GREATER NEW YORK HEALTH CARE FACILITIES ASSOCIATION
519 8th Avenue, 16th Floor, New York, NY, 10018
Phone: 212-643-2828 Fax: 212-643-2956 www.gnyhcfa.org

MEMO 14-58

TO: **Administrator, DNS, Medical Director, and QA Committee**

FROM: **Mary Gracey-White RN, Director of Quality Assurance and Clinical Compliance**

DATE: **August 5, 2014**

RE: **CMS Memorandum 14-37: Revisions to State Operations Manual (SOM), Appendix PP - Guidance for Surveyors for LTC Facilities and Chapter 4**

Please be advised that CMS has released an Advance Guidance for revisions to the State Operations Manual (SOM) to incorporate all Survey and Certification policy memos issued from **October 2003 through May 2014**.

Please be advised that although GNYHCFA has issued Memos summarizing these individual revisions during this time frame, we have also prepared and attached a summary outlining the F tag revisions. The Advance Guidance document in its entirety can be accessed at: http://www.cms.gov/Medicare/ProviderEnrollmentandCertification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-37.pdf.

In addition to the summary, we have attached the individual update for F332-Medication Errors/Free of Medication Errors of 5% or Greater and F333-Medication Errors/Residents are Free of Significant Medication Errors. These individual F tags are emphasized for your review to assist facilities in educating staff and working with the facility pharmacy consultant to conduct quality improvement efforts at reducing medication errors as well as distinguishing between medication errors that are defined as significant. "**Significant medication error**" means one which causes the resident discomfort or jeopardizes his or her health and safety. Of particular note in the guidance is the clarification between significant and non-significant medication errors outlined below:

"Significant and non-significant medication errors observed at 5% or greater during the Medication Administration Observation task should continue to be cited at F332. However, any **significant** medication error included in the F332 (5% or greater) citation should also be cited at F333. If concerns are identified related to the administration of medications at F332-Medication Errors, then additional requirements may also be considered and investigated such as F425-Pharmacy *Services.* Criteria for judging significant medication errors as

well as examples are provided under significant and non-significant medication errors.

If you need further information or have any questions please contact the Association.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-37-NH

DATE: **July 3, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Guidance - Revisions to State Operations Manual (SOM), Appendix PP-Guidance to Surveyors for Long-Term Care (LTC) Facilities and Chapter 4

Memorandum Summary

- **Revisions to Appendix PP of the SOM:** We have revised the Interpretive Guidelines and, where appropriate, Investigative Protocols for the following F Tags to incorporate Survey & Certification (S&C) policy memos issued from October 2003 through May 2014. Specifically, the guidelines have been updated for the following F Tags:

  F161 - Assurance of Financial Security
  F202 - Documentation for Transfer and Discharge
  F208 - Admission Policy
  F221 - Physical Restraints
  F278 - Accuracy of Assessment/Coordination/Certification/Penalty for Falsification
  F281 - Services Provided Meet Professional Standards of Quality
  F286 - Maintaining 15 Months of Resident Assessments (Use)
  F332 - Medication Errors/Free of Medication Errors of 5% or Greater
  F333 - Medication Errors/Residents are Free of Significant Medication Errors
  F371 – Sanitary Conditions
  F387 - Frequency of Physician Visits/Timeliness of Visits
  F388 - Personal Visits by the Physician
  F390 - Physician Delegation of Tasks in SNFs/Performance of Physician Tasks in NFs
  F425 - Pharmacy Services
  F428 - Drug Regimen Review
  F431 - Service Consultation/Labeling of Drugs and Biologicals/Storage of Drugs and Biologicals
  F441 - Infection Control
  F492 - Compliance with Federal, State and local laws and Professional Standards
  F514 - Clinical Records
  F516 - Resident Identifiable Information/Safeguard against loss, destruction, or unauthorized use

- **Revisions to SOM Chapter 4:** Section 4132.1E Waiver of Program Prohibition has been revised to incorporate information consistent with CFR 483.151(c)(1). Section 4542.2 State Agency (SA) Expenses for Training of SA Personnel has been revised to include Association of Health Facility Survey Agencies (AHFSA) to the list of annual meetings.

A. Background

The Centers for Medicare & Medicaid Services (CMS) is committed to revising and updating the SOM by incorporating published S&C policy memos. This includes clarification of guidance, and/or changes to acceptable standards of practice related to the regulatory guidance.

In this transmittal, revisions have been made to Appendix PP based on the following:

- F161- Assurance of Financial Security and F208 - Admission Policy are related to S&C memo 04-17, "Clarification of Nursing Homes Requiring Promissory Notes or Deposit Fees as a Condition of Admission and Implications related to Surety Bonds" dated Jan.8, 2004.

