

Preparing for the Seven Mandatory Tasks in the Quality Indicator Survey

Welcome to Medline University. This continuing education course is designed for licensed and registered nurses at long-term care facilities. It is approved for 2 contact hours through the California Board of Registered Nursing and the Florida Board of Nursing. It will focus on the Preparing for the Quality Indicator Survey and the Seven Mandatory Facility-Level Tasks.

Nursing Board CE Credit

To obtain the CE credit hour(s), you must:

- 1) Attend the entire continuing education course
- 2) Take a post-test with a proficiency score of at least 80% or higher,
- 3) Complete the evaluation survey

After successful completion of the proficiency exam and evaluation survey, you will be prompted with a course completion certificate. Partial credit will not be awarded for this educational course.

Course Overview

CMS is transitioning from its traditional, paper-based survey process to the Quality Indicator Survey on a state-by-state basis as surveyors are trained in the new process and technology. Like traditional state surveys, the QIS starts with offsite preparation by the survey team and an onsite entrance conference with the survey team and key members of the facility staff.

This continuing education course will focus on two different aspects of the Quality Indicator Survey. The first part of the course will focus on the types of documents—such as the resident census list, dining room schedules and meal times or facility records—needed by surveyors to conduct a Quality Indicator Survey. After we've reviewed the QIS preparation process, we'll review the Mandatory Facility-Level Tasks used in Stage 1 of each Quality Indicator Survey.

Preparing for the Quality Indicator Survey

The Quality Indicator Survey is a computer-based, two-stage investigative tool used by the Centers for Medicare and Medicaid Services to determine how well nursing homes that serve CMS beneficiaries comply with federal regulations. Unlike traditional state surveys, with QIS each state and each surveyor follows the same structured process for assessing compliance with federal guidelines.

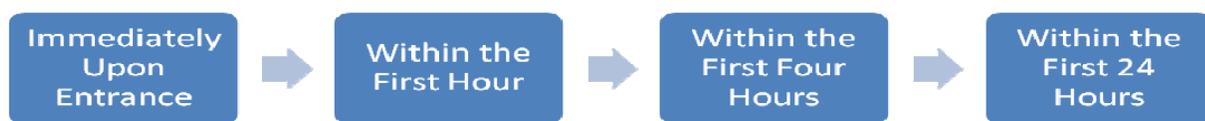
QIS surveyors are rigorously trained to ensure that they will conduct consistent and structured reviews from facility to facility and from state to state when investigating quality of care and quality of life issues during the survey. Each Quality Indicator Survey covers 51 different care areas and 128 Quality of Care and Life Indicators, or QCLIs.

QIS refers to the same federal regulations and interpretative guidance as traditional state surveyors. It is currently the state survey of record in numerous states, and all states—plus the U.S. Virgin Islands and Puerto Rico—will shift to QIS as their state survey of record as surveyors are trained.

Like traditional state surveys, the QIS starts with offsite preparation by the survey team and an onsite entrance conference with the survey team and key members of the facility staff. The first part of this continuing education course will focus on the different types of documents—such as resident census lists, dining room schedules and meal times or facility records—needed by surveyors to conduct a Quality Indicator Survey.

QIS Documentation Time Frame

Surveyors conducting a Quality Indicator Survey will require information from the facility at four different intervals:



Let's start by reviewing what is needed by surveyors from the facility at each of these four intervals.

CMS Goals

One of the goals that CMS wanted to achieve with the Quality Indicator Survey was to improve the consistency and accuracy of identifying problems in providing quality of life and quality of care at nursing homes through the annual survey process.

To help achieve this goal, CMS developed a highly structured process for conducting each survey that includes a systematic review of critical regulatory requirements and an objective investigation of potentially problematic issues that arise either during the course of the survey or from resident complaints.

This structure applies to how survey teams are instructed to start each Quality Indicator Survey. Like the QIS survey itself, the Entrance Conference and documents required are approached in a highly structured manner.

QIS Overview

The Quality Indicator Survey includes two distinct stages.

In Stage 1, surveyors will interview and observe residents, interview and observe staff members and conduct chart reviews. In addition to this work, they are required to complete seven different compliance reviews. The Seven Mandatory Facility-level Tasks include:

- 1) Liability Notices & Beneficiary Appeal Rights Review
- 2) Dining Observation
- 3) Infection Control
- 4) Kitchen/Food Service Observation
- 5) Medication Administration Observation
- 6) Quality Assessment and Assurance Review
- 7) Resident Council President/Representative Interview

Surveyors will proceed through the requirements for each of these seven tasks, entering their findings in the Data Collection Tool of the Tablet PCs that each surveyor carries, as well as entering in information from observations, interviews and chart reviews.

The Data Collection Tool then calculates whether the nursing home has exceeded the nationally-set threshold for compliance with each of these tasks. If the facility exceeds the threshold, they will be triggered for investigation in Stage 2. In Stage 2, surveyors will investigate triggered tasks, utilize CE Pathways, conduct reviews using Guidance to Surveyors.

The Five Triggered Tasks in the QIS are:

- 1) Abuse Prohibition
- 2) Admission, Transfer & Discharge
- 3) Environmental Observations
- 4) Personal Funds
- 5) Resident Council

Offsite Survey Preparation: Resident Samples

Every QIS begins with offsite survey preparation. During the offsite preparation, surveyors will start by creating the admission and census sample from which the majority of the residents interviewed and observed will be drawn.

Unlike the traditional survey process, QIS does not require surveyors to preselect potential residents for review prior to the survey. Instead, the resident sample is randomly determined using the Minimum Data Set and the Data Collection Tool (DCT). The Data Collection Tool is a software application that all surveyors carry on their Tablet PC computers. The tool provides a structured method for conducting the QIS surveys and the algorithm for determining if the facility exceeds nationally set thresholds for determining compliance. The resident samples include an admission sample of up to 30 current or discharged resident records from the previous 180 days of admissions, 40 current residents from the

current census and MDS. If the facility has less than 40 residents in its census, all current residents will be included in the Census Sample. These residents are interviewed during the first two days of the survey.

Offsite Survey Preparation: OSCAR Reports

QIS also makes use of the Online Survey, Certification and Reporting network or OSCAR, which is maintained by CMS for compiling facility-level data collected during the state survey inspection process and for recording complaints.

QIS also does not require surveyors to review the OSCAR 4 data from the Quality Measure/Quality Indicator (QM/QI) report. Surveyors will, however, continue to review the OSCAR 3 Report, which contains the facility profile. They will also review complaints entered into OSCAR. Surveyors will provide a copy of the OSCAR 3 report to the facility and review it to determine whether the facility has any patterns of repeat deficiencies and review any complaints filed with the survey agency. They will also contact the ombudsman's office, in accordance with state policy, to notify them of the impending survey and review any information relevant to the survey, and note any federal waivers or variances for review once they are onsite at the facility.

Entrance Conference

In QIS, as in traditional state surveys, the goal is to assess what it's like to live in a particular nursing home, not just on the day of the survey, but on a daily basis.

Once surveyors arrive at the facility, they will announce their presence to the person in charge and introduce members of the survey team. The survey is designed to be unannounced, and it is not possible to re-schedule or decline the survey. Doing so may result in the loss of certification and funding from CMS.

QIS Survey -- Immediately Upon Entrance. Once the survey team arrives, they will require four documents from the facility immediately upon arrival:

An Alphabetical Resident Census	A Completed New Admission Information Form	The Facility Floor Plan	Licensed and Registered Nurse Schedule
<ul style="list-style-type: none"> •The alphabetical listing of residents on the current census should include the room number and unit for each resident. •If some residents are not at the facility during the time of the survey, because they are in the hospital, at a home visit or engaged in some other activity outside the facility, this should be noted on the census document, which gets handed over to surveyors. 	<ul style="list-style-type: none"> •Surveyors will provide a date for the New Admission Information Form and will want a list of any new admissions occurring after that date, roughly from the last 30 days. •This listing should include only residents still residing in the facility, as well as the admission date, date of birth and room and unit number for each resident. 	<ul style="list-style-type: none"> •The surveyors will need to make their way throughout out the facility during the course of the survey. •This document will help the surveyors become acquainted with the layout of the facility and to plan the survey accordingly. 	<ul style="list-style-type: none"> •Surveyors will need the staffing schedules for licensed and registered nursing staff, in case they have questions or need assistance during the survey. •The survey also calls for interviews with the nurses on schedule at the facility.

