various times of the day, including early morning and evening, over the entire survey period. Observe residents in both informal and structured settings, e.g., receiving specialized rehabilitation services, participating in formal and informal activities. Also, observe staff-resident interactions;

- Gather resident-specific information, including information on the resident's functional ability, potential for increasing ability, and any complications concerning special care needs;

- Evaluate implementation of the care plan. Determine if the care plan is consistently implemented by all personnel at all times of the day, and if the care plan is working for the resident. If the care plan is not working, look for evidence that the facility has identified this and acted on it even if the care plan has not formally been revised;

- Determine if there is a significant difference between the facility's assessment of the resident and observations; and

- Evaluate the adequacy of care provided to the resident using the Guidance to Surveyors.

Do not continue to follow residents once enough information has been accrued to determine whether the resident has received care in accordance with the regulatory requirements.

If there are indicators to suggest the presence of a quality of care problem that is not readily observable, e.g., a leg ulcer covered with a dressing, or a sacral pressure sore, ask facility staff to assist in making observations by removing, for example, a dressing or bedclothes.

Resident care observations should be made by those persons who have the clinical knowledge and skills to evaluate compliance.

When observing residents, respect their right to privacy, including the privacy of their bodies. If the resident's genital or rectal area or female breast area must be observed in order to document and confirm suspicions of a care problem, a member of the nursing staff must be present at this observation, and the resident must give clear consent.

If the resident is unable to give consent, e.g., is unresponsive, incompetent, and a legal surrogate (family member who can act on the resident's behalf or legal representative as provided by State law) is present, ask this individual to give consent.

An observation of a resident's rectal or genital area (and for females, the breast area) may be made without a resident's or legal surrogate's consent, under the following conditions:

1. It is determined that there is a strong possibility that the resident is receiving less than adequate care, which can only be confirmed by direct observation;

2. The resident is unable to give clear consent; and

3. A legal surrogate is not present in the facility.

Only a surveyor who is a licensed nurse, a physician's assistant or a physician may make an observation of a resident's genitals, rectal area, or, for females, the breast area.

I. Record Review

Conduct a record review to provide a picture of the current status of the resident as assessed by the facility; information on changes in the resident's status over the last 12 months for those areas identified for review; and information on planned care, resident goals, and expected outcomes.

Use the record review to help determine whether the assessments accurately reflect the resident's status and are internally consistent. An example of inconsistency may be that the facility assessed the resident's ADLs as being independently performed yet had indicated that the resident requires task segmentation for performing ADLs.

For sampled residents selected for either a comprehensive or a focused review, conduct a review of the RAI information including:

- The face sheet of the MDS for background information including customary routines and demographic information to provide an understanding of the resident prior to admission. This assists in assessing the quality of life of the resident.

- The latest MDS to determine which RAPS were triggered. For a sampled resident receiving a comprehensive review, note all triggered areas. Also, review the facility's assessment of the resident's level of functioning and note particularly drug therapy and cognitive, behavior, and ADL function. For a resident receiving a focused review in Phase I of the survey, review both the areas of concern specific to the resident and the other care areas that have been identified with the Roster/Sample Matrix. For Phase 2 residents, review only those areas that have been identified by the team as areas of concern.

If the RAI is less than 9 months old, review and compare with the previous RAI and the most recent quarterly review. If the RAI is 9 months or older, compare the current RAI with the most recent quarterly review. Review the following:

- The RAP summary sheet to see where the assessment documentation is located for any RAP triggered;

- The information summarizing the assessments (RAPS) and decision to proceed or not to proceed to care planning. Determine if the assessments indicate that the facility used the RAPs and considered the nature of the problem, the causal and risk factors, the need for referrals, complications, and decisions for care planning. If this is a reassessment, review whether the facility determined if the care plan required revision or was effective in moving the resident toward his/her goals;

- The care plan to identify whether the facility used the RAI to make sound care planning decisions. Determine whether the facility identified resident strengths, needs, and problems which needed to be addressed to assist the resident to maintain or improve his/her current functional status. Determine whether the facility identified resident-centered, measurable goals and specific interventions to achieve those goals. With observations, interviews, and record review, determine if the facility implemented the interventions defined; and

- Determine whether the facility documentation and resident status as observed indicate the decision to proceed or not to proceed to care planning was

appropriate. This information will assist in determining whether a resident's decline or failure to improve was avoidable or unavoidable.

- It is not necessary to review the entire resident record. Review only those sections that are necessary to verify and clarify the information necessary to make compliance decisions. These sections may include, for example, laboratory reports, progress notes, and drug regimen review reports.

- In any care area in which it is determined that there has been a lack of improvement, a decline, or failure to reach highest practicable well being, assess if the change for the resident was avoidable or unavoidable. Note both the faulty facility practice and its effect on resident(s). Determine if a reassessment based on significant change should have been conducted, and if the absence of reassessment contributed to the resident's decline or lack of improvement.

- Verify that the information needed has been obtained to determine if the facility fulfilled its obligation to provide care that allowed the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being.

NOTE: When conducting either a focused or comprehensive review, if there are areas of concern which fall outside the care areas identified, investigate these, as necessary.

The following are special investigative protocols which should be used in Task 5C to gather information and in Task 6, to determine facility compliance in the care areas of pressure sore/ulcer(s), hydration, unintended weight loss, sufficient nursing staffing, and dining and food services.

NOTE: "Although the RAI assessments discussed in the following [investigative protocols] must occur at specific times, by Federal regulation, a facility's obligation to meet each resident's needs through ongoing assessment is not neatly confined to these mandated time frames. Likewise, completion of the RAI in the prescribed time frame does not necessarily fulfill a facility's obligation to perform a comprehensive assessment. Facility's are responsible for assessing areas that are relevant to individual residents regardless of whether these areas are included in the RAI." ("CMS Long-Term Care Facility Resident Assessment Instrument User's Manual," Version 2.0.)

Investigative Protocol

Hydration

Objectives:

- To determine if the facility identified risk factors which lead to dehydration and developed an appropriate preventative care plan; and

- To determine if the facility provided the resident with sufficient fluid intake to maintain proper hydration and health.

Task 5C: Use:

Use this protocol for the following situations:

- A sampled resident who flagged for the sentinel event of dehydration (QM/QI 7.3);

- A sampled resident who has one or more of the following QM/QI conditions:

    - 5.4 – Prevalence of fecal impaction;

    - 6.1 – Residents with a urinary tract infection;

    - 7.1 – Residents who lose too much weight;

    - 7.2 – Prevalence of tube feeding;

    - 9.1 – Residents whose need for help with daily activities has increased; and

    - Any of the three pressure ulcer QM/QIs: 12.1, 12.2, or 13.3.

- A sampled resident who was discovered to have any of the following risk factors: vomiting/diarrhea resulting in fluid loss, elevated temperatures and/or infectious processes, dependence on staff for the provision of fluid intake, use of medications including diuretics, laxatives, and cardiovascular agents, renal disease, dysphagia, a history of refusing fluids, limited fluid intake or lacking the sensation of thirst.

Procedures:

- Observations/interviews conducted as part of this procedure should be recorded on the Forms CMS-805 and/or the Form CMS-807.

- Determine if the resident was assessed to identify risk factors that can lead to dehydration, such as those listed above and whether there were abnormal laboratory test values which may be an indicator of dehydration.

NOTE: A general guideline for determining baseline daily fluid needs is to multiply the resident's body weight in kilograms (kg) x 30ml (2.2 lbs = 1 kg), except for residents with renal or cardiac distress, or other restrictions based on physician orders. An excess of fluids can be detrimental for these residents.

- Determine if an interdisciplinary care plan was developed utilizing the clinical conditions and risk factors identified, taking into account the amount of fluid that the resident requires. If the resident is receiving enteral nutritional support, determine if the tube feeding orders included a sufficient amount of free water, and whether the water and feeding are being administered in accordance with physician orders?

- Observe the care delivery to determine if the interventions identified in the care plan have been implemented as described.

    - What is the resident's response to the interventions? Does staff provide the necessary fluids as described in the plan? Do the fluids provided contribute to dehydration, e.g., caffeinated beverages, alcohol? Was the correct type of fluid provided with a resident with dysphagia?

    - Is the resident able to reach, pour and drink fluids without assistance and is the resident consuming sufficient fluids? If not, are staff providing the fluids according to the care plan?

    - Is the resident's room temperature (heating mechanism) contributing to dehydration? If so, how is the facility addressing this issue?

    - If the resident refuses water, are alternative fluids offered that are tolerable to the resident?

    - Are the resident's beverage preferences identified and honored at meals?

    - Does staff encourage the resident to drink? Are they aware of the resident's fluid needs? Are staff providing fluids during and between meals?

    - Determine how the facility monitors to assure that the resident maintains fluid parameters as planned. If the facility is monitoring the intake and output of the resident, review the record to determine if the fluid goals or calculated fluid needs were met consistently.

- Review all related information and documentation to look for evidence of identified causes of the condition or problem. This inquiry should include interviews with appropriate facility staff and health care practitioners, who by

level of training and knowledge of the resident, should know of, or be able to provide information about the causes of a resident's condition or problem.

NOTE: If a resident is at an end of life stage and has an advance directive, according to State law, (or a decision has been made by the resident's surrogate or representative, in accordance with State law) or the resident has reached an end of life stage in which minimal amounts of fluids are being consumed or intake has ceased, and all appropriate efforts have been made to encourage and provide intake, then dehydration may be an expected outcome and does not constitute noncompliance with the requirement for hydration. Conduct observations to verify that palliative interventions, as described in the plan of care, are being implemented and revised as necessary, to meet the needs/choices of the resident in order to maintain the resident's comfort and quality of life. If the facility has failed to provide the palliative care, cite noncompliance with 42 CFR 483.25, F309, Quality of Care.

- Determine if the care plan is evaluated and revised based on the response, outcomes, and needs of the resident.

Task 6: Determination of Compliance:

- Compliance with 42 CFR 483.25(j), F327, Hydration:
    - For this resident, the facility is compliant with this requirement to maintain proper hydration if they properly assessed, care planned, implemented the care plan, evaluated the resident outcome, and revised the care plan as needed. If not, cite at F327.
- Compliance with 42 CFR 483.20(b)(1) & (2), F272, Comprehensive Assessments:
    - For this resident in the area of hydration, the facility is compliant with this requirement if they assessed factors that put the resident at risk for dehydration, whether chronic or acute. If not, cite at F272.
- Compliance with 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans:
    - For this resident in the area of hydration, the facility is compliant with this requirement if they developed a care plan that includes measurable objectives and timetables to meet the resident's needs as identified in the resident's assessment. If not, cite at F279.
- Compliance with 42 CFR 483.20(k)(3)(ii), F 282, Provision of care in accordance with the care plan:

- For this resident in the area of hydration, the facility is compliant with this requirement if qualified persons implemented the resident's care plan. If not, cite at F282.

Investigative Protocol

Dining and Food Service

Objectives:

- To determine if each resident is provided with nourishing, palatable, attractive meals that meet the resident's daily nutritional and special dietary needs;
- To determine if each resident is provided services to maintain or improve eating skills; and
- To determine if the dining experience enhances the resident's quality of life and is supportive of the resident's needs, including food service and staff support during dining.

Task 5C: Use

This protocol will be used for:

- All sampled residents identified with malnutrition, unintended weight loss, mechanically altered diet, pressure sores/ulcers, and hydration concerns; and
- Food complaints received from residents, families and others.