- F202 - Documentation for Transfer and Discharge is related to S&C memo 03-10, "Binding Arbitration in Nursing Homes" dated Jan. 9, 2003.

- F221- Physical Restraints is related to S&C memo 07-22, "Clarification of Terms Used in the Definition of Physical Restraints as Applied to the Requirements for Long Term Care Facilities" dated June 22, 2007.

- F281 - Services Provided Meet Professional Standards of Quality , F332 - Medication Errors/Free of Medication Errors of 5% or Greater, F333- Medication Errors/Residents are Free of Significant Medication Errors, F425- Pharmacy Services, F428- Drug Regimen Review, F431- Service Consultation/Labeling of Drugs and Biologicals/Storage of Drugs and Biologicals and the Investigative Protocols for F428 and F431 are related to S&C memo 13-02, "Nursing Homes - Clarification of Guidance related to Medication Errors and Pharmacy Services" dated Nov. 2, 2012.

- F278 - Accuracy of Assessment/Coordination/Certification/Penalty for Falsification, F286 - Maintaining 15 Months of Resident Assessments (Use), and F514 - Clinical Records are related to S&C memo 05-14, "Electronic Signature Guidance – Clarification" published on Jan. 13, 2005 (which replaced S&C memo 04-46, "Electronic Signature Guidance" dated Sept. 9, 2004).

- F332 - Medication Errors/Free of Medication Errors of 5% or Greater and F333 - Medication Errors/Residents are Free of Significant Medication Errors related to S&C policy memos 07-39, "Medication Pass Clarification for Surveying F Tags F332 and 333 During Nursing Home Surveys," published on Sept. 28, 2007 and 06-30 "Exceptions to the Observation Requirement When Determining Significant Medication Errors" dated Sept. 29, 2006.

- F371- Sanitary Conditions and the associated investigative protocol related to S&C policy memo11-38 "Compliance with Food Procurement Requirements for Nursing Homes with Gardens" dated Sept. 7, 2011 and S&C policy memo 14-34 "Advance Copy of Revised F371; Interpretive guidance and Procedures for Sanitary Conditions, Preparation of Eggs in Nursing Homes" dated May 20, 2014.

- F387- Frequency of Physician Visits/Timeliness of Visits, F388- Personal Visits by the Physician, and F390 - Physician Delegation of Tasks in SNFs/Performance of Physician Tasks in NFs related to S&C policy memo 13-15 Physician Delegation of Tasks (which replaced S&C policy memos 04-08 and 03-18 titled Physician Delegation of Tasks in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs).

- F425- Pharmacy Services related to S&C policy memo 06-06 "Use of Foreign Acquired Drugs in LTC Facilities" published Nov. 14, 2005 and S& C policy memo 13-02 "Nursing Homes – Clarification of Guidance related to Medication Errors and Pharmacy Services." dated November 2, 2012.

- F441- Infection Control and the associated Investigative Protocol related to S&C policy memo 12-30 "Use of Insulin Pens in Health Care Facilities" dated May 18, 2012, S&C policy memo 12-35 "Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections" dated June 15, 2012, S&C policy memo 10-28 "Point of Care Devices and Infection Control in Nursing Homes" dated August 27, 2010, S&C policy memo 13-09 "Clarification of Interpretive Guidance at F Tag 441 – Laundry and Infection Control" dated January 25, 2013 and "Advance Copy – Single-Use Device Reprocessing under Tag F441. Revisions to Interpretive Guidance in Appendix PP, State Operations Manual (SOM) on Infection Control" dated May 9, 2014.

- F492- Compliance with Federal, State and local laws and Professional Standards related to S&C policy memo 12-34 "Clarification and revisions to Interpretive Guidance at F Tag 492, as Part of Appendix PP, State Operations Manual (SOM) for Long Term Care (LTC) Facilities" dated June 1, 2012.

- F514- Clinical Records and F516 - Resident Identifiable Information/Safeguard against loss, destruction, or unauthorized use related to S&C policy memo 09-53 "Surveying Facilities that use Electronic Health Records (EHR)" dated August 14, 2009.

In this transmittal, we have also revised Section 4132.1E, Waiver of Program Prohibition, to incorporate information consistent with 42 CFR 483.151(c)(1).

An advance copy of the guidance revisions is attached. The final version of this document, when published in the online SOM, may differ slightly from this advanced copy.

If you have any questions regarding this memorandum, please contact Alisa Overgaard at 410-786-2167 or via e-mail at Alisa.Overgaard@cms.hhs.gov.

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

/s/
Thomas E. Hamilton

Attachments: (19)

Advance Copy, SOM Interpretive Guidance Revisions for Appendix PP and Chapter 4

cc: Survey and Certification Regional Office Management

The following represents a summary of revisions/updates that have been made in the State Operating Manuel during the period from October 2003 through May 2014. Although there has been a memo sent for each revision, the following summary will serve as a guide to ensure compliance in all areas.

