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Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 21 **Date: OCTOBER 20, 2006**

SUBJECT: Revised Appendix P & Appendix PP-New Tag F334

I. SUMMARY OF CHANGES: Revised Appendix P Task 2 and Sub-Task 5C. Also a new regulatory Tag, F334, Influenza and Pneumococcal Immunizations has been added to Appendix PP.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: October 15, 2006
IMPLEMENTATION DATE: October 15, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix P/II-The Survey Process/IIB-The Traditional Survey/Task 2-Entrance conference/Onsite Preparatory Activities
R	Appendix P/II-The Survey Process/IIB-The Traditional Survey/Task 5/ Sub-Task 5C-Resident Review
N	Appendix PP/§483.25(n)/Influenza and Pneumococcal Immunizations/Tag F334

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
x	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

Appendix P – Survey Protocol for Long Term Care Facilities – Part I

Task 2 - Entrance Conference/Onsite Preparatory Activities

(Rev.21, Issued: 10-20-06, Effective: 10-15-06, Implementation: 10-15-06)

A. Entrance Conference

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

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

3. The team coordinator should:

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

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

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

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

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

   - Inform the administrator that there will be interviews with individual residents, groups of residents, family members, friends, and legal representatives, and that these interviews are conducted privately, unless the interviewees request the presence of a staff member. Ask the administrator to ensure that there are times during the survey when residents can contact the

survey team without facility staff present and without having to ask facility staff to leave or to allow access to the team.

- Determine through interview with the administrator if the facility has a functioning QA&A committee. Determine:
  - Which staff participate on the committee;
  - Who leads the committee;
  - How often the committee meets; and
  - With whom should the survey team discuss QA&A concerns.
- Ask the administrator to provide the following information within 1 hour of the conclusion of the entrance conference (or later at the survey team's option):

1. List of key facility personnel and their locations, e.g., the Administrator; directors of finance, nursing services, social services, and activities; dietitian or food supervisor; rehabilitation services staff; charge nurses; pharmacy consultant; plant engineer; housekeeping supervisor; persons responsible for infection control and quality assurance; health information management professional; and the medical director;
2. A copy of the written information that is provided to residents regarding their rights;
3. Meal times, dining locations, copies of all menus, including therapeutic menus, that will be served for the duration of the survey;
4. Medication pass times (by unit, if variable);
5. List of admissions during the past month, and a list of residents transferred or discharged during the past 3 months with destinations;
6. A copy of the facility's layout, indicating the location of nurses' stations, individual resident rooms, and common areas, if not obtained in Task 1;
7. A copy of the facility admission contract(s) for all residents, i.e., Medicare, Medicaid, other payment sources;
8. Facility policies and procedures to prohibit and investigate allegations of abuse and the name of a person the administrator designates to

answer questions about what the facility does to prevent abuse. (See Task 5G, Abuse Prohibition Review, for further information);

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

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

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

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

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

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

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

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

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

- Also, ask the administrator the following questions:

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

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

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

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

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

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

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

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

B. Onsite Preparatory Activities

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

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

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

Sub-Task 5C - Resident Review

(Rev.21, Issued: 10-20-06, Effective: 10-15-06, Implementation: 10-15-06)

A. General Objectives

The general objectives of the Resident Review are to determine:

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

B. General Procedures

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

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

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

1. Meals;

2. Medications;

3. Activities;

4. Tube feedings and special treatments;

5. Specialized rehabilitation therapies; and

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

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

C. Comprehensive Care Review

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

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

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

    - Use of the Resident Assessment Protocols (RAPs);

    - Evaluation of assessment information not covered by the RAPs;

    - Identification of risks and causes of resident conditions;

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

- A review of the implementation of the care plan and resident response;
- A review of the relationship of the resident's drug regimen to the resident's condition (see the description of procedures for completing part C below);
- A thorough review of any of the following conditions that apply to the resident: weight loss, dehydration, pressure sores. This review is completed using the investigative protocols found below as a guide. (NOTE: All the residents selected for comprehensive reviews should have one or more of these concerns checked on the QM/QI reports [unless there are no residents with these concerns in the facility]); and
- An evaluation of the resident's dining experience (see Dining Observation Protocol below).

D. Focused Care Review Phase 1

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

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

E. Focused Care Review Phase 2

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

F. Closed Record Review

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

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

G. Conducting the Resident Review

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

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

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

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

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, Form CMS-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.