General Considerations:

- Use this protocol at two meals during the survey, preferably the noon and evening meals.
- Record information on the Form CMS-805 if it pertains to a specific sampled resident, or on the Form CMS-807 if it relates to the general observations of the dining service/dining room.
    - Discretely observe all residents, including sampled residents, during meals keeping questions to a minimum to prevent disruption in the meal service.
- For each sampled resident being observed, identify any special needs and the interventions planned to meet their needs. Using the facility's menu, record in

writing what is planned in writing to be served to the resident at the meal observed.

- Conduct observations of food preparation and quality of meals.

Procedures:

1. During the meal service, observe the dining room and/or resident's room for the following:

    - Comfortable sound levels;
    - Adequate illumination, furnishings, ventilation; absence of odors; and sufficient space;
    - Tables adjusted to accommodate wheelchairs, etc.; and
    - Appropriate hygiene provided prior to meals.

2. Observe whether each resident is properly prepared for meals. For example:

    - Resident's eyeglasses, dentures, and/or hearing aids are in place;
    - Proper positioning in chair, wheelchair, gerichair, etc., at an appropriate distance from the table (tray table and bed at appropriate height and position); and
    - Assistive devices/utensils identified in care plans provided and used as planned.

3. Observe the food service for:

    - Appropriateness of dishes and flatware for each resident. Single use disposable dining ware is not used except in an emergency and, other appropriate dining activities. Except those with fluid restriction, each resident has an appropriate place setting with water and napkin;
    - Whether meals are attractive, palatable, served at appropriate temperatures and are delivered to residents in a timely fashion.
        - Did the meals arrive 30 minutes or more past the scheduled mealtime?
        - If a substitute was needed, did it arrive more than 15 minutes after the request for a substitute?

- Are diet cards, portion sizes, preferences, and condiment requests being honored?

4. Determine whether residents are being promptly assisted to eat or provided necessary assistance/cueing in a timely manner after their meal is served.
    - Note whether residents at the same table or in resident rooms, are being served and assisted concurrently.

- If you observe a resident who is being assisted by a staff member to eat or drink, and the resident is having problems with eating or drinking, inquire if the staff member who is assisting them is a paid feeding assistant. If so, follow the procedures at tag F373.

5. Determine if the meals served were palatable, attractive, nutritious and met the needs of the resident. Note the following:

    - Whether the resident voiced concerns regarding the taste, temperature, quality, quantity and appearance of the meal served;

    - Whether mechanically altered diets, such as pureed, were prepared and served as separate entree items (except when combined food, e.g., stews, casseroles, etc.);

    - Whether attempts to determine the reason(s) for the refusal and a substitute of equal nutritive value was provided, if the resident refused/rejected food served; and

    - Whether food placement, colors, and textures were in keeping with the resident's needs or deficits, e.g., residents with vision or swallowing deficits.

    Sample Tray Procedure

    If residents complain about the palatability/temperature of food served, the survey team coordinator may request a test meal to obtain quantitative data to assess the complaints. Send the meal to the unit that is the greatest distance from the kitchen or to the affected unit or dining room. Check food temperature and palatability of the test meal at about the time the last resident on the unit is served and begins eating.

6. Observe for institutional medication pass practices that interfere with the quality of the residents' dining experience. This does not prohibit the administration of medications during meal service for medications that are necessary to be given at a meal, nor does this prohibit a medication to be given during a meal upon request of a

resident who is accustomed to taking the medication with the meal, as long as it has been determined that this practice does not interfere with the effectiveness of the medication.

- Has the facility attempted to provide medications at times and in a manner to support the dining experience of the resident, such as:
    - Pain medications being given prior to meals so that meals could be eaten in comfort;
    - Foods served are not routinely or unnecessarily used as a vehicle to administer medications (mixing the medications with potatoes or other entrees).

7. Determine if the sampled resident consumed adequate amounts of food as planned.

    - Determine if the facility is monitoring the foods/fluids consumed. Procedures used by the facility may be used to determine percentage of food consumed, if available; otherwise, determine the percentage of food consumed using the following point system:
        - Each food item served except for water, coffee, tea, or condiments equals one point. Example: Breakfast: juice, cereal, milk, bread and butter, coffee (no points) equals four points. If the resident consumes all four items in the amount served, the resident consumes 100% of breakfast. If the resident consumes two of the four food items served, then 50% of the breakfast would have been consumed. If three-quarters of a food item is consumed, give one point; for one-half consumed, give .5 points; for one-fourth or less, give no points. Total the points consumed x 100 and divide by the number of points given for that meal to give the percentage of meal consumed. Use these measurements when determining the amount of liquids consumed: Liquid measurements: 8 oz. cup = 240 cc, 6 oz. cup = 180 cc, 4 oz. cup = 120 cc, 1 oz. cup = 30 cc.
        - Compare these findings with the facility's documentation to determine if the facility has accurately recorded the intake. Ask the staff if these findings are consistent with the resident's usual intake; and
        - Note whether plates are being returned to the kitchen with 75% or more of food not eaten.

8. If concerns are noted with meal service, preparation, quality of meals, etc., interview the person(s) responsible for dietary services to determine how the staff are assigned and monitored to assure meals are prepared according to the menu, that the meals are

delivered to residents in a timely fashion, and at proper temperature, both in the dining rooms/areas and in resident rooms.

NOTE: If concerns are identified in providing monitoring by supervisory staff during dining or concerns with assistance for residents to eat, evaluate nursing staffing in accord with 42 CFR 483.30(a), F353, and quality of care at 42 CFR 483.25(a)(2) and (3).

Task 6: Determination of Compliance:

- Compliance with 42 CFR 483.35(d)(1)(2), F364, Food
  - The facility is compliant with this requirement when each resident receives food prepared by methods that conserve nutritive value, palatable, attractive and at the proper temperatures. If not, cite F364.
- Compliance with 42 CFR 483.35(b), F362, Dietary services, sufficient staff
  - The facility is compliant with this requirement if they have sufficient staff to prepare and serve palatable and attractive, nutritionally adequate meals at proper temperatures. If not, cite F362.

  NOTE: If serving food is a function of the nursing service rather than dietary, refer to 42 CFR 483.30(a), F353.
- Compliance with 42 CFR 483.15(h)(1), F252, Environment
  - The facility is compliant with this requirement if they provide a homelike environment during the dining services that enhances the resident's quality of life. If not, cite F252.
- Compliance with 42 CFR 483.70(g)(1)(2)(3)(4), F464, Dining and Resident Activities
  - The facility is compliant with this requirement if they provide adequate lighting, ventilation, furnishings and space during the dining services. If not, cite F464.

Investigative Protocol

Nursing Services, Sufficient Staffing

Objectives:

- To determine if the facility has sufficient nursing staff available to meet the residents' needs.

- To determine if the facility has licensed registered nurses and licensed nursing staff available to provide and monitor the delivery of resident care.

Task 5C: Use:

NOTE: This protocol is not required during the standard survey, unless it is triggered in the event of care concerns/problems which may be associated with sufficiency of nursing staff. It is required to be completed for an extended survey.

This protocol is to be used when:

- Quality of care problems have been identified, e.g., residents not receiving the care and services to prevent pressure sore/ulcer(s), unintended weight loss and dehydration, and to prevent declines in their condition as described in their comprehensive plans of care, such as bathing, dressing, grooming, transferring, ambulation, toileting, and eating; and

- Complaints have been received from residents, families or other resident representatives concerning services, e.g., care not being provided, call lights not being answered in a timely fashion, and residents not being assisted to eat.

Procedures:

- Determine if the registered/licensed nursing staff are available to:

    - Supervise and monitor the delivery of care by nursing assistants according to residents' care plans;

    - Assess resident condition changes;

    - Monitor dining activities to identify concerns or changes in residents' needs;

    - Respond to nursing assistants' requests for assistance;

    - Correct inappropriate or unsafe nursing assistants techniques; and

    - Identify training needs for the nursing assistants.

- If problems were identified with care plans/services not provided as needed by the resident, focus the discussion with supervisory staff on the situations which led to using the protocol: how do they assure that there are adequate staff to meet the

needs of the residents; how do they assure that staff are knowledgeable about the needs of the residents and are capable of delivering the care as planned; how do they assure that staff are appropriately deployed to meet the needs of the residents; how do they provide orientation for new or temporary staff regarding the resident needs and the interventions to meet those needs; and how do they assure that staff are advised of changes in the care plan?

- Determine if nursing assistants and other nursing staff are knowledgeable regarding the residents' care needs, e.g., the provision of fluids and foods for residents who are unable to provide these services for themselves; the provision of turning, positioning and skin care for those residents identified at risk for pressure sore/ulcers; and the provision of incontinence care as needed;

- If necessary, review nursing assistant assignments in relation to the care and or services the resident requires to meet his/her needs;

- In interviews with residents, families and/or other resident representatives, inquire about the staff's response to requests for assistance, and the timeliness of call lights being answered; and

- Determine if the problems are facility-wide, cover all shifts or if they are limited to certain units or shifts, or days of the week. This can be based on information already gathered by the team with additional interviews of residents, families, and staff, as necessary.

Task 6: Determination of Compliance:

NOTE: Meeting the State-mandated staffing ratio, if any, does not preclude a deficiency of insufficient staff if the facility is not providing needed care and services to residents.

- Compliance with 42 CFR 483.30(a), F353, Sufficient Staff:

    - The facility is compliant with this requirement if the facility has provided a sufficient number of licensed nurses and other nursing personnel to meet the needs of the residents on a 24-hour basis. If not, cite F353.

J. Closed Record Reviews

Closed records are included in the total resident sample. If possible, select closed records of residents who have been identified through the use of offsite information concerning a particular care issue. If there is a care area that is an identified concern, try to obtain the closed records of residents who had the same care needs before death, discharge, or transfer. Document information on the Form CMS-805, Sections C and D, as appropriate.

Look for information to determine compliance with quality of care and other requirements such as:

- Assessment and care of infections;
- Pressure sores;
- Significant weight loss;
- Restraints;
- Multiple falls or injuries;
- Discharge planning; and
- Transfer and discharge requirements.

Unless there is a reason to review the entire record, focus the review on the appropriateness of care and treatment surrounding the resident's discharge or transfer, and the events leading up to that discharge or transfer. For example, if the survey team has identified a concern with inadequate identification and care of residents with infections, and several residents have recently been hospitalized with serious infections, the review would be a focused review on the care and assessment these residents received before they were hospitalized. In addition:

- Look for documentation related to transfer, discharge, and bed-hold, including facility's discharge planning, notices, and reasons for facility-initiated moves, e.g., proper planning and transferring subsequent to a change in payor or care needs; and

- Determine if within 30 days of the death of a resident, the facility conveyed the deceased resident's personal funds and a final accounting to the individual or probate jurisdiction administering the individual's estate as provided by State law (see 42 CFR 483.10(c)(6), F160).

K. Review of Influenza and Pneumococcal Immunizations

Use the Investigative Protocol contained at Tag F334 to complete a review of the implementation of the facility's immunization policies and procedures.

L. Liability Notices and Beneficiary Appeal Rights

Medicare-participating long term care facilities are obligated to inform Medicare Part A and B beneficiaries about specific rights related to billing, and to submit bills to the Fiscal

Intermediary (FI) or Medicare Administrative Contractor (MAC) when requested by the beneficiary. In a Medicare-participating long term care facility, verify compliance with these requirements.

Listed below are the requirements of the Skilled Nursing Facility (SNF).

