### NEW PROCEDURES -- EFFECTIVE DATE: July 1, 1999

Exhibit 265, **Roster/Sample Matrix, HCFA-802**, is revised to reflect changes in the survey procedures, including the use of automated quality indicator (QI) reports.

Exhibit 270, **QI Reports**, is a set of new automated facility reports that survey agencies will generate from their mainframe computer systems for use in offsite survey preparation.

Appendix P: **Survey Procedures for Long Term Care Facilities**, is significantly revised to incorporate the use of QI reports, to add a new task (5G) and to provide new investigative protocols and a new drug review process.

Appendix PP: **Guidance to Surveyors**, is revised to incorporate changes in interpretive guidelines for abuse, drugs, and sufficient staffing.

**DISCLAIMER:** The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

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LIST OF EXHIBITS (Cont.)

245 CLIA Adverse Action Extract, HCFA-462A/B Reserved
246 Model Letter: Regional Office Notifying a State-Operated Laboratory of Cited Deficiencies and Requesting a Plan of Correction
247 Notice of (Limitation or) Revocation of a Laboratory’s CLIA Certificate - No Immediate Jeopardy
248 Notice of Proposed Limitation, Suspension, or Revocation of the CLIA Certificate; Opportunity for a Hearing - No Immediate Jeopardy
249 Model Letter: Send to the Laboratory in Conjunction With the Notice of Sanction. In Order to Officially Inform the Laboratory that the Responsibility Lies With the Laboratory to Achieve Compliance, Even if They Have Successfully Completed the Directed Plan of Correction
250 Notice of the Reissuance of a CLIA Certificate In Order to Keep a Laboratory Operational if it is Due to Expire Prior to the Administrative Hearing
251 Model Letter: Offering the Opportunity for a Reconsideration of the Addition of Specialties or Subspecialties by a Laboratory is Denied by HCFA
252 Model Letter: To Laboratory Director to Accompany the AQAS Instrument
253 Reserved for SAQIP
254 Model Letter: Notification to Applicant that Medicare General Enrollment Health Care Provider/Supplier Application Has Been Denied
255A Model Letter: Notification of Pending Involuntary Termination Based on CHOW Review of the Medicare General Enrollment Health Care Provider/Supplier Application
255B Model Letter - Notification of Involuntary Termination Based on CHOW Review of the Medicare General Enrollment Health Care Provider/Supplier Application
256 Form HCFA-855 - Medicare and Other Federal Health Care Program General Enrollment Health Care Provider/Supplier Application
257 Form HCFA-855C - Medicare and Other Federal Health Care Program Change of Information Health Care Provider/Supplier Application
258 Form HCFA-855R - Medicare and Other Federal Health Care Program Individual Reassignment of Benefits Health Care Provider/Supplier Application
259 Minimum Data Set Automation Contract/Agreement Approval RO Checklist
260 MDS Key Field Correction Form
261 Privacy Act Statement - Health Care Records

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255B Model Letter - Notification of Involuntary Termination Based on CHOW Review of the Medicare General Enrollment Health Care Provider/Supplier Application

256 Form HCFA-855 - Medicare and Other Federal Health Care Program General Enrollment Health Care Provider/Supplier Application

257 Form HCFA-855C - Medicare and Other Federal Health Care Program Change of Information Health Care Provider/Supplier Application

258 Form HCFA-855R - Medicare and Other Federal Health Care Program Individual Reassignment of Benefits Health Care Provider/Supplier Application

259 Minimum Data Set Automation Contract/Agreement Approval RO Checklist

260 MDS Key Field Correction Form

261 Privacy Act Statement - Health Care Records

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LIST OF EXHIBITS (Cont.)

262 Overview of MDS Version 2.0 Correction Policy for Locked Records
263 Maximum Time Frames for MDS Completion, Data Entry, Editing, Locking and Transmission
264 HCFA-672 - Resident Census and Conditions of Residents
265 HCFA-802P - Roster/Sample Matrix
266 HCFA-802P - Roster/Sample Matrix Provider Instructions (use with HCFA Form 802)
267 HCFA-802S - Roster/Sample Matrix Instructions for Surveyors (Use with Form HCFA-802)
268 Facility Characteristics
269 Resident Level Summary
270 Quality Indicator Matrix
271 Quality Indicator Glossary
PAGES 9-751- 9-787 ARE RESERVED FOR EXHIBITS 265 - 271
They are in hard copy only

Exhibit 265 - HCFA-802P - Roster/Sample Matrix

Exhibit 266 - HCFA-802P - Roster/Sample Matrix Provider Instructions
(use with HCFA Form 802)

Exhibit 267 - HCFA-802S - Roster/Sample Matrix Instructions for Surveyors
(Use with Form HCFA-802)

Exhibit 268 - Facility Characteristics

Exhibit 269 - Resident Level Summary

Exhibit 270 - Quality Indicator Matrix

Exhibit 271 - Quality Indicator Glossary
APPENDIX P

SURVEY PROTOCOL
FOR LONG TERM CARE FACILITIES

PART I

Survey Procedures for Long Term Care Facilities

I. Introduction

II. Survey Tasks
   o Task 1 - Offsite Survey Preparation
   o Task 2 - Entrance Conference/Onsite Preparatory Activities
   o Task 3 - Initial Tour
   o Task 4 - Sample Selection
   o Task 5 - Information Gathering
     A - General Observations of the Facility
     B - Kitchen/Food Service Observation
     C - Resident Review
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     F - Quality Assessment and Assurance Review
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   |   o Task 6 - Information Analysis for Deficiency Determination
   |   o Task 7 - Exit Conference

III. The Partial Extended and Extended Survey

IV. Writing the Statement of Deficiencies

V. Deficiency Categorization

VI. Post Survey Revisit (Follow-up)

VII. Abbreviated Standard Surveys
   A. Complaint Investigations
   B. Substantial Changes in a Facility's Organization and Management

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SURVEY PROCEDURES FOR LONG TERM CARE FACILITIES

Part II
Guidance to Surveyors - Long Term Care Facilities

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I. INTRODUCTION

Skilled nursing facilities (SNFs) and nursing facilities (NFs) are required to be in compliance with the requirements in 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, (Forms HCFA-670, 671, 672, 677, and 801 through 807). (See Exhibits 85, 86, and 88 to 95.)

Do not announce SNF/NF surveys to the facility. Conduct standard surveys and complete them on consecutive workdays, whenever possible. They may, at your discretion, 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 the mentally retarded (ICFs/MR), 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 Appendices J (ICFs/MR) and T (Swing-bed hospitals and hospitals with non-distinct part SNFs).

When the surveyor team suspects substandard quality of care (SQC), expand the standard (or abbreviated) survey sample as necessary to determine scope. (See Task 4, Supplementary Sample, for further information). If, at Task 6, the existence of SQC is verified, then inform the administrator that the facility is in SQC and an extended (or partial extended) survey will be conducted.

A. Surveys.--If in conducting the information gathering tasks of the survey you identify a possible noncompliant situation related to any requirement, investigate the situation to determine whether the facility is in compliance with the requirements.

1. Standard Survey.--A standard survey is composed of Tasks 1 - 7, and is a resident-centered, outcome-oriented inspection which relies 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

2. 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 you make a determination 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, then you must conduct an extended survey within 14 days after completion of a standard survey. (See Appendix P, Part I, Section III, the extended and partial extended survey.)

3. 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 the aspects covered in the standard survey, but rather concentrates on a particular area of concern or concerns. 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 standard survey if, during the abbreviated standard survey, they find evidence that warrants a more extensive review.

4. 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 you make a determination 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, then you must conduct a partial extended survey. (See Appendix P, Part I, Section III, the extended and partial extended survey.)

5. Post-Survey Revisit (Follow-up).--The post-survey revisit is an on-site visit intended to verify correction of deficiencies cited in a prior survey. See §2732 and Appendix P, Part I, Section VI. 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.

B. Initial Certification Survey.--In a survey for initial certification of SNFs or NFs, perform the tasks of both the 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 you identify problems 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 HCFA-2567) in Exhibit 7.

C. 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) may be onsite only 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 or 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.