- 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 his/her 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 CMS 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 Adverse Drug Reactions (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.

    - 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:

- 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;

- 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;

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

- 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.

- This protocol does not supersede 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

- 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.

- 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 he/she is receiving tube feedings, observe the care and the outcomes of the interventions, facility monitoring and assessment, and nutritional needs/adequacy related to tube feeding.

Complete the following tasks:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I. Record Review

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

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

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

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

- The latest MDS to determine which RAPS were triggered. For a sampled resident receiving a comprehensive review, note all triggered areas. Also, review the

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

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

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

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

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

- Determine whether the facility documentation and resident status as observed indicate the decision to proceed or not to proceed to care planning was appropriate. This information will assist in determining whether a resident's decline or failure to improve was avoidable or unavoidable.

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

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

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

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

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

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

Investigative Protocol

Hydration

Objectives:

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

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

Task 5C: Use:

Use this protocol for the following situations:

- A sampled resident who flagged for the sentinel event of dehydration (QM/QI 7.3);
- A sampled resident who has one or more of the following QM/QI conditions:
    - 5.4 – Prevalence of fecal impaction;
    - 6.1 – Residents with a urinary tract infection;

- 7.1 – Residents who lose too much weight;
- 7.2 – Prevalence of tube feeding;
- 9.1 – Residents whose need for help with daily activities has increased; and
- Any of the three pressure ulcer QM/QIs: 12.1, 12.2, or 13.3.

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

Procedures:

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

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

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

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

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

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

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

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

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

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

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

- Review all related information and documentation to look for evidence of identified causes of the condition or problem. This inquiry should include interviews with appropriate facility staff and health care practitioners, who by level of training and knowledge of the resident, should know of, or be able to provide information about the causes of a resident's condition or problem.

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

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

Task 6: Determination of Compliance:

- Compliance with 42 CFR 483.25(j), F327, Hydration:
    - For this resident, the facility is compliant with this requirement to maintain proper hydration if they properly assessed, care planned, implemented the care plan, evaluated the resident outcome, and revised the care plan as needed. If not, cite at F327.
- Compliance with 42 CFR 483.20(b)(1) & (2), F272, Comprehensive Assessments:
    - For this resident in the area of hydration, the facility is compliant with this requirement if they assessed factors that put the resident at risk for dehydration, whether chronic or acute. If not, cite at F272.
- Compliance with 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans:
    - For this resident in the area of hydration, the facility is compliant with this requirement if they developed a care plan that includes measurable objectives and timetables to meet the resident's needs as identified in the resident's assessment. If not, cite at F279.
- Compliance with 42 CFR 483.20(k)(3)(ii), F 282, Provision of care in accordance with the care plan:
    - For this resident in the area of hydration, the facility is compliant with this requirement if qualified persons implemented the resident's care plan. If not, cite at F282.

Investigative Protocol

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 Form CMS-805 if they pertain to a specific sampled resident and on the Form CMS-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.

        BMI = weight (Kg)/height (M^2) or

        BMI = weight (lbs.)/height ($inches^2$) X 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.

- 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?

- 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 noncompliance 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 noncompliance with 42 CFR 483.25, F309, Quality of Care.

- Observe the delivery of care as described in the care plan, e.g., 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.

- 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), F 282, 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.

Task 5C: Use

This protocol will be used for:

- All sampled residents identified with malnutrition, unintended weight loss, mechanically altered diet, pressure sores/ulcers, and hydration concerns; and

- Food complaints received from residents, families and others.

General Considerations:

- Use this protocol at two meals during the survey, preferably the noon and evening meals.

- Record information on the Form CMS-805 if it pertains to a specific sampled resident, or on the Form CMS-807 if it relates to the general observations of the dining service/dining room.

    - Discretely observe all residents, including sampled residents, during meals keeping questions to a minimum to prevent disruption in the meal service.

- For each sampled resident being observed, identify any special needs and the interventions planned to meet their needs. Using the facility's menu, record in writing what is planned in writing to be served to the resident at the meal observed.

- Conduct observations of food preparation and quality of meals.

Procedures:

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

    - Comfortable sound levels;

    - Adequate illumination, furnishings, ventilation; absence of odors; and sufficient space;

    - Tables adjusted to accommodate wheelchairs, etc.; and

    - Appropriate hygiene provided prior to meals.