F TAG	TITLE AND SUMMARY OF REVISIONS	RESPONSIBLE FOR COMPLIANCE COMMENTS
161	**ASSURANCE OF FINANCIAL SECURITY** 1. Each facility must ensure that all resident personal funds and any other funds entrusted to the facility are ensured by a Surety Bond. This bond must cover the total amount of resident personal funds.	Administrator Business Office
202	**DOCUMENTATION FOR TRANSFER AND DISCHARGE** 1. Documentation by the Physician for residents who transfer or are discharged to another facility must clearly indicate the reason for transfer/discharge. 2. The indication for transfer must not be related to the source of payment.	Medical Director Social Services Nursing
208	**ADMISSION POLICY** 1. The facility is responsible to inform the resident/significant other of charges covered and not covered by Medicaid insurance	Admission Office Social Services
222	**PHYSICAL RESTRAINTS** 1. Before the application of a restraint, the facility must determine the specific medical symptom that requires the use of a restraint. 2. The order must state how the use of this restraint will treat the medical symptom and assist the resident in attaining or maintaining the highest degree of wellness	Primary Care Physicians Nursing Social Services
278	**ACCURACY OF ASSESSMENTS COORDINATION/CERTIFICATION/PENALTY FOR FALSIFICATION** 1. Facilities may use electronic signatures on the MDS. Facilities must have a written policy in place to ensuring the security and protection of the document.	Administration MDS Coordinator
281	**SERVICES PROVIDED MEET PROFESSIONAL STANDARDS** 1. Facility must ensure that each resident has a sufficient supply of medications and that staff adhere to the facility system for re-ordering medications.	Nursing Pharmacy Consultant *(Daily tracking of missed medications and medications not given will help monitor compliance)*

286	**MAINTAINING 15 MONTHS OF RESIDENT ASSESSMENTS** 1. Facilities may maintain MDS Data electronically regardless of whether the entire medical record is electronic. 2. The MDS assessments must be readily and easily accessible at all times.	MDS Coordinator *(Electronic MDS assessments must be able to be downloaded easily and made available quickly to surveyors)*
332 **333**	**MEDICATION ERROR/FREE OF SIGNIFICANT MEDICATION ERRORS** 1. Significant and non-significant medication errors observed at a 5% or greater are cited under F332. 2. When a significant medication error is observed during a medication administration observation it should be cited regardless of whether the facility rate is 5% or greater. 3. Significant medication errors are also cited in F333 4. Medications errors due to failure to follow manufacturers specifications or acceptable professional standards include but are not limited to: • Failure to shake a medication that is labeled shake well • Crushing medications or capsules which the manufacturer instructs "do not crush" • Failure to administer the recommended amount of adequate fluid. • Failure to administer the medication with food or antacids when this is recommended by the manufacturer • Failure to ascertain placement of enteral feeding tube prior to administration • When administering medications via enteral feeding tubes, failure to administer each medication separately and failure to flush the tubing between each medication	Nursing Medical Director Pharmacy Consultant ***(The attached download of F332 and F333 goes into specific detail regarding significant versus non-significant medication errors and is a valuable resource.)***
371	**SANITARY CONDITIONS/PROCUREMENT OF FOOD** 1. The use of pasteurized eggs is recommended. When unpasteurized eggs are used they must be cooked until all parts of the egg are firm. 2. Nursing Homes may grow vegetable gardens as long as the Nursing Home is compliant with the food procurement policy. Nursing Homes with a garden should have a policy and procedure in place for maintaining the garden.	Food Service Director Dietary Department

387 **388** **390**	**FREQUENCY OF PHYSICIAN VISITS/PERSONAL VISITS BY THE PHYSICIAN/PHYSICIAN DELEGATION OF TASKS** 1. In an SNF, only a PMD may conduct the initial physical exam and assessment. 2. A Nurse Practitioner/Physician Assistant may conduct a monthly assessment every other month alternating with the PMD. 3. The Nurse Practitioner/ Physician Assistant conducting the monthly assessments may not be employed by the facility.	Medical Director Nursing
425	**PHARMACY SERVICES** 1. The facility must ensure that each resident has a sufficient supply of his or her medications. 2. The facility must have a policy and procedure to follow when residents' medications are unavailable. 3. Facilities must collaborate with pharmacists to ensure that all medication provided is obtained from an approved source and does not violate the FFDCA. 4. Facilities must ensure that correct medicine is administered in the correct dose in accordance with the manufacturers' recommendation. This includes proton pump inhibitors, metered dose inhalers and medications given via enteral feeding tubes. Emphasis on the following areas with respect to medication administration is noted: • Specific attention to site documentation • Adherence to the parameters for administration • Proper checking for enteral feeding tube placement • Proper preparation for administration of drugs via enteral feeding tube	Nursing Pharmacy Consultant
428	**DRUG REGIMEN REVIEW** 1. The resident's drug regimen review must be conducted at least monthly by a licensed pharmacist. This includes: • Residents receiving Hospice Care • Have an anticipated stay of less than 30 days • Have experienced a significant change in condition • A complex resident during the transition from hospital to SNF • Residents receiving respite care	Nursing Pharmacy Consultant *(Nursing must be in communication with the Pharmacy Consultant to alert them regarding drug regimen reviews that may need to be done outside the routine schedule)*