D. 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 TASKS

TASK 1 - OFFSITE SURVEY PREPARATION

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 Indicator Profile (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 Summary (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 Indicator (QI) Reports from the Standard Analytic Reporting System of the HCFA National Resident Assessment Data Base.--(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 QI reports which can be downloaded from the State database:

   - Facility Characteristics (Exhibit 268).--Provides demographic information about the resident population (in percentages) for a selected facility compared to all the facilities in the State. This report is read left to right. It provides information such as gender and age of residents, payment source, diagnostic characteristics, assessments completed by type, and a summary of the number of assessments completed per month.
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- Facility Quality Indicator Profile (Exhibit 268).--Provides facility status for each of the MDS-based QIs as compared to a peer group of the facilities in the State. The report is read left to right. Listed are the individual QIs (grouped by Domains). For each QI, (reading across a row) are:
  - The numerator - the number of residents in the facility who have the QI condition;
  - The denominator - the number of residents in the facility who could have the QI condition;
  - The facility percentage of residents who have the QI condition;
  - The State percentage of residents who have the QI condition;
  - The percentile ranking of the facility on the 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; and
  - A flag is present in any row in which the facility “flags” on an indicator, which means that facility is at or above the 90th percentile; or a flag is present in one of the three sentinel event QI rows if any resident has the condition. (See D. below for more information.)

- Resident Level Summary (Exhibit 269).--Provides resident-specific QI information. This report is generated using the most current MDS records in the State data base at the time the report was generated, including all residents who have an MDS in the system. It is used to preselect residents for the Phase 1 sample who have conditions representing the concerns selected using the Facility Quality Indicator Profile. Reading from left to right, the report lists:
  - Each resident in alphabetical order;
  - MDS date and type of assessment:
    + A = admission;
    + Y = any full assessment (annual, significant change, or significant correction);
    + Q = quarterly;
    + O = other; and
    + M, when added to A, Y, Q, or O = also coded as a Medicare assessment.
  - Columns which list each QI with subcolumns for high and low risk; and
  - The total number of QIs flagged for the resident.

A checkmark (✓) appears in a QI column for a resident who has that QI condition. If a QI is risk adjusted, this checkmark (✓) is in either the high or low risk subcolumn for the QI, indicating...
whether this resident was at high or low risk to develop the QI condition. This specification of high or low risk can help survey teams to select which residents to review. If the team has selected incontinence as a QI concern, it may be most productive to select residents for whom incontinence would not have been expected (those at low risk).

NOTE: Resident-specific information in the Resident Level Summary must be kept confidential according to the Privacy Act. The report is only for the use of the State agency, HCFA representatives, and the facility.

2 The Statement of Deficiencies (HCFA-2567) and Statement of Isolated Deficiencies Which Cause No Actual Harm With Only Potential For Minimal Harm (Form A).--These 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, determining 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 HCFA's 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 (HCFA-672). This report compares facility population characteristics with State, HCFA 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 mental retardation. 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. Ask if 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:
   - Quality Indicator (QI) Reports:
     - Facility Characteristics Report;
     - Facility Quality Indicator Profile; and
     - Resident Level Summary;
   - Form HCFA-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 three QI reports to be given to the facility’s administrator;
   - Obtain an extra copy of the group interview worksheet (see HCFA-806B, Exhibit 94) to give to the council president.
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If the State does not use an alternate mechanism to obtain the ownership disclosure information, in accord with 42 CFR 420.206(b) for Medicare facilities, obtain ownership disclosure forms; HCFA-1513 (Exhibit 6), HCFA-855, (Exhibit 256) and/or HCFA-855C (Exhibit 257). If the facility has already completed a HCFA-855 and no changes have occurred since that filing, the facility may present a copy of the previously filed HCFA-855. If changes have occurred since filing the HCFA-855, the facility will need to complete a new HCFA-855 or HCFA-855C as directed by §2005 of the State Operations Manual. If the facility has not previously filed a HCFA-855 and has had a change of ownership, a HCFA-855 must be completed. In other cases (including Medicaid facilities), the facility must complete a Form HCFA-1513.

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 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 (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 HCFA-802, Exhibit 90) to highlight concerns the team identifies for Phase 1 of the survey, and to list residents preselected and the 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. Use the Facility Quality Indicator Profile to select concerns based on the following:
   - Any sentinel health event QI that is flagged. A “sentinel health event” is a 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 QIs are Prevalence of Fecal Impaction, Prevalence of Dehydration, and Prevalence of Pressure Ulcers (low risk). This means that if even one resident has any of these conditions, this 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 QI, it is not necessary to select all of them);
   - Any other QI that is flagged (at the 90th percentile); and
   - Any unflagged QI in which the facility is at the 75th percentile or greater.

The survey team may also wish to select as concerns any other QIs that are of interest to them because they are related to QIs that have been selected, or because their percentile number is extremely low in comparison to the remaining QIs. They may also select other areas of concern derived from sources of information other than the QI reports.

3. Preselect potential residents for the Phase 1 sample to represent the concerns that have been selected, including selecting residents who have sentinel event QI conditions (if multiple residents have a sentinel event 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. Preselect a few more residents (three to five) than the actual number that will be required for the Phase 1 sample to accommodate the fact that some residents who have been preselected may no longer be at the facility (these residents could fill Closed Record slots on the sample).

   - In any facility in which the team has noted concerns with weight loss, dehydration, and/or pressure sores, select approximately ½ of the preselected sample as residents who have one or more of these conditions. For the condition of hydration, you must select a resident who
has flagged for the sentinel event QI #15 (dehydration) and you may select residents with any of
the following QI conditions: #11 - Fecal Impaction; #12 - Urinary tract infections; #13 - weight
loss; #14 - Tube feeding; and #17 - Decline in Activities of Daily Living (ADL’s). The best
residents to select will be those who also have multiple care areas that have been selected as
concerns. In any facility in which these concerns were not identified, the team should still select
some residents who have these QI conditions (if any) on the Resident Level Summary, but this
need not be 50% of the Phase 1 sample size.

   o 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 QIs that have been selected as concerns, the team may select
residents based on other sources of information (such as 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
quality indicator or resident specific QI information available. Preselection of 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.

   o The survey team should be alert to inconsistencies on the Facility Quality
   Indicator Profile that may indicate facility error in completing and/or transmitting its Minimum
   Data Set (MDS) records, or a problem with State’s software or HCFAs data base. The following
   are some possible indicators of data quality problems:
      - The denominator for QIs that use “all residents” substantially exceeds
   or is substantially smaller than the facility bed size;
      - The number of residents with a QI condition (i.e., the numerator)
   exceeds the resident population; or
      - The numerator for a particular QI is zero although other information
   sources indicate otherwise. For example, the 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 Indicator Profile is generated using the most current MDS records in the
State data base 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 Summary is calculated using the most
recently transmitted MDS record (e.g., annual, significant change, quarterly, or initial MDS
record). You could see differences between the Facility Quality Indicator Profile and the Resident
Level Summary since the facility profile does not use the admission MDS data. For example, the
Resident Level Summary may indicate a resident had a catheter, but the Facility Quality Indicator
Profile might show a “0”. This is not an accuracy problem, it only reflects the use of different data
to generate each report.

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4. Review the OSCAR reports after the review of the QI reports to add corroborative information to the QI information (e.g., a pattern of repeat deficiencies in a requirement related to a flagged QI) and/or point out areas of large discrepancies between the QI Facility Quality Indicator Profile 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 QI report 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 QI reports.

NOTE: Both the OSCAR reports and the 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 one year old, and the QI information may be from two to six 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 QI information.

5. Review all other sources of information and record additional information on the Offsite Preparation Worksheet (Form HCFA-801, Exhibit 89), for example, residents' names for possible inclusion in the Phase 2 sample based on non-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**

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:
   
   o 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 §2713A 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.
   
   o Explain the survey process and answer any questions from facility staff.
   
   o Give the administrator copies of the three QI reports and the OSCAR 3 and
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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 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?

- 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.

- Ask the administrator to provide the following information within one 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 (such as: 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. (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: This evidence, at the discretion of the facility, could include or be a record of accident and incident reports.
10. The current resident activity schedule/calendar;

NOTE: The facility is not required by Federal regulations to maintain this record.