Immediately Upon Entrance

Surveyors will provide signs, announcing the survey to the facility, during the entrance conference. Facility staff should post these signs in high visibility areas to make residents, visitors and staff aware that surveyors are in the building and will be conducting the survey.

They will also provide a copy of the Entrance Conference Worksheet for the facility. CMS Form CMS Form 20045 (01/09) focuses on residents receiving special services. Surveyors may require a workspace while they are in the building.

The survey team coordinator will conduct the entrance conference after the administrator or designee has arranged to provide the resident census and admission data, while the rest of the survey team will begin an initial tour of the facility. Facilities should assign someone to escort the survey team on a brief tour of the building, while the administrator or designee attends the entrance conference. During the entrance conference, the team lead will provide the facility contact with a copy of a QIS brochure.

Lastly, the survey team lead will ask if the facility has any nursing staffing waivers, and if it does, one surveyor will be assigned to review the facility's compliance with federal tag 355. Under F355, nursing homes can receive a waiver from state regulatory authorities if they are unable to provide licensed nursing staff on a 24-hour basis. Waivers are provided for several reasons, such as not able to recruit staff or if services can be provided without endangering resident health and safety.

Surveyors will also request information identifying the facility's emergency water source; verbal confirmation of this information—at any time during the survey—is acceptable.

Within the First Hour

Once the surveyors arrive, they will require five documents from facility staff within their first hour of arriving at the facility. While the survey team takes the initial tour, a staff member should be assigned to locate the five documents, so that they are ready at the conclusion of the tour.

Key Personnel

Surveyors will need to interact with key staff members during the survey. Provide a list of the title and location of key personnel, in case surveyors need to contact that individual.

Resident Council

One of the seven mandatory tasks of a QIS survey involves the Resident Council. To complete this mandatory task, surveyors must interview either the President of the Resident Council or a representative. If no Resident Council exists, the surveyor will skip this task but may also investigate whether residents have attempted to form a council in the past, and if an attempt was made, the surveyor will ascertain the reason why it was unsuccessful.

Meal Schedule & Locations

The Dining and Kitchen/Food Service Observation Reviews, two mandatory facility-level tasks in the QIS, both require that the surveyor observe meals in the dining room and other locations where residents eat to ensure that their needs are accommodated, that they receive appropriate assistance and that the food is adequate.

Medication Administration Schedule

The Medication Administration Observation, another mandatory task, requires that survey team observe at least 50 medication administrations to at least 10 randomly selected residents from different units within

the nursing home. Surveyors are trained to observe medication delivery on multiple routes and during multiple medication administration times to ascertain the medication error rate for the facility.

Closed Admission Sample Records

Surveyors will need all the closed records from the admission sample to complete the survey. Surveyors may need to store these and other documents in a secure location, which should be provided and accessible to the survey team during the course of the survey.

Within the First Four Hours

Within the first four hours of the commencement of the survey, the surveyors will require an additional seven documents from the facility staff. Many of these documents can be created in advance and updated as the census and admission lists change.

Ventilator/Dialysis/Hospice Residents

Surveyors will need a list of residents who receive ventilator, dialysis, Medicare hospice and/or end of life services—whether inside or outside of the facility. This information should be captured on CMS Form 20045 (01/09), which the survey team provided to the facility when they first arrived.

The bottom half of CMS Form 20045 concerns End Stage Renal Disease (ESRD) residents. If there are residents receiving dialysis within the facility, the facility will need:

- The name of those residents
- Their room number
- Dialysis treatment days and times
- The name of their assigned ESRD caregiver/technician, and
- The type of ESRD care, whether provided by a DME supplier or a ESRD or long-term care facility

It may be necessary to provide access to the written contract, agreement, policy and procedures and/or care plan, which specifies how ESRD care is coordinated to assist surveyors in evaluating the quality of care.

If there are residents receiving dialysis within the facility, the surveyor will also alert the state survey agency's ESRD survey team that home dialysis is being provided by the facility, informing them of any home dialysis care concerns that they identify.

Influenza / Pneumococcal Immunization

For the Infection Control Mandatory task, surveyors will need to review a list of each facility's vaccination policy and procedures. Infection Control is composed of two federal tags: 441 and 334. F441 deals with preventing and controlling infectious outbreaks, while 334 requires that facilities educate all residents or their legal representatives about the potential benefits and harmful side effects associated with both the influenza and pneumococcal immunizations.

For some residents, immunization may be contraindicated due to medication that they are already taking or for another medical reason. If an immunization is medically contraindicated or should be delayed due to some other precaution, the resident must be made aware. All nursing home residents have the right to refuse vaccination, but it is critically important that they understand the risks, if they decline the immunization.

For nursing homes whose annual state survey takes place during October 1st to March 30th, surveyors will select five resident files from the Census Sample Report to review. If the survey takes place outside of

influenza season, the surveyors will select five residents from the Census Sample Report, who were living in the facility during the previous influenza season. CMS requires that the facility document in the resident's medical record that they or their legal representative have received education on the benefits and risks of these vaccines, along with whether or not the resident received or refused the vaccine or if a vaccine was contraindicated by a medical officer. The surveyor will want to see that this documentation is provided in the charts of the five residents chosen for review.

Room Variance List

CMS sets a number of requirements for the rooms in certified nursing homes. Surveyors require a list of all rooms that meet any one of the following conditions and require a variance:

- Rooms with less than the required square footage
- Rooms with more than four residents
- Rooms below ground level
- Rooms without a window to the outside
- Rooms with no direct access to an exit corridor

Quality Assessment and Assurance Committee Information

Investigating compliance with the Quality Assessment and Assurance (QAA) requirement is one of the seven mandatory tasks in the QIS. The facility must provide the name of a lead contact for the committee, as well as the names of members and frequency of QAA meetings. QAA committees often take notes on the issues addressed by the group, however, facilities are not required to provide their meeting notes to surveyors.

Preadmission Screening and Resident Review (PASRR) Information

Preadmission Screening and Resident Review (PASRR) Information. CMS mandates Preadmission Screening and Resident Review (PASRR) for individuals suspected of having serious mental illness or mental retardation to ensure that long-term care facilities only admit those individuals requiring nursing facility care and that the facilities determine and provide the specialized services identified through preadmission screening. All individuals who apply to or reside in Medicaid nursing facility are required to receive a Level I PASRR screen to identify suspected mental retardation. Those suspected of having mental retardation must receive a Level II PASRR evaluation to confirm that they have mental retardation, to determine whether they require nursing facility

Experimental Research & Abuse Contact

Description of any experimental research occurring in the facility. If the facility is participating in any experimental research or study, information on the research and the residents involved must be provided to the survey team. The surveyors may launch an investigation into the nature of the research, if they deem necessary.

Abuse Prohibition Policy and Procedure Contact. Abuse Prohibition is one of the Triggered Tasks in the QIS. Surveyors will need the contact name for this individual to complete the survey.

With the First 24 Hours

Within the first 24 hours of the QIS, surveyors will need two additional types of documents to complete the survey:

Surveyors will provide the facility with a Medicare/Medicaid Application (CMS-671) and Resident Census and Conditions (CMS-672) for the facility to complete and return to the survey team.

To comply with the mandatory Liability Notices & Beneficiary Appeal of Rights Review task, each facility must demonstrate its compliance with the requirements for advising residents of potential liability and appealing to Medicare on their behalf. The facility must provide a list of Medicare residents who requested demand billing in the past six months, and a list of Medicare beneficiaries discharged from the facility in the past six months. This requirement applies only to facilities that accept Medicare beneficiaries.

For Medicare facilities, surveyors will select one file, preferably that of a private pay resident, for review to determine compliance with Federal Tags 156 and 492, which underscore each resident's right to be informed of the costs of any item or service offered by the facility that may not be covered by Medicare. Residents must be informed in writing and using certain forms of the probable costs of any such item or service, and given the opportunity to have the potential charge reviewed by a Financial Intermediary or Medicare Administrative Contract within the required time frame of one full calendar year following the year in which the item or service was provided. Residents should also not be billed while the review of their demand bill is pending.