431	**SERVICE CONSULTATION** **LABELING OF DRUGS AND BIOLOGICALS** **STORAGE OF DRUGS AND BIOLOGICALS** 1. Facility must ensure that all staff adheres to the standards of professional practice re: the monitoring, storing, and counting of controlled substances. 2. If the facility identifies that controlled substances have been diverted, the facility must notify the appropriate state and local agencies. (This includes but is not limited to the local law enforcement agency, Drug Enforcement Agency, Health Department, and Office of Professional Licensing)	Nursing Pharmacy Consultant *(Yearly Competency check should be done on all licensed nurses to ensure compliance and best practices with regards to controlled substances)*
441	**INFECTION CONTROL** 1. Facilities must establish policies that when medication is administered from a multi-dose vial the vial must be labeled for a single resident only. Multi-dose vials should not be used for more than one resident. 2. Facility must ensure that insulin pens are clearly labeled for each individual resident and that staff are in serviced on the safe use of such. 3. Facility must ensure that when not in use, washing machines are open to air to allow machine to dry completely and prevent the growth of microorganisms. 4. Facility that uses Ozone cleaning systems for laundry must have a written agreement with the laundry service and a policy and procedure in place 5. Facilities must have written policies and procedures which include training for staff who handles linens and laundry.	Nursing Pharmacy Consultant Director of Housekeeping Director of Maintenance
492	**COMPLIANCE WITH FEDERAL STATE AND LOCAL LAWS AND PROFESSIONAL STANDARDS** 1. Facility must be in compliance with Federal, State, and local laws regulations and codes relating to health, safety, and sanitation. 2. The facility must follow professional standards and principles that apply to professionals providing services in facilities.	Administration Nursing Social Services *(Routine checking of the non-Medicare/Medicaid provider list as well as systematic checking of licenses and certifications will assist with compliance)*

514	**CLINICAL RECORDS** 1. Electronic signatures are acceptable whether or not the record is entirely electronic, and when permitted to do so by state and local law. 2. Facilities must have policies in place that identify those that are authorized to sign electronically and describe the safeguards to prevent unauthorized use of electronic signatures. 3. Facilities must have a built in safeguard to minimize the possibility of fraud. 4. Facilities must ensure that each staff member has an individualized identifier 5. Facilities must be able to provide direct print capability of any part of the medical record in a time frame that does not impede the survey process 6. Facilities must provide the surveyor with access to the electronic medical record as well as any needed education, and/or assistance in obtaining information from the electronic record. 7. Facilities must ensure that data is backed up ,secure and access does not impede the survey process or the provision of care and services to the resident	Administration Nursing Medical Records Electronic Medical Records Company
516	**RESIDENT IDENTIFIABLE INFORMATION/SAFEGUARD AGAINST LOSS, DESTRUCTION OR UNAUTHORIZED USE** 1. Facilities that utilize electronic Health Records are responsible for ensuring the necessary back up of data and security of information in the resident's medical record. 2. Facilities using Electronic Health Records must ensure that computer screens showing clinical record information are not left unattended, and that they are not readily observable or accessible by other residents and visitors. 3. Facilities using Electronic Health Records must ensure that there are no publicly posted passwords which would be evidence of noncompliance with confidentiality.	

F332 and F333

(Rev.)

§483.25(m) Medication Errors

The facility must ensure that--

[F332] §483.25(m)(1) It is free of medication error rates of 5 percent or greater; and

[F333] §483.25(m)(2) Residents are free of any significant medication errors.

Interpretive Guidelines §483.25(m) *(1) and (2)*

Definitions §483.25(m)(1) and (2)

"Medication Error" the observed preparation or administration of *medications* or biologicals which is not in accordance with:

1. *The prescriber's order*;

2. Manufacturer's specifications (not recommendations) regarding the preparation and administration of the *medication* or biological;

3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils.

"**Significant medication error**" means one which causes the resident discomfort or jeopardizes his or her health and safety. Criteria for judging significant medication errors as well as examples are provided under significant and non-significant medication errors. Discomfort may be a subjective or relative term used in different ways depending on the individual situation. (Constipation that is unrelieved by an ordered laxative that results in a *medication* error that is omitted for one day may be slightly uncomfortable or perhaps not uncomfortable at all. When the constipation persists for greater than three days, the constipation may be more significant. Constipation causing obstruction or fecal impaction can jeopardize the resident's health and safety.)

"**Medication error rate**" is determined by calculating the percentage of medication errors observed during a medication administration observation. The numerator in the ratio is the total number of errors that the survey team observes, both significant and non-significant. The denominator consists of the total number of observations or "opportunities for errors" and includes all the doses the survey team observed being administered plus the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors (doses given plus doses ordered but not given) X 100.

The error rate must be 5% or greater in order to cite F332. Rounding up of a lower rate (e.g., 4.6%) to a 5% rate is not permitted. *A medication error rate of 5% or greater may indicate that the facility has systemic problems with its medication distribution system.*

NOTE: *Significant and non-significant medication errors observed at 5% or greater during the Medication Administration Observation task should continue to be cited at F332. However, any* ***significant*** *medication error included in the F332 (5% or greater) citation should* <u>*also*</u> *be cited at F333. If concerns are identified related to the administration of medications at F332-Medication Errors,, then additional requirements may also be considered and investigated such as F425 - Pharmacy Services.*

Significant and Non-significant Medication Errors

Determining Significance

The relative significance of medication errors is a matter of professional judgment. Follow three general guidelines in determining whether a medication error is significant or not:

- Resident Condition - The resident's condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated resident may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant.

- Drug Category - If the *medication* is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a *medication* that has a Narrow Therapeutic Index (NTI) (i.e., a *medication* in which the therapeutic dose is very close to the toxic dose). Examples of *medications* with NTI are as follows: Anticonvulsant: phenytoin (Dilantin), carbamazepine (Tegretol), Anticoagulants: warfarin (Coumadin) Antiarrhythmic (digoxin) Lanoxin) Antiasthmatics: theophylline (TheoDur) Antimanic Drigs: lithium salts (Eskalith, Lithobid).

- Frequency of Error - If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's *medication* was omitted several times, as verified by reconciling the number of tablets delivered with the number administered, classifying that error as significant would be more in order. This conclusion should be considered in concert with the resident's condition and the *medication* category.

Significant medication errors are cited in the following circumstances:

- *When observed during the medication administration observation. A significant medication error observed during a medication administration observation should be cited, regardless of whether the facility error rate is 5% or greater;*

- *When identified during the course of a resident record review, including a revisit survey or a complaint investigation. A surveyor may cite a deficiency at F333 based upon either a resident record review and/or an observation of a medication preparation or administration. Surveyors must conduct any follow up investigation to obtain corroborating information regarding the error, such as interviews with the nurse, Director of Nursing, or the pharmacist, and document that information and facts as required by the Principles of Documentation. Also, it may be necessary to apply the past non-compliance protocol when determining a deficient practice or citation.*

Examples of Significant and Non-Significant Medication Errors

Some of these errors are identified as significant. This designation is based on expert opinion without regard to the status of the resident. Most experts concluded that the significance of these errors, in and of themselves, have a high potential for creating problems for the typical long term care facility resident. Those errors identified as non-significant have also been designated primarily on the basis of the nature of the *medication*. Resident status and frequency of error could classify these errors as significant.

Examples of Medication Errors
In the following tables, S=Significant; NS=Not Significant.
Omissions Examples (*Medication* ordered but not administered at least once):

***Medication* Order**	**Significance**
Quinidine 200mg TID	S
Nitrol Oint. one inch	S
Haldol 1mg BID	NS
Motrin 400mg TID	NS
Tearisol Drops 2 both eyes TID	NS
Metamucil one packet BID	NS
Multivitamin one daily	NS
Mylanta Susp. one oz., TID AC	NS

Unauthorized *Medication* Examples (*Medications* administered without a physician's order):

***Medication* Order**	**Significance**
Coumadin 4mg	S
Feosol	NS
Zyloprim 100mg	NS
Tylenol 5 gr	NS

Medication Order	Significance
Motrin 400mg	NS

Wrong Dose Examples:

Medication Order	Administered	Significance
Digoxin 0.125mg everyday	0.25mg	S
Dilantin 125 SUSP 12ml	2ml	S
Timoptic 0.25% one drop in the left eye TID	Three drops in each eye	NS
Amphojel 30ml QID	15ml	NS

Wrong Route of Administration Examples:

Medication Order	Administered	Significance
Cortisporin Ear Drops 4 to 5 left ear QID	Left Eye	S

Wrong Dosage Form Examples:

Medication Order	Administered	Significance
Dilantin Kapseals 100 mg three Kapseals p.o. HS	Prompt Phenytoin 100 mg three capsules p.o. HS	S*
Colace Liquid 100mg BID	Capsule	NS
Mellaril Tab 10mg	Liquid Concentrate	NS (if correct dose was given)

* Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not.

Wrong *Medication* Examples:

Medication Order	Administered	Significance
Vibramycin	Vancomycin	S
Tums	Oscal	NS

Wrong Time Examples:

Medication Order	Administered	Significance
Percocet 2 Tabs 20 min. before painful treatment	2 Tabs given after treatment	S
Digoxin 0.25mg daily at 8 a.m.	At 9:30 am	NS

Medication Errors Due to Failure to Follow Manufacturers Specifications or Accepted Professional Standards

Failure to "Shake Well"

The failure to "shake" a medication that is labeled "shake well" may lead to an under dose or over dose depending on the product and the elapsed time since the last "shake." The surveyor should use common sense in determining the adequacy of the shaking of the medication. Some *medications*, for example *phenytoin*, are more critical to achieve correct dosage delivery than others.

- Insulin Suspensions: Also included under this category is the failure to "mix" the suspension without creating air bubbles. Some individuals "roll" the insulin suspension to mix it without creating air bubbles. Any motion used is acceptable so long as the suspension is mixed and does not have air bubbles in it prior to the administration.

Crushed Medications

The crushing of tablets or capsules for which the manufacturer instructs to "do not crush" requires further investigation. Some exceptions to the "Do Not Crush" instruction include:

- If the prescriber orders a *medication* to be crushed which the manufacturer states should not be crushed, the prescriber or the pharmacist must explain, in the clinical record, why crushing the medication will not adversely affect the resident. Additionally, the pharmacist should inform the facility staff to observe for pertinent adverse effects.

- If the facility can provide literature from the *medication* manufacturer or from a reviewed health journal to justify why modification of the dosage form will not compromise resident care.

Giving Adequate Fluids with Medications

Administering medications without adequate fluid when the manufacturer specifies that adequate fluids be taken with the medication requires further investigation. If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. Surveyors should also be aware if a resident is on a fluid restriction, and not apply this standard to residents who are fluid restricted. For example, the surveyor should count fluids consumed during meals or snacks (such as coffee, juice, milk, soft drinks, etc.) as fluids taken with the medication, as long as they have consumed within a reasonable time of taking the medication (e.g., within approximately 30 minutes).

Medications that are recommended to be given with adequate fluid include, but are not limited to:

- Bulk laxatives (e.g., Metamucil, Fiberall, Serutan, Konsyl, Citrucel);
- Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) should be administered with adequate fluid. Adequate fluid is not defined by the manufacturer but is usually four to eight ounces; and
- Potassium supplements (solid or liquid dosage forms) such as: Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K, or Ten K should be administered with or after meals with a full glass (e.g., approximately 4 - 8 ounces of water or fruit juice). This will minimize the possibility of gastrointestinal irritation and saline cathartic effect. If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted.

Medications that must be taken with food or antacids

The administration of medications without food or antacids when the manufacturer specifies that food or antacids be taken with or before the medication is considered a medication error. The most commonly used *medications* that should be taken with food or antacids are the Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). There is evidence that elderly, debilitated persons are at greater risk of gastritis and GI bleeds, including silent GI bleeds. Determine if the time of administration was selected to take into account the need to give the medication with food.

Examples of commonly used NSAIDs are as follows:

Generic Name	**Brand Name**
Diclofenac	Voltaren, Cataflam
Diflunisal	Dolobid
Etodolac	Lodine

Generic Name	Brand Name
Fenoprofen	Nalfon
Ibuprofen	Motrin, Advil
Indomethacin	Indocin
Ketoprofen	Orudis, Oruvail
Mefenamic Acid	Ponstel
Nabumetone	Relafen
Naproxen	Naprosyn, Aleve
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin

Medications Administered Via Enteral Feeding Tubes

The placement of the feeding tube should be confirmed in accordance with the facility's policy.

NOTE: *If the placement of the tube is not checked, it is not a medication error, but should be evaluated under F322, §483.25(g)(1) and (2) – Nasogastric Tubes.*

Determine if the staff member administers each medication separately and flushes the tubing between each medication. An exception would be if there is a physician's order that specifies a different flush schedule because of a fluid restriction. For a resident who requires fluid regulation, the physician's order should include the amount of water to be used for the flushing and administration of medications.

NOTE: *Failure to flush before and in between each medication administration is considered a single medication error and would be included in the facility's medication error rate calculation.*

The administration of enteral nutrition formula and administration of phenytoin (Dilantin) should be separated to minimize interaction. The surveyor should look for appropriate documentation and monitoring if the two are administered simultaneously. If the facility is not aware that there is a potential for an interaction between the two when given together, and is not monitoring for outcome of seizures or unwanted side effects of phenytoin, then the surveyor should consider simultaneous administration a medication error.