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

12. 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 the Roster/Sample Matrix (HCFA-802), including all residents on hold to the best of their ability 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, within 24 hours of the Entrance Conference:
  1. A completed Long Term Care Facility Application for Medicare and Medicaid (HCFA-671), (See Exhibit 85); A Resident Census and Conditions of Residents (HCFA-672), (See Exhibit 86); and the completed ownership document (HCFA-1513, or HCFA-855), if not obtained through other State mechanisms;
  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.
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B. Onsite Preparatory Activities.--

1. In areas easily observable by residents and visitors, post (or ask the facility to post) signs announcing that you are performing a survey and 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 him/herself 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 it is all right with the group that the ombudsman attend the meeting. If the reply is affirmative, 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 you with 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;
- Confirm or invalidate the preselected concerns (if any) and add concerns discovered onsite.

B. General Procedures.--The initial tour is used to gather information about concerns which have been preselected; new concerns discovered onsite; and whether residents preselected for the Phase 1 sample offsite are still present in the facility. In addition, during the tour, attempt to meet and talk with as many residents as possible 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 kitchen.

Document tour information, on either the Roster/Sample Matrix (HCFA-802), or the Surveyor Notes Worksheet (HCFA-807). Document any concerns regarding the general environment on the General Observations of the Facility Worksheet, (HCFA-803) or Surveyor Notes Worksheets, (HCFA-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 (HCFA-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.
accompanying 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 such as: 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, be sure to determine for each resident pre-selected offsite for the Phase 1 sample whether the resident is still there. Determine which (if any) of the preselected 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 used 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 preselected 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 (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 preselected 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 in your documentation the details of your observation including any effects on the residents involved.

Conduct a brief initial observation of the kitchen. See Task 5B for further information.
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While on tour, identify the licensed and registered nursing staff who are currently on duty, and later 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 (such as 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 such as, 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.

   o Impact of the facility environment and safety issues.--
      1. Infection control practices (such as 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

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 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.--

   o The Phase 1 sample is preselected during Task 1, Offsite Survey Preparation, based on QIs and other areas of concern. The preselected sample is reviewed during the sample selection meeting and residents are retained for the sample unless they are discharged (some of these may be selected as closed records, at the team’s discretion). Each team member is assigned to review 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.

   o 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, and residents from both heavy and light care categories.

NOTE: If the team is conducting sample selection during a 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.
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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;
  - 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 (HCFA-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 in Exhibit 90.)

D. Protocol.--

1. Phase 1 - Sample Selection.--The Phase 1 sample is preselected during Task 1, Offsite Survey Preparation, based on the facility’s 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 (HCFA-802, Exhibit 90), or to provide 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 preselect concerns or potential sampled residents. In that instance Phase 1 sample selection will occur during this task.
   - First determine if any preselected concerns should be dropped due to the QI data not representing the conditions of current residents. For example, there was a preselected 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 preselected 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 preselected resident who is no longer in the facility can be considered for the closed record review. The team may substitute other residents for those preselected, if necessary. They can select either from the QI reports, the tour, or the facility’s Roster/Sample Matrix.
SURVEY PROCEDURES FOR LONG TERM CARE FACILITIES

If any resident is substituted for a preselected 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 (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, out of 12 residents selected for the Phase 1 sample, in a facility with 96 residents, a minimum of 6 will be those who have any of the conditions mentioned above, if any of these 3 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 subsample 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:
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- Initial concerns noted during Offsite Survey Preparation or the Initial Tour that have not been reviewed as yet;

- Currently unreviewed 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:

It is a statutory requirement to select a “case mix stratified” sample (but not for each phase of the sample selection, just for the total sample). This stratification is defined by HCFA 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;

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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 believes 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, you identify many more residents than can be selected to represent the concerns of interest, you may consider the factors below in your determination of 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 mental retardation; and
- Residents who communicate with non-oral communication devices, sign language, or who speak a language other than the dominate 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)?

o Complete Task 5F Quality Assessment Assurance Review.

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

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

o Review the Resident Census and Condition of Residents (HCFA-672) that the facility has completed. Note any new areas of concern and determine if there appear 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.

o 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: 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 was 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 preselected 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
RESIDENT SAMPLE SELECTION

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<th>Resident Census</th>
<th>Phase 1/Phase 2</th>
<th>Comprehensive Reviews *</th>
<th>Focused Reviews *</th>
<th>Closed Rec. Reviews *</th>
<th>Res./Family Interviews</th>
<th>W, H, P Group **</th>
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* 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.
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TASK 5 - INFORMATION GATHERING

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 subtasks:

- **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 Observation**: Application of Medication Error Detection Methodology;
- **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 your investigation and to help determine whether, based on your investigation and findings, the facility has met the requirements.

Worksheet documentation should be resident-centered, as appropriate. For example, if you are documenting the lack of a reading light near the resident’s bedroom chair, also note that this resident has told you he prefers to read in his 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 you collect information, keep in mind that the information you write on your
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worksheet will be used by the team to decide if there are any deficiencies, and, if so, the degree of severity and scope. Make your 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 your 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 you are 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 your 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 you need, not the whole record. The information gathering tasks are interrelated. Information acquired while doing observations and interviews will direct your 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 in which you are engaged, be alert at all times to the care environment and activities around you. 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 your 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 you with additional information in considering any alternative explanations before you make deficiency decisions. This, however, does not mean that you report every negative observation on a daily basis, i.e., 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 you have verified through observation and record review, that a resident’s condition has declined, start your 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 show you documentation in the resident’s chart that provides the reasons for why they believe this decline occurred. Use this information to guide your investigation, but use your professional judgment and team approach to determine if a deficient practice has occurred.

In conducting the tasks of the Standard Survey, you may identify situations that lead you to believe that the facility may not be meeting a requirement not routinely reviewed in the Standard Survey.

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Investigate this further. For example, residents at the council meeting tell you 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 your information and observations in terms of credibility and reliability. If you doubt the credibility or reliability of information, 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 give you 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 you 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 your 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 you with 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
- Notify the ombudsman of the resident's concerns if you have the resident's permission.

D. Record Review.--The objectives of the record review are to:

- Acquire information to direct initial and/or additional observations and interviews;
- Provide you with 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.

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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 you have obtained through observation and interviews. Ask facility staff to assist you in finding any information that you have been unable to find on your own or that requires validation.

TASK 5A - GENERAL OBSERVATIONS OF THE FACILITY.

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 (HCFA-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. This surveyor assures that all items on this worksheet are completed. All surveyors should share any additional concerns regarding the environment with the surveyor assigned to complete the worksheet. Begin your 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 HCFA-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 you are observing. If additional documentation space is needed, use the Surveyor Notes Worksheet, HCFA-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.

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

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

- The availability of food in relation to the number of residents;
- 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 thirty 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.

TASK 5C - RESIDENT REVIEW

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. Your review will include aspects of the environment, staff interactions, and provision of services that affect sampled residents in their daily lives;
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- 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 both sections of the Surveyor Minimum Qualifications Test (SMQT) or if the complexity of a resident's care requires expertise of more than one discipline, two surveyors should work jointly to complete the review. A surveyor must successfully complete Module B of the SMQT to survey independently the requirements of quality of care, clinical dietary and medication.

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, 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 QIs identified for the resident on the Resident Level Summary. At least 2 of the QIs identified for the resident must be matched against the QI definitions (see the QI definition matrix, Exhibit 270) and against evidence other than the MDS to verify that the resident’s condition is accurately recorded in the MDS. Keep in mind that you are verifying 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;
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- 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;

  o A review of the implementation of the care plan and resident response;
  o 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);
  o 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 QI reports [unless there are no residents with these concerns in the facility.]); and
  o 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. (That is, 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 (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 (HCFA-805, Exhibit 93) for specific areas to review.
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1. **Section A.**--The Resident Room Review assesses aspects of accommodation of needs, environmental quality, and quality of life in the resident's room. Evaluate through your observations and interviews how the resident's environment affects her/his 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 your 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.

**General Procedures:**

Conduct an assessment of drug therapies for residents selected for comprehensive and focused review. (In addition, if the team has identified a concern that relates to the medication regimen, include a review of medication regimen in closed record reviews).

- Record the information on the Resident Review Worksheet, HCFA 805. Review and record, as pertinent, all non prescription and prescription medications taken by the resident during the past 7 days.