Nursing homes have the option of using the Skilled Nursing Facility Advanced Beneficiary Notice Form (CMS Form 10055) or one of the five uniform Denial Letters from CMS¹ when providing denial and liability information. If no demand bills were requested in the previous six months, surveyors will close this task.

The survey will also include a closed record review of three Medicare beneficiaries who were discharged from the facility in the previous six months. The surveyor will look for a copy of the appropriate liability and appeal notice to ensure that it was given to the resident, that the appeal was submitted during Medicare's claim window and that the facility did not charge the resident on any appealed charges, while the decision was pending.

We're now concluded our review of the how to prepare for QIS; now let's review the Seven Mandatory Facility-Level Tasks that are part of Stage 1 of the QIS.

Seven Mandatory Tasks

The next part of this continuing education course will clearly explain the different aspects of each of the Seven Mandatory Facility-Level Tasks of the Quality Indicator Survey:

- 1) Liability Notices & Beneficiary Appeal Rights Review
- 2) Dining Observation
- 3) Infection Control
- 4) Kitchen/Food Service Observation
- 5) Medication Administration Observation
- 6) Quality Assessment and Assurance Review
- 7) Resident Council President/Representative Interview

In this section of the course, for each Mandatory Task we will:

- a) Describe the Federal Tags that comprise the task
- b) Review the Intent of the Federal Tags
- c) List all the documents, data and information facilities may need to provide to surveyors
- d) Describe the interviews and observations surveyors may engage in and document during the survey
- e) Review the critical element pathways surveyors will use to determine regulatory compliance

Facility-Level Tasks

In QIS, there are 12 different facility-level tasks. The first set of seven, which are the focus of this continuing education course, are mandatory tasks, meaning that these tasks will be investigated during the course of each Quality Indicator Survey.

The remaining five tasks are called *triggered* tasks. The Five Triggered Tasks are Abuse Prohibition, Administration Transfer and Discharge, Environmental Observations, Personal Funds and Sufficient Staffing Requirements. Surveyors may investigate one or all five of these tasks if data collected in Stage 1 of the survey exceeds the threshold set by CMS for a particular care area. In other words, these five tasks are only performed if a Quality of Care and Life Indicators (QCLI) in Stage 1 *triggers* these tasks for investigation in Stage 2. It only takes one QCLI rate exceeding a threshold to trigger a Stage 2 investigation, such as a Triggered Task.

Some Federal Tags reviewed in the Mandatory Tasks area, like F156 Resident Rights, also are included in Triggered Tasks. But for the most part, these two sets of facility-level tasks do not overlap. Let's start by reviewing all seven mandatory facility-level tasks.

We'll break periodically during the course to review the investigative direction that surveyors will use to determine whether the facility is meeting the compliance requirements for a particular mandatory task. Like other aspects of the QIS or traditional state surveys, the survey process is designed to help ascertain whether certified providers meet the regulatory requirements set by CMS by assessing the quality of care and services at that facility. However, surveyors are trained to avoid consulting with providers on how to put together a plan of corrective action. The surveyor may explain the deficiency, but it is not their responsibility to examine policies and procedures to determine the root cause of deficiencies or to provide a remedy for the provider.²

In this section of the course, we will explain the requirements of all seven mandatory tasks—*in specific enough terms*—to help you identify the most feasible means to achieve compliance. We'll also describe the Federal Tags on which this task is based, as well as the intent of regulation.

Liability Notices & Beneficiary Appeal Rights Review

The Liability Notices & Beneficiary Appeal of Rights review was formerly called the Demand Billing Review. This particular review got its name because Medicare Part A and Part B beneficiaries have the right to *demand* to see a bill for any charges that the facility believes Medicare will not cover. The charges may stem from any items or services provided by the facility, whether it's a skilled nursing service, rehabilitation service or a specialty item, that the facility believes may be denied by Medicare on the grounds that the item or service is not reasonable or not medically necessary. The resident, or their legal representative, must be informed of the possible denial in writing before or on the date of non-coverage. Demand billing issues may arise at the time of admission or at any time during the individual's stay at the facility.

In the QIS, surveyors will review the records of residents who were discharged from the facility in the preceding six months, as well as review the records of one Medicare beneficiary, who specifically requested a demand bill in the six months prior to the annual survey. To determine compliance, the appropriately written notices, demand bills, appeals and delayed charges must be properly documented in the files of the beneficiaries reviewed during

Federal Tags

There are two Federal Tags that provide the basis for this Mandatory Task: F156 and F492.

Federal Tag 156

The Federal Tag 156 covers the rights of all nursing home residents to be informed of both their rights as a Medicare beneficiary and the rules governing the facility in which they reside. This includes being informed of any fees that may fall outside of the scope of their Medicare coverage.

Residents of skilled nursing facilities have all the rights and protections of any United States citizen. These rights extend to the right to be informed in writing about fees and services before moving into any facility. Residents also have the right to be informed about their medical condition, medications and to see their own doctor, if they wish. They also have the right to refuse any medications or treatments.

To ensure that these rights are met, the review of their rights must be acknowledged in writing by the resident or his or her legal representative or surrogate.

Federal Tag 492

Federal Tag 492 focuses on the technical elements of demand billing compliance. If a facility fails to submit a demand bill to the Financial Intermediary or Medicare Administrative Contact within the required timeframe or charges the resident while an appeal decision is pending, this constitutes a violation of the facility's provider agreement with CMS and can result in a deficiency.

F492 also requires the facility to issue a Notice of Medicare Provider Non-Coverage (CMS Form 10123) when Medicare Part A services are terminated. This notice is sometimes called the "Expedited Appeal Notice" because the form provides the option to the beneficiary to have their termination of coverage reviewed in an expedited manner by their local Quality Improvement Organization.

However, the facility should not issue this notice if the beneficiary exhausts the Medicare covered days, as benefit days are set in law and cannot be extended. As with probable non-covered items or services, the facility must keep a copy of the Termination form on file, must file a claim when requested by the beneficiary and may not charge the resident while a decision is pending.

Intent

This regulation contains numerous stipulations about how and when the beneficiary, or their legal representative, must be informed of costs that they may be liable to pay as a resident in a skilled nursing facility. The intent of the two F Tags under review are two-fold. The goal of the regulations are to ensure that residents are not erroneously billed for services or items that Medicare may cover or unknowingly billed for items or services that the beneficiary would have declined had they understood that they were personally liable for the costs.

Secondly, this Task underscores the right of all nursing home residents to achieve their highest level of practical well-being. This may include receiving services that fall outside of the scope of Medicare coverage. Some residents may want to receive a certain item or services even if it is not covered. By issuing the Skilled Nursing Advance Beneficiary Notice, the facility and resident are protected as it clearly details the item of service, why it may not be covered, the estimated cost, the contact information of their Medicare Administrative Contact and the option to accept the item or service, which triggers the appeal, or to decline the item or service with the recommendation to consult with their physician.

By formally submitting all requests that the nursing home believes are not covered, it helps to ensure that fraudulent costs are not passed on to nursing home residents because a Financial Intermediary or Medicare Administrative Contact will review all claims submitted by the facility before the resident is charged for rendering the item or service.

Beneficiary Services

A qualifying Medicare beneficiary residing in skilled nursing facility must receive certain services—at no additional or outside cost to the beneficiary. These services include a semi-private room, meals, medical social services, medications, medical supplies and equipment used in the facility, ambulance transportation to the nearest facility supplier of medical services not offered at the nursing home and dietary counseling. The beneficiary will also received skilled nursing care as part of their coverage.

Skilled Care is defined as care that requires skilled staff to administer, manage, observe and evaluate. An example is the administration of intravenous injections. Skilled nursing and rehabilitation staff include registered nurses, licenses practical and vocational nurses, physical and occupational therapists, speech-language pathologists or audiologists.³ Medicare will also cover the costs of physical therapy, occupation therapy and speech language pathology services, if these services are needed to help the resident achieve their health goal.

There are numerous care options and services offered at skilled nursing facilities. Nursing home residents also have the right to refuse any of these treatments, and to understand if an item or services is not covered, though recommended by a physician. This right extends to the legal representative of any nursing home resident.