1. If a SNF provider believes on admission or during a resident's stay that Medicare will not pay for skilled nursing or specialized rehabilitative services, and that an otherwise covered item or service may be denied as not reasonable and necessary, the facility must notify the resident or his/her legal representative in writing and explain:

    - Why these specific services may not be covered;
    - The beneficiary's potential liability for payment for the non-covered services;
    - The beneficiary right to have a claim submitted to Medicare; and
    - The beneficiary's standard claim appeal rights that apply if the claim is denied by Medicare.

    This notice requirement may be fulfilled by use of either the Skilled Nursing Facility Advanced Beneficiary Notice (SNFABN) (Form CMS-10055) **or** one of the five uniform Denial Letters. The SNFABN and the Denial Letters inform the beneficiary of his/her right to have a claim submitted to Medicare and advises them of the standard claim appeal rights that apply if the claim is denied by Medicare. These claims are often referred to as "demand bills" and are reviewed by the FI or MAC. (See Chapter 1, §60.3 of the Medicare Claims Processing Manual, Pub. 100-04 for detailed instructions on submitting institutional demand bills.) The SNF:

    - Must keep a copy of the SNFABN or Denial Notice on file;
    - Must file a claim when requested by the beneficiary; and
    - May not charge the resident for Medicare covered Part A services while a decision is pending.

2. The SNF must issue the Notice of Medicare Provider Non-coverage (Form CMS-10123) when there is a termination of all Medicare Part A services for coverage reasons. The Notice of Medicare Provider Non-coverage informs the beneficiary of his/her right to an expedited review of a service termination by the Quality Improvement Organization (QIO). The Notice to Medicare Provider Non-coverage is sometimes referred to as an "Expedited Appeal Notice" or a "Generic Notice." The SNF should not issue this notice if the beneficiary exhausts the Medicare covered

days as the number of SNF benefit days is set in law and the QIO cannot extend the benefit period. Thus, a service termination due to the exhaustion of benefits is not considered a termination for "coverage" reasons. The SNF:

- Must keep a copy of the Notice of Medicare Provider Non-coverage on file;
- Must file a claim when requested by the beneficiary; and
- May not charge the resident for Medicare covered Part A services while a decision is pending.

Failure to provide written liability of payment and/or appeal notice(s), to submit the bill (if requested by a resident), or to charge the resident for Medicare covered Part A services while a decision is pending may constitute a violation of the facility's provider agreement. Refer to S&C-09-20 or go to http://www.cms.hhs.gov/bni/ for more details about liability notices and resident appeal rights.

Procedure to Determine Compliance

1. During the entrance conference, obtain a list of Medicare beneficiaries who requested demand bills in the past 6 months. From the list, randomly select one resident's file to determine if the facility submitted the bill to the FI or MAC. In general, Medicare claims must be filed within one full calendar year following the year in which the services were provided. (For more information, refer to 42 CFR 424.44 and the Medicare Claims Processing Manual, Pub. 100-04, Chapter 1, General Billing Requirements, §70.1.) If the facility failed to submit the bill to the FI or MAC within the required time frame or charged the resident while the decision was pending, the facility is in violation of the provider agreement with respect to resident billing requirements. Cite Tag F492, 42 CFR 483.75(b), Compliance with Federal, State and local laws and professional standards, and refer to 42 CFR 489.21, Specific limitations on charges.

   NOTE: If no Medicare beneficiaries requested a demand bill in the past 6 months, this portion of the review is complete, and the surveyor should continue with the closed record review.

2. During closed record review, review three charts of discharged Medicare beneficiaries from the SNF. If the current closed record review sample does not include three Medicare beneficiaries discharged from the SNF, expand the sample. Look for a copy of appropriate liability and appeal notice(s). If the facility failed to provide the resident the appropriate liability and/or appeal notice(s), the facility is in violation of the notice requirements. Cite Tag F156, 42 CFR 483.10, Resident Rights.

If the record indicates the resident requested the facility submit the bill for appeal, determine if the facility submitted the bill to the FI or MAC within the required time frame. In general, Medicare claims must be filed within one full calendar year following the year in which the services were provided. (For more information refer to 42 CFR 424.44 and the Medicare Claims Processing Manual, Pub. 100-04, Chapter 1, General Billing Requirements, §70.1.) If the facility failed to submit the bill to the FI or MAC within the required timeframe or charged the resident while the decision was pending, the facility is in violation of the provider agreement with respect to resident billing requirements. Cite Tag F492, 42 CFR 483.75(b), Compliance with Federal, State and local laws and professional standards, and refer to 42 CFR 489.21, Specific Limitations on Charges.

Sub-Task 5D - Quality of Life Assessment

A. Introduction

The assessment of the quality of life and rights of residents incorporates review of selected tags within the following requirements:

- 42 CFR 483.10, Resident Rights;
- 42 CFR 483.12, Admission, Transfer and Discharge Rights;
- 42 CFR 483.13, Resident Behavior and Facility Practices;
- 42 CFR 483.15, Quality of Life; and
- 42 CFR 483.70, Physical Environment.

Since quality of life and quality of care are closely interrelated concepts, the survey process holistically integrates the quality of life assessment into the following tasks or sub-tasks:

- Task 5A, General Observations of the Facility (see Task 5A for further description);
- Task 5C, Resident Review, Sections A and B (see Task 5C for further description); and
- Task 5D, Quality of Life Assessment.

B. General Objectives

The general objectives of the quality of life assessment are:

- To determine if the facility protects and promotes the rights of residents;
- To assess the impact of the facility's environment, facility schedules and policies, and staff interactions with residents on the quality of residents' lives;
- To determine if the facility is assisting residents to achieve and maintain their highest practicable well-being; and
- To determine if the facility provides equal access to quality care for all residents, regardless of payment source.

5D. Quality of Life Protocols

Task 5D includes the following sub-tasks: interviews of interviewable residents, a meeting with the resident group or council, family interviews of residents who are not interviewable, and observations of these same non-interviewable residents. These are each described below.

1. Resident Interview

These interviews are conducted with a subsample of interviewable residents from the resident sample. Refer to Table 1 in Task 4 to determine how many residents to interview. For example, in a facility with a census of 100, Table 1 directs the team to select 5 residents to interview.

It is helpful to divide the interview into two or more short segments. Seeing the resident more than once helps to establish rapport and gives the resident a chance to think over the questions and provide more information later. Surveyors are encouraged to have several short conversations with interviewable residents during the course of the survey.

Locate a private place for the interview, and arrange interview times at the resident's convenience. Resident interviews should be conducted privately unless the resident expresses a preference to have a family member, staff member or the ombudsman present.

Prior to the interview, complete question 11 by writing any concerns that have been discovered about this resident or about the facility that you would like to discuss with the resident. Issues that are already covered in the other questions of the interview need not be listed.

For example, during Offsite Survey Preparation, the team has noted that the facility has had repeated deficiencies for pest control of roaches. On the Initial Tour, it may have been noticed the resident and her roommate were speaking angrily to each other. During the survey, the team has discovered disagreeable smells in this resident's unit, low levels of lighting in the dining room and some residents who go into others' rooms and rummage through drawers. Also, add items discovered in the Resident Review about any of this resident's special needs and preferences that the facility should be taking into account. For example, a preference for a shower instead of a bath, or a need to have extra strong lighting because of a vision deficit. Add all these items to Question 11.

At the beginning of the first interview segment, use the probes on the first page of the interview to guide the explanation to the resident of the purpose of the interview. Discuss with the resident that some of his/her answers may be written down, and ask if that is all right. Then take a few minutes to establish rapport by letting the resident direct the conversation. For residents who are uncommunicative at first, use cues from their surroundings or from what is known about this resident to begin the conversation. Try to seek some commonality that will allow the resident to develop some ease in talking. For example, remark on family pictures and other personal items seen in the resident's room, or bring up a past occupation or hobby or a current activity preference of the resident that is of mutual interest. Share a little about yourself, as appropriate.

Use the resident interview protocol to guide the conversation with the resident, but bring up topics in an order that is sensible to the conversation. Probe for further information if the answer the resident is giving is incomplete or unclear. After the interview, follow-up on the concerns the resident has raised. Include in the documentation both the facility practice in question and its effect on the resident. Share these concerns with team members so that they can pursue them during the remainder of the survey. (See the tag numbers in parentheses after particular questions for interpretive guidance on following up on resident comments.)

NOTE: There are some problems that a resident will express that are not within the scope of the long-term care requirements. For example, a resident is complaining during an interview that he/she is displeased that he/she does not have a private room. This facility does not have private rooms, nor do the requirements mandate private rooms. If there is no issue related to one of the requirements, further investigation is not needed.

2. Group Interview

This interview is conducted with members of the resident council if one exists, or with an informal group of residents if there is no council. Staff members and residents' family members are not to be present at this interview unless the group specifically requests a certain person's presence. The group need not be restricted to officers of the resident council. The survey team members should feel free to invite other residents they encounter who are able to converse and provide information. The resident council should

also be encouraged to invite other residents at their discretion. It is preferable to keep the group size manageable, e.g., usually no more than 12, to facilitate communication. Residents who are not able to participate should not be included in this interview.

Prior to the meeting, review council minutes if they were provided by the council. Determine if there are any particular concerns you would like to discuss. Write in Question 13 these concerns and any other special concerns the team has learned about this facility during Offsite Survey Preparation, the Initial Tour, or during other observations and interviews. Concerns that are already covered in other questions of the interview need not be written.)

During the meeting, it may be helpful to have one surveyor conduct the interview while another takes notes. At the beginning of the meeting, use the probes on the first page of the protocol to guide introductions and describing the purpose of the interview. Spend a few minutes establishing rapport with the group by letting them direct the conversation. If residents have nothing to say at this time, use a general question such as, "Tell me what life is like in this facility," or "What makes a good day for you here?" Then continue with the protocol questions, probing for more information where necessary and presenting questions in an order that is sensible to the conversation. Get residents to talk in terms of actual situations or examples, using open-ended probes such as: "Can you tell me more about that? Can you give me an example?" or "How does that work here?"

After the meeting, follow-up on any concerns the residents have raised that are within the scope of the long-term care requirements. Share these concerns with the team to focus their investigations.

3. Interview With Family Member or Friend of Non-Interviewable Resident

The family interview is the first part of a two-part protocol. The purpose of this interview is to obtain information about the prior and current preferences of a subsample of non-interviewable residents to help assess whether the facility is individualizing daily life activities, care and services to the highest practicable level. The information gained through the interview will be used to complete Part D. below, the Observation of Non-Interviewable Resident. Follow-up on any concerns raised by the family member about the resident's treatment by the facility.

Use Table 1 in Task 4, to determine how many residents will receive the family interview and resident observation. For example, in a facility with a census of 100, 2 residents are selected.

Prior to the interview, review the relevant sections of the Minimum Data Set about past activities and preferences, and the resident's social history and activities assessment, if any. Begin completing this worksheet with information from the chart, and then use the interview to fill in missing information.

Information about a resident's past lifestyle and preferences may be more or less relevant, depending on the resident's condition and on the length of time spent in the nursing home. However, even after years of institutionalization, some features of a resident's prior life may still be relevant, even if the resident is now debilitated and uncommunicative. Collect information about how the resident's current cognitive status and physical condition have changed his/her past preferences.

Family members do not always know the prior history of a nursing home resident. Therefore, Question 1 of this interview serves to obtain information about the family member's knowledge of the resident. If the family member's answers to Question 1 show that he/she has little or no knowledge of the resident's past history, this interview may be discontinued. If discontinued, end the interview with a general question such as, "What would you like to tell me about this facility and how your relative is treated?" This resident can still remain as part of the survey sample. Select another non-interviewable resident from the sample for a family interview and observation of non-interviewable resident protocol.

If the family member has partial knowledge, the interview may be partially completed with whatever information is obtained in answer to the protocol questions.

Be aware that family members may have strong emotions about their relative's decline and institutionalization. Allow them to express their feelings, but gently direct them back to the questions of the protocol.

The interview may be conducted in person with a family member who was met on tour or by telephone, if necessary.

The second part of this protocol is the Observation of Non-Interviewable Resident. The purpose of this protocol is to obtain information through direct observation about the quality of life of the non-interviewable residents who have received family interviews.

Combine the information gained during the interview with what has been learned about the resident during the Resident Review to write any special items to observe in item 1. What special needs and preferences does this resident have that the nursing home should be taking into account? For example, a resident is ambulatory with Alzheimer's Disease. Her prior life included meeting the school bus at 3 p.m. every day to pick up her children. Now she attempts to leave the facility around that time. What is the facility doing to accommodate this agenda of the resident? Another resident enjoyed being outdoors, and the family member stated she believes this resident would still like the opportunity to go outdoors. Is the facility responding to this preference? Another resident preferred tea to coffee. Is this preference taken into account? A resident preferred to be addressed as Mrs. Hernandez. How does staff address this resident? A resident liked to ski, but can no longer do so due to her condition. However, she may like to see a movie on skiing, have a skiing picture in her room, or go outside in the snow. Has the facility noted this preference? A resident always watched a certain soap opera every day. The family

member says that even though she is now confused, this show may still attract her interest. Is this show being made available to the resident?

Use this protocol to complete approximately 1 hour of observations per resident, divided into short segments in at least three settings, at different times of the day. This need not be dedicated time -- surveyors can complete other tasks while conducting this observation. Part of the time should be spent in a location in which what is happening as staff interact with the resident in his/her room can be observed. The remainder of the time should be divided among other locations frequented by the resident, including the dining room, activities rooms, other common areas, and therapy rooms. Some observations of this resident may have already been completed prior to the interview, as part of the Resident Review. Continue making observations until all probes on the worksheet are covered, including the special items noted for observation. When making observations of the resident in particular settings, e.g., an activity or physical therapy, observations need not be for the entire duration of the activity or therapy session.

Use the probes in this protocol to guide observations. Note the areas of concern on the Resident Review Worksheet. For each concern, be specific in noting time, location, and exact observations. Record what is seen and heard, rather than a judgment of the situation. Instead of writing that the resident's dignity was violated by some interaction, simply record the interaction.

NOTE: During the individual, group and family interviews, ask questions regarding their awareness of to whom and how to report allegations, incidents and/or complaints. Share this information with the surveyor assigned to complete Task 5G.

Follow-up on areas of concern observed. For example, at lunch it was observed that the resident was given only one food item at a time. The resident was reaching out for other food and his/her drink. Determine through staff interview and chart review if this method of feeding this resident has a therapeutic purpose or if it is an unnecessary restriction on his/her freedom to select the food he/she wishes to eat.

Share observations with the team to assist them in their investigations of quality of life of other residents.

D. Follow-Up on Concerns Raised Through Interviews

Whenever information is obtained about areas of concern through resident interviews, attempt to investigate these areas through whatever means are appropriate. These might include interviews with other residents, staff, and families, and reviews of written facility information such as policies and procedures, and the admission rights information given to residents.

Sometimes these other sources will provide no other corroborating information. If that is the case, the team will determine during decision-making if the requirement is met or not met through the information obtained in resident interviews.

E. Confidentiality

If residents or family members have stated during interviews that they do not want certain information they have shared in confidence to be shared with the facility, respect their wishes. However, the issue can still be investigated. During the survey, discuss the issue with the team and make the topic the subject of other interviews and observations. For example, a resident has said that certain staff "make fun" of him/her, but he/she asks you to keep that in confidence. The resident's comment may not be referred to in the statement of deficiencies. However, discuss this with the team and decide how best to pursue the matter while respecting the resident's wishes. Team members may want to address this topic with other residents, family members or the resident group. When aware of which staff are involved, attempt to observe these staff interacting with residents.

If other residents have complained about the same problem, their comments may be referred to generally as a group. For example, "Three out of five residents interviewed reported that…" Use judgment to determine if the statement would compromise the resident's confidentiality

Sub-Task 5E - Medication Pass and Pharmacy Services

(Rev. 22, Issued: 12-15-06, Effective/Implementation: 12-18-06)

A. Objectives

- To determine whether the facility safely administers medications including:
    - Accuracy of medication administration (including preparation and technique);
    - Labeling that contains at least the name and strength/concentration of the medication, as well as expiration date when applicable, and
    - Security of medications;
- To determine whether medications are stored and handled in accordance with manufacturers' recommendations and/or state or federal requirements;
- To determine whether the facility reconciles controlled medications, as appropriate;

- To determine whether the facility obtains the services of a licensed pharmacist; and

- To determine whether the facility provides or obtains pharmaceutical services, including routine and emergency medications, to meet the needs of each resident.

B. Use

- The medication pass (C.1) and a review of storage and access to medications (C.2) must be conducted on every Initial and Standard survey; and on Partial Extended, Abbreviated Standard and Revisit, as necessary;

- Review for the provision of licensed pharmacist consultation (C.5) on the initial survey and on any other survey type, if the survey team has identified concerns that indicate:

    - That the facility does not have a licensed pharmacist; and/or

    - That the licensed pharmacist may not have performed his/her functions related to the provision of pharmaceutical services;

- Review for the development and implementation of pharmaceutical procedures (C.4) if, during the course of the survey, concerns have been identified regarding the availability of medications; accurate and timely medication acquisition; receiving, dispensing, administering, labeling, and storage of medications; reconciliation of controlled medications (C.3); and the use of qualified, authorized personnel to handle and dispense medications.

C. General Procedures

1. Medication Pass (includes labeling)

See Guidance to Surveyors at 483.25(m) for information on conducting the medication pass and for the identification of medication errors. Use the Medication Pass Worksheet (Form CMS-677, Exhibit 88) to record observations. On Form CMS-677, the column marked "Record" is for the purpose of recording the prescriber's actual order if different than what was observed as administered.

When observing the medication pass:

- Be as neutral and unobtrusive as possible;

- Observe different routes and/or forms of medications such as intravenous (IV), intramuscular (IM), or subcutaneous (SQ) injections; transdermal patches;

inhaler medications; eye drops; and medications provided through enteral tubes;

- Initially observe the administration at least 20-25 medications, observing as many staff administering medications as possible to facilitate a review of the facility's entire medication distribution system;

- Record, from the medication label, the name and dose/concentration of each medication administered. Also record the route of administration (if other than oral) and the expiration date, if expired;

- Record all multiples, such as 2 drops or 2 tablets. For liquids, record actual volume, or in the case of items such as psyllium, record number of "rounded teaspoonfuls" and the amount of liquid. In the absence of a number, it is assumed to be one;

- Observe whether staff confirmed the resident's identity prior to giving medications and whether the medications were identified up to the point of administration. Note any concerns;

- Record the techniques and procedures that staff used to handle and administer medications, such as proper hand hygiene, checking pulses, flushing gastric tubes, crushing medications, route and location of administration (e.g., sub-Q or IM injection, eye, ear, inhalation, or skin patch), shaking and/or rotating medication, giving medications with or between food or meals, whether medications are under the direct control/observation of the authorized staff; and

- Observe whether staff immediately documented the administration and/or refusal of the medication after the administration or the attempt. Note any concerns.

After the medication pass, compare your observations with the prescriber's orders. Review to assure that medication records, including prescriber's orders and the Medication Administration Record (MAR) are accurate and complete. Determine whether there was an error(s) in medication administration. A medication error is the preparation or administration of medications or biologicals that is not in accordance with any of the following:

- The prescriber's order (whether given incorrectly or omitting an ordered dosage);

- Manufacturer's specifications (not recommendations) regarding the preparation and administration of the medication or biological;

- Accepted professional standards and principles that apply to professionals providing services;

  NOTE: If no errors are found after reconciliation of the pass with the prescriber's orders, the medication pass observation is complete.

- If one or more errors are found, observe the administration of another 20-25 medications.

After completion of the observations and reconciliations, calculate the facility's medication error rate, if one or more errors are found. Add the number of significant and non-significant errors (see guidance at F332/333) and divide by the opportunities for error (doses given plus the doses ordered but not given). Multiply this by 100.

If it is determined that the facility's overall error rate (including significant and non-significant errors) is 5 percent or more, a medication error deficiency exists at F332.

If one or more significant errors were identified, a medication error deficiency exists at F333.

NOTE: If a **significant** medication error has been identified during the course of a Resident Review, including a complaint investigation, it is not necessary to have observed a medication pass in order to cite a deficiency at F333.

2. Medication Storage (includes labeling)

Review medication storage (Use CMS Form 803 for documentation) in order to determine whether:

- Medications and biologicals are accessible only to authorized staff and are locked when not under the direct observation of the authorized staff;

- Controlled medications are stored in a manner to limit access and to facilitate reconciliation in accordance with the facility policies;

- Medications are stored to maintain their integrity and to support safe administration of the correct medication to the correct resident, by the correct route and in the correct dose, such as:

  - Temperature, light, and humidity controls meet specifications for the medication;

  - Medications available for use are not expired, contaminated, or unusable;

- Medication labels are legible; intact; contain the name and dose/concentration of the medication, appropriate cautionary/accessory instructions such as “do not crush,” expiration date when applicable; and support the safe administration of the medication; and

- Multi-dose vials are labeled per facility policy and manufacturer’s specifications once use of the vial has been initiated.

3. Controlled Medications

If a concern regarding controlled medications was identified during the survey process or during the medication pass, interview facility staff, such as the director of nursing, and the licensed pharmacist regarding the concern. If a potential problem has been identified regarding lack of reconciliation or loss of controlled medications:

- Determine whether Scheduled II controlled medications are in separately locked, permanently affixed compartments (or are a minimal amount of unit dose packages);

- Review the facility procedure and a sample of the reconciliation records, and compare the amount of medication available with the amount the records indicate should be available; and

- Interview the director of nursing and/or licensed pharmacist regarding:

  - Actual frequency of the reconciliation;

  - How the facility investigates loss or inability to reconcile controlled medications; and

  - How the licensed pharmacist has been involved in recognizing the situation and collaborating with the facility to review and update its practices and procedures.

4. Pharmaceutical Services

If concerns have been identified regarding pharmaceutical services (such as: any of the required components related to safe medication use, storage, labeling; the use of authorized staff to administer medications; emergency medication issues; licensed pharmacist consultation), review the facility’s evidence (e.g., licensed pharmacist’s reports to the facility) that they have been receiving ongoing pharmacy consultation regarding all aspects of the provision of pharmaceutical services in the facility, including identification of problems and recommendations for corrective actions. Determine whether the licensed pharmacist is available during the survey or identify how to contact the licensed pharmacist in order to respond to surveyor questions

about pharmaceutical services. Review procedures and interview staff and/or the licensed pharmacist regarding the areas of concern.

For example, the following steps might be used, if a concern has been identified regarding medications not being administered in a timely manner:

- Identify the types of medications (such as antibiotics, pain medications) that are not being passed on a timely basis,
- Interview the director of nursing and/or the staff responsible for passing medications regarding:
  - A delay in obtaining or administering a medication(s);
  - The potential causes of the delay; and
  - Facility procedures for scheduled times of administration;
- Interview the licensed pharmacist to determine if he/she identified the concern regarding timely medication administration and had made recommendations to facility staff in order to address the concern;
- Interview facility staff regarding the response to recommendations made by the licensed pharmacist; and
- As necessary, if concerns are identified regarding sufficient authorized staff to pass medications, interview the director of nursing regarding staff assignments and work allocation in relation to medication passes in order to meet the needs of the residents.

5. Provision of a Licensed Pharmacist

If there is no licensed pharmacist providing services in the facility, interview the administrator and others, as appropriate, regarding:

- The length of time the facility has been without the services of a licensed pharmacist; and
- Current efforts underway to obtain the services of a licensed pharmacist.

If the facility has a licensed pharmacist, and concerns have been identified regarding the provision of services related to his/her functions, interview the licensed pharmacist, administrator, and, as necessary, the director of nurses and/or medical director regarding the processes to provide and oversee pharmaceutical services consultation.

Sub-Task 5F - Quality Assessment and Assurance **(QA&A)** Review

A. General Objectives—The QA&A review protocol is designed to determine if:

- A QA&A committee exists and meets in accordance with the regulatory requirements of 42 CFR 483.75 (o); and

- The QA&A committee is functional, i.e., it identifies, develops, plans, implements, monitors, and ensures correction of deviations from quality.

B. General Procedures—to complete Sub-Task 5F, follow the Investigative Protocol contained in the Guidance to Surveyors at F520.

NOTE: The surveyor(s) completing Sub-Task 5F should not conduct a review of the minutes of the QA&A committee, as the regulation does not require the facility to disclose the records of the QA&A committee.

Sub-Task 5G - Abuse Prohibition Review

A. General Objective

To determine if the facility has developed and operationalized policies and procedures that prohibit abuse, neglect, involuntary seclusion and misappropriation of property for all residents. The review includes components of the facility's policies and procedures as contained in the Guidance to Surveyors at 42 CFR 483.13(c), F226. (See Guidance to Surveyors for further information.)

These include policies and procedures for the following:

- Screening of potential hirees;

- Training of employees (both for new employees, and ongoing training for all employees);

- Prevention policies and procedures;

- Identification of possible incidents or allegations which need investigation;

- Investigation of incidents and allegations;

- Protection of residents during investigations; and

- Reporting of incidents, investigations, and facility response to the results of their investigations.

B. General Procedures:

- Utilize the Abuse Prohibition Investigative Protocol to complete this task.

Investigative Protocol

Abuse Prohibition

Objective:

To determine if the facility has developed and operationalized policies and procedures that prohibit abuse, neglect, involuntary seclusion and misappropriation of property for all residents.

Use:

Use this protocol on every standard survey.

Task 5G Procedures:

- Obtain and review the facility's abuse prohibition policies and procedures to determine that they include the key components, i.e. screening, training, prevention, identification, investigation, protection and reporting/response. (See Guidance to Surveyors at F226.) It is not necessary for these items to be collected in one document or manual.

- Interview the individual(s) identified by the facility as responsible for coordinating the policies and procedures to evaluate how each component of the policies and procedures is operationalized, if not obvious from the policies. How do you monitor the staff providing and/or supervising the delivery of resident care and services to assure that care service is provided as needed to assure that neglect of care does not occur? How do you determine which injuries of unknown origin should be investigated as alleged occurrences of abuse? How are you ensuring that residents, families, and staff feel free to communicate concerns without fear of reprisal?

- Request written evidence of how the facility has handled alleged violations. Select 2-3 alleged violations (if the facility has this many) since the previous standard survey or the previous time this review has been done by the State.

    - Determine if the facility implemented adequate procedures:

- For reporting and investigating;
- For protection of the resident during the investigation;
- For the provision of corrective action;

NOTE: The reporting requirements at 483.13(c) specify both a report of the alleged violation and a report of the results of the investigation to the State survey agency.

  - Determine if the facility reevaluated and revised applicable procedures as necessary.

- Interview several residents and families regarding their awareness of to whom and how to report allegations, incidents and/or complaints. This information can be obtained through the resident, group, and family interviews at Task 5D.

- Interview at least five direct care staff, representing all three shifts, including activity staff and nursing assistants, to determine the following:

  - If staff are trained in and are knowledgeable about how to appropriately intervene in situations involving residents who have aggressive or catastrophic reactions.

    NOTE: Catastrophic reactions are extraordinary reactions of residents to ordinary stimuli, such as the attempt to provide care. One definition in current literature is: ". . . catastrophic reactions [are] defined as reactions or mood changes of the resident in response to what may seem to be minimal stimuli (e.g., bathing, dressing, having to go to the bathroom, a question asked of the person) that can be characterized by weeping, blushing, anger, agitation, or stubbornness. "Catastrophic reactions and other behaviors of Alzheimer residents: Special unit compared to traditional units." Elizabeth A Swanson, Meridean L. Maas, and Cathleen Buckwalter. Archives of Psychiatric Nursing. Vol. VII No. 5 (October 1993). Pp. 292-299.

  - If staff are knowledgeable regarding what, when and to whom to report according to the facility policies.

- Interview at least three front line supervisors of staff who interact with residents (Nursing, Dietary, Housekeeping, Activities, Social Services). Determine how they monitor the provision of care/services, the staff/resident interactions, deployment of staff to meet the residents' needs, and the potential for staff burnout which could lead to resident abuse.

- Obtain a list of all employees hired within the previous 4 months, and select five from this list. Ask the facility to provide written evidence that the facility conducted pre-screening based on the regulatory requirements at 42 CFR 483.13(c).

Task 6 Determination of Compliance:

Take account of all the information gained during this review as well as all other information gained during the survey. When a deficiency exists, determine if F225 or F226 provides the best regulatory support for the deficiency.

- 483.13(c), F226, Staff Treatment of Residents:
    - The facility is compliant with this requirement if they have developed and implemented written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property. If not, cite at F226.
- 483.13(c)(1)(2)(3)and (4), F225, Staff Treatment of Residents:
    - The facility is compliant with this requirement if they took appropriate actions in the areas of screening, reporting, protecting, investigating and taking appropriate corrective actions. If not, cite at F225.

Task 6 - Information Analysis for Deficiency Determination

A. General Objectives

The objectives of information analysis for deficiency determination are:

- To review and analyze all information collected and to determine whether or not the facility has failed to meet one or more of the regulatory requirements; and
- To determine whether to conduct an extended survey.

B. Overview

The worksheets and procedures are designed to assist the surveyor in gathering, investigating, organizing, and analyzing information about the quality of services provided by the facility in order to determine whether the facility has failed to meet long-term care requirements.

The information gathering portions of the survey have focused on the resident and the delivery of services by the facility using observation, interview and record review as sources of information. The information analysis and decision-making portion of the survey focuses on making determinations about whether the facility meets requirements.

Information analysis and decision Making builds on discussions of the daily team meetings, which should include discussions of observed problems, areas of concern, and possible failure to meet requirements.

Decisions about deficiencies are to be team decisions with each member of the team, including specialty surveyors (see Section I.C.), having input into the decisions. The team coordinator or designee should document the deficiency decisions and the substance of the evidence on the Form CMS- 807.

For initial surveys, a determination must be made regarding whether the facility meets every long-term care requirement.

C. Decision-Making Process

Each member of the team should review his/her worksheets to identify concerns and specific evidence relating to requirements that the facility has potentially failed to meet. In order to identify the facility's deficient practices and to enable collating and evaluating the evidence, worksheets should reflect the source of the evidence and should summarize the concerns on relevant data tags.

- Begin the decision-making task by taking into account the daily discussions, the findings documented on the worksheets, discussions with the facility, observations over the course of the survey, and the discussions regarding definitions of deficiencies in the following section. At a minimum, focus on the regulatory groupings 42 CFR 483.10, Resident Rights; 42 CFR 483.13, Resident Behavior and Facility Practice; 42 CFR 483.15, Quality of Life; 42 CFR 483.20, Resident Assessment' and 42 CFR 483.25, Quality of Care. Gather information from all worksheets pertinent to the particular requirements being reviewed (e.g., documentation from all worksheets concerning resident rights). In general, what is the facility's performance in meeting these requirements? Does the facility protect and promote resident rights? Discuss results of the information-gathering phase in the context of facility conformance with these resident-centered requirements and the examples of resident-facility interactions that cause you to believe there may be deficiencies.

- Prioritize the review of worksheets so that the first information the team discusses relates to those requirements that the facility has potentially failed to meet. For example, what documentation on the Quality of Life Assessment worksheet supports the belief that the facility does not protect and promote resident rights? What information on other worksheets supports or does not support the team's

assessment of Resident Rights? Evaluate the specifics of the regulatory language and the specific data collected (e.g., observation, resident, family and staff interview information) with respect to the facility's performance in each requirement. Review the worksheets on an individual tag-by-tag basis. If data indicate that the facility has not met a specific requirement (see Task 6, Section D), document that deficiency.

- In order to ensure that no requirements are missed, proceed through the requirements sequentially as they appear in the interpretive guidelines, preferably section by section. Findings/evidence within each section should be shared by each team member during this discussion. Consider all aspects of the requirements within the tag/section being discussed and evaluate how the information gathered relates to the specifics of the regulatory language and to the facility's performance in each requirement. The team should come to consensus on each requirement for which problems have been raised by any member. If no problems are identified for a particular tag number during the information gathering process, then no deficiency exists for that tag number.

- The team coordinator, or a designee, collates all information and records the substance of the decision-making discussion on the Form CMS-807. (See Exhibit 95.)

- Determine if there is substandard quality of care.

- If substandard quality of care exists, conduct an extended survey.

D. Deficiency Criteria

To determine if a deficiency exists, use the following definitions and guidance:

- A "deficiency" is defined as a facility's failure to meet a participation requirement specified in the Social Security Act or in Part 483, Subpart B (i.e., 42 CFR 483.5 - 42 CFR 483.75).

- To help determine if a deficiency exists, look at the language of the requirement. Some requirements need to be met for each resident. Any violation of these requirements, even for one resident, is a deficiency.

- Other requirements focus on facility systems.

For some requirements, especially those in the regulatory grouping of Quality of Life (42 CFR 483.15), the team will evaluate the sum of the staff actions and/or decisions for an individual resident to determine if the requirement is met for that individual. Quality of Life requirements are best evaluated comprehensively, rather than in terms of a single

incident. However, a single incident which is considered severe enough may result in a deficiency.

Certain facility systems requirements must be met in an absolute sense, e.g., a facility must have a RN on duty 7 days a week unless it has received a waiver. Other facility system requirements are best evaluated comprehensively, rather than in terms of a single incident. In evaluating these requirements, the team will examine both the individual parts of the system, e.g., the adequacy of the infection control protocol, the adequacy of facility policy on hand washing, as well as the actual implementation of that system.

E. Evidence Evaluation

The survey team must evaluate the evidence documented during the survey to determine if a deficiency exists due to a failure to meet a requirement and if there are any negative resident outcomes due to the failure. Failure to meet requirements related to quality of care, resident rights, and quality of life generally fall into two categories:

1. Potential or Actual Physical, Mental or Psychosocial Injury or Deterioration to A Resident Including Violation of Residents' Rights

   Some situations which illustrate this level of harm could be:

   a. Development of, or worsening of, a pressure sore;

   b. Loss of dignity due to lying in a urine-saturated bed for a prolonged period; and

   c. Social isolation caused by staff failure to assist the resident in participating in scheduled activities.