- Evaluate for the presence of any unnecessary drugs. (Review of the unnecessary drug requirements includes drugs and protocols or circumstances described in all sections of 42 CFR 483.25(l), and as pertinent, 42 CFR 483.60(c)(2).) The surveyor is to review the medication regimen for the following:
  - Indications/reason for use;
  - Effectiveness of therapeutic goal;
  - Dose;
  - Presence of monitoring (including drug regimen review and response to identified irregularities);
  - Presence of duplicative therapy; and
  - Presence of possible Adverse Drug Reactions (ADR) or side effects. In addition, review for the presence of any medications with “High Potential for Severe ADRs” or “High Potential for Less Severe ADRs” as identified in the Guidance to Surveyors. (If any of these medications are identified, use the “Investigative Protocol: Adverse Drug Reactions” below).

**NOTE:** An ADR is a secondary effect of a drug that is usually undesirable and different from the therapeutic and helpful effects of the drug. The term “side effect” is often used interchangeably with ADR. Technically, however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse drug interactions. Formal definitions stress an ADR is any response to a drug that is noxious and unintended and occurs in doses used for prophylaxis, diagnosis or therapy.
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- Correlate the review of the drugs with the resident’s clinical condition and any extenuating circumstances, such as recent admission, a change in the resident’s environment, and hospitalization, etc.

- Evaluate how the drugs the resident receives affect her/his quality of care and quality of life through the following methods:
  - A review of the clinical record (i.e., any section that has useful information pertaining to the resident);
  - Observations of the resident; and
  - Interviews with the resident or interested parties.

- Allow the facility the opportunity to provide their rationale for use of drugs which are prescribed contrary to HCFA guidelines.

- If problems or concerns with drug therapy are noted, review the results of the pharmacist’s drug regimen review, and the response from the attending physician/director of nurses. (The Medical Director may have provided additional information regarding the specific issues identified during the resident’s medication review.)

Use the following investigative protocol for the review of apparent adverse drug reaction.
INVESTIGATIVE PROTOCOL:
ADVERSE DRUG REACTIONS (ADR)

Objectives:

- To determine if the resident may be experiencing any ADRs as a result of receiving one or more of the medications identified with high potential for severe ADRs or high potential for less severe ADRs.

- To determine whether the facility’s drug regimen review process identified and reported any potential irregularities associated with the use of medications listed as having a high potential for ADRs, and whether there was any response to this notification.

Task 5C: Use:

Use this protocol if the resident meets the following criteria:

- Is over 65 years old;
- Has been in the facility over 7 days (or appears to be having a noticeable ADR within the first 7 days); and
- Is receiving any of the medications which has a high potential for severe ADRs or a high potential for less severe ADRs at 42 CFR 483.25(l) and 42 CFR 483.60(c)(2) in the guidance to surveyors, respectively.

NOTE: An Adverse Drug Reaction (ADR) is a secondary effect of a drug that is usually undesirable and different from the therapeutic and helpful effects of the drug. The term “side effect” is often used interchangeably with ADR. Technically, however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse drug interactions. An ADR is any response to a drug that is noxious and unintended and occurs in doses for prophylaxis, diagnosis or therapy.

Procedures:

These procedures are not intended to instruct surveyors to determine if a resident outcome is an actual ADR (except in obvious circumstances), but are guidelines intended to guide surveyors to find the pertinent facts that will assist them in determining compliance. In addition, the list of drugs and adverse reactions in the guidelines are not all inclusive and other medication sources may be reviewed for evaluation of the drug regimen.

1. Screening.-- If the criteria for use of the protocol are met, use the following (additional resources may be used, e.g., information provided by the facility, journals, etc.) to identify whether the resident may be experiencing a potential ADR.

   - Review of Drugs With High Potential for Severe ADRs.--For this review, refer to the drugs and the Adverse Drug Reactions found in the surveyor guidance at 42 CFR 483.25(l), Section H, Unnecessary Drugs.

      - Determine if there is evidence in the record explaining why the benefit of this medication outweighs the risk of a potential ADR, that is, the facility notes indicate the reasons that the medication is the one of choice for a particular resident.
- Determine if the resident is experiencing decline or other negative outcome as a result of the apparent ADR.
  
  o **Review of Drugs With High Potential For Less-Severe ADRs.**--For this review, refer to the list of drugs in the surveyor guidance at F429, Drug Regimen Review.

- Determine if there is evidence in the record explaining why the benefit of this medication outweighs the risk of a potential ADR, that is, the facility notes indicate the reasons that the medication is the one of choice for a particular resident.

2. **Analyze.**--Base evidence that an apparent ADR occurred or is occurring on two sources of information (clinical record review, interview with the resident or interested party, and observation, or one source for closed records).

3. **Review Facility Response.**--If the resident is experiencing any potential ADR, determine whether the facility has identified and addressed/acknowledged the potential ADR.

4. **Additional Considerations.**--When conducting the review, consider the following:

  o The use of any medication that appears in the Guidance to Surveyors at 42 CFR 483.25(l) and 42 CFR 483.60(c)(2) could be an appropriate therapy, if valid documentation supporting its use is provided;

  o The prescribing of medication should always take into consideration its risks and benefits (e.g., the benefits of a pain medication versus the risk of worsened constipation in a person already prone to constipation);

  o The side effects of many medications are similar or the same as for other medications or disease processes; and

  o In some cases, the benefits of a particular medication may not be self-evident, and additional pertinent information (either written or verbal) should be requested from the facility.

  o This protocol does not supercede current regulation. The surveyor has the option to cite at F329 (Unnecessary Drugs) or F429 (Drug Regimen Review) based on the situation.

**Task 6: Determination of Compliance:**

  o Compliance with 42 CFR 483.25(l)(1)(i-vi), of F329: Unnecessary Drugs.

    - For this resident, the medication is not an unnecessary drug if the facility: identified the risks; determined that the benefit of this drug outweighs the risk or development of a potential ADR, that is, the facility indicates the reasons that the drug is the one of choice for a particular resident; and the facility continually assessed the use of the drug and determined that this continued to be a valid therapeutic intervention for the resident. If not, the medication is an unnecessary drug--Cite F329.

  o Compliance with 42 CFR 483.60(c)(2), F429, Drug Regimen Review:

    - For this resident, the drug regimen review is in compliance if the facility identified the risks, assessed, and determined if the benefit of this drug outweighs the risk of a potential ADR, that is, the facility notes indicate the reasons for the drug is the one of choice for a particular resident. If the facility has not completed the above review and assessment, but the pharmacist has identified and reported the apparent irregularity to the attending physician/director of nursing as part of the drug regimen review process, the drug regimen review is in compliance. If not--Cite F429.
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 she/he 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 your observations; and

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

Do not continue to follow residents once you have accrued enough information 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 you in making your 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 you must observe the resident's genital or rectal area or female breast area to document and confirm your 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.

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

1. You determine 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 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;
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- 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 you determine 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 you have the information needed 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, YOU MUST 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.” (HCFA Long Term Care Resident Assessment Instrument User’s Manual, Version 2.0, 10/95.)
INVESTIGATIVE PROTOCOL
PRESSURE SORE/ULCER

Objectives:
- To determine if the identified pressure sore/ulcer(s) is avoidable or unavoidable; and
- To determine the adequacy of the facility’s pressure sore/ulcer treatment and prevention interventions.

Task 5C: Use:
Utilize this protocol for a sampled resident who has been selected as having a pressure sore/ulcer from either the high or low risk group as shown on the Resident Level Summary Report.

NOTE: The Facility QI Profile will flag a sentinel event if the development of a pressure sore/ulcer occurred for a person who was at low risk. To identify the resident, refer to the Resident Level Summary, QI #24, Pressure Ulcer, Low Risk column.

Procedures:
- Observations/interviews conducted as part of this procedure should be recorded on the HCFA-805.
- Conduct a brief review of the assessment and care plan noting the facility’s interventions.
- Observe care delivery to determine if the interventions identified in the care plan have been implemented, such as incontinence care with frequency to keep the resident clean and skin dry, repositioning and evaluation of skin condition, nutritional interventions, treatment interventions and changes in skin condition and healing.

NOTE: The development of a pressure sore/ulcer may not have triggered a significant change RAI. In addition, if the pressure sore/ulcer has just developed, the facility may be in the process of assessment. Regardless of the timing of the assessment, the facility is required to develop and implement a care plan to meet the needs of the resident.

- Evaluate if the assessment that was conducted identified conditions that may put the resident at risk for development of a pressure sore/ulcer such as the following:
  - Diabetes, peripheral vascular disease, chronic obstructive pulmonary disease, a terminal condition, hip fractures or other surgical interventions which might limit mobility, cerebral vascular accident; immobility, hemiplegia/hemiaparesis, physical restraints, decreased sensory perception, history of a pressure sore, incontinence, edema, compromised nutritional status, such as unintended weight loss, or malnutrition. (Also see Guidance to Surveyors at F314 for additional examples.)

- 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.
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- Determine if the facility developed a care plan with interventions for the prevention of the development of a pressure sore/ulcer for a resident who was identified at risk for the development of a pressure sore/ulcer. Determine if the facility maintained an ongoing evaluation of their interventions to evaluate the effectiveness of their approaches, with revision of the care plan, as needed. The identification of risk factors and/or clinical conditions does not necessarily indicate that a pressure sore/ulcer development was unavoidable. The facility must continue to evaluate the interventions and implementation of the care plan.

- Determine for a resident who was at low risk for development of a pressure sore/ulcer, whether the facility identified, assessed and intervened to address the changes which contributed to the development of the pressure sore/ulcer. For example, an ambulatory resident who developed a heel ulcer from an ill fitting shoe or an ulcer/sore which developed from pressure from clothing, such as support hosiery, or pressure from medical devices.

- For a resident who was admitted with a pressure sore/ulcer, determine if an interdisciplinary care plan was developed for the conditions identified. Are care plan interventions, such as pressure relieving devices, nutritional interventions and other measures, developed to provide an aggressive program of prevention and/or treatment?

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

- Determine if the resident refused treatment (for example, refusing to be positioned off the affected side). If this situation occurred, did the facility counsel the resident about possible alternatives and consequences, if appropriate? Did the facility reevaluate and attempt other interventions?

Task 6: Determination of Compliance:

- Compliance with 42 CFR 483.25(c)(1), F314, Pressure Sores:

  - For this resident, the pressure sore/ulcer is unavoidable if the facility properly assessed, care planned, implemented the care plan, evaluated the resident outcome, and revised the care plan as needed. If not, the pressure sore/ulcer is avoidable; cite at F314.

- Compliance with 483.25(c)(2), F314, Pressure Sore Treatment:

  - For this resident, the facility is compliant with the portion of this requirement dealing with treatment of existing pressure sore/ulcer(s) if the facility provided appropriate care planning and treatment, evaluated the resident outcome, and revised the care plan as needed. If not, cite at F314.

- Compliance with 42 CFR 483.20(b)(1), F272, Comprehensive Assessments:

  - For this resident in the area of pressure sore/ulcer(s), the facility is compliant with this requirement if they assessed factors that put the resident at risk for the development of a pressure sore/ulcer. If not, cite at F272.

- Compliance with 42 CFR 483.20(k), F279, Comprehensive Care Plans:

  - For this resident in the area of pressure sore/ulcer(s), 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), F282, Provision of Care in Accordance with the Care Plan:

- For this resident in the area of pressure sore/ulcer(s), the facility is compliant with this requirement if qualified persons implemented the resident’s care plan. If not, cite at F282.
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 on the Resident Level Summary;
- A sampled resident who has one or more QI conditions identified on the Resident Level Summary, such as:
  - #11 - Fecal impaction;
  - #12 - Urinary tract infections;
  - #13 - Weight loss;
  - #14 - Tube feeding;
  - #17 - Decline in ADLs;
  - #24 - Pressure Ulcer
- 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 HCFA-805 and/or the HCFA-807.
- Determine if the resident was assessed to identify risk factors that can lead to dehydration, such as those listed above and also 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? Do staff provide the necessary fluids as described in the plan? (Do the fluids provided contribute to dehydration, for example, 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?

- Do 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 non-compliance 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 non-compliance 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 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.
SURVEY PROCEDURES FOR LONG TERM CARE FACILITIES

INVESTIGATIVE PROTOCOL

UNINTENDED WEIGHT LOSS

Objectives:

- To determine if the identified weight loss is avoidable or unavoidable; and
- To determine the adequacy of the facility’s response to the weight loss.

Task 5C: Use:

Utilize this protocol for a sampled resident with unintended weight loss.

Procedures:

- Observations/interviews conducted as part of this procedure should be recorded on the HCFA-805 if they pertain to a specific sampled resident and on the HCFA-807 if they relate to general observations of the dining service/dining room.

- Determine if the resident was assessed for conditions that may have put the resident at risk for unintended weight loss such as the following:
  - Cancer, renal disease, diabetes, depression, chronic obstructive pulmonary disease, Parkinson’s disease, Alzheimer’s disease, malnutrition, infection, dehydration, constipation, diarrhea, Body Mass Index (BMI) below 19, dysphagia, chewing and swallowing problems, edentulous, ill fitting dentures, mouth pain, taste/sensory changes, bedfast, totally dependent for eating, pressure ulcer, abnormal laboratory values (review in accordance with the facility’s laboratory norms) associated with malnutrition (serum albumin, plasma transferrin, magnesium, hct/hgb, BUN/creatinine ratio, potassium, cholesterol), and use of medications such as diuretics, laxatives, and cardiovascular agents.

NOTE: Amputation of a body part will contribute to a significant decrease in previously targeted weight range. Once the new weight goals are established the resident should be assessed within the parameters of the unintended weight loss investigative protocol.

NOTE: Body Mass Index (BMI) estimates total body mass and is highly correlated with the amount of body fat. It provides important information about body composition, making it a useful indicator of nutritional status. BMI is easy to calculate because only information about height and weight are needed.

\[
\text{BMI} = \frac{\text{weight (Kg)}}{\text{height (M}^2)} \quad \text{or} \\
\text{BMI} = \frac{\text{weight (lbs.)}}{\text{height (inches}^2)} \times 705
\]

- Determine if the facility has assessed the resident’s nutritive and fluid requirements, dining assistance needs, such as assistive devices, food cultural/religious preferences, food allergies, and frequency of meals.

- 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.
o Determine if the care plan was developed utilizing the clinical conditions and risk factors identified in the assessment for unintended weight loss. Were the care plan interventions, such as oral supplements, enteral feeding, alternative eating schedule, liberalized diet, nutrient supplements, adaptive utensils, assistance and/or increased time to eat developed to provide an aggressive program of consistent intervention by all appropriate staff?

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

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 nutrients are being consumed or intake has ceased, and all appropriate efforts have been made to encourage and provide intake, then the weight loss may be an expected outcome and may not constitute non-compliance with the requirement for maintaining nutritional parameters. 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 non-compliance with 42 CFR 483.25, F309, Quality of Care.

o Observe the delivery of care as described in the care plan (such as staff providing assistance and/or encouragement during dining; serving food as planned with attention to portion sizes, preferences, nutritional supplements, and/or between-meal snacks) to determine if the interventions identified in the care plan have been implemented. Use the Dining and Food Service Investigative Protocol to make this determination.

Task 6: Determination of Compliance:

- Compliance with 42 CFR 483.25 (I ), F325, Nutrition
  - For this resident, the unintended weight loss is unavoidable if the facility properly assessed, care planned, implemented the care plan, evaluated the resident outcome, and revised the care plan as needed. If not, the weight loss is avoidable; cite at F325.

- Compliance with 42 CFR 483.25, F309, Quality of Care:
  - For the resident who is in an end-of-life stage and 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, then for this resident, in the area of palliative care, the facility is compliant with this requirement. If not, cite F309.

- Compliance with 42 CFR 483.20(b)(1) and (2), F272, Comprehensive Assessments:
  - For this resident in the area of unintended weight loss, the facility is compliant with this requirement if they assessed the factors that put the resident at risk for weight loss. If not, cite at F272.
SURVEY PROCEDURES FOR LONG TERM CARE FACILITIES

- Compliance with 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans:
  - For this resident in the area of unintended weight loss, 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), F282, Provision of care in accordance with the care plan:
  - For this resident in the area of unintended weight loss, 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.

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 HCFA-805 if it pertains to a specific sampled resident, or on the HCFA-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.
- Identify for each sampled resident being observed, any special needs and the interventions planned to meet their needs. Using the facility’s menu, record 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:
   - Appropriate dishes and flatware for each resident. (Single use disposable dining ware is not used except in an emergency and, other appropriate dining activities.) Each resident (except those with fluid restriction) 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 meal time?
     - If a substitute was needed, did it arrive more than 15 minutes after the request for a substitute?
   - Whether 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 room’s) are being served and assisted concurrently.

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: such as 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.

   o 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.

   o Determine if the facility is monitoring the foods/fluids consumed. You may use procedures used by the facility 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-fourths 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 \( \times 100 \) 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 your 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) & (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, such as: 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, such as: 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 your 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, such as: 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 twenty-four 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 HCFA-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 483.10(c)(6), F160).

K. Review of a Resident Receiving Hospice Care.--When a facility resident has also elected the Medicare hospice benefit, the hospice and the nursing facility must communicate, establish, and agree upon a coordinated plan of care for both providers which reflects the hospice philosophy, and is based on an assessment of the individual's needs and unique living situation in the facility. The plan of care must include directives for managing pain and other uncomfortable symptoms and be revised and updated as necessary to reflect the individual's current status.

The hospice must designate a registered nurse from the hospice to coordinate the implementation of the plan of care.

This coordinated plan of care must identify the care and services which the SNF/NF and hospice will provide in order to be responsive to the unique needs of the patient/resident and his/her expressed desire for hospice care.
The SNF/NF and the hospice are responsible for performing each of their respective functions that have been agreed upon and included in the plan of care. The hospice retains overall professional management responsibility for directing the implementation of the plan of care related to the terminal illness.

For residents receiving Hospice benefit care, evaluate if:

- The plan of care reflects the participation of the hospice, the facility, and the patient to the extent possible;
- The plan of care includes directives for managing pain and other uncomfortable symptoms and is revised and updated as necessary to reflect the individual's current status;
- Drugs and medical supplies are provided as needed for the palliation and management of the terminal illness and related conditions;
- The hospice and the facility communicate with each other when any changes are indicated to the plan of care;
- The hospice and the facility are aware of the other's responsibilities in implementing the plan of care;
- The facility's services are consistent with the plan of care developed in coordination with the hospice, (the hospice patient residing in a SNF/NF should not experience any lack of SNF/NF services or personal care because of his/her status as a hospice patient); and
- The SNF/NF offers the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. The patient/resident has the right to refuse any services.

NOTE: If you have concerns about the resident in relation to care provided by the hospice agency then refer the issue to the State Agency (SA) responsible for surveying hospices.

L. Review of a Resident Receiving Dialysis Services.--When dialysis is provided in the facility by an outside entity, or the resident leaves the facility to obtain dialysis, the nursing home must have an agreement or arrangement with the entity in accord with 42 CFR 483.75 (h). This agreement/arrangement should include all aspects of how the resident's care is to be managed, including:

- Medical and non-medical emergencies;
- Development and implementation of the resident's care plan;
- Interchange of information useful/necessary for the care of the resident; and
- Responsibility for waste handling, sterilization, and disinfection of equipment.

If there is a sampled resident who is receiving dialysis care, evaluate the following, in addition to the standard Resident Review protocol:

- Whether medication is given at times for maximum effect;
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- Whether staff know how to manage emergencies and complications, including equipment failure and alarm systems (if any), bleeding/hemorrhaging, and infection/bacteremia/septic shock;
- Whether facility staff are aware of the care of shunts/fistulas, infection control, waste handling, nature and management of end stage renal disease (including nutritional needs, emotional and social well being, and aspects to monitor); and
- Whether the treatment for this (these) resident(s), affects the quality of life, rights or quality of care for other residents (e.g., restricting access to their own space, risk of infections).

**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.

C. **Quality of Life Protocols.**-- Task 5D includes the following subtasks: 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 also 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 you have discovered about this resident or about the facility that you would like to discuss with the resident. (You need not list issues that are already covered in the other questions of the interview.)

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, you may have 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 you have 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 your explanation to the resident of the purpose of the interview. Discuss with the resident that you may want to write some of her/his answers 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 you know about this resident to begin the conversation. Try to seek some commonality between the resident and yourself that will allow the resident to develop some ease in talking with you. For example, you might remark on family pictures and other personal items you see in the resident’s room, or you might bring up a past occupation or hobby or a current activity preference of the resident that also interests you. Share a little about yourself, as appropriate.

Use the resident interview protocol to guide your 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 your 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, you need not investigate further.
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 (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. (You need not write concerns that are already covered in other questions of the interview.)

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 you in introducing yourself 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, you may want to 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 you 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. You will also 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. You will also 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, you may want to discontinue this interview. If you choose to do so, 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, you may want to partially complete the interview with whatever information you can obtain 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 you have 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 you have learned about the resident during the Resident Review to write any special items you wish 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 is this resident being addressed by staff? 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 one 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 you can observe what is happening as staff interact with the resident in his/her room. 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. You may already have completed some observations of this resident prior to the interview, as part of the Resident Review. Continue making observations until you have covered all probes on the worksheet, including the special items you noted for observation. When making observations of the resident in particular settings, such as an activity or physical therapy, you need not observe for the entire duration of the activity or therapy session.
Use the probes in this protocol to guide your 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 you see and hear, 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 you observed. For example, you observed at lunch, 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 your 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 you have obtained information 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 told you in confidence to be shared with the facility, respect their wishes.

However, you can still investigate the issue. During the survey, you can discuss the issue with the team and make the topic the subject of other interviews and observations. For example, a resident has told you that certain staff "make fun" of him/her, but he/she asks you to keep that in confidence. You may not refer to the resident's comment 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. If you are aware of which staff are involved, attempt to observe these staff interacting with residents.

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

TASK 5E - MEDICATION PASS

A. General Objective.--The general objective of the medication pass is to observe the actual preparation and administration of medications in order to assess compliance with 42 CFR 483.25(m).

B. General Procedures.--Record observations on the Medication Pass Worksheet (HCFA-677, Exhibit 88). The column marked "Record" is for the purpose of recording the
physician's actual order. Do this only if the physician's order differs from your observation of the administration of the drug. When observing the medication pass, do the following:

- See Guidance to Surveyors for specific information on conducting the medication pass.
- Be as neutral and unobtrusive as possible during the medication pass observation.
- Initially observe a minimum of 20-25 opportunities for errors (opportunities are both the drugs being administered and the doses ordered but not administered). Strive to observe as many individuals administering medications as possible. This provides a better overall picture of the accuracy of the facility's entire drug distribution system. Ideally, the medication observation could include residents representative of the care needs in the sample, or the actual sampled residents. This would provide additional information on these residents, and provide a more complete picture of the care they actually receive. For example, if blood sugars are a problem, insulin administration may be observed. If eye infections are a problem, antibiotic eye drops may be observed, if residents are in pain, as needed pain medications may be observed, etc. Observe different routes of administration (i.e., eye drops, injections, NG administration, inhalation). If you found no errors after reconciliation of the pass with the medical records, this task is complete. If you found 1 or more errors, observe another 20-25, opportunities for errors.
- Calculate the facility's medication error rate. If you determine that the facility's significant and non-significant error rate is 5 percent or more, or that one significant error has occurred, a medication error deficiency exists.

**TASK 5F - QUALITY ASSESSMENT AND ASSURANCE REVIEW**

**A. General Objectives.--**The quality assessment and assurance review protocol is designed to determine if:

1. A Quality Assessment and Assurance Committee exists and meets in accordance with the regulatory requirements of 42 CFR 483.75(o); and
2. The committee has a method, on a routine basis, to identify, respond to, and evaluate its response to issues which require quality assessment and assurance activity.

Facility compliance with CFR 483.75(o) is not dependent upon identification of quality deficiencies identified by the survey team, but rather by survey team identification of an effective QA committee that is constituted and meets according to the regulatory requirements, and identifies and resolves quality deficiencies pertinent to the quality of care and quality of life of facility residents.

