

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

(Rev.)

Sub-Task 5E – Medication Pass *and Pharmacy Services*

Task 5 – Information Gathering

(Rev.)

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

Task 5 includes the following sub-tasks:

- 5A General Observations of the Facility: Assessment of the environment of the facility affecting the resident's life, health and safety;
- 5B Kitchen/Food Service Observations: Assessment of the facility's food storage, preparation and service;
- 5C Resident Review: An integrated, holistic assessment of the sampled residents which includes the assessment of: drug therapies, the quality of life of the resident as affected by his/her room environment and daily interactions with staff, and assessment of those pertinent care concerns identified for each sampled resident by the survey team. Closed record reviews and dining observations are integrated into the resident review;
- 5D Quality of Life Assessment: Assessment of residents' quality of life through individual interviews, a group interview, family interviews, and observations of residents who are non-interviewable;
- 5E *Medication Pass and Pharmacy Services: An assessment of the pharmaceutical services provided in the facility, including the provision of the medication pass observation; the application of the medication error detection methodology; the provision of services by a licensed pharmacist; and facility procedures and processes in place regarding the acquiring, receiving, dispensing and administering medications, use of controlled medications, and medication access and storage.*
- 5F Quality Assessment and Assurance Review: An assessment of the facility's Quality Assessment and Assurance program to determine if the facility identifies and addresses specific care and quality issues and implements a program to resolve those issues; and
- 5G Abuse Prohibition Review: A determination of whether the facility has developed and operationalized policies and procedures designed to protect residents from abuse, neglect, involuntary seclusion, and misappropriation of their property. This includes policies and procedures for hiring practices, training and ongoing supervision for employees and volunteers who provide services, and the reporting and investigation of allegations and occurrences that may indicate abuse.

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

A. General Procedures

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

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

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

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

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

The information gathering tasks are interrelated. Information acquired while doing observations and interviews will direct the record review. Likewise, information obtained while doing the record review may help direct what observations or interviews are needed. Acquire the information that is necessary to make deficiency decisions in [Task 6](#) using the survey worksheets and corresponding Guidance to Surveyors for each of the sub-tasks in Task 5.

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

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

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

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

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

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

B. Observations

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

C. Informal and Formal Interviews

The objectives of interviews are to:

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

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

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

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

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

D. Record Review

The objectives of the record review are to:

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

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

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

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

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

- Interviews with facility staff, such as the administrator, nursing staff, social services staff, medical director, quality assessment and assurance committee members, and/or other facility staff, as indicated, to determine what procedures, systems, structures, and processes have been changed.
- Reviewing through observation, interview, and record review, how the facility identified and implemented interventions to address the noncompliance. Examples of interventions may include, but are not limited to:
 - The facility's review, revision, or development of policies and/or procedures to address the areas of concerns;
 - The provision and use of new equipment, as necessary;
 - The provision of staff training required to assure ongoing compliance for the implementation and use of new and/or revised policies, procedures, and/or equipment, especially with new and/or temporary staff;
 - The provision of additional staffing, changes in assignments or deployment of staff, as needed; and

- The provision of a monitoring mechanism to assure that the changes made are being supervised, evaluated, and reinforced by responsible facility staff.
- Evaluating whether the facility has a functioning quality assessment and assurance committee, whose responsibilities include the identification of quality issues; providing timely response to ascertain the cause; implementing corrective action; implementing monitoring mechanisms in place to assure continued correction and revision of approaches as necessary to eliminate the potential risk of occurrence to other residents and to assure continued compliance.

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

Sub-Task 5A - General Observations of the Facility

(Rev.)

A. General Objective

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

B. General Procedures

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

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

C. Making Observations

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

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

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

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

Sub-Task 5C - Resident Review

(Rev.)

G. Conducting the Resident Review

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

1. Section A - The Resident Room Review assesses aspects of accommodation of needs, environmental quality, and quality of life in the resident's room. Through observations and interviews, evaluate how the resident's environment affects his/her quality of life.
2. Section B - The Daily Life Review is a review of the resident's daily quality of life, especially in the areas of staff responsiveness to resident grooming and other needs, staff interactions, choices, and activities. Through ongoing observations and interviews, evaluate the resident's daily life routines and interactions with staff.
3. Section C - The Assessment of Drug Therapies is a review of the medications the resident is receiving to evaluate whether the effectiveness of the therapeutic regimen, including all drugs that may play a significant role in the resident's everyday life, is being monitored and assessed. *Record the information on the Resident Review Worksheet, Form CMS-805. Review and record, as pertinent, all non-prescription and prescription medications taken by the resident during the past 7 days. In addition follow the guidance in Appendix PP, Tag F329 for the determination of unnecessary medications.*
4. Section D -- The care review is an assessment of those quality of care areas (see [42 CFR 483.25](#)) that are pertinent to the sampled resident. The survey team, through use of the Roster/Sample Matrix, determines what care areas will be reviewed for each sampled resident. Additional areas for evaluation may be identified during the review.

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

Sub-Task 5E - Medication Pass *and Pharmacy Services*

(Rev.)

