



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-36-NH

DATE: June 7, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Copy– Changes for Sub-Task 5E, Medication Pass Observation Protocol for Long Term Care (LTC) Facilities

Memorandum Summary

- **Revisions to Appendix P of the State Operations Manual (SOM):** Changes have been made to the Sub-Task 5E - Medication Pass Observation Task in the Traditional Survey.
 - The number of observations required to calculate the facility medication error rate is revised to a minimum of 25 medication administration opportunities. A minimum number is specified because it is acceptable to include more than 25 observations in a medication observation to capture multiple routes, times, and caregivers.
 - This revision eliminates the current requirement to extend the medication pass for another 20-25 opportunities if errors are detected in the first 20-25 observations.
 - Form CMS–20056 (2/2013), Medication Administration Observation will be used; this form replaces Form CMS-677, Medication Pass Worksheet.
 - This change matches the Quality Indicator Survey (QIS) Medication Administration Observation protocol, thus standardizing the medication error rate calculation for both the Traditional and QIS surveys.

A. Background

In an effort to more effectively utilize surveyor resources and maximize on-site survey time, the Centers for Medicare & Medicaid Services (CMS) has undertaken a review of the current LTC survey protocols with a primary goal of optimizing the survey process. We made this change in response to feedback received from a technical expert panel convened in August 2012 and subsequent consultations with State Survey Agencies, the CMS Regional Offices and other stakeholders.

B. Medication Pass Sample Size Change

The number of observations required to calculate a facility's medication error rate is changed to a minimum of 25 medication administration opportunities. A minimum number is specified because it is acceptable to include more than 25 observations in a medication observation to capture multiple routes, times, and caregivers. For the Traditional Survey this protocol revision eliminates the requirement to extend the medication pass for another 20-25 opportunities if errors are detected in the first 20-25 observations. Additional guidance specifies that the surveyor will

watch and document all of the resident's medications being administered at the time of the observation. Surveyors will not stop the observation in the middle of a resident's medication pass. If the surveyor reaches 25 medication observation opportunities when there are medications remaining for that resident, observe all medications being administered and add those opportunities to the total medication administration sample.

C. Rationale

Between 2009 and 2011, F332 citations for the standard QIS ranged between 7 and 9 percent, and between 9 and 10 percent for the standard Traditional Survey. These changes will provide CMS with consistent data collection procedures to monitor medication administration errors. In March, the QIS Medication Administration Observation sample size was changed to a minimum of 25 observations. This change will align the two Long Term Care Survey processes.

D. Forms

Form CMS-20056 (2/2013), Medication Administration Observation will be used to document the Medication Administration Observation, see Attachment B. This form replaces CMS Form-677, Medication Pass Worksheet. CMS-20056 is available for download from the QIES Technical Support Office/QIS/QIS Forms: https://www.qtso.com/download/qis/forms/CMS-20056_MedAdmin_03062013.pdf. The printed version will be available by order with the existing CMS LTC Survey forms ordering process.

E. State Operations Manual

Attachment A provides an advance copy of the interim Survey protocol guidance. CMS is in the process of updating the SOM to reflect these revisions, as well as further clarifications on the Medication Administration Observation procedure. The final version of this document, when published in the on-line SOM may differ slightly from this interim advanced copy.

F. Effective Date

Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

G. Comments

Comments or questions about this memorandum may be addressed to Sharon Lash at sharon.lash@cms.hhs.gov.

/s/

Thomas E. Hamilton

Attachments:

Attachment A: Advance copy of updated SOM Appendix P/Sub-Task 5E

Attachment B: Form CMS 20056 (2/2013) Medication Administration Observation

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations

Provider Certification

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

Transmittal -Advance Copy

Date: May XX, 2013

SUBJECT: Revisions to Appendix P – “Survey Protocol for Long Term Care Facilities – Part I Sub-Task 5E – Medication Pass and Pharmacy Services”

I. SUMMARY OF CHANGES: This instruction updates the procedures at Sub-Task 5E – Medication Pass and Pharmacy Services, 1. Medication Pass (includes labeling).

**NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: 07/01/2013**

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix P/Sub-Task 5E/Medication Pass

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

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

ADVANCE COPY

Advance Copy Appendix P/Sub-Task 5E - Medication Pass and Pharmacy Services

(Rev. XX, Issued: 05/24/2013, Effective/Implementation: 7/1/2013)

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 *Administration Observation*

See Guidance to Surveyors at 483.25(m) for information on conducting the medication pass and for the identification of medication errors. Use *form CMS-20056 (2/2013)*, Medication *Administration Observation*.

Observation Instructions:

- *Make random observations of a minimum of 25 medication opportunities; a minimum number is specified because it is acceptable to include more than 25 observations in a medication observation to capture multiple routes, times, and caregivers.*
- *Observe several staff over different shifts and units to capture a review of the facility's medication distribution system.*
- *Observe for multiple routes of administration including:* intravenous (IV), intramuscular (IM), or subcutaneous (SQ) injections; transdermal patches; inhaler medications; eye drops; and medications provided through enteral tubes;
- Be as neutral and unobtrusive as possible;
- *Watch and document all of the resident's medications being administered. Do not stop the observation in the middle of a resident's medication pass. If the surveyor reaches 25 medication observation opportunities when there are medications remaining for that resident, observe all medications and add those opportunities to the total medication administration sample.*
- Observe how the staff confirmed the resident's identity prior to giving medications;
- Confirm that the medication can be identified by the staff administering the medication after being removed from the packaging.
- Observe whether staff immediately documented the administration and/or refusal of the medication after the administration or the attempt. Note any concerns.

NOTE: If the surveyor has reason to believe that a medication may be given to the wrong resident or that the wrong medication and/or dose may be given to a resident, the surveyor will intervene as appropriate. The surveyor will continue to observe the staff person until the point where the error is actually going to occur, allowing the staff administering the medication to catch their mistake before the surveyor brings it to their attention. If the staff person catches the mistake, this would not be considered an error. However, if a surveyor must intervene, this observation would be counted as a medication error.

- *Record the following, including:*
 - *The name and dose/concentration of each medication administered, obtained from the label;*
 - *The route of administration;*
 - *The time of medication administration;*
 - *If the medication is expired, note the expiration date;*
 - 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;
 - 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;

Medication Reconciliation

Following the medication administration observation, compare your findings with the prescribers’ 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;

Calculating Facility Medication Error Rate - If no errors are found after reconciliation of the observation with the prescriber’s orders, the medication observation is complete. *If* one or more errors are found, calculate the medication error rate.

Step 1. Combine all surveyor observations into one overall calculation for the facility. Record the Total Number of Errors. Record the number of Opportunities for Errors (doses given plus doses ordered but not given).

Step 2. Medication Administration Error Rate (%) = Number of Errors divided by Opportunities for Errors multiplied by 100. A dose of medication that was ordered but not given (by omission) is considered an error to be added to the number of opportunities.

Step 3. After the overall error rate is determined, the team will determine whether a facility citation is appropriate during the team meetings. If the Medication Administration Error Rate is 5% or greater, cite F332. If any medication error is determined to be significant, cite F333.

NOTE: If a **significant** medication error has been identified during the course of a Resident Review, including a revisit or 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.

Attachment B: Medication Administration Observation

Facility Name: _____

Facility ID: _____

Surveyor Name: _____

Observation Instructions: Make random medication observations of:

- Several staff over different shifts and units,
- Multiple routes of administration (oral, enteral, intravenous, intramuscular, subcutaneous, topical, optical, etc.), and
- A minimum (not maximum) of 25 medication opportunities.

Note: Do NOT preselect residents for observation. Watch and document all of the resident's medications for each observed medication administration (this does not mean all of the medications for that resident on different shifts or times).