   This category of negative outcome may be identified when an identified facility practice is so divergent from accepted principles of practice that harm has occurred or a future negative outcome or harm is probable. An example would be nurse aides in a facility who often fail to wash their hands between caring for residents. In this example, there is a strong potential for harm although there has been no evidence of a high facility infection rate, or of infections spreading from one resident to another. Should a resident contract an infection or become colonized with a highly contagious bacteria, there is a high potential for a major outbreak of nosocomial infection.

2. Lack of (or the Potential for Lack of) Reaching the Highest Practicable Level of Physical, Mental or Psychosocial Well-Being

No deterioration occurred, but the facility failed to provide necessary care for resident improvement. For example:

a. The facility identified the resident's desire to reach a higher level of ability, e.g., improvement in ambulation, and care was planned accordingly. However, the facility failed to implement, or failed to consistently implement the plan of care, and the resident failed to improve, i.e., did not reach his/her highest practicable well-being;

b. The facility identified a need in the comprehensive assessment, e.g., the resident was withdrawn/depressed, but the facility did not develop a care plan or prioritize this need of the resident, planning to address it at a later time. The resident received no care or treatment to address the need and did not improve, i.e., remained withdrawn/depressed. Therefore, the resident was not given the opportunity to reach his/her highest practicable well-being;

c. The facility failed to identify the resident's need/problem/ability to improve, e.g., the ability to eat independently if given assistive devices, and, therefore, did not plan care appropriately. As a result, the resident failed to reach his/her highest practicable well-being, i.e., eat independently.

d. A facility's written procedures or oral explanations do not provide information about which residents are supposed to be fully informed, e.g., the resident is provided treatment which they may have wished to refuse.

If the resident is the primary source of information, the team should conduct further information gathering and analysis. This may include additional interviews with family and staff or record reviews to supplement or corroborate the resident's report. If additional sources of information are not available, determine if the interviewees are reliable sources of information and if the information received is accurate. If so, citation of a deficiency may be based on resident information alone.

In cases where residents are unable to speak for themselves, the survey team should assess how most people would react to the situation in question. For example, a female resident who is unable to express herself is wheeled down the hall in a wheelchair on the way to her shower with only a towel partially covering her body. The team will decide if this incident is inappropriate because the resident is unable to express herself. Quality of life and Residents' Rights requirements are most often evaluated using this type of analysis.

F. Determination of Substandard Quality of Care

The team must determine if substandard quality of care exists. Substandard quality of care is defined as one or more deficiencies related to participation requirements under 42 CFR 483.13, Resident Behavior and Facility Practices, 42 CFR 483.15, Quality of Life, or 42 CFR 483.25, Quality of Care which, constitute either immediate jeopardy to resident health or safety, pattern or widespread deficiencies at severity level 3, or widespread deficiencies at severity level 2. (See Section V., Deficiency Categorization.)

G. Special Circumstances

Substandard quality of care and immediate jeopardy determinations trigger additional survey tasks and must be determined during the information gathering tasks of the survey and/or during information analysis and decision-making.

Immediate jeopardy is defined as a situation in which the facility's failure to meet one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident. At any time during the survey, if one or more team members identifies possible immediate jeopardy, the team should meet immediately to confer. The guiding principles to determine immediate jeopardy and serious threat make it clear that the threat can be related to mental, as well as physical well-being, and that the situation in question need not be a widespread problem. If the team concurs, the team coordinator must consult immediately with his/her supervisor. If the supervisor concurs that the situation constitutes immediate jeopardy, the team coordinator informs the facility Administrator or designee that the immediate jeopardy termination procedures are being invoked. The team coordinator should explain the nature of the immediate jeopardy to the Administrator or designee. The survey team should complete the entire survey. See Appendix Q for guidance regarding determination of immediate jeopardy, and §3010 for procedures to follow if the immediate jeopardy termination procedures are invoked.

When surveyors suspect substandard quality of care (SQC), they expand the standard (or abbreviated) survey sample as necessary to determine scope (Refer to Task 4, Supplementary Sample for further information). If there is no deficiency(ies) classified as substandard quality of care and there is a deficiency under the regulatory Groupings of 42 CFR 483.13, 42 CFR 483.15 and/or 42 CFR 483.25, that are classified as an isolated incident of severity level 3, or, as a pattern of severity level 2, then determine if there is sufficient evidence to make the decision that there is not substandard quality of care.

If the evidence is not adequate and the number of observations only allowed for isolated scope when there is a severity level 3, or pattern for scope when there is a severity level 2, then expand the sample to include additional reviews of that requirement. For example, if residents in the facility are receiving care for a colostomy, and for the one resident with a colostomy in the sample, it is determined that care provided caused actual harm to the resident, there would be a deficiency of isolated actual harm, but there would not be

sufficient evidence to determine that there was substandard quality of care. Thus, the sample would need to be expanded before determining that substandard quality of care did or did not exist. On the other hand, if the number of individuals with a colostomy in the facility was the same (6), and 4 residents with colostomies were included in the sample and only one had deficient care, there would be no need to expand the sample. If the team verifies the existence of SQC, the Administrator should be informed that the facility is in SQC and an extended (or partial extended) survey will be conducted. If expanding the sample determines that SQC does not exist, no extended or partial extended survey will be conducted.

H. Determining Citations of Past Noncompliance at the Time of the Current Survey

Past noncompliance may be identified during any survey of a nursing home. To cite past noncompliance with a specific survey data tag (F-tag or K-tag), all of the following three criteria must be met:

1. The facility was not in compliance with the specific regulatory requirement(s) (as referenced by the specific F-tag or K-tag) at the time the situation occurred;

2. The noncompliance occurred after the exit date of the last standard recertification survey and before the survey (standard, complaint, or revisit) currently being conducted; and

3. There is sufficient evidence that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey for the specific regulatory requirement(s), as referenced by the specific F-tag or K-tag.

Task 7 - Exit Conference

A. General Objective

The general objective of the exit conference is to inform the facility of the survey team's observations and preliminary findings.

B. Conduct of Exit Conference

Conduct the exit conference with facility personnel. Invite the ombudsman and an officer of the organized residents group, if one exists, to the exit conference. Also, invite one or two residents to attend. The team may provide an abbreviated exit conference specifically for residents after completion of the normal facility exit conference. If two exit conferences are held, notify the ombudsman and invite the ombudsman to attend either or both conferences.

Do not discuss survey results in a manner that reveals the identity of an individual resident. Provide information in a manner that is understandable to those present, e.g., say the deficiency "relates to development of pressure sores," not "Tag F314."

Describe the team's preliminary deficiency findings to the facility and let them know they will receive a report of the survey which will contain any deficiencies that have been cited (Form CMS-2567). If requested, provide the facility with a list of residents included in the standard survey sample. Do not give the team's Roster/Sample Matrixes to the facility, because they contain confidential information.

If an extended survey is required and the survey team cannot complete all or part of the extended survey prior to the exit conference, inform the Administrator that the deficiencies, as discussed in the conference, may be amended upon completion of the extended survey. (See §2724 for additional information concerning exit conferences.)

During the exit conference, provide the facility with the opportunity to discuss and supply additional information that they believe is pertinent to the identified findings. Because of the ongoing dialogue between surveyors and facility staff during the survey, there should be few instances where the facility is not aware of surveyor concerns or has not had an opportunity to present additional information prior to the exit conference.

II.B – The Traditional Survey (Continued)

II.B.2. - The Traditional Extended and/or Partial Extended Survey

Conduct an extended survey subsequent to a standard survey and conduct a partial extended survey subsequent to an abbreviated survey when you have determined that there is a substandard quality of care in:

- 42 CFR 483.13, Resident behavior and facility practices;
- 42 CFR 483.15, Quality of life; and/or
- 42 CFR 483.25, Quality of care.

When conducting the extended/partial extended survey, at a minimum, fully review and verify compliance with each tag number within 42 CFR 483.30, Nursing Services; 42 CFR 483.40, Physician Services; and 42 CFR 483.75, Administration. Focus on the facility's policies and procedures that may have produced the substandard quality of care. As appropriate, include a review of staffing, inservice training and the infection control program. An extended/partial extended survey explores the extent to which structure and process factors such as written policies and procedures, staff qualifications and functional responsibilities, and specific agreements and contracts of the facility may have contributed to the outcomes. If the extended/partial extended survey was triggered by a deficiency in quality of care, conduct a detailed review of the accuracy of resident

assessment. During the partial extended survey, consider expanding the scope of the review to include a more comprehensive evaluation of the requirements at 42 CFR 483.13, 42 CFR 483.15, and/or 42 CFR 483.25 in which substandard quality of care was found.
Document the observations from the extended or partial extended survey on the Form CMS-805, (see Exhibit 93) or the Form CMS-807 (see Exhibit 95).

Review of the Accuracy of Resident Assessments During an Extended/Partial Extended Survey

The objective of this review is to determine if resident assessments are accurate.

If an extended/partial extended survey is conducted based on substandard quality of care in Quality of Care (42 CFR 483.25), review the accuracy of resident assessments by:

- Reviewing a sample of comprehensive resident assessments completed no more than 30 days prior to conducting the survey;

- Comparing observations of the resident with the facility's assessment;

- Conducting the number of assessment reviews needed to make a decision concerning the accuracy of the facility's resident assessments; and

- Determining if observations of the resident, and interviews with resident/staff/family, "match" the facility's assessment (or specific portions of the assessment) of the resident. If observations and interviews do not "match," investigate further.

Record the indepth review of the accuracy of resident assessments on page 3 of the Form CMS-805. (See Exhibit 93.)

Timing for Conducting the Extended Survey and Partial Extended Survey

Conduct the extended or partial extended survey:

- Prior to the exit conference, in which case the facility will be provided with information from the standard, abbreviated standard, partial extended or extended surveys; or,

- Not later than 2 weeks after the standard/abbreviated survey is completed, if the team is unable to conduct the extended survey or partial extended survey concurrent with the standard survey or the abbreviated survey. Advise the facility's Administrator that there will be an extended or partial extended survey conducted and that an exit conference will be held at the completion of the survey.

II.B. – The Traditional Survey (Continued)

II.B.3 - The Traditional Post Survey Revisit (Follow-Up)

In accordance with §7317, the State agency conducts a revisit, as applicable, to confirm that the facility is in compliance and has the ability to remain in compliance. The purpose of the post-survey revisit (follow-up) is to re-evaluate the specific care and services that were cited as noncompliant during the original standard, abbreviated standard, extended or partial extended survey(s). Ascertain the status of corrective actions being taken on all requirements not in substantial compliance. Section 7304 contains the 5 elements a facility must address in developing an acceptable plan of correction. One of these elements is what continuous quality improvement system(s) a facility has in place to monitor its performance in identifying the deficient practice/care and assuring that it does not recur.

Because this survey process focuses on the care of the resident, revisits are generally necessary to ascertain whether the deficient practices have been corrected. The nature of the noncompliance dictates the scope of the revisit. For example, do not perform another drug pass if no drug distribution related deficiencies were cited on the initial survey. Do interviews and closed record reviews, as appropriate. Prior to the revisit, review appropriate documents, including the plan of correction, to focus the revisit review.

Conduct as many survey tasks as needed to determine compliance status. Always conduct Sub-Task 5F. However, the team is not prohibited from gathering information related to any requirement during a post-survey revisit.