Demand Bill Compliance

For F492 compliance, nursing homes must explain in writing why a particular service may not be covered, the potential cost of the non-covered item or service, and the right of a Medicare beneficiary to have a claim submitted to Medicare and to appeal a claim if it is ultimately denied. Nursing homes have the option of using the Skilled Nursing Facility Advanced Beneficiary Notice Form (CMS Form 10055) or one of the five uniform Denial Letters from CMS.⁴

The Skilled Nursing Facility Advanced Beneficiary Notice (SNF ABN) is very important because it clearly state unless the resident receives the item or service, Medicare cannot determine whether or not it will pay for that particular item or service. This provision puts the onus on the resident to determine whether they truly want the item or service in question. Nursing home residents always have the right to refuse a treatment if they so desire.

If the resident decides that they both want the item or service in question and are willing to assume the liability for the costs if it is not covered by Medicare, the facility must submit a claim on the resident's behalf and not bill the resident for the item or service until Medicare makes a decision. If the resident declines to receive the item or service, they cannot submit a claim or appeal.

The facility must keep a copy of the SNFABN or denial notice on file, must file a claim when requested by a beneficiary and must not charge the resident for a Medicare covered Part A item or service while a decision is pending.

If Medicare Part A services are terminated, the facility must issue the Notice of Medicare Provider Non-coverage (CMS Form 10123) when there is a termination of all Medicare Part A services for coverage reasons. This form informs the beneficiary of their right of an expedited review of service termination by their local Quality Improvement Organization. Like the SNFABN form, the facility must keep a copy of the Notice of Medicare Provider Non-coverage on file, file a claim when requested by the beneficiary and must not charge the resident for Medicare covered Part A services or items while a decision is under appeal.

The facility must submit these demand bills to the Fiscal Intermediary (FI) or Medicare Administrative Contact (MAC), whenever requested by the Medicare Part A or B beneficiary. Accordingly, this task is only

mandatory for nursing home facilities that serve Medicare beneficiaries.

Notification & Appeal

All facilities must perform two critical functions if they believe a service is not covered by Medicare: First, the facility must provide a liability and appeal notice to the resident. This is done to ensure that the resident is aware that they are liable—may need to pay for the bill in question. Second, the facility must also allow the resident to appeal the billing decision by submitting the bill to the Financial Intermediary or Medicare Administrative Contact. The bill must be submitted within one full calendar year following the year in which the services were provided. For example, if the services were rendered between March 8, 2010 and April 20, 2011, the claim would need to be submitted by December 31, 2012.

Survey Prep

Within the first 24 hours of the survey, the surveyors will request a list of all Medicare beneficiaries who requested a demand bill in the past six months and a list of Medicare beneficiaries discharged from the facility in the past six months. From the list of beneficiaries who requested demand bills, the surveyor will randomly select the file of one resident for review. The surveyor will review the file to ensure that the demand bill was sent to the Financial Intermediary or Medicare Administrative Contract for review within the required time frame of one full calendar year following the year in which the item or service was provided.

The survey will include a closed record review of three Medicare beneficiaries who were discharged from the facility in the previous six months. The surveyor will look for a copy of the appropriate liability and appeal notice to ensure that it was given to the resident, that the appeal was submitted during Medicare's claim window and that the facility did not charge the resident on any appealed charges, while the decision was pending.

The Liability Notices & Beneficiary Appeal of Rights review Task only applies to facilities that serve Medicare beneficiaries. So, if your facility only serves Medicaid beneficiaries or private insurance patients, this particular task will not apply to your facility. If no Medicare beneficiaries requested a demand bill in the last six months, the surveyor will close this portion of the review and move on the review of discharged patients.

Infection Control & Immunizations

Infection Control and Immunizations is one of the seven mandatory facility-level tasks that state surveyors will conduct at all nursing homes during Quality Indicator Surveys. In this section of the course, we'll describe the Federal Tags on which this task is based, as well as the intent of regulation and recent changes to the interpretative guidance. We'll also review the investigative direction surveyors will utilize to determine if the nursing home is in compliance with federal regulations.

Federal Tags

The Infection Control and Immunizations Task is comprised of two Federal Tags: F441 and F334. The Investigative Protocol for F441 was recently updated by CMS, collapsing tags 441, 442, 443, 444 and 445 into one comprehensive Federal Tag—F441 covering Infection Prevention and Control.⁵ The resulting comprehensive Federal Tag, requires that the facility demonstrate practices to reduce, control and prevent outbreaks through transmission-based and cross-contamination precautions and corrective actions. Additionally, F441 requires that facility demonstrate consistent hand hygiene practices, which includes washing hands after each resident contact and prohibiting employees with communicable diseases or

infected skin lesions from direct contact with residents or their food. Lastly, compliance also requires that facilities demonstrate proper handling of linens to prevent the spread of infections.

F334

F334 focuses on the regulatory requirements for immunizing nursing home residents with particular focus on the influenza and pneumococcal vaccines. Because some residents may not want to take a vaccine due to the risks associated with immunization or if a vaccine is contraindicated by a medical professional, CMS requires that all residents or their legal representative be educated about these two annual vaccines each year, and for influenza immunizations, this process should take place during flu season, which occurs between October 1st and March 31st. As with any medication, a resident has the right to refuse a vaccination.

Intent F441

The intent of F441 is to protect residents from infection outbreaks and cross-contamination should they occur, and to also prevent these types of infections and outbreaks through best practices and precautions whenever possible. To assure compliance, CMS requires that a program be developed that performs surveillance and investigation to prevent and control outbreaks to the extent possible and record outcomes to improve practices. Lastly, Federal Tag 441 is also intended to assure consistent hand hygiene practices and processes to properly store, handle, process and transport potentially contaminated linens.

Intent F334

The intent of Federal Tag 334 is to minimize the risk that residents will acquire, transmit or experience complications from influenza or pneumococcal pneumonia by assuring that all residents understand the benefits and risks of immunizations and they have the opportunity to receive these vaccines, if they chose to receive them and if it's not medically contraindicated. To assure that these stipulations are met, every resident's medical record should include a signed acknowledgement of patient education about immunization and whether the vaccines were administered, refused or contraindicated.

According to CMS, infections account for up to half of all nursing home resident transfers to the hospital and when a resident is hospitalized with a primary diagnosis of infection the mortality rate can reach as high as 40 percent.⁶ The top three infections to nursing home residents are urinary tract, respiratory and skin/soft tissue infections.

Hepatitis B Infections

Although infection outbreaks from blood-borne pathogens like the Hepatitis B virus (HBV)⁷ are rare, the CDC has documented several cases of long-term residents becoming fatally infected with HBV in recent years. In its investigations, the CDC attributed the outbreaks to contaminated environmental surfaces or inadequately disinfected equipment, like glucose monitors.

The amended F441 regulation went into effect in late September 2009. Numerous nursing homes have faced the repercussions of lax infection prevention and control efforts during their annual state surveys, as a consequence. Some states are proactively investigating whether facilities in that state have effective infection prevention and control programs,⁸ focusing on whether glucometers that are used for multiple residents are properly cleaned and disinfected to prevent blood born pathogen transmission. Numerous state departments of health are recommending that facilities clean and disinfect shared glucose monitors after each resident use with a 1:10 bleach solution or an EPA-registered disinfectant or effective against HBV, HVC and Human Immunodeficiency Virus (HIV).⁹

Infection Control

The F441 regulation requires that all facilities create an Infection Prevention and Control Program with written policy and procedures to monitor, document and resolve issues. CMS also recommends, but does not require, that the program be lead by an *infection preventionist*, who oversees compliance and education. Surveyors will review each facility's infection prevention and control program to determine compliance. In particular, surveyors will want to determine that the facility demonstrates ongoing surveillance, recognition and control of infections to prevent the onset and spread of infection.

Proper Hand Washing & Glove Usage Techniques

To determine compliance with infection control guidelines, surveyors will observe staff practices during the course of the survey and enter narrative-style documentation for any areas of concern. Surveyors will look for adherence to proper hand hygiene techniques, glove usage and glove changes.

Facilities must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice. The surveyor will want to determine that proper hand washing techniques are followed by the staff as residents can be exposed to potentially pathogenic organisms through improper hand hygiene and glove use. An example of improper glove usage would be to wear a single pair of gloves for multiple tasks or when caring for multiple residents.