**B. General Procedures.--**

1. The review of requirements at 42 CFR 483.75(o) will be conducted only after the Phase 2 sampling meeting.
2. The review is postponed until this time to ensure that facility quality deficiencies are not identified by the survey team through the use of records of the facility's quality assessment and assurance activities.
3. The protocol has 2 parts:
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a. Part 1 applies to all facilities; and

b. Part 2 is initiated and builds upon Part 1, when the survey team has identified actual or probable quality deficiencies during the first phase of the survey.

C. Protocol --

1. **Part 1 - All Facilities.** -- Through interview with administrative staff and Quality Assessment and Assurance Committee members, determine if:
   
   - The facility has a Quality Assessment and Assurance Committee;
   - The committee consists of, at a minimum, the Director of Nursing, a physician designated by the facility and 3 members of the facility staff;
   - The committee meets at least quarterly;
   - The committee has a formal method to identify issues in the facility which require quality assessment and assurance activities; and
   - The committee has a formal method to respond to identified quality deficiencies and evaluate the effectiveness of that response.

   Part 1 should not include a review of committee minutes that address actual quality deficiencies. A written description of the Committee's process or protocol for identifying quality deficiencies, coupled with interviews indicating that this process is actually followed, is satisfactory documentation for Part 1.

2. **Part 2 - Facilities With Identified Actual or Probable Quality Deficiencies.** -- The survey team conducts this investigation through interviews with Committee members and, as necessary, directs care staff to determine if the facility:

   - Has identified quality deficiencies;
   - Has developed and implemented a plan to address those quality deficiencies; and
   - Has evaluated, or has a plan to evaluate, the effectiveness of the planned implementation.

The surveyors' goal in this part of the survey is to determine whether the facility has an effective method of identifying quality deficiencies and dealing with them. You may do this by asking the facility to describe a sample of the quality deficiencies they have identified and dealt with. Surveyors should be guided by the following principles in this part of the survey:

   - The surveyors' goal during this part of the survey is to ascertain whether the facility has a QA committee which addresses quality concerns and that staff know how to access that process;
   - Surveyors may ask QA committee members and/or direct care staff how the QA committee functions, what the quality assurance and assessment process in the facility is, whether direct care staff know how to access the QA process and committee, and whether the QA committee is responsive to QA concerns submitted to it;
   - Committee records and/or minutes, including those identifying details of the
specific quality deficiencies which have been dealt with or are currently being dealt with should not be reviewed;

  o Surveyors may also ask the facility (i.e., the QA committee) to describe a sample of the types of quality deficiencies the facility has identified and how it addressed them. These need not be practices that the survey team has identified as concerns. Such a sample should consist only of quality deficiencies which the facility believes it has resolved through its quality assurance process (i.e., past corrected problems);

  o Determine compliance in this phase by interviewing direct care staff to determine if they are familiar with the specific plan(s) for care described by the QA committee and have implemented them. It is not necessary that direct care staff know that the care they are providing is the result of a quality assurance plan, however, they should be implementing the plan as develop as a routine part of their resident care. Also, if the plan described by the QA committee is not being followed, determine whether there is a justifiable reason for the (for example, the facility replaced the process described by the QA committee with a different process based on updated protocols, medical knowledge, etc.);

  o If the facility has been out of compliance with a regulatory requirement between two surveys in which they were in compliance, that past noncompliance will not be cited by the survey team if a quality assurance program is in place and has corrected the noncompliance. An exception to this policy may be made in cases of egregious past noncompliance.

**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:

  o Screening of potential hires;

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

  o Prevention policies and procedures;

  o Identification of possible incidents or allegations which need investigation;

  o Investigation of incidents and allegations;

  o Protection of residents during investigations; and

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

B. **General Procedures:**

  o Utilize the Abuse Prohibition Investigative Protocol to complete this task.
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 (5) 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 as follows: “...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 four months, and select 5 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.
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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 HCFA-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 or 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 pertinent information from all worksheets for the 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 your review of worksheets so that the first information the team discusses relates to those requirements that the facility has potentially failed to meet.
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 you have 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 your 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 your 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 decisionmaking discussion on the HCFA-807. (See Exhibit 98.)

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 seven 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 falls 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:
   - Development of, or worsening of, a pressure sore;
   - Loss of dignity due to lying in a urine-saturated bed for a prolonged period;
   - 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 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 you must determine if you have 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 your
sample, you determined that care provided caused actual harm to the resident, you would have
a deficiency of isolated actual harm, but you would not have sufficient evidence to determine that
there was substandard care. Thus, you would need to expand your sample before determining
that substandard 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
your sample and only one had deficient care, there would be no need
to expand your sample. If the team verifies the existence of SQC, they inform the administrator 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.

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

III. THE EXTENDED SURVEY AND PARTIAL EXTENDED SURVEY

A. 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
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procedures that may have produced the substandard quality of care. For an extended survey and partial extended survey, 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 your observations from the extended or partial extended survey on the HCFA-805, (see Exhibit 93) or the HCFA-807 (see Exhibit 95).

B. 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 your 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 your 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 your observations and interviews do not "match," investigate further.

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

C. 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.

IV. 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. Indicate the data prefix tag and regulatory citation, followed by a summary of the evidence and supporting observations

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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 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 HCFA-2567. A plan of correction is not required, but a facility is expected to correct all deficiencies.

The statement of deficiencies should:
  o Specifically reflect the content of each requirement that is not met;
  o Clearly identify the specific deficient entity practices and the objective evidence concerning these practices;
  o Identify the extent of the deficient practice, including systemic practices, where appropriate; and
  o Identify the source(s) of the evidence (e.g., interview, observation, or record review).

Following deficiency categorization (Section V), enter on Form HCFA-2567L the letter corresponding to the box of the scope and severity grid (SOM Part 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 HCFA-2567L.

V. 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:

- 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.

- 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.

- 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.

VI. POST SURVEY REVISIT (FOLLOW-UP)

In accordance with §7317, the State agency conducts a revisit 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 4 elements a facility must address in developing 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 almost always necessary to ascertain whether the deficient practices have indeed 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. 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 HCFA forms during this survey. However, if the need for documentation is minimal, use the Surveyor Notes Worksheet (HCFA-808). (See Exhibit 95 to record the results of the revisit.)

VII. ABBREVIATED STANDARD SURVEYS

A. Complaint Investigations.--The survey agency must review all complaint allegations and conduct a standard or an abbreviated standard survey to investigate complaints of violations of requirements if its review of the allegation concludes that:

- A deficiency in one or more of the requirements may have occurred;
- Only a survey can determine whether a deficiency or deficiencies exist; and
The complaint is general or specific and may involve staff, residents, volunteers, the physical environment or administration.

Complaint investigations follow, as appropriate, the pertinent survey tasks, and information gathered is recorded on the appropriate survey worksheets. However, if the documentation required is minimal, use the HCFA-807 to record information during the complaint investigation. Record deficiencies on the HCFA-2567 or the Notice of Isolated Deficiencies, or both as applicable.

The survey agency does not conduct a survey if the complaint raises issues that are outside the purview of Federal participation requirements.

The timing, scope, duration and conduct of a complaint investigation are at the discretion of the State survey agency, except when the complaint involves an allegation of immediate jeopardy to resident health and safety, which must be investigated within 2 working days of receipt. (See §7700.) The team should conduct the necessary investigation to resolve the complaint. If the complaint concerns conditions on a certain day (e.g., on weekends), or on a certain shift (e.g., 11 p.m. - 7 a.m.), the survey agency should make an attempt to investigate it at the time relevant to the complaint. In most cases, the following tasks, or portion of tasks, should be performed in a complaint investigation:

1. Task 1 - Offsite Survey Preparation. --Obtain as much information as you can about the complaint before you begin to plan your investigation, including:
   a. Name of complainant;
   b. Nature of the complaint - describe exactly the facts of the complaint situation;
   c. Information about when the complaint situation occurred, whether it was an isolated event or an ongoing situation - date, time, time between different events;
   d. Place where the incident happened - care unit, resident room;
   e. How it happened - sequence of events;
   f. Whether a resident or a family member of a resident was involved;
   g. Witnesses to complaint situation - anyone who saw incident happen;
   h. Staff or other residents involved; and
   i. Other persons involved - volunteers or visitors.