When selecting the resident sample for the revisit survey, determine the sample size using 60% of the sample size for a standard survey as described in Table 1, Resident Sample Selection. (Phase 1 sample size is 60%.) The follow-up survey does not require a 2 Phase sample selection.

Focus on selecting residents who are most likely to have those conditions/needs/problems cited in the original survey. If possible, include some residents identified as receiving substandard quality of care during the prior survey. If, after completing the revisit activities, you determine that the cited incidence(s) of noncompliance was not corrected, initiate enforcement action, as appropriate. (See §7400 for specific guidance concerning initiation of enforcement action.)

Use appropriate CMS forms during this survey. However, if the need for documentation is minimal, use the Surveyor Notes Worksheet (Form CMS-808). (See Exhibit 95 to record the results of the revisit.)

II.B. – The Traditional Survey (Continued)

II.B.4 - The Traditional Abbreviated Standard Survey

A. Complaint Investigations

(See also Chapter 5)

B. Substantial Changes in a Facility's Organization and Management

If a facility notifies the survey agency of a change in organization or management, review the change to ensure compliance with the regulations. Request copies of the appropriate documents, e.g., written policies and procedures, personnel qualifications and agreements. If changes in a facility's organization and management are significant and raise questions of its continued compliance, determine, through a survey, whether certain changes have caused a decline in quality of care furnished by a SNF or NF.

III. Writing the Statement of Deficiencies

A. General Objective

The general objective of this section is to write the statement of deficiencies in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. For findings of past noncompliance and or current noncompliance indicate the data prefix tag and regulatory citation, followed by a summary of the evidence and supporting observations using resident identifiers. This documentation must be written in language specific enough to use to identify levels of severity and scope at the completion of the survey. If information was identified during confidential resident interviews, do not include a resident identifier when recording the source of the evidence. List the data tags in the order specified in the Code of Federal Regulations.

When a citation of past noncompliance is written, a nursing home does not provide a plan of correction as the deficiency is already corrected; however, the survey team documents the facility's corrective actions on Form CMS-2567. (Additional information about citations of past noncompliance is found at Chapter 7.)

When a facility is in substantial compliance, but has deficiencies which are isolated with no actual harm and potential for only minimal harm, the deficiencies are recorded on the "Notice of Isolated Deficiencies" instead of on the Form CMS-2567. A plan of correction is not required but a facility is expected to correct all deficiencies.

The statement of deficiencies should:

- Specifically reflect the content of each requirement that is not met;

- Clearly identify the specific deficient entity practices and the objective evidence concerning these practices;

- Identify the extent of the deficient practice, including systemic practices, where appropriate; and

- Identify the source(s) of the evidence, e.g., interview, observation, or record review.

Following deficiency categorization (Section V), enter on Form CMS-2567L the letter corresponding to the box of the scope and severity grid (Chapter 7, §7400.E.) for at least any deficiency which constitutes substandard quality of care and any deficiency which drives the choice of a required remedy category. Enter these letters in ID prefix tag column immediately below the tag number of the Form CMS-2567L.

IV. Deficiency Categorization

A. General Objective

After the survey team determines that a deficiency (ies) exists, assess the effect on resident outcome (severity level) and determine the number of residents potentially or actually affected (scope level). Use the results of this assessment to determine whether or not the facility is in substantial compliance or is noncompliant. When a facility is noncompliant, consider how the deficient practice is classified according to severity and scope levels in selecting an appropriate remedy. (See §7400 for discussion of remedies.)

Scope and severity determinations are also applicable to deficiencies at §483.70(a), Life Safety from Fire.

B. Guidance on Severity Levels

There are four severity levels. Level 1, no actual harm with potential for minimal harm; Level 2, no actual harm with potential for more than minimal harm that is not immediate jeopardy; Level 3, actual harm that is not immediate jeopardy; Level 4, immediate jeopardy to resident health or safety. These four levels are defined accordingly:

1. Level 1 is a deficiency that has the potential for causing no more than a minor negative impact on the resident(s).

2. Level 2 is noncompliance that results in no more than minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential (not yet realized) to compromise the resident's ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being as defined by

an accurate and comprehensive resident assessment, plan of care, and provision of services.

3. Level 3 is noncompliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. This does not include a deficient practice that only could or has caused limited consequence to the resident.

4. Level 4 is immediate jeopardy, a situation in which immediate corrective action is necessary because the facility's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility. (See Appendix Q.)

C. Guidance on Scope Levels

Scope has three levels: isolated; pattern; and widespread. The scope levels are defined accordingly:

III. Scope is isolated when one or a very limited number of residents are affected and/or one or a very limited number of staff are involved, and/or the situation has occurred only occasionally or in a very limited number of locations.

IV. Scope is a pattern when more than a very limited number of residents are affected, and/or more than a very limited number of staff are involved, and/or the situation has occurred in several locations, and/or the same resident(s) have been affected by repeated occurrences of the same deficient practice. The effect of the deficient practice is not found to be pervasive throughout the facility.

3. Scope is widespread when the problems causing the deficiencies are pervasive in the facility and/or represent systemic failure that affected or has the potential to affect a large portion or all of the facility's residents. Widespread scope refers to the entire facility population, not a subset of residents or one unit of a facility. In addition, widespread scope may be identified if a systemic failure in the facility (e.g., failure to maintain food at safe temperatures) would be likely to affect a large number of residents and is, therefore, pervasive in the facility.

D. General Procedures

After the team makes a decision to cite a deficiency(ies), evaluate the deficient practice's impact on the resident(s) and the prevalence of the deficient practice. Review deficiency statements, worksheets, and results of team discussions for evidence on which to base these determinations. The team may base evidence of the impact or prevalence for

residents of the deficient practices on record reviews, interviews and/or observations. Whatever the source, the evidence must be credible.

After determining the severity level of a deficient practice, determine scope. When determining scope, evaluate the cause of the deficiency. If the facility lacks a system/policy (or has an inadequate system) to meet the requirements and this failure has the potential to affect a large number of residents in the facility, then the deficient practice is likely to be widespread. If an adequate system/policy is in place but is being inadequately implemented in certain instances, or if there is an inadequate system with the potential to impact only a subset of the facility's population, then the deficient practice is likely to be pattern. If the deficiency affects or has the potential to affect one or a very limited number of residents, then the scope is isolated.

If the evidence gathered during the survey for a particular requirement includes examples of various severity or scope levels, surveyors should generally classify the deficiency at the highest level of severity, even if most of the evidence corresponds to a lower severity level. For example, if there is a deficiency in which one resident suffered a severity 3 while there were widespread findings of the same deficiency at severity 2, then the deficiency would be generally classified as severity 3, isolated.

E. Psychosocial Outcome Severity Guide

Purpose

The purpose of the Psychosocial Outcome Severity Guide is to help surveyors determine the severity of psychosocial outcomes resulting from the identified noncompliance at a specific F tag. The Guide is used to determine the severity of a deficiency in any regulatory grouping (e.g., Quality of Care, Quality of Life) that resulted in a negative psychosocial outcome.

This Guide is not intended to replace the current scope and severity grid. It is to be used in conjunction with the scope and severity grid to determine the severity of outcomes to each resident involved in a deficiency that has resulted in a psychosocial outcome. The team should select the level of severity for the deficiency based on the highest level of physical or psychosocial outcome. For example, a resident who was slapped by a staff member may experience only a minor physical outcome from the slap but suffer a greater psychosocial outcome. In this case the severity level based on the psychosocial outcome would be used as the level of severity for the deficiency.

Overview

Psychosocial outcomes (i.e., mood and behavior) may result from a facility's noncompliance with any regulatory requirement. Although a resident may experience either a negative physical outcome or a negative psychosocial outcome, some may experience or have the potential to experience both types of negative outcomes.

Psychosocial outcomes and physical outcomes are equally important in determining the severity of noncompliance, and both need to be considered before assigning a severity level. The severity level assigned should reflect the most significant negative outcome or highest level of harm/potential harm.

The presence of a given affect (i.e., behavioral manifestation of mood demonstrated by the resident) does not necessarily indicate a psychosocial outcome that is the direct result of noncompliance. A resident's reactions and responses (or lack thereof) also may be affected by pre-existing psychosocial issues, illnesses, medication side effects, and/or other factors. Because many nursing home residents have sadness, anger, loss of self-esteem, etc. in reaction to normal life experiences, the survey team must have determined that the psychosocial outcome is a result of the noncompliance.

Psychosocial outcomes of interest to surveyors are those caused by the facility's noncompliance with any regulation. This also includes psychosocial outcomes resulting from facility failure to assess and develop an adequate care plan to address a resident's pre-existing psychosocial issues, which led to continuation or worsening of the condition.

Instructions

This Guide is designed to be used separately for each resident included in the deficiency. Each resident's psychosocial response to the noncompliance is the basis for determining psychosocial severity of a deficiency. To determine severity, use the information gathered through the investigative process (Task 5). Compare the resident's behavior (e.g., their routine, activity, and responses to staff or to everyday situations) and mood before and after the noncompliance.

If the survey team determines that a facility's noncompliance has resulted in a negative psychosocial outcome to one or more residents, the team should use this Guide to evaluate the severity of the outcome for each resident identified in the deficiency (in accordance with the instructions at Task 6). The team should determine severity based on the resident's response in the following circumstances:

- If the resident can communicate a psychosocial reaction to the deficient practice, compare this response to the Guide; or

- If the resident is unable to express her/himself verbally but shows a noticeable non-verbal response that is related to the deficient practice, compare the non-verbal response to the Guide.

Application of the Reasonable Person Concept

There are circumstances in which the survey team may apply the "reasonable person concept" to determine severity of the deficiency. To apply the reasonable person concept, the survey team should determine the severity of the psychosocial outcome or potential

outcome the deficiency may have had on a reasonable person in the resident's position (i.e., what degree of actual or potential harm would one expect a reasonable person in a similar situation to suffer as a result of the noncompliance).

NOTE: The reasonable person concept described in this Guide is merely a tool to assist the survey team's assessment of the severity level of negative psychosocial outcomes. Although the reasonable person concept is used in many areas of the law, the application of common law defenses to the assessment of severity pursuant to this Guide would be inappropriate and is expressly precluded.

The survey team should use the reasonable person concept when the resident's psychosocial outcome may not be readily determined through the investigative process:

- When there is no discernable response or when circumstances obstruct the direct evaluation of the resident's psychosocial outcome. Such circumstances may include, but are not limited to, the resident's death, subsequent injury, cognitive impairments, physical impairments, or insufficient documentation by the facility. In this situation, the survey team may use the reasonable person concept to evaluate the severity (Level 2, Level 3, or Level 4) of the deficient practice; or

- When the resident's reaction to a deficient practice is markedly incongruent with the level of reaction the reasonable person would have to the deficient practice. In this situation, the survey team may use the reasonable person concept to evaluate the potential severity (Level 2 or Level 4) of the deficient practice.

Clarification Of Terms

"Anger" refers to an emotion caused by the frustrated attempts to attain a goal, or in response to hostile or disturbing actions such as insults, injuries, or threats that do not come from a feared source.[1]

"Apathy" refers to a marked indifference to the environment; lack of a response to a situation; lack of interest in or concern for things that others find moving or exciting; absence or suppression of passion, emotion, or excitement.[2]

"Anxiety" refers to the apprehensive anticipation of future danger or misfortune accompanied by a feeling of distress, sadness, or somatic symptoms of tension. Somatic symptoms of tension may include, but are not limited to, restlessness, irritability, hyper-vigilance, an exaggerated startle response, increased muscle tone, and teeth grinding. The focus of anticipated danger may be internal or external.[3]

"Dehumanization" refers to the deprivation of human qualities or attributes such as individuality, compassion, or civility.[4] Dehumanization is the outcome resulting from having been treated as an inanimate object or as having no emotions, feelings, or sensations.