Surveyors will observe if gloves are worn when there is contact with blood, specimens, tissue, body fluids and/or excretions. Additionally, they will also observe if gloves are changed between resident contacts. Staff should wear disposable gloves that are in good condition and hand hygiene should occur before and after putting on gloves. The facility should don sterile gloves when sterile techniques are utilized.

Practice Hand Hygiene

The following list includes some key instances when proper hand washing is required, but this is not a comprehensive list.

Hand Hygiene Required:



- At the start and end of duty*
- Before and after direct resident contact*
- Before and after performing an invasive procedure*
- Before and after eating or handling food*
- Before and after insertion of indwelling catheters*
- Before and after wound dressing changes*
- After personal use of the toilet*
- After blowing or wiping nose*
- After handling soiled or used linens*
- After handling soiled equipment or utensils*

Proper Hand Washing

CMS recommends wetting hands first with warm running water, applying the proper amount of soap, rubbing hands together vigorously for at least 15 seconds and covering all surfaces of the hands and fingers, then rinsing hands with water and drying hands with a disposable towel. The disposable towel can be used to turn off the faucet.¹⁰

Except for situations where hand washing is specifically required, antimicrobial agents such as alcohol-based hand rubs, are acceptable for cleaning hands and direct resident care.

Communicable Disease Prevention

A communicable disease, or contagious disease, is defined as an infection that is transmissible from person-to-person via direct contact with an infected individual or via direct contact with that individual's body fluids or by other indirect means. It is important that each facility create a process, which assists in complying with state and local health department requirements, as well as federal CMS guidelines, for reporting communicable diseases. Facilities must also maintain procedures and documentation for how to handle staff with communicable infections or open skin lesions.

In order to remain in compliance with F441, facilities must prohibit employees with a communicable disease or infected skin lesions from having direct contact with residents or their food, if direct contact has the possibility of transmitting the disease. Staff should also follow recommended precautions for isolated residents with communicable diseases.

Disposal of Soiled Linens, Dressings & Disposable Equipment

Glove usage also applies to the disposal and handling of equipment or items in the resident environment, which may have been contaminated with infectious fluids or other potentially infectious matter. CMS requires that "these materials must be handled in a manner so as to prevent transmission of infectious agents."¹¹ One example of an appropriate precaution is for staff to wear gloves when handling soiled equipment or linens, and properly cleaning and disinfecting or sterilizing reusable equipment before use on another resident. Disposal waste falls under the scope of this task. Potentially contaminated articles should be stored and disposed of in appropriate sharps containers or biohazard bags.

Another example is to clean and disinfected shared medical equipment, like glucose monitors. As noted earlier, although rare, the CDC has documented several cases of long-term residents becoming fatally infected with HBV in recent years and attributed the outbreaks to contaminated environmental surfaces or inadequately disinfected glucose monitors.¹²

During the survey, surveyors will observe various departments within the nursing home, like nursing and housekeeping, to determine if infection prevention and control practices are followed appropriately, such as handling, processing and transporting lines to prevent contamination and the transmission of infection.



Influenza & Pneumococcal

Influenza season typically lasts six months, starting at the beginning of October and concluding at the end of March. During this time period, nursing homes must educate all their residents about both the influenza and pneumococcal vaccines, which prevent the flu and pneumonia, and provide the vaccine to those who would like to receive it as long as it is medically safe for them to receive it.

To determine compliance with influenza and pneumococcal guidelines, surveyors will need to determine that procedures exist to educate all residents or their legal representatives about the potential benefits and harmful side effects associated with both the influenza and pneumococcal immunizations. For some residents, immunization may be contraindicated due to medication that they are already taking or for another medical reason. If an immunization is medically contraindicated or should be delayed due to some other precaution, the resident must be made aware.

Nursing home residents have the right to refuse vaccination, but it is critically important that they understand the risks, if they decline the immunization.

Survey Preparation

Once surveyors arrive at the facility, they will request four sets of documents and information upon arrival, after one hour, after four hours and then after 24 hours on site. Within the first four hours, surveyors will request the facility's influenza and pneumococcal immunization policy and procedures. One surveyor will be assigned overall responsibility for completion of this task, and review the results from all surveys to make an assessment as to whether the facility is in compliance with regulations calling for the establishment and maintenance of an infection control program that is designed to provide "a safe, sanitary and comfortable environment and help prevent the development and transmission of disease."¹³

For nursing homes whose annual state survey takes place during October 1st to March 30th, surveyors will select five residents from the Census Sample Report. If the survey takes place outside of influenza season, the surveyors will select five residents from the Census Sample Report, who were living in the facility during the previous influenza season.

CMS requires that the facility document in the resident's medical record that they or their legal representative have received education on the benefits and risks of these vaccines, along with whether or not the resident received or refused the vaccine or if a vaccine was contraindicated by a medical officer. The surveyor will want to see that this documentation is provided in the charts of the five residents chosen for review.

In some cases, a vaccine may not be available due to production issues with pharmaceutical manufacturers or other factors beyond the control of the facility. If this situation should arise, the facility must also document any delay in immunizing residents during influenza season and when it was able to resume immunizations.

This process of educating residents about immunizations and documenting when they received or refused a vaccination or where medical contraindication exists must take place each year.

As you prepare for the Quality Indicator Survey ensure that staff understand each of these vital components of Federal Tags 441 and 334.

The specific observations and documentation related to the Infection Control and Immunizations Mandatory Facility-Level task are available for review on CMS Form—20054.

Resident Council President or Representative Interview

In response to concerns about the quality of care in the nation's nursing homes, Omnibus Budget Reconciliation Act of 1987 (or OBRA '87) was signed into law by President Ronald Reagan. OBRA '87 contained numerous provisions for improving care and established a uniform set of standards for facilities serving Medicare and Medicaid beneficiaries to follow.

One of requirements included creation of a Resident Ombudsman program and resident council at nursing homes.¹⁴ Federal regulators hoped that by mandating the establishment of Resident Councils, nursing home residents would have a means to voice grievances about the quality of care they received without fear of retribution. State surveyors were required to meet with the Resident Council President and review meeting minutes to help identify concerns.

The Resident Council Mandatory Facility Task involves a review of the council, responding to grievances, resident rights, facility rules and fair treatment.

Federal Tags & Intent

F243 addresses the resident's right to participate in groups within the facility. To determine compliance, the surveyor will interview the Resident Council President or Representative to determine if the Resident Council meets on a regular basis, that the facility assists council members in making arrangements for council meetings, that there is adequate space for all residents who would like to attend, and that residents are able to meet privately—without staff members present—for council meetings if they so desire.

One of the most important functions of the Resident Council is to provide a means for residents to discuss their experiences in the nursing home and address grievances with the facility as they arise. F244 covers the facility's obligation to listen to and respond to grievances, concerns and suggestions from residents. To determine compliance the surveyor interview will ask the Resident Council President or Representative directly about their experiences with facility staff where grievances are concerned.

F151 addresses resident rights. Nursing home residents have numerous rights that facilities are bound to respect. Those rights include the right to privacy, to meet with visitors, to access a phone, to send and receive mail, to complain and the right to be free of coercion. To determine compliance with this F-tag, surveyors will ask whether residents or the Council can complain about care issues without worrying about retaliation or that someone will 'get back at them' for voicing their concern.

CMS also requires that residents can send and receive mail unopened and on Saturdays, review their own medical records and review the results of the facility's annual state survey.

Survey Preparation

In Quality Indicator Surveys, surveyors will interview the Resident Council President to ensure that residents do indeed have a means to meet and address issues of concern. If there is no resident council President, Officer or Leader, an active member or representative may be interviewed instead. The Resident Council President or Representative is always interviewed for the Quality Indicator Survey, however, that interviewee should not be included in the resident sample. If no Resident Council exists, the surveyor will skip this task but may also determine whether residents have attempted to form a council in the past, and if an attempt was made, ascertain the reason why it was unsuccessful.

The surveyor will interview the Resident Council President or Representative about a wide range of resident rules and rights to ensure that facility treats residents fairly and consistently and in accordance with several specific aspects of CMS regulations.