A. Objectives

- *To determine whether the facility safely administers medications including:*
 - *Accuracy of medication administration (including preparation and technique);*
 - *Labeling that contains at least the name and strength/concentration of the medication, as well as expiration date when applicable, and*
 - *Security of medications;*
- *To determine whether medications are stored and handled in accordance with manufacturers' recommendations and/or state or federal requirements;*
- *To determine whether the facility reconciles controlled medications, as appropriate;*
- *To determine whether the facility obtains the services of a licensed pharmacist; and*
- *To determine whether the facility provides or obtains pharmaceutical services, including routine and emergency medications, to meet the needs of each resident.*

B. Use

- *The medication pass (C.1) and a review of storage and access to medications (C.2) must be conducted on every Initial and Standard survey; and on Partial Extended, Abbreviated Standard and Revisit, as necessary;*
- *Review for the provision of licensed pharmacist consultation (C.5) on the initial survey and on any other survey type, if the survey team has identified concerns that indicate:*
 - *That the facility does not have a licensed pharmacist; and/or*
 - *That the licensed pharmacist may not have performed his/her functions related to the provision of pharmaceutical services;*
- *Review for the development and implementation of pharmaceutical procedures (C.4) if, during the course of the survey, concerns have been identified regarding the availability of medications; accurate and timely medication acquisition;*

receiving, dispensing, administering, labeling, and storage of medications; reconciliation of controlled medications (C.3); and the use of qualified, authorized personnel to handle and dispense medications.

C. General Procedures

1. Medication Pass (includes labeling)

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

When observing the medication pass:

- Be as neutral and unobtrusive as possible;*
- Observe different routes and/or forms of medications such as intravenous (IV), intramuscular (IM), or subcutaneous (SQ) injections; transdermal patches; inhaler medications; eye drops; and medications provided through enteral tubes;*
- Initially observe the administration at least 20-25 medications, observing as many staff administering medications as possible to facilitate a review of the facility’s entire medication distribution system;*
- Record, from the medication label, the name and dose/concentration of each medication administered. Also record the route of administration (if other than oral) and the expiration date, if expired;*
- Record all multiples, such as 2 drops or 2 tablets. For liquids, record actual volume, or in the case of items such as psyllium, record number of “rounded teaspoonfuls” and the amount of liquid. In the absence of a number, it is assumed to be one;*
- Observe whether staff confirmed the resident’s identity prior to giving medications and whether the medications were identified up to the point of administration. Note any concerns;*
- Record the techniques and procedures that staff used to handle and administer medications, such as proper hand hygiene, checking pulses, flushing gastric tubes, crushing medications, route and location of administration (e.g., sub-Q or IM injection, eye, ear, inhalation, or skin patch), shaking and/or rotating medication, giving medications with or*

between food or meals, whether medications are under the direct control/observation of the authorized staff; and

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

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

- *The prescriber's order (whether given incorrectly or omitting an ordered dosage);*
- *Manufacturer's specifications (not recommendations) regarding the preparation and administration of the medication or biological;*
- *Accepted professional standards and principles that apply to professionals providing services;*

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

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

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

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

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

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

2. Medication Storage (includes labeling)

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

- *Medications and biologicals are accessible only to authorized staff and are locked when not under the direct observation of the authorized staff;*
- *Controlled medications are stored in a manner to limit access and to facilitate reconciliation in accordance with the facility policies;*
- *Medications are stored to maintain their integrity and to support safe administration of the correct medication to the correct resident, by the correct route and in the correct dose, such as:*
 - *Temperature, light, and humidity controls meet specifications for the medication;*
 - *Medications available for use are not expired, contaminated, or unusable;*
 - *Medication labels are legible; intact; contain the name and dose/concentration of the medication, appropriate cautionary/accessory instructions such as “do not crush,” expiration date when applicable; and support the safe administration of the medication; and*
 - *Multi-dose vials are labeled per facility policy and manufacturer’s specifications once use of the vial has been initiated.*

3. *Controlled Medications*

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

- *Determine whether Scheduled II controlled medications are in separately locked, permanently affixed compartments (or are a minimal amount of unit dose packages);*
- *Review the facility procedure and a sample of the reconciliation records, and compare the amount of medication available with the amount the records indicate should be available; and*
- *Interview the director of nursing and/or licensed pharmacist regarding:*

- *Actual frequency of the reconciliation;*
- *How the facility investigates loss or inability to reconcile controlled medications; and*
- *How the licensed pharmacist has been involved in recognizing the situation and collaborating with the facility to review and update its practices and procedures.*

4. Pharmaceutical Services

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

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

- *Identify the types of medications (such as antibiotics, pain medications) that are not being passed on a timely basis,*
- *Interview the director of nursing and/or the staff responsible for passing medications regarding:*
 - *A delay in obtaining or administering a medication(s);*
 - *The potential causes of the delay; and*
 - *Facility procedures for scheduled times of administration;*
- *Interview the licensed pharmacist to determine if he/she identified the concern regarding timely medication administration and had made recommendations to facility staff in order to address the concern;*
- *Interview facility staff regarding the response to recommendations made by the licensed pharmacist; and*

- *As necessary, if concerns are identified regarding sufficient authorized staff to pass medications, interview the director of nursing regarding staff assignments and work allocation in relation to medication passes in order to meet the needs of the residents.*

5. Provision of a Licensed Pharmacist

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

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

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