Centers for Medicare and Medicaid Services Survey and Certification Letters:

- Rollout of Quality Assurance and Performance Improvement (QAPI) Materials for Nursing Homes (6/7/13);

- Advance Copy– Changes for Sub-Task 5E, Medication Pass Observation Protocol for Long Term Care (LTC) Facilities (6/7/13)

1. Rollout of Quality Assurance and Performance Improvement (QAPI) Materials for Nursing Homes (6/7/13)


   This memo announces the rollout of the CMS QAPI website, including “…introductory materials to help nursing homes establish a foundation to implement and sustain QAPI…”:

   - **QAPI at a Glance**: [link](http://cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/QAPIAtaGlance.pdf)
     - QAPI at a Glance is a detailed guide illustrating ‘QAPI in action’; it describes the five elements of QAPI; the action steps for implementing the QAPI principles; and provides tools and resources nursing homes may use as they further develop their systems.
   - **QAPI Tools**: [link](http://cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/qapitools.html)
     - 'QAPI at a Glance' includes the following tools to assist nursing facilities in establishing a QAPI program:
       - **QAPI Self-Assessment**: evaluates the extent to which components of QAPI are in place within an organization and identifies areas requiring further development.
       - **Guide for Developing Purpose, Guiding Principles, and Scope**: identifies principles to guide decision making and help set priorities.
       - **Guide for Developing a QAPI Plan**: guides the organization’s quality efforts and serves as the main document to support implementation of QAPI.
       - **Goal Setting Worksheet**: helps set goals that are specific, measurable, attainable, relevant, and time-bound.
  o CMS created a newsletter that describes some of the basic principles of QAPI. The newsletter “…may be printed and posted for review by caregivers, and nursing home residents and their families.”

• **Video – Nursing Home QAPI – What’s in it for you?**:
  [www.youtube.com/watch?v=XjkNNEjOEc&feature=player_embedded](http://www.youtube.com/watch?v=XjkNNEjOEc&feature=player_embedded)
  o An introductory video “…which provides insight into what quality means to residents, their families, and advocates, and presents a ‘business case’ for what is in it for nursing homes that embrace QAPI.”

• **Nursing Home Quality Improvement Questionnaire**
  o The Nursing Home Quality Improvement Questionnaire administered by Abt Associates to 4200 randomly selected nursing homes in summer, 2012, resulted in a 71% response rate. Detailed results from the questionnaire, “…designed to identify baseline information related to quality systems and processes in nursing homes…” will be posted to the QAPI website ‘in the near future’.

• **Visiting the Website**
  o Questions may also be emailed to: Nhqapi@cms.hhs.gov.

• **Next Steps**
  o CMS will expand QAPI by developing resources to “…empower residents and their families to be engaged in the quality efforts in their nursing home…” These materials will be posted to the QAPI website as they become available.

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2. **Advance Copy– Changes for Sub-Task 5E, Medication Pass Observation Protocol for Long Term Care (LTC) Facilities (6/7/13)**


This memo details changes made to the Traditional LTC Facility Survey, Sub-Task 5E-Medication Pass Observation.

• **Medication Pass Sample Size Change**
  o 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 to capture multiple routes, times, and caregivers.”
  o This 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 surveyors will watch and document all of the resident’s medications being administered at the time of observation.
    ▪ Surveyors will not stop the observation in the middle of a resident’s medication pass.
    ▪ If surveyors reach 25 medication observation opportunities when there are medications remaining for that resident, they are to observe all medications being administered and add those opportunities to the total medication administration sample.
• **Rationale**
  o Between 2009 and 2011, F332 citations for the standard QIS ranged from 7 - 9%; from 9 - 10% for the standard Traditional Survey.
  o In March, 2013, the QIS Medication Administration Observation sample size was changed to a minimum of 25 observations. These changes to the Traditional Survey process provide CMS with consistent data collection procedures and align the two survey processes.

• **Forms**
  o CMS–20056 (2/2013), Medication Administration Observation, replaces CMS Form-677, Medication Pass Worksheet, and will be used to document the Medication Administration Observation [see Attachment B].
  o 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 via the existing CMS LTC Survey forms ordering process.

• **State Operations Manual (SOM)**
  o Attachment A is an advance copy of the interim Survey protocol guidance.
    - Please note: CMS remains in 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 as published in the SOM may differ slightly from the advanced copy.

**Attachment A**

- All changes to the SOM are redlined. Only the revised sections are highlighted below:

**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:** No revisions

**B. Use:** No revisions.

**C. General Procedures**

1. **Medication Administration Observation**
   ...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:
  o The name and dose/concentration of each medication administered, obtained from the label;
  o The route of administration;
  o The time of medication administration;
  o If the medication is expired, note the expiration date;
  o 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;
  o 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:
  o The prescriber’s order (whether given incorrectly or omitting an ordered dosage);
  o Manufacturer’s specifications (not recommendations) regarding the preparation and administration of the medication or biological;
  o 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.

3. Controlled Medications: No revisions.
4. Pharmaceutical Services: No revisions.
5. Provision of a Licensed Pharmacist: No revisions.

Attachment B: Form CMS 20056 (2/2013) Medication Administration Observation
- Surveyor 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.
- Residents are not to be preselected for observation.
- Includes a list of potential ‘error situations’ that may be observed during medication administration; Observation Findings / Calculation process.

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