The surveyor will determine through the interview process whether residents are informed of facility rules, whether these rules are applied fairly to all residents and if the facility acts on suggestions from the Resident Council to modify any facility rules.

The surveyor will ask whether staff members review rights with residents, whether these rights are respected and encouraged by the facility, if residents have been informed of their right to formally complain about the care they receive and whether residents know who their ombudsman is and how to contact that person. Nursing home residents have the right to voice any concerns, complaints or grievances to the nursing home state, state health officials or their local ombudsman. The numbers for state health officials and the local ombudsman should be posted at the facility.

Surveyors will ask whether or not staff members listen to, act upon and appropriately respond to concerns raised by the Resident Council. Not all concerns raised by the Council can be addressed by the facility. F244 requires that the facility provides a reasonable explanation if it is unable to respond to a concern. In addition to interviewing the President or a Representative, the surveyor may also seek permission to review Resident Council minutes and become familiar with issues that have been discussed in the past. Surveyors may also interview certain staff members to determine how concerns and grievances are resolved.

Before ending the Resident Council interview phase of the Quality Indicator Survey, the surveyor will give the interviewee the opportunity to discuss whatever other issues they care to share. The specific interview questions related to the Resident Council President Mandatory Facility-Level task are available for review on CMS Form—20057.

Quality Assessment and Assurance Review

Like the mandate for Resident Councils, the requirement that nursing homes serving Medicare and Medicaid beneficiaries maintain an active Quality Assessment and Assurance (QAA) committee stems from the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) as well. The QAA committee's main function is to identify and correct problems, which is the overall goal of improving the quality of care for residents on an ongoing basis.

Federal Tags

Federal Tag 520 requires that the QAA committee convene four times per year or more and include at least three staff members in addition to the director of nursing and a physician designated to the facility, such as the medical director. However, while the medical director may fulfill the requirement that a physician participate on the QAA committee, it is not required that the medical director assume that role. During the Entrance Conference, the surveyor will request the name of a QAA contact person, the names of the QAA committee members and the frequency of QAA committee meetings. The surveyor will interview the QAA contact person to determine whether the committee is functional, how often it meets, who leads the committee and who participates on it. Proper functioning means that the committee identifies problems and then takes appropriate actions to correct any identified quality deficiencies. While the facility will need to provide names of committee members and meeting dates, nursing homes are not required to disclose notes from their QAA committee meetings to surveyors. The QAA committee was designed to be a confidential opportunity for nursing homes to address quality issues. But the facility has the option of providing these records if they so desire. CMS recommends that surveyors complete their investigation before reviewing QAA records, if the facility chooses to provide these documents to the surveyor.

Intent

A report by the Inspector General found that 99 percent of nursing homes met the frequency and membership requirements for QAA committees. The Inspector General reported that 80 percent of those committees consisted of seven or more members from several areas of the nursing home, and 61 percent

met more frequently than once per quarter.¹⁵ Still, the report found that while QAA committees were able to pinpoint problems in nursing homes, staff turnover and staff shortages, often impeded the ability of these committees to make effective changes.

To determine compliance, the surveyor will need to assess four aspects of compliance: Frequency, membership, identification and addressing issues. Does the committee meet the basic frequency and membership requirements and does it make good faith efforts to identify and address quality issues and problems?

Good Faith

The good faith concept plays a key role in determining compliance with this Federal Tag. It may take numerous, and sometimes, repetitive corrective actions to adequately address a concern. For this reason, surveyors must take good faith efforts into consideration when evaluating compliance with F520 regulation.

With the use of the investigative protocols, the surveyors will make a determination of whether the facility's committee identifies quality concerns, has developed and implemented corrective plans of actions to correct deficiencies. Surveyors are instructed not to cite an F520 deficiency if the facility demonstrates that it has made good faith efforts to identify and correct quality issues.

Survey Preparation

If the surveyor or survey team identifies actual or probable noncompliance during Stage 1 or Stage 2 of the Quality Indicator Survey, surveyors are instructed to investigate whether the facility's QAA committee effectively identifies quality problems and creates corrective plans of action. Through an interview with the QAA contact person, the surveyor will try to assess how the committee identifies issues, what methods the committee uses to develop corrective action plans and how any current action plans are being implemented.

In this interview, the surveyor may ask the QAA contact person if the quality issue or deficiency was brought to the attention of the committee and if the committee developed a corrective action plan and made a good faith effort to address the concern.

Corrective Action Plans

For example, the surveyor may ask facility staff to demonstrate how they developed, implemented and revised a corrective action plan by the QAA committee in the past. Surveyors may also observe care as it is being delivered to determine if any practices or processes reflect issues that were brought to the attention of the QAA committee. Additionally, the surveyor may interview staff members, who are not on the QAA committee, to investigate whether they know how to bring issues to the attention of the QAA committee.

If staff members, who are not members of the committee, do not know how to bring issues to the committee for review, this may indicate that the QAA committee is not functioning properly. Furthermore, if the survey team finds actual or probable deficiencies, they may interview staff and residents, as well look for other evidence that the facility revises its corrective plans or strategies and deals with quality issues. Examples of good faith efforts to correct quality deficiencies could include providing additional staff training in a particular care area, monitoring care delivery or processes more closely or revising protocols and practices.

The specific interview questions related to the Quality Assessment and Assurance Review Mandatory Facility-Level task are available for review on CMS Form—20058.

Medication Administration Observation & Drug Storage

As a Mandatory Facility-level task, the Medication Administration Observation and Storage review is conducted on all state surveys by one or more nurse(s) or pharmacist(s) members of the survey team. While several team members may participate in this aspect of the survey, one surveyor will be responsible for organizing and completing this task. That surveyor will also conduct the drug storage and labeling requirements of the mandatory facility-level tasks.

Federal Tags

There are primarily four Federal Tags related to Medication Administration: F281, F332, F333 and F425. A comprehensive tag, F281 deals with professional standards. F332 requires that facilities keep their medication error rate to less than 5 percent, while F333 requires that the facilities limit significant medical errors. F425 deals with drugs and biologicals, requiring that facilities maintain accepted professional standards and adhere both to manufacturer's specifications and physician orders.

Intent

While it may not be possible to administer all medications at the exact time given by the physician or pharmacist, staff should attempt to administer medications as close to the prescribed time as possible. The professional standard is to administer within one hour of the stipulated time. When a prescription states that the medication should be taken "before meals," this usually means 15 to 30 minutes before the meal is served; "with meals" usually means during the meal or up to 30 minutes after the meal; "after meals" usually means up to 60 minutes after the meal is eaten.¹⁶

There are numerous indications, manufacturer's specifications and dosage requirements for many different types of drugs and biologicals that nursing home residents receive, which is why a nurse or pharmacist from the survey team is assigned to observe and document improper administration.

Common Errors

Nursing homes have been cited for noncompliance under the medical administration task for a wide range of reasons. For example, did the physician's order call for administering the medication with or without food, fluids or supplements like potassium? Let's review some of the most common medical errors that surveyors may encounter during the medication administration observation task. Obviously, it's important that all medications be administered only if there is a physician order. Even with a physician's order, common errors include giving the wrong medication to a resident, supplying the wrong dose or administering a medication past its expiry date. Improper administration may include utilizing improper techniques for intravenous, intramuscular or subcutaneous injection of medication, not rotating injection sites or failing to mix an insulin suspension without creating air bubbles.

Nursing home residents with nasogastric and gastrostomy tubes also receive medication. Depending on the medication, the tube should be flushed with water before and after administering the medication based on the clinical condition of the resident. These tubes may also need to be checked to ensure proper placement prior to medication dispersal. Failure to check or flush tubing when administering medication, if required, could result in an error finding.

Drug Storage and Labeling

For this aspect of the survey, surveyors will observe whether drugs and other biological items in medication rooms, carts, boxes and refrigerators are maintained properly. This includes a range of considerations, such as whether these items are kept in secured locations, accessible only to designated staff and stored in a clean and sanitary manner. Refrigerated medications must be kept at cool temperatures between 36 and 46 degrees Fahrenheit, while medications kept in a storage room must not exceed 86 degrees Fahrenheit. Schedule II designated controlled drugs, which are subject to abuse, must be accessible only to authorized personnel and stored in a locked location. A separate key is required for Schedule II drugs, which must be kept in the possession of an authorized staff member.

To determine compliance with F431, surveyors will also observe whether drug and biologicals are properly stored and labeled in accordance with current accepted professional principles. The Food & Drug Administration defines a biological as a product that replicates natural substances, such as enzymes, antibodies or hormones. Therapeutic serums like vaccines and antitoxins also fall under the category of a biological agent.¹⁷

For example, if a drug or biological comes with accessories or cautionary instructions, surveyors will investigate whether these items are kept together. Most medications will also display the name, strength and lot number of the medication, along with instructions for safe administration and the expiration date, where applicable. Not all medications list or have an expiry date.

Medication Administration Error Rate

After observing medication administration and drug storage, the surveyor will make a calculation of the Medication Administration Error Rate for the facility.

The Error Rate is determined by dividing the number of errors by the number of opportunities for errors that were observed. This quotient is then multiplied by 100 to ascertain the percentage of errors.

$$\left(\frac{\text{Total Number of Errors}}{\text{Total Doses Given} + \text{Total Doses Ordered but Not Given}} \right) \times 100$$

After the overall error rate is determined, the survey team will meet to assess whether to cite the facility under F332. Surveyors are instructed to cite a F332 deficiency if the Medication Error rate exceeds 5 percent or if any one observed medication error is determined to be significant.

Nutritional and dietary supplements are not considered medications for purposes of federal nursing home surveys. A nursing home's noncompliance with the administration of nutritional and dietary supplements should not be included in the calculation of the facility's medication error rate for F332 or as a significant medication error for F333. Medication errors involving vitamins and/or minerals should be documented at F332 and counted towards the 5 percent error rate but would not be considered a significant medication error unless the criteria of F333 were met.¹⁸

Clinically Significant Medication Errors

To determine the significance of a medication administration error, the surveyors will consider the condition of the resident, the category of the medication that was administered and the frequency of the error.

A clinically significant medication error is defined by CMS as one that results in *"consequences that materially affect or are likely to affect an individual's physical, mental, or psychosocial well-being either*

positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.”¹⁹

Survey Preparation

Within an hour after the Entrance Conference, the surveyor will request a number of documents from the nursing home administrator, including the schedule of Medication Administration pass times. Using the med pass schedule, the survey team will need to observe at least 50 medication administrations to at least 10 randomly selected and observed residents from different units within the nursing home. It may take more than one day to complete the medication administration task requirement of 50 total medications from at least 10 residents. As with other aspects of the Quality Indicator Survey, the surveyors are attempting to observe and understand what it is like to live in a particular nursing home. In terms of medication administration, their goal is to observe whether the right medications are administered to the right resident, in the correct dosage, in accordance with the manufacturer’s specifications, using the proper technique and other criteria.

Surveyors are trained to observe medication delivery on multiple routes and during multiple medication administration times per resident, as long as at least 10 residents are included in the observation. Surveyors can also include medication administration that is refused by the resident as part of their 50 required medication observations.

After observing 50 instances of medication administration, the surveyor will need to determine whether these medications were administered appropriately—within accepted professional standards and manufacturer’s specifications. To properly assess this task, surveyors will need to determine if the medication was administered with or without a physician’s order and also identify any problems in how, when, where and what was administered to the resident.

The specific observational guidance related to the Medication Administration Observation and Drug Storage Mandatory Facility-Level task is available for review on CMS Form—20056.

Kitchen/Food Service Observation

As a Mandatory Facility-level task, the Kitchen/Food Service Observation is unstaged, meaning that this task can take place during Stage 1 or Stage 2 of the Quality Indicator Survey.

During the course of the Quality Indicator Survey, survey team members will make numerous visits to the nursing home’s kitchen to complete the observation of naturally occurring tasks during meal preparation, services and clean up. These repeated visits should be unannounced and will occur as many times as is necessary to fully complete the task protocol. Surveyors will observe the general sanitation practices, cleanliness of the kitchen and any practices that might indicate potential food-borne illness. Surveyors assigned to this task may also conduct interviews with kitchen/food service staff.

Federal Tags

There are several Federal Tags that play a part in the Kitchen/food service review. Federal Tag 371 makes up the bulk of this survey area, which covers the preparation and distribution of food under sanitary conditions and by approved procurement sources. F441 documents infection control guidelines, F456 requires that food be stored at appropriate temperatures and prepared with equipment in clean and safe operating condition and F364 reviews whether foods are prepared and served under sanitary conditions and in a manner that conserves nutritive value, flavor and appearance. This compliance area also includes

F469, which requires that food storage, preparation and services areas are free of the visible signs of insects and/or rodents.

Intent

The Kitchen/Food Service aspect of the QIS survey begins with a brief tour of the kitchen. According to CMS, the intent of this initial brief tour is to identify any practices that might indicate the potential for food borne illness and unsanitary or unsafe conditions.

There are six different parts of food preparation and storage that surveyors will want to assess through observation, such as storage temperatures, food storage, food preparation and service, dinnerware sanitation and storage, equipment safety and cleaning and refuse and pest control.

Sanitary Food Storage

To comply with F371, surveyors will observe whether foods are stored and prepared under sanitary conditions. Unsanitary conditions include, but are not limited to, leaving food containers on the floor or unclean surfaces, water damage, raw foods and meats thawing at room temperature, raw meats stored in a manner that allows juices to drip onto other foods, food in contact with rust or unclean surfaces, uncovered, unlabeled and undated foods in the refrigerator or freezer or canned goods with punctured seals.

For example, surveyors will observe whether potentially hazardous foods, such as beef, chicken or pork, are thawing at room temperature and that these foods thawing in a manner that their juices could drip onto other foods, that food items in the refrigerator are properly labeled and dated and that proper hand washing facilities are available and convenient for staff use. Any of these practices could indicate unsanitary kitchen practices.

Surveyors may also review the facility's policy for leftovers to see that it is appropriate and followed.

Infection Control

F441 prevents facilities from permitting staff with open lesions, signs of infection and other illnesses from handling foods. Surveyors will check that proper infection control measures are in practice by food preparation and dietary staff members. Surveyors may also ask staff about the facility's policy for dealing with employees, who come to work with symptoms of contagious illnesses or open wounds. Examples of potentially contagious symptoms that surveyors may investigate include coughing, sneezing or vomiting.

Storage Temperatures

During follow-up visits to the kitchen, surveyors will observe whether or not food is stored at the appropriate temperatures, a regulatory component addressed in Federal Tags 371 and 456. Surveyors may check temperatures between meal service times to allow the temperature of the refrigerators to stabilize. The target temperature for refrigerators is 41 degrees Fahrenheit or below. Freezers must be maintained at a temperature sufficient to keep frozen food solid. Internal temperatures of potentially hazardous foods, which require constant refrigeration—like meat, poultry, fish, milk and eggs—should be checked to ensure that they are within the acceptable range of 41 degrees Fahrenheit or lower.

The target temperatures used by CMS are taken from the current FDA code.

Food Preparation and Service

There are a wide range of stipulations that kitchen/food service professionals must follow to ensure that food is not unnecessarily exposed to contamination and prepared and served under sanitary conditions that preserve nutrition, flavor and appearance. Facilities must prepare foods to ensure that they reach the proper internal cooking temperature or are held at a certain temperature and within time limits to ensure that microorganisms can no longer survive and that pathogenic bacteria are killed.

This aspect of the review also includes an observation for Federal Tag 364, which requires that foods be purchased from approved or satisfactory sources. Food must be procured from vendors that meet federal, state and local approval.

Dish & Utensil Cleaning and Storage

To determine compliance, surveyors will need to see that manual methods of dish washing or dishwasher operation temperatures are within the required ranges and utilize the proper chemical concentrations to assure sanitary washing, rinsing and drying. Drying equipment and utensils with a towel may increase cross contamination risks. They will observe whether soiled and clean areas are separated in the kitchen and that dishes are stored in dry, clean locations to limit exposure to dust, splash and other contaminants. The surveyor may ask staff how they test for proper chemical sanitation and how they monitor equipment to ensure proper functioning; and additionally, the surveyor may review logs and chemical sanitation tests to determine compliance levels.