Nutritional and Dietary Supplements

Nutritional Supplements are medical foods that are used to complement a resident's dietary needs. Examples of these are total parenteral products, enteral products, and meal replacement products (e.g., Ensure, Glucerna and Promote.)

Herbal and alternative products are considered to be dietary supplements. They are not regulated by the Food and Drug Administration (e.g., they are not reviewed for safety and effectiveness like medications) and their composition is not standardized (e.g., the composition varies among manufacturers). If a dietary supplement that is given to a resident between meals and has a vitamin(s) as one or more of its ingredients, it should be documented and evaluated as a dietary supplement, rather than a medication. For clinical purposes, it is important to document a resident's intake of such substances elsewhere in the clinical record and to monitor their potential effects, as they can interact with other medications.

NOTE: *Because nutritional and dietary supplements are not considered to be medications for purposes of the medication administration observation, noncompliance with the administration of these products should not be included in the calculation of the facility's medication error rate at F332 or as a significant medication error at F333. Medication errors involving vitamins and/or minerals should be documented at F332 and counted towards the error rate calculation. Medication errors involving vitamins and minerals would not be considered to be a significant medication error unless the criteria at F333 were met.*

It is expected that the facility staff, along with the prescriber and consulting pharmacist, are aware of, review for, and document any potential adverse consequences between medications, nutritional supplements, and dietary supplements that a resident is receiving.

Medications Instilled into the Eye

When observing the administration of eye drops, confirm that the medication makes full contact with the conjunctival sac, so that the medication is washed over the eye when the resident closes eyelid. The eye drop must contact the eye for a sufficient period of time before the next eye drop is instilled. The time for optimal eye drop absorption is approximately 3 to 5 minutes. (It should be encouraged that when the procedures are possible, systemic effects of eye medications be reduced by pressing the tear duct for one minute after eye drop administration or by gentle eye closing for approximately three minutes after the administration.)

Sublingual Medications

If the resident persists in swallowing a sublingual tablet (e.g., nitroglycerin) despite efforts to train otherwise, the facility should endeavor to seek an alternative dosage form for this *medication.*

Metered Dose Inhalers (MDI)

Ensuring that a device is administered correctly is vital to optimizing inhalation therapy. The surveyor would observe the administration of MDIs for the following:

- Shake the container well;

- Position the inhaler in front of or in the resident's mouth. Alternatively a spacer *or valved holding chamber* may be used;

- For cognitively impaired residents, many clinicians believe that the closed mouth technique is easier for the resident and more likely to be successful. However, the open mouth technique often results in better and deeper penetration of the medication into the lungs, when this method can be used.

- *If more than one puff is required (whether the same medication or a different medication), follow the manufacturer's product information for administration instructions including the acceptable wait time between inhalations.*

NOTE: If the person administering the *medication* follows all the procedures outlined above, and there is a failure to administer the medication because the resident can't cooperate (for example, a resident with dementia may not understand the procedure), this should not be counted as a medication error. The surveyor should evaluate the facility's responsibility to assess the resident's circumstance, and possibly attempt other dosage forms such as oral dosage forms or nebulizers.

Determining Medication Errors

Timing Errors

If a *medication* is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a *medication* is ordered PC and is given AC, count as a medication error. Count a wrong time error if the *medication* is administered 60 minutes earlier or later than its scheduled time of administration, BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY. Counting a *medication* with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this *medication* has a long half-life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors).

To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

Prescriber's Orders

The latest recapitulation of *medication* orders is sufficient for determining whether a valid order exists provided the prescriber has signed the "recap." The signed "recap," if the facility uses the "recap" system and subsequent orders constitute a legal authorization to administer the *medication.*

Omitted Dose

One of the most frequent types of errors is an omitted dose, *i.e. a dose of medication that is ordered but not given.* If a surveyor detects an omitted dose, investigate the omission further:

- Ask the person administering *medications*, if possible, to describe the system for administering the *medications* given. Occasionally, a respiratory therapist may administer inhalers, a designated treatment person may only administer topical treatments, a hospice nurse may administer hospice medications, another person may administer eye drops or as needed *medications*, etc.

- Sometimes people may share medication carts. Under these circumstances, these individuals should be interviewed about the omitted dose, if they were involved, if possible.

- When persons that were actually responsible for administering the *medications* are not available, ask their supervisor for clarification.

Procedures §483.25(m) ***(1) and (2)***

Medication *Administration Observation* Methodology

The survey team should observe the administration of *medications*, on several different *medication* "passes," when necessary. Record what is observed; and reconcile the record of observation with the prescriber's *medication* orders to determine whether or not medication errors have occurred.