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

    - Resident's eyeglasses, dentures, and/or hearing aids are in place;

- Proper positioning in chair, wheelchair, gerichair, etc., at an appropriate distance from the table (tray table and bed at appropriate height and position); and

- Assistive devices/utensils identified in care plans provided and used as planned.

3. Observe the food service for:

    - Appropriateness of dishes and flatware for each resident. Single use disposable dining ware is not used except in an emergency and, other appropriate dining activities. Except those with fluid restriction, each resident has an appropriate place setting with water and napkin;

    - Whether meals are attractive, palatable, served at appropriate temperatures and are delivered to residents in a timely fashion.

        - Did the meals arrive 30 minutes or more past the scheduled mealtime?

        - If a substitute was needed, did it arrive more than 15 minutes after the request for a substitute?

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

4. Determine whether residents are being promptly assisted to eat or provided necessary assistance/cueing in a timely manner after their meal is served.

    - Note whether residents at the same table or in resident rooms, are being served and assisted concurrently.

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

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

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

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

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

Sample Tray Procedure

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

6. Observe for institutional medication pass practices that interfere with the quality of the residents' dining experience. This does not prohibit the administration of medications during meal service for medications that are necessary to be given at a meal, nor does this prohibit a medication to be given during a meal upon request of a resident who is accustomed to taking the medication with the meal, as long as it has been determined that this practice does not interfere with the effectiveness of the medication.

    - Has the facility attempted to provide medications at times and in a manner to support the dining experience of the resident, such as:

        - Pain medications being given prior to meals so that meals could be eaten in comfort;

        - Foods served are not routinely or unnecessarily used as a vehicle to administer medications (mixing the medications with potatoes or other entrees).

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

    - Determine if the facility is monitoring the foods/fluids consumed. Procedures used by the facility may be used to determine percentage of food consumed, if available; otherwise , determine the percentage of food consumed using the following point system:

        - Each food item served except for water, coffee, tea, or condiments equals one point. Example: Breakfast: juice, cereal, milk, bread and butter, coffee (no points) equals four points. If the resident consumes all four items in the amount served, the resident consumes 100% of breakfast. If the resident consumes two of the four food items served, then 50% of the breakfast would have been consumed. If three-quarters of a food item is consumed, give one point; for one-half consumed, give .5 points; for one- fourth or less, give no points. Total the points consumed x 100 and divide by the number of points given

for that meal to give the percentage of meal consumed. Use these measurements when determining the amount of liquids consumed: Liquid measurements: 8 oz. cup = 240 cc, 6 oz. cup = 180 cc, 4 oz. cup = 120 cc, 1 oz. cup = 30 cc.

- Compare these findings with the facility's documentation to determine if the facility has accurately recorded the intake. Ask the staff if these findings are consistent with the resident's usual intake; and

- Note whether plates are being returned to the kitchen with 75% or more of food not eaten.

8. If concerns are noted with meal service, preparation, quality of meals, etc., interview the person(s) responsible for dietary services to determine how the staff are assigned and monitored to assure meals are prepared according to the menu, that the meals are delivered to residents in a timely fashion, and at proper temperature, both in the dining rooms/areas and in resident rooms.

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

Task 6: Determination of Compliance:

- Compliance with 42 CFR 483.35(d)(1)(2), F364, Food

  - The facility is compliant with this requirement when each resident receives food prepared by methods that conserve nutritive value, palatable, attractive and at the proper temperatures. If not, cite F364.

- Compliance with 42 CFR 483.35(b), F362, Dietary services, sufficient staff

  - The facility is compliant with this requirement if they have sufficient staff to prepare and serve palatable and attractive, nutritionally adequate meals at proper temperatures. If not, cite F362.

  NOTE: If serving food is a function of the nursing service rather than dietary, refer to 42 CFR 483.30(a), F353.

- Compliance with 42 CFR 483.15(h)(1), F252, Environment

  - The facility is compliant with this requirement if they provide a homelike environment during the dining services that enhances the resident's quality of life. If not, cite F252.

- Compliance with 42 CFR 483.70(g)(1)(2)(3)(4), F464, Dining and Resident Activities

    - The facility is compliant with this requirement if they provide adequate lighting, ventilation, furnishings and space during the dining services. If not, cite F464.