Surveyors will need to determine that food preparation equipment is clean, as well as that it's in safe operating condition, by observing refrigerators and freezers, fans, utensils and equipments, food trays and other kitchen supplies. Surveyors may ask staff how they identify and problems with temperature controls, equipment maintenance and equipment cleaning schedules.

Refuse/Pest Control

Facilities must dispose of their garbage properly and ensure that the kitchen/food service areas are free of visible signs of insects and/or rodents

Surveyors are instructed to request documentation of pest services and notify other team members to observe for best concerns in other areas of the nursing home environment, if these conditions are not met Surveyors must determine if the facility is aware of the problem and what steps it's taking to correct it The specific observational guidance related to the Kitchen/Food Service Observation Mandatory Facility-Level task is available for review on CMS Form—20055 (09/09)

Dining Observation

The Dining Observation Mandatory Task currently includes requirements from 16 different Federal Tags, and may take several days for surveyors to complete. The Federal Tags including in the Dining Mandatory Task concentrate on providing a positive and dignified dining experience and providing assistance to residents, who need it during meal times, and the ability to dine independently for those who do not require assistance. An optimal dining experience also includes providing a sanitary dining environment where staff members practice proper hygienic and infection control practices as well.

Federal Tags

Several aspects of the Dining Experience observation fit together with Kitchen/Food Service, particularly Federal Tags 371, 441 and 364.

Federal Tag 371 focuses on the preparation and distribution of food under sanitary conditions and whether nursing home food is purchased from approved procurement sources, while 441 documents infection

control guidelines. To determine compliance in this review, surveyors will observe whether staff follows proper tableware handling techniques and hygienic practices, such as keeping hands away from their hair and face and that staff handling food are free from signs of infection, illness and open skin lesions. Federal Tags 353, 362 and 368 pertain to how well staff prepare, serve and assist with dining during scheduled meal times, and ensure that the facility provides meals and snacks frequently enough to satisfy the residents under their care. F368 stipulates that there should be no more than 14 hours between the evening meal and breakfast. Food services can extend to a 16 hour window between the first and last meal given the approval of the resident council and the provision of a substantial evening snack.

Assistance & Positioning at Mealtimes

Surveyors will interview staff to determine how residents are monitored in the dining room and other locations to ensure that their needs are accommodated and that they receive timely and appropriate assistance, a requirement outlined in Federal Tags 311 and 312. This includes providing assistance with positioning residents to maximize their ability to eat, such as checking to make sure wheelchairs fit underneath the table (F310). There may be wheelchair bound residents, who are independent eaters. Tables should be set to accommodate the standard height of wheelchair arms.

Dining Room Furnishing & Atmosphere

Surveyors will observe for adequate lighting and ventilation (F464), noise levels that promote socialization (F258) and that the dining area and patient rooms are free from offensive odors (F253). The intent for these federal tags is to ensure that none of these issues negatively impact residents. Additionally, surveyors will take the furnishings and dining space into consideration for the Dining Observation Mandatory Task. They will focus on whether dining areas are adequately furnished to meet the physical and social needs of the residents and if there is sufficient space to accommodate activities (F464). The surveyors will also explore whether mobile residents can enter and exit independently, whether there is sufficient space for an emergency resident exit and the staff's ability to assist resident experiencing an emergency, like choking.

Dignity and Independence

Dignity and Independence are two very important concepts and throughout the QIS, surveyors will look for indications that staff act in a manner that demonstrates their regard for each residents need to be treated with respect and dignity.

Surveyors will observe whether residents are given adequate time to finish their meals and whether staff wait for the residents to finish their meal before clearing plates. They will also observe how staff members interact and socialize with residents during meal service and whether they behave politely and respectfully to residents. F241 requires staff to act and interact with residents during meals in a manner that promotes dignity, which includes providing non-disposable cutlery, plates and napkins at meals and factoring in the resident's input on whether or not wear clothing protectors. This section of the review also includes providing assistive devices to residents to help promote independence under F369.

Food Quality, Meal Substitutes & Liquids

In terms of food quality, residents should receive foods that are attractively presented and not combined together under F364 and they should be offered a substitute if they refuse the meal served under F366. Lastly, surveyors will observe whether the facility provides residents with sufficient liquids and assistance when needed (F327). If adequate fluid intake is not observed, surveyors will conduct staff interviews to determine if liquids are provided, and within the resident's reach, if residents are encouraged (or reminded) to consume fluids and if they are provided assistance with consumption. Additionally, if

residents refuse the liquids offered, surveyors will want to observe whether alternatives are made available to promote proper hydration, such a different beverage, soup or ice cream.

Survey Preparation

During the first hour after the survey team arrives at a facility for a QIS interview, the survey team will request a schedule of meal times and the location of the dining room or rooms, if there are more than one. Surveyors are instructed to conduct a dining observation of the first full meal after the team members enter the facility. If dining takes place in resident rooms and other areas, surveyors are instructed to make observations in those areas as well.

Surveyors will primarily observe the dining experience, but should also ask residents to confirm or validate observations made about the taste and temperate of foods served by the facility. The majority of time should be spent watching residents who require the most assistance.

If concerns are observed during the Dining Observation, such as resident complaints that their food is cold or unpalatable, the surveyor may request a sample tray be sent to the unit furthest from the kitchen or another dining area. The surveyor will check the food temperature and taste a test meal at about the same time that the last served resident begins eating. This will give the surveyor the opportunity to sample food as it would be served to a resident. If concerns are identified, the surveyor will apply the appropriate F tag.

The specific observational guidance related to the Kitchen/Food Service Observation Mandatory Facility-Level task is available for review on CMS Form—20053 (09/09).

¹ CMS Form 10055

² State Operations Manual, Chapter 4 - Program Administration and Fiscal Management 4018 - Regulatory Role of Surveyor and Consultant U.S. Department of Health and Human Services, Centers for Medicaid and Medicare Services, (Rev. 1, 05-21-04), P. 41.

³ Medicare Coverage of Skilled Nursing Facility Care, U.S. Department of Health and Human Services, Centers for Medicaid and Medicare Services, CMS Publication No. 10153, Revised September 2007, p. 4.

⁴ CMS Form 10055

⁵ CMS Manual System, Pub. 100-07 State Operations Provider Certification, Department of Health & Human Services, Centers for Medicare and Medicaid Services, Transmittal 51, July 20, 2009/Effective date: 9/30/2009.

⁶ F441 §485.65 Infection Control, p.5.

⁷ F441 §485.65 Infection Control, CMS Manual System, Pub. 100-07 State Operations Provider Certification, Transmittal 51: July 20, 2009, Department of Health & Human Services, Centers for Medicare & Medicaid Services, p.1.

⁸ Idaho Department of Health and Welfare, Infection and Prevention Control Training Questions and Answers, October 26-29, 2009, p.1.

⁹ Safe Injection, Infusion and Medication Vial Practices in Healthcare, Association for Professionals in Infection Control and Epidemiology, Inc., June 2009.

¹⁰ F441, p. 17.

¹¹ CMS Manual System, Department of Health & Human Services, Centers for Medicare and Medicaid Services, Transmittal 51, July 20, 2009/Effective date: 9/30/2009, p. 16.

¹² F441 §485.65 Infection Control, CMS Manual System, Pub. 100-07 State Operations Provider Certification, Transmittal 51: July 20, 2009, Department of Health & Human Services, Centers for Medicare & Medicaid Services, p.1.

¹³ CMS Form 20054 (09/09), p. 3.

¹⁴ Federal Nursing Home Reform Act of 1987. <http://www.allhealth.org/BriefingMaterials/OBRA87Summary-984.pdf>

¹⁵ Quality Assurance Committees in Nursing Homes, Department of Health and Human Services, Office of Inspector General, January 2003, p.i.

¹⁶ Medication Administration in the Nursing Facility, American Society of Consultant Pharmacists and Med-Pass Inc., p. 3.

¹⁷ Federal Drug Administration, Department of Health & Human Services (Accessed last on 03/02/2010 <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048341.htm>).

¹⁸ Memo to State Survey Directors, Nursing Homes – Medication Pass Clarification for Surveying F Tags 332 and 333 During Nursing Home Surveys, September 28, 2007, Ref: S&C-07-39 p. 2.

¹⁹ Clinically significant defined