Do not rely solely on a paper review to determine medication errors. Detection of blank spaces on a medication administration record does not constitute the detection of actual medication errors. Paper review only identifies possible errors in most cases. In some cases paper review can help identify actual errors but research has shown that the procedure is time consuming for the number of actual errors detected.

Observation Technique

The survey team must know without doubt, what *medications*, in what strength, and dosage forms, are being administered. This is accomplished prior to *medication* administration and may be done in a number of ways depending on the *medication* distribution system used (e.g. unit dose, vial system, punch card). *Refer to Medication Administration Observation and Pharmacy Services in Appendix P for additional information related to the Medication Administration Observation.*

1. Identify the *medication*. There are two principal ways to do this. In most cases, they are used in combination:

- Identify the *medication* by its size, shape, and color. Many *medications* are identifiable by their distinctive size, shape, or color. This technique is problematic because not all *medications* have distinctive sizes, shapes, or color.

- Identify the *medication* by observing the label. When the punch card or the unit dose system is used, the survey team can usually observe the label and adequately identify the *medication*. When the vial system is used, observing the label is sometimes more difficult. Ask the nurse to identify the medication being administered.

2. Observe and record the administration of *medications* ("pass"). Follow the person administering *medications* and observe residents receiving *medications* (e.g., actually swallowing oral dosage forms). Be neutral and as unobtrusive as possible during this process.

    - Make every effort to observe residents during several different *medication* "passes," if possible, so the survey team will have an assessment of the entire facility rather than one staff member on one *medication* pass.

    - Identifying residents can present a problem. The surveyor should ask appropriate staff to explain the facility policy or system for the identification of residents.

    - *Multiple tablets or capsules required to deliver a dose of medication count as one observation;*

    - *Observe infection prevention practices by staff administering medications, including the procedures used for insulin pens and single dose vial use. If the caregiver fails to observe appropriate infection control and prevention standards of practice, it should also be evaluated under F441, Preventing the Spread of Infection/Indirect Transmission.*

3. Reconcile the surveyor's record of observation with physician's orders. Compare the record of observation with the most current orders for *medications*. This comparison involves two distinct activities:

    - For each *medication* on the surveyor's list: Was it administered according to the prescriber's orders? For example, in the correct strength, by the correct route? Was there a valid order for the *medication*? Was the *medication* the correct one?

    - For *medications* not on the surveyor's list: Are there orders for *medications* that should have been administered, but were not? Examine the record for *medication* orders that were not administered and should have been. Such circumstances may represent omitted doses, one of the most frequent types of errors.

Do not rely solely on a paper review of the *Medication Administration Record (MAR)* to determine medication errors. Detection of blank spaces on a *MAR* does not constitute the detection of actual medication errors. Paper review only identifies possible errors in most cases.

The surveyor should now have a complete record of what was observed and what should have occurred according to the prescribers' orders. Determine the number of errors by adding the errors on each resident. Before concluding for certain that an error has occurred, discuss the apparent error with the person who administered the *medications* if possible. There may be a logical explanation for an apparent error. For example, the surveyor observed that a resident had received Lasix 20 mg, but the order was for 40 mg. This was an apparent error in dosage. But the nurse showed the surveyor another more recent order which discontinued the 40 mg order and replaced it with a 20 mg order.

4. Reporting Errors -- Describe to the facility each error that the survey team detects (e.g., Mary Jones received digoxin in 0.125 instead of 0.25 mg). The survey team is not required to analyze the errors and come to any conclusions on how the facility can correct them. Do not attempt to categorize errors into various classifications (e.g., wrong dose, wrong resident). Stress that an error occurred and that future errors must be avoided.

5. Observe Many Individuals Administering Medications. Strive to observe as many individuals administering medications as possible. This provides a better picture of accuracy of the facility's entire *medication* distribution system.

Dose Reconciliation Technique Supplement to the Observation Technique -- When an omission error has been detected through the observation technique, the dose reconciliation technique can sometimes enable the survey team to learn how frequently an error has occurred in the past. Learning about the frequency of an error can assist in judging the significance of the error. (See Significant and Non-Significant Medication Errors above.) The dose reconciliation technique requires a comparison of the number of doses remaining in a supply of *medications* with the number of days the *medication* has been in use and the directions for use. For example, if a *medication* were in use for 5 days with direction to administer the *medication* 4 times a day, then 20 doses should have been used. If a count of the supply of that *medication* shows that only 18 doses were used (i.e., two extra doses exist) and no explanation for the discrepancy exists (e.g., resident refused the dose, or resident was hospitalized), then two omission errors may have occurred.

Use the dose reconciliation technique in facilities that indicate the number of *medications* received, and the date and the specific "pass" when that particular *medication* was started. Unless this information is available, do not use this technique. If this information is not available, there is no Federal authority under which the survey team may require it, except for controlled drugs.