Investigative Protocol

Nursing Services, Sufficient Staffing

Objectives:

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

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

Task 5C: Use:

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

This protocol is to be used when:

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

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

Procedures:

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

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

    - Assess resident condition changes;

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

- Respond to nursing assistants' requests for assistance;

- Correct inappropriate or unsafe nursing assistants techniques; and

- Identify training needs for the nursing assistants.

- If problems were identified with care plans/services not provided as needed by the resident, focus the discussion with supervisory staff on the situations which led to using the protocol: how do they assure that there are adequate staff to meet the needs of the residents; how do they assure that staff are knowledgeable about the needs of the residents and are capable of delivering the care as planned; how do they assure that staff are appropriately deployed to meet the needs of the residents; how do they provide orientation for new or temporary staff regarding the resident needs and the interventions to meet those needs; and how do they assure that staff are advised of changes in the care plan?

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

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

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

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

Task 6: Determination of Compliance:

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

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

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

J. Closed Record Reviews

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

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

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

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

- Look for documentation related to transfer, discharge, and bed-hold, including facility's discharge planning, notices, and reasons for facility-initiated moves, e.g., proper planning and transferring subsequent to a change in payor or care needs; and
- Determine if within 30 days of the death of a resident, the facility conveyed the deceased resident's personal funds and a final accounting to the individual

or probate jurisdiction administering the individual's estate as provided by State law (see 42 CFR 483.10(c)(6), F160).

K. Review of a Resident Receiving Hospice Care

When a facility resident has also elected the Medicare hospice benefit, the hospice and the nursing home 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 there are concerns about the resident in relation to care provided by the hospice agency, refer the issue to the State Agency 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 accordance 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;
- 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.

M. Review of Influenza and Pneumococcal Immunizations

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

Appendix PP - Guidance to Surveyors for Long Term Care Facilities

F334

(Rev.21, Issued: 10-20-06, Effective: 10-15-06, Implementation: 10-15-06)

§483.25(n) Influenza and pneumococcal immunizations---

(Rev. 19, Issued: 06-01-06, Effective/Implementation: 06-01-06)

(1) Influenza. The facility must develop policies and procedures that ensure that--

i. Before offering the influenza immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;

ii. Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;

iii. The resident or the resident's legal representative has the opportunity to refuse immunization; and

iv. The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of influenza immunization; and

(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.

(2) Pneumococcal disease. The facility must develop policies and procedures that ensure that—

i. Before offering the pneumococcal immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;

ii. Each resident is offered an pneumococcal immunization, unless the immunization is medically contraindicate or the resident has already been immunized;

iii. The resident or the resident's legal representative has the opportunity to refuse immunization; and

iv. The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and

(B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.

v. Exception. As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal immunization may be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization.

Intent:

The intent of this requirement is to:

- *Minimize the risk of residents acquiring, transmitting, or experiencing complications from influenza and pneumococcal pneumonia by assuring that each resident:*
    - *Is informed about the benefits and risks of immunizations; and*
    - *Has the opportunity to receive, unless medically contraindicated or refused or already immunized, the influenza and pneumococcal vaccine; and*
- *Assure documentation in the resident's medical record of the information/education provided regarding the benefits and risks of immunization and the administration or the refusal of or medical contraindications to the vaccine(s).*

Definitions

Medical contraindication – A condition or risk that precludes the administration of a treatment or intervention because of the substantial probability that harm to the individual may occur.

Precaution - A condition in a potential recipient that might increase the risk for a serious adverse reaction or that might compromise the vaccine's induction of immunity. However, the risk for this happening is less than expected with a contraindication. For example, as a result of the resident's condition, complications could result, or a person might experience a more severe reaction to the vaccine than would have otherwise been expected; however, the risk for this happening is less than expected with medical contraindications.

Overview

Receipt of vaccinations is essential to the health and well-being of long term care residents. Establishing an immunization program facilitates achievement of this objective. Flu outbreaks place both the residents and the nursing facility staff at risk of infection. Pneumococcal pneumonia, a type of bacterial pneumonia, is a common cause of hospitalization and death in older people. People 65 years or older, are two to three times more likely than the younger population to get pneumococcal infections.

According to the Centers for Disease Control and Prevention (CDC), (see http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm) "the primary option for reducing the effect of influenza is immuno-prophylaxis with vaccine. Inactivated (i.e., killed virus) influenza vaccine and live, attenuated influenza vaccine are available for use in the United States. Vaccinating persons at high risk for complications and their contacts each year before seasonal increases in influenza virus circulation is the most effective means of reducing the effect of influenza. When vaccine and epidemic strains are well-matched, achieving increased vaccination rates among persons living in closed settings (e.g., nursing homes and other chronic-care facilities) and among staff can reduce the risk for outbreaks by inducing herd immunity. Vaccination of health-care workers and other persons in close contact with persons at increased risk for severe influenza illness can also reduce transmission of influenza and subsequent influenza-related complications. Antiviral drugs used for chemoprophylaxis or treatment of influenza are a key adjunct to vaccine …However, antiviral medications are not a substitute for vaccination."

Because of the clinically complex conditions of most nursing home residents, it is especially important for the facility to have a program in place for the prevention of disease. The Long Term Care regulations at 42 CFR 483.65 (Tag F441) Infection Control, requires that each "facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection." The regulation for immunization complements this existing infection control regulation in the areas of prevention of the development and transmission of disease. (For more information on immunizations programs, see http://www.cdc.gov/nip/publications/long-term-care.pdf.)

An effective immunization program involves collaborating with the medical director to develop resident care policies for immunization(s) that reflect current standards of practice and that include:

- *Physician approved policies for orders for influenza and pneumococcal polysaccharide vaccines (administration must be based on an assessment of each resident for possible medical contraindications – See Tag F386 for physician orders for vaccinations);*

- *Identification, of each resident's immunization status, including assessment for potential medical contraindications and record of vaccination;*

- *The vaccination schedule including mechanisms for recording and monitoring for administration of both influenza and pneumococcal pneumonia vaccines; and*

- *How pertinent information will be provided to residents. The facility may wish to use educational resources such as those provided by the U. S. Centers for Disease Control (CDC):*

    - *For trivalent inactivated vaccine (TIV)**:*** *http://www.cdc.gov/nip/publications/VIS/vis-flu.pdf;*

    - *For live attenuated vaccine (LAIV)LAIV: http://www.cdc.gov/nip/publications/VIS/vis-flulive.pdf; and*

    - *For pneumococcal polysaccharide vaccine; http://www.cdc.gov/nip/publications/vis/vis-ppv.pdf.*

For information on the influenza vaccines, the following site contains information on the background, types of vaccines, medical contraindications and other information: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm.

PROVISION OF IMMUNIZATIONS

In order for a resident to exercise his or her right to make informed choices, it is important for the facility to provide the resident with education regarding the benefits and potential side effects of immunizations. Facilities are required by 42 CFR 483.25(n)(1)(iv) and 42 CFR 483.25(n)(2)(iv) to document the provision of this education and the administration or refusal of the immunization or the medical contraindication of the immunization. There may be clinical indications or other reasons that a resident may not have received immunizations. Examples may include, but are not limited to the following:

- *A decision may have been made to delay vaccination for a resident because a precaution is present. According to the CDC, "under normal circumstances, vaccinations should be deferred when a precaution is present. However, a vaccination might be indicated in the presence of a precaution because the benefit of protection from the vaccine outweighs the risk for an adverse reaction. The*

presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines;"

- *A resident may be in the end stages of a terminal illness and receiving care that is limited to comfort or palliative measures only. Vaccination decisions for residents in the end stages of a terminal illness should be made jointly by the physician and resident;*

- *A resident may have medical contraindications for live attenuated influenza vaccine (LAIV) that, according to the Centers for Disease Control and Prevention (www.cdc.gov/flu/professionals/vaccination/shouldnotlaiv.htm) include,but are not limited to:*

    - *Persons who are 50 years of age or older, have asthma, reactive airway disease, or other chronic disorders of the pulmonary or cardiovascular systems;*

    - *Persons with underlying medical conditions, including such metabolic diseases such as diabetes, renal dysfunction, and hemoglobinopathies;*

    - *Persons with known or suspected immunodeficiency diseases or who are receiving immuno-suppressive therapies; and*

    - *Persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs;*

- *A resident may have already received the influenza vaccine for this season; and the pneumococcal immunization status is current; and*

- *The resident refused the immunization.*

NOTE: *Inactivated influenza vaccine contains noninfectious killed viruses and cannot cause influenza. Since there is a delay in developing antibodies after vaccination, the resident may develop influenza if there was exposure prior to receiving the vaccine. Coincidental respiratory disease unrelated to influenza vaccination can occur at any time after vaccination.*

Following vaccination with inactivated vaccine a person may experience local reaction and/or systemic reactions. Local reactions typically include soreness at the vaccination site and body aches. Systemic reactions include fever, malaise and myalgia and persons who have had no previous exposure to the influenza virus antigens in the vaccine are most often affected.

Other reactions as identified by the CDC, which may occur immediately, presumably allergic reactions (e.g., hives, angioedema, allergic asthma, and systemic anaphylaxis) rarely are due to the influenza component of the vaccination, but probably result from

hypersensitivity to other vaccine components; the majority of reactions probably are caused by residual egg protein. Persons who have had hives or swelling of the lips or tongue, or who have experienced acute respiratory distress or collapse after eating eggs should consult a physician for appropriate evaluation to help determine if vaccine should be administered. Persons who have documented immunoglobulin E (IgE)-mediated hypersensitivity to eggs, including those who have had occupational asthma or other allergic responses to egg protein, might also be at increased risk for allergic reactions to influenza vaccine, and consultation with a physician should be considered.

The following resource contains information on side effects of influenza vaccines:

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm

The resident's record should show vaccination administration to the resident unless the record contains documentation as to why vaccine was not administered, including but not limited to:

- *Precautions necessitating delay in administering the vaccination;*
- *Medical contraindications to the use of the vaccines;*
- *The eligible resident refused the vaccine; or*
- *The resident has already been immunized.*

***NOTE**: The influenza vaccine is given seasonally. Although the vaccines usually are representative of the influenza viruses likely to circulate during the flu season, occasionally the vaccine may not be as closely representative. The CDC indicates that administering the vaccine during October or November is generally most effective. However, residents admitted late in the influenza season, February or March, should be offered the influenza vaccine as late season outbreaks do occur. If a resident was admitted outside the influenza season (which is October 1 through March 31), the facility is not expected to offer the influenza vaccine to the resident, but they may, at their discretion.*

There should be documentation in the medical record if there is reason to believe that the pneumococcal vaccine was given previously but the date cannot be verified and this had an impact upon the decision regarding administration of the vaccine.

According to the CDC, "Pneumococcal polysaccharide vaccine generally is considered safe based on clinical experience since 1977, when the pneumococcal polysaccharide vaccine was licensed in the United States. Approximately half of persons who receive pneumococcal vaccine develop mild, local side effects (e.g., pain at the injection site, erythema, and swelling). These reactions usually persist for less than 48 hours. Moderate systemic reactions (e.g., fever and myalgia) and more severe local reactions (e.g., local induration) are rare. Intradermal administration may cause severe local reactions and is

inappropriate. Severe systemic adverse effects (e.g., anaphylactic reactions) rarely have been reported after administration of pneumococcal vaccine. For more information for the pneumococcal vaccine, see http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm

The pneumococcal vaccine does not prevent or lessen the impact of other types of pneumonia, such as aspiration, fungal, or viral.

INVESTIGATIVE PROTOCOL

Immunizations for Influenza and Pneumococcal Pneumonia

Objectives:

- *To determine if the facility's immunization program has been implemented and assures that residents are offered vaccines, and that residents or legal representatives receive related education;*

- *To determine if education regarding the benefits and potential side effects of immunization(s) was provided to the resident or legal representative each time a vaccine was offered; and*

- *To determine if each resident received the influenza and/or pneumococcal immunization(s) unless medically contraindicated, refused, or already immunized, or because of circumstances outside of the facility's control, such as vaccine production delays.*

Sampling*:*

For surveys during influenza season (October 1-March 31), follow the Procedure below for all residents who are selected for Comprehensive Reviews in Task 5C – Resident Review. If this number is below 5 residents, select additional residents from the Phase 1 Focused Review sample residents to meet the minimum number of 5 residents.

For surveys conducted outside influenza season, select 5 residents from the list the facility provided (see Task 2 – Entrance Conference) of all current residents who were in the facility during the previous influenza season. Give precedence in selection to those residents whom the survey team has selected as Phase 1 sample residents.

Procedure

For all residents selected for this review, determine the following:

For the provision of Pneumococcal Pneumonia Vaccine, review all selected residents for:

- *The provision of education related to the vaccine; and*

- *Either documentation of the administration of the vaccine; or*

- *If not provided, documentation as to why the vaccine was not provided, such as medical contraindications, refusal, or vaccine was already given prior to admission.*

For the provision of Influenza Vaccine:

- *For surveys occurring outside of influenza season, review selected residents for the provision of influenza education and immunization during the previous influenza season.*

- *For surveys occurring during influenza season, review all selected residents for the provision of influenza education and immunization during the current influenza season.*

  Review residents for:
  - *The provision of education for the vaccine; and*

  - *The administration of the vaccine, or if the vaccine was not provided, the reason why the vaccine was not provided, such as medical contraindications, refusal, unavailability of the vaccine, or vaccine was already given prior to admission.*

***NOTE**: (For surveys occurring during influenza season) - Unavailability of the influenza vaccine can be a valid reason why a facility has not implemented the influenza vaccine program, especially during the early weeks of the influenza season. It is also likely that a facility surveyed during October may not have administered the vaccine, yet. In these instances, ask the facility to demonstrate that:*

- *The vaccine has been ordered and the facility received either the vaccine or a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available;*

- *Plans are developed on how and when the vaccines are to be administered;*

- *Residents have been screened to determine how many and which residents are eligible and wish to receive the vaccine; and*

- *Education regarding immunizations has been implemented.*

For surveys occurring during influenza season, review the facility's immunization program if:

- *There has been no shortage or lack of availability of the vaccines and residents have not refused the vaccine, but the residents have not yet been vaccinated;*
- *The resident(s), have not been evaluated for vaccination status, or*
- *The resident(s) has not received information/education about the benefits and potential risks of the immunizations.*

For all facilities, determine if the facility developed influenza and pneumococcal vaccine policies and procedures including, but not limited to the following:

- *The type of information/education provided to the resident prior to administration of the immunization(s);*
- *How the influenza vaccine program is implemented during the influenza season (October through March), including physician orders and standing orders (if standing orders are used);*
- *How the pneumococcal vaccine will be provided (i.e., throughout the calendar year);*
- *How residents and families are educated about the benefits and risks of the vaccines;*
- *Processes to address issues that are out of the facility's control such as non-availability of vaccines due to production delay or distribution problems, or the presence of a precaution in a resident that may warrant a delay in vaccine;*
- *The identification and tracking/monitoring of a resident's vaccination status (including medical contraindications or delayed administrations); and*
- *The location of documentation of education and administration of the vaccines.*

If there are significant discrepancies between the facility's policies and procedures and the follow through for the vaccine program, ask the person responsible for implementing the procedures to explain the discrepancies.

Determination of Compliance (Task 6, Appendix P)

Synopsis of Regulation (F334)

The influenza and pneumococcal vaccination requirement has five aspects:

1. *The resident is provided education regarding the benefits and potential side effects of the vaccinations;*

2. *The facility must offer each resident influenza and pneumococcal immunizations unless the immunization is medically contraindicated, or the resident's immunization status is current;*

3. *The resident, or the resident's legal representative, has the right to refuse the vaccinations;*

4. *Each eligible resident is administered the influenza and pneumococcal vaccine (unless refused or contraindicated or the resident has already been immunized); and*

5. *The facility must document that education was provided and that the resident either received the vaccine(s) or, if not received, that the vaccines(s) was (were) refused or medically contraindicated or the resident had already been immunized.*

Criteria for Compliance

- *Compliance with 42 CFR 483.25 (n), F334, Influenza and Pneumococcal Immunizations*
    - *The facility is in compliance with this requirement:*
        - *If each resident receives education regarding the benefits and potential side effects of the vaccine(s);*
        - *If each resident has been evaluated for eligibility to receive the vaccine(s);*
        - *If each resident is offered, unless medically contraindicated or already vaccinated, an influenza vaccine October 1 through March 31 annually, and a pneumococcal vaccine;*
        - *If the resident has the opportunity to refuse; and*
        - *If the record includes documentation that indicates, at a minimum:*
            - *The resident was provided education regarding the benefits and potential side effects; and*

- *That the resident received the immunizations, refused the vaccination(s), or did not receive the vaccine(s) because of already being immunized, or as a result of a medical contraindication (including the nature of the resident's medical contraindications), unavailability, or a precaution that delayed the administration and a later date for administration has been planned.*

If the facility is not in compliance with each of these aspects of the requirement, cite F334.

Non-compliance for F334

After completing the investigative protocol, determine whether noncompliance with the regulation exists. Noncompliance for F334 may include, but is not limited to, one or more of the following:

- *An eligible resident did not receive either the influenza and/or the pneumococcal vaccines without a valid reason;.*
- *The facility did not evaluate to identify potential medical contraindications to the vaccines;*
- *The facility administered either of the vaccines to a resident who had refused them;*
- *The facility administered the influenza vaccine to a resident with medical contraindications, without physician involvement and/or approval;*
- *The facility administered the vaccine(s) to a resident who had an identified precaution, such as moderate or severe acute illness with or without fever, without physician involvement and/or approval;*
- *The facility administered the live attenuated influenza vaccine without physician approval to a resident who has a medical contraindication for live attenuated influenza vaccine;*
- *The facility failed to provide the pertinent information regarding the immunizations to the resident;*
- *The facility failed to document that the resident or resident's legal representative was provided education regarding the benefits and potential side effects of the influenza and, as applicable, the pneumococcal immunization; and*
- *The facility failed to document that the resident either received the vaccine(s) or did not receive the vaccine(s) due to medical contraindications or refusal.*

Potential Tags for Additional Investigation

During the investigation of F334, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Examples of some of the related requirements that may be considered when non-compliance F334 has been identified include the following:

- *42 CFR 483.20(b), F272, Comprehensive Assessments*
    - *Review whether the resident's comprehensive assessment documented whether the influenza and/or pneumococcal vaccines were administered in the facility, including the reason(s) why a vaccine may not have been received in the facility.*
- *42 CFR 483.65, F441, Infection Control Program*
    - *Review whether the facility's program for infection control includes the prevention of the development and transmission of disease and infections including influenza and pneumococcal pneumonia.*
- *42 CFR 483.75(i)(2), F501, Medical Director*
    - *Determine whether the medical director has collaborated with the facility to develop policies and procedures based on current standards of practice for an immunization program, including the assessment of the resident, identification of medical contraindications/precautions and emergency medical interventions in the case of allergic reactions to the vaccines.*

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that non-compliance with the regulation at F334 exists, the team must determine the severity of the deficient practice(s) and the resultant harm or potential for harm to the resident. The key elements for severity determination for F334 are as follows:

1. ***Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care.***

    Non-compliance related to an actual or potential harm/negative outcome for F334 may include, but is not limited to:

- *A resident who is not eligible to receive the vaccines is administered the vaccine and has a reaction;*

- *A resident who is eligible for the vaccine refuses the immunization, however, the resident is administered the vaccine; or*

- *The facility fails to implement the immunization program and the residents experience an outbreak of influenza.*

2. Degree of harm (actual or potential) related to the non-compliance.

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

- *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or*

- *If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.*

3. The immediacy of correction required.

Determine whether the non-compliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F334. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

NOTE: *The death or transfer of a resident who was harmed or injured as a result of facility non-compliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the non-compliance which allowed or caused the immediate jeopardy.*

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

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

- *Has allowed/caused/resulted in, or is likely to cause/allow/result in serious injury, harm, impairment, or death to a resident; and*
- *Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.*

Examples of the facility's non-compliance that may cause or contribute to negative outcomes at severity level 4 include:

- *A resident who is not eligible to receive the vaccine due to medical contraindications is administered the vaccine and experiences a life threatening reaction, such as anaphylactic shock; or*

- *Residents who were eligible to receive vaccines did not receive them as a result of the facility's failure to have any program for vaccinating residents.*

NOTE: *If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at severity level 3.*

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

Level 3 indicates non-compliance that results in actual harm, and can include, but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being. Examples of negative outcomes may include, but are not limited to:

- *A resident who was not eligible to receive the vaccine due to medical contraindications receives the vaccine and experiences a reaction that is not life threatening, but requires treatment; or*

- *Because of an unwarranted delay (e.g., several weeks after it is available to the facility) in administering the influenza vaccine despite its availability, an eligible resident who has agreed to receive the influenza vaccine develops influenza.*

NOTE: *If severity level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy

Level 2 indicates non-compliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided. Examples of outcomes may include, but are not limited to:

- *An eligible resident did not receive the vaccine, but did not develop symptoms of influenza;*

- *An eligible resident received two doses of the pneumococcal vaccine, due to a failure to document the receipt of the first dose, but did not experience any untoward reactions; or*

- *The staff did not assess for medical contraindications prior to providing the vaccines, but there were no reactions to the vaccine.*

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

- *The facility failed to document that information/education was provided to the resident prior to administering the immunizations.*