Review any information about the facility that you think would be helpful to know in planning your investigation such as Oscar Reports 3 and 4, and State agency files. Contact the ombudsman to discuss the nature of the complaint and whether there have been any similar complaints reported to and substantiated by the ombudsman.

Review the related regulatory requirements or standards that pertain to the complaint. For example, if it is a complaint about abuse, review the requirements at 42 CFR 483.13.

Plan the investigation. Before you go to the facility, plan what information you need to obtain during the complaint investigation based on the information you have already acquired. Consider practical methods to obtain that information.
2. Task 2 - Entrance Conference/Onsite Preparatory Activities.--Onsite complaint investigations should always be unannounced. Upon entrance, advise the facility's administrator of the general purpose of the visit. It is important to let the facility know why you are there, but protect the confidentiality of those involved in the complaint. Do not release information that will cause you to lose opportunities for pertinent observations, interviews, and record reviews required for a thorough investigation. For example, if the complaint is that food that is intended to be served hot is always served cold, you would not tell the facility the exact complaint. Rather, you may say it is a situation related to dietary requirements.

3. Task 5 - Information Gathering.--The order and manner in which you gather information will depend on the type of complaint you are investigating. Conduct comprehensive, focused, and/or closed record reviews as appropriate for the type of complaint. It is very important to remember that the determination of whether the complaint happened is not enough. The surveyor needs to determine noncompliant facility practices related to the complaint situation and which, if any, requirements are not met by the facility.

Do your information gathering in order of priorities, i.e., obtain the most critical information first. Based on this critical information about the incident, determine what other information to obtain in the investigation.

Observations, record review and interviews can be done in any order necessary. As you obtain information, use what you have learned to determine what needs to be clarified or verified as you continue the investigation.

Observe the physical environment, situations, procedures, patterns of care, delivery of services to residents, and interactions related to the complaint. Also, if necessary, observe other residents with the same care need. After determining what occurred, i.e., what happened to the resident and the outcome, investigate what facility practice(s) or procedures led to the occurrence of the incident.

EXAMPLE: It was verified through your investigation that a resident developed a pressure sore/ulcer which progressed to a Stage IV, became infected and resulted in the resident requiring hospitalization for aggressive antibiotic therapy. Observe as appropriate: dressing changes, especially to any other residents with Stage III or IV pressure sores; infection control techniques such as hand washing, linen handling, and care of residents with infections; care given to prevent development of pressure sores (such as turning and repositioning, use of specialized bedding when appropriate, treatments done when ordered, keeping residents dry, and provision of adequate nutritional support for wound healing).

Record review: If a specific resident is involved, focus on the condition of the resident before and after the incident. If there are care issues, determine whether the appropriate assessments, care planning, implementation of care, and evaluations of the outcome of care have been done as specified by the regulatory requirements.

EXAMPLE: For a complaint of verbal and physical abuse, review the record to determine the resident’s mood and demeanor before and after the alleged abuse. Determine if there are any other reasons for the change in the resident’s demeanor and behavior. Determine whether an assessment has been done to determine the reason for the change in mood and behavior. Does the record document any unexplained bruises and/or complaints of pain, and whether they occurred in relation to the alleged incident?

Interviews: Interview the person who made the complaint. If the complainant is not at the facility at the time of the survey, he or she should be interviewed by telephone, if possible. Also, interview the person the complaint is about. Then, interview any other witnesses or staff.
involved. In order to maintain the confidentiality of your witnesses, change the order of interviews if necessary. You may not want to interview the person who made the complaint first, as that may identify the person to the facility as the complainant. Interview residents with similar care needs at their convenience.

As interviews proceed, prepare outlines you need for other identified witnesses and revise outlines as new information is obtained.

4. Task 6 - Information Analysis. --Review all information collected. If there are inconsistencies, do additional data collection as needed, to resolve the inconsistencies. Determine if there is any other information still needed.

Determine whether:

- The complaint is substantiated;
- The facility failed to meet any of the regulatory requirements; and
- The facility practice or procedure that contributed to the complaint has been changed to achieve and/or maintain compliance.

5. Task 7 Exit Conference: Advise the administrator of the complaint investigation findings and any present deficiencies. Do not inform him/her of confidential information unless the individual who provided you with the information specifically authorizes you to do so.

If a deficiency is not present now, but was present and has been corrected (past noncompliance), notify the facility orally and in writing that the complaint was substantiated because deficiencies existed at the time that the complaint situation occurred. (See Task 5F, Section A and §7510 for specific information when a CMP is imposed for egregious non-compliance concerning past noncompliance.)

If the complaint is unsubstantiated, that is the surveyor(s) cannot determine that it occurred and there is no indication of deficient practice, notify the facility of this decision.

Follow your usual office procedure in notifying the resident and/or person who made the complaint of your findings.

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. Collect information about the changes in the facility's organization and management on the Ownership and Control Interest Disclosure Statement (HCFA-1513). (See Exhibit 6.)

VIII. 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 HCFA-2567 in place of the resident's name, which should never be used on the HCFA-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.

Your 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 HCFA-2567 has been written, portions of the worksheets explaining the findings reported on the HCFA-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.

IX. 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 Health Care Financing Administration, 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.

X. ADDITIONAL PROCEDURES FOR MEDICARE PARTICIPATING LONG TERM CARE FACILITIES

Medicare-participating long term care facilities are obligated to inform Medicare beneficiaries about specific rights related to billing, and to submit bills to the Medicare intermediary when requested by the beneficiary. In a Medicare-certified long term care facility, verify compliance with these requirements. Listed below are the requirements and the survey process you must follow:
If a Medicare SNF provider believes, on admission, or during a resident's stay, that Medicare will not pay for skilled nursing or specialized rehabilitative services, the facility must inform the resident or his/her legal representative in writing why these specific services may not be covered. The facility must use the mandatory denial notice found in §358 of the Skilled Nursing Facility Manual, and keep a copy of this uniform denial notice on file. Failure to give notice using the uniform facility denial notice or to submit the bill, if requested by a resident, may constitute a violation of the facility's provider agreement to submit information to the intermediary. (See 42 CFR 489.21(b).)

The facility is also required to inform each Medicare resident of his or her right to request that the facility submit the bill to the Medicare payor (demand bill). If the resident requests that the bill be submitted to the intermediary or carrier for a Medicare decision, then evidence that the submission has occurred should also appear in the resident's record. The facility must not charge the resident while the demand bill is under review by the Medicare payor.

During the entrance conference, obtain a list of Medicare residents who requested demand bills in the past 6 months. From this list, randomly select one resident's file to determine if the bill was properly submitted to the intermediary. In addition, draw a sample of all residents in the facility.

The number sampled for this procedure must be equal to the sample size selected for quality of life resident interviews. Use the Sample Selection Table (see page 19) to obtain the correct sample size. Check to determine that the denial letters included appropriate notice information and that bills were submitted upon request. Review billing records for the last 6 months for each resident selected. During resident interviews use the following probes:

- [Individual] Do you know what things or services you pay for out of your own pocket? Who handles the payment for these items?
- [Individual] How do you find out how much these services or things cost?
- [Individual] Tell me how you find out what you have to pay for here?
- [Individual] When you receive a bill to pay for services out-of-pocket, does the facility explain why it believes Medicare will not pay for the services? Does the facility let you know that, if you disagree, you can have a bill submitted to Medicare?
- [Individual] Have you received a bill which you asked to have submitted to Medicare or your insurance company? How has the facility helped you or discouraged you from submitting the bill?
- [Group] Have there been any changes in the charges since you've been here? How do you find out about these changes?
- [Group] How does the facility give you information about your Medicare or Medicaid benefits?
- [Group] Did you or your family receive an explanation of any charges or monthly bills?

If residents are not clear about the scope of services they are entitled to, or the additional services provided by the facility and the cost of these services, or their right to have bills submitted to Medicare, and/or you identify problems during the review of resident records, either in the uniform notice or the bill submittal process, interview administrative staff to determine how the facility informs
residents about their Medicare and Medicaid benefits, the non-covered services the facility provides, and the facility's charges for these services. Review additional resident records to assure the facility is using the uniform facility denial notice.

If 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. If the facility is in violation of notice requirements, cite tag F156.

When reviewing facility plans of correction, if a deficiency is noted with respect to billing procedures, it may be appropriate to expect submission of past claims.