"Depressed mood" (which does not necessarily constitute clinical depression) is indicated by negative statements; self-deprecation; sad facial expressions; crying and tearfulness; withdrawal from activities of interest; and/or reduced social interactions.[5] Some residents such as those with moderate or severe cognitive impairment may be more likely to demonstrate nonverbal symptoms of depression.

"Humiliation" refers to a feeling of shame due to being embarrassed, disgraced, or depreciated. Some individuals lose so much self-esteem through humiliation that they become depressed.[6]

PSYCHOSOCIAL OUTCOME SEVERITY GUIDE

The following are levels of negative psychosocial outcomes that developed, continued, or worsened as a result of the facility's noncompliance. This Guide is only to be used once the survey team has determined noncompliance at a regulatory requirement. The survey team must have established a connection between the noncompliance and a negative psychosocial outcome to the resident as evidenced by observations, record review, and/or interviews with residents, their representatives, and/or staff.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed/caused/resulted in, or is likely to allow/cause /result in serious injury, harm, impairment, or death to a resident; and

- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of negative psychosocial outcomes as a result of the facility's noncompliance may include but are not limited to:

- Suicidal ideation/thoughts and preoccupation (with a plan) or suicidal attempt (active or passive) such as trying to jump from a high place, throwing oneself down a flight of stairs, refusing to eat or drink in order to kill oneself.

- Engaging in self-injurious behavior that is likely to cause serious injury, harm, impairment, or death to the resident (e.g., banging head against wall).
- Sustained and intense crying, moaning, screaming, or combative behavior.

- Expressions (verbal and/or non-verbal) of severe, unrelenting, excruciating, and unrelieved pain; pain has become all-consuming and overwhelms the resident.

- Recurrent (i.e., more than isolated or fleeting) debilitating fear/anxiety that may be manifested as panic, immobilization, screaming, and/or extremely aggressive or agitated behavior(s) (e.g., trembling, cowering) in response to an identifiable situation (e.g., approach of a specific staff member).

- Ongoing, persistent expression of dehumanization or humiliation in response to an identifiable situation, that persists regardless of whether the precipitating event(s) has ceased and has resulted in a potentially life-threatening consequence.

- Expressions of anger at an intense and sustained level that has caused or is likely to cause serious injury, harm, impairment, or death to self or others.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Severity Level 3 indicates noncompliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

Examples of negative psychosocial outcomes as a result of the facility's noncompliance may include but are not limited to:

- Significant decline in former social patterns that does not rise to a level of immediate jeopardy.

- Persistent depressed mood[7,8,9] that may be manifested by verbal and nonverbal symptoms such as:

    - Social withdrawal; irritability; anxiety; hopelessness; tearfulness; crying; moaning;

    - Loss of interest or ability to experience or feel pleasure nearly every day for much of the day;

    - Psychomotor agitation[10] (e.g., inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects), accompanied by a bothered or sad expression;

    - Psychomotor retardation (e.g., slowed speech, thinking, and body movements; increased pauses before answering);

    - Verbal agitation[11] (e.g., repeated requests for help, groaning, sighing, or other repeated verbalizations), accompanied by sad facial expressions;

- Expressions of feelings of worthlessness or excessive guilt nearly every day (not merely self-reproach or guilt about being sick or needing care);

- Markedly diminished ability to think or concentrate;

- Recurrent thoughts of death (not just fear of dying) or statements without an intent to act (e.g., "I wish I were dead" or "my family would be better off without me").

- Expressions (verbal and/or non-verbal) of persistent pain or physical distress (e.g., itching, thirst) that has compromised the resident's functioning such as diminished level of participation in social interactions and/or ADLs, intermittent crying and moaning, weight loss and/or diminished appetite. Pain or physical distress has become a central focus of the resident's attention, but it is not all-consuming or overwhelming (as in Severity Level 4).

- Chronic or recurrent fear/anxiety that has compromised the resident's well-being and that may be manifested as avoidance of the fear-inducing situation(s) or person(s); preoccupation with fear; resistance to care and/or social interaction; moderate aggressive or agitated behavior(s) related to fear; sleeplessness due to fear; and/or verbal expressions of fear. Expressions of fear/anxiety are not to the level of panic and immobilization (as in Severity Level 4).

- Ongoing, persistent feeling and/or expression of dehumanization or humiliation that persists regardless of whether the precipitating, dehumanizing event(s) or situation(s) has ceased. The feelings of dehumanization and humiliation have not resulted in a life-threatening consequence.

- Apathy and social disengagement such as listlessness; slowness of response and thought (psychomotor retardation); lack of interest or concern especially in matters of general importance and appeal, resulting from facility noncompliance.
- Sustained distress (e.g., agitation indicative of understimulation as manifested by fidgeting; restlessness; repetitive verbalization of not knowing what to do, needing to go to work, and/or needing to find something).

- Anger that has caused aggression that could lead to injuring self or others. Verbal aggression can be manifested by threatening, screaming, or cursing; physical aggression can be manifested by self-directed responses or hitting, shoving, biting, and scratching others.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Severity Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

Examples of negative psychosocial outcomes as a result of the facility's noncompliance may include but are not limited to:

- Intermittent sadness, as reflected in facial expression and/or demeanor, tearfulness, crying, or verbal/vocal agitation (e.g., repeated requests for help, moaning, and sighing).

- Feelings and/or complaints of discomfort or moderate pain. The resident may be irritable and/or express discomfort.

- Fear/anxiety that may be manifested as expressions or signs of minimal discomfort (e.g., verbal expressions of fear/anxiety; pulling away from a feared object or situation) or has the potential, not yet realized, to compromise the resident's well-being.

- Feeling of shame or embarrassment without a loss of interest in the environment and the self.

- Complaints of boredom and/or reports that there is nothing to do, accompanied by expressions of periodic distress that do not result in maladaptive behaviors (e.g., verbal or physical aggression).

- Verbal or nonverbal expressions of anger that did not lead to harm to self or others.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

Severity Level 1 is not an option because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. The deficiency is, therefore, at least a Severity Level 2 because it has the potential for more than minimal harm.

ENDNOTES

[1] Gall, S., Beins, B., & Feldman, J. (1996). The Gale Encyclopedia of Psychology. Detroit, MI: Gale Research.

[2] Random House. (1981). The Random House Dictionary of the English Language. New York: Author.

[3] American Psychiatric Association (1994). Diagnostic and statistical manual of mental disorders (Fourth Edition). Washington, DC: Author.

[4] Random House. (1981).

[5] Minimum Data Set Version 2.0, Section E.
[6] Corsini, R. (1999). The Dictionary of Psychology. Ann Arbor, MI: Taylor and Francis.

[7] Alexopolous, G., Abrams, R., Young, R., & Shamoian, C. (1988). Cornell scale for depression in dementia. Biological Psychiatry, 23, 271-284.

[8] Brink, T.L., Yesavage, J.A., Lum, O., Heersema, P., Adey, M., & Rose, T.L. (1982). Screening tools for geriatric depression. Clinical Gerontologist, 1, 37-43.

[9] Warren, W.L. (1994). Revised Hamilton Rating Scale for Depression (RHRSD). Los Angeles, CA: Western Psychological Services.

[10] Cohen-Mansfield, J. (2003). Agitation in the elderly: Definitional and theoretical conceptualizations. In D.P. Hay, D. Klein, L. Hay, G. Grossberg, & J.S. Kennedy (Eds.) Agitation in Patients with Dementia: A Practical Guide to Diagnosis and Management (pp. 1-22). Washington, DC: American Psychiatric Publishing Inc.

[11] Cohen-Mansfield, J. (2003). Agitation in the elderly: Definitional and theoretical conceptualizations.

V. Confidentiality and Respect for Resident Privacy

Conduct the survey in a manner that allows for the greatest degree of confidentiality for residents, particularly regarding the information gathered during the in-depth interviews. Use the resident identifier (e.g., a code number the survey team has assigned to each resident in the sample) on the Form CMS-2567 in place of the resident's name, which should never be used on the Form CMS-2567.

When communicating to the facility about substandard quality of care, fully identify the resident(s) by name if the situation was identified through observation or record review. Improperly applied restraints, medication error, cold food, gloves not worn for a sterile procedure, and diet inconsistent with order are examples of practices that can be identified to the facility by resident name. Information about injuries due to broken equipment, prolonged use of restraints, and opened mail is more likely to be obtained through resident and family interviews. Do not identify residents or family members providing this information without their permission.

Notes and worksheets contain pre-decisional information and are, therefore, not required to be disclosed to the facility at the time of the survey. However, once the Form CMS-2567 has been written, portions of the worksheets explaining the findings reported

on the Form CMS-2567 may become subject to release under the Freedom of Information Act (FOIA). Information on the worksheets that was not subsequently used as a basis for writing a deficiency remains pre-decisional and is exempt from disclosure. That information would have to be deleted, according to FOIA guidelines, before the worksheets could be released.

The requirements of the FOIA apply only to those documents held by the Federal government. They do not apply to State or local governments. Therefore, surveyor worksheets held by the State are subject to State disclosure laws only.

VI. Information Transfer

In conjunction with conducting surveys, the State should provide information to the facility about care and regulatory topics that would be useful to the facility for understanding and applying best practices in the care and treatment of long term care residents.

This information exchange is not a consultation with the facility, but is a means of disseminating information that may be of assistance to the facility in meeting long term care requirements. States are not liable, nor are they to be held accountable if training which occurs during information transfer does not “correct” problems at the facility.

Performance of the function is at the discretion of the State and can be performed at various times, including during the standard survey, during follow-up or complaint surveys, during other conferences or workshops or at another time mutually agreeable to the survey agency and the facility. The time allotted for this information transfer should not usually exceed one hour. In no instance should the information transfer delay the survey process.

The Centers for Medicare & Medicaid Services, in cooperation with State survey agencies and consumer and provider groups, will develop and provide packages of training materials suitable for use in this activity.

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
R106SOM	04/04/2014	State Operations Manual (SOM) Appendix P revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)	04/04/2014	N/A
R42SOM	04/24/2009	Revision to Appendix P, "Survey Protocol for Long Term Care Facilities - Part I," "Investigative Protocol – Unintended Weight Loss"	04/24/2009	N/A
R41SOM	04/10/2009	Revisions to Appendices P and PP	04/10/2009	N/A
R31SOM	01/04/2008	Revision of Appendix P-Survey Protocol for Long Term Care Facilities	01/04/2008	N/A
R26SOM	08/17/2007	Revised Appendix P and Appendix PP-New Tag F373	08/17/2007	N/A
R22SOM	12/15/2006	Revisions to Appendix P and Appendix PP	12/18/2006	N/A
R21SOM	10/20/2006	Revised Appendix P & Appendix PP-New Tag F334	10/15/2006	N/A
R20SOM	06/09/2006	Revisions to Appendix P	06/08/2006	N/A
R09SOM	08/05/2005	Revision to Appendix P and Certain Exhibits	08/05/2005	N/A
R05SOM	11/19/2004	Revisions to Appendix P and Appendix PP	11/19/2004	N/A
R01SOM	05/21/2004	Initial Release of Pub. 100-07	N/A	N/A

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