Coordination Instructions: At team meetings, discuss the number of residents and opportunities observed.

During observation of medication administration, determine whether any of the following situations occur:

- Incorrect medication administered to resident;
- Incorrect medication dose administered to resident;
- Medication administered without a physician's order;
- Medication not administered as ordered before, after, or with food/antacids;
- The administration of medications without adequate fluid as manufacturer specifies such as bulk laxatives, NSAIDs, and potassium supplements;
- Failure to check pulse and/or blood pressure prior to administering medications when indicated/ordered;
- Crushing tablets or capsules that manufacturer states "do not crush," such as enteric coated or time released medications;
- Medication administered after date of expiration on label;
- Medication administered to resident via wrong route;
- Prior to medication administration, nasogastric or gastrostomy tube placement not checked (**NOTE:** If the placement of the tube is not checked, this is not a medication error; it is a failure to follow accepted professional practice and should be evaluated under Tag F281 requiring the facility to meet professional standards of quality and Tag F322 requiring appropriate treatment and services for tube feedings);
- Nasogastric or gastrostomy tube not flushed with the required amount of water before and after medication administration based on the resident's clinical condition;
- Improper technique used for IV/IM/SQ injection;
- Insulin Suspensions – the failure to "mix" the suspension without creating air bubbles;
- The failure to "shake" a drug product that is labeled "shake well," such as Dilantin Elixir;
- IM/SQ injection sites not rotated;
- Transdermal patch sites not rotated;
- Inhaler medication not administered according to physician's orders and/or manufacturer's guidelines;
- Multiple eye drops administered without adequate time sequence between drops;
- Did not observe the complete medication administration process, such as leaving the medication at bedside;
- Medication administered in presence of adverse effects, such as signs of bleeding with anticoagulants.

Medication Administration Observation

	Date/Time	Resident Name	Room/Bed	Drug / Dosage / Route <i>(oral, enteral, intravenous, intramuscular, subcutaneous, topical, optical, etc.)</i>	Adminis- tration Error	Prescriber's Order If Administration Error (Describe Error as Necessary)	Staff Name
1.					<input type="checkbox"/>		
2.					<input type="checkbox"/>		
3.					<input type="checkbox"/>		
4.					<input type="checkbox"/>		
5.					<input type="checkbox"/>		
6.					<input type="checkbox"/>		
7.					<input type="checkbox"/>		
8.					<input type="checkbox"/>		
9.					<input type="checkbox"/>		
10.					<input type="checkbox"/>		
11.					<input type="checkbox"/>		
12.					<input type="checkbox"/>		
13.					<input type="checkbox"/>		
14.					<input type="checkbox"/>		
15.					<input type="checkbox"/>		
16.					<input type="checkbox"/>		
17.					<input type="checkbox"/>		
18.					<input type="checkbox"/>		
19.					<input type="checkbox"/>		
20.					<input type="checkbox"/>		

Medication Administration Observation

Observation Findings

Calculations for Team's Combined Medication Administration Observations

- Step 1. Combine all surveyor observations into one overall calculation for the facility. Record the Total Number of Errors. Record the number of Opportunities for Errors (doses given plus doses ordered but not given).
- Step 2. Medication Administration Error Rate (%) = Number of Errors divided by Opportunities for Errors (doses given plus doses ordered but not given) multiplied by 100.
- Step 3. After the overall error rate is determined, the team will determine whether a facility citation is appropriate during the team meetings. If the Medication Administration Error Rate is 5% or greater, cite F332. If any one medication error is determined to be significant, cite F333.

Total Number of Errors _____ * 100: Medication Administration Error Rate = _____%
Opportunities for Errors

1. Does the facility ensure that it is free of medication error rates of five percent or greater? Yes No **F332**
2. Does the facility ensure that residents are free of any significant medication errors? Yes No **F333**
3. Did the facility provide medications and/or biologicals and pharmaceutical services to meet the needs of the resident? Yes No **F425**

Notes: