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 *was* 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 *declined* the dose, or resident was hospitalized), then two omission errors may have occurred. *The surveyor should investigate further through interviews and record review to determine if actual medication errors occurred.*

Use the dose reconciliation technique *when* the number of medications received, and the date and the specific "pass" when that particular medication was started *are captured in the resident's medical record*. 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.

F761
§483.*45*(*g*) Labeling of Drugs and Biologicals
Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

§483.*45*(*h*) Storage of Drugs and Biologicals

§483.4*5*(*h*)(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

§483.*45*(*h*)(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

INTENT §*483.45(g) Labeling of Drugs and Biologicals and §483.45(h) Storage of Drugs and Biologicals*
The intent of this requirement is that the facility, in coordination with the licensed pharmacist, provides for:

- Accurate labeling to facilitate consideration of precautions and safe administration, of medications; and
- Safe and secure storage (including proper temperature controls, *appropriate humidity and light controls,* limited access, and mechanisms to minimize loss or diversion) of all medication.

NOTE: For purposes of this guidance, references to "the pharmacist" mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

Effective November 28, 2017

DEFINITIONS §483.*45*(*g*) *Labeling of Drugs and Biologicals and §483.45(h) Storage of Drugs and Biologicals*

"Biologicals" *are made from a variety of natural sources—human, animal, or microorganisms. Biologics are used to treat, prevent, or diagnose diseases and medical conditions. They may include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.*

"Controlled Medications" *are substances that have an accepted medical use (medications which fall under US Drug Enforcement Agency (DEA) Schedules II—V), have a potential for abuse, ranging from low to high, and may also lead to physical or psychological dependence.*

GUIDANCE §483.*45*(*g*) *Labeling of Drugs and Biologicals and §483.45(h) Storage of Drugs and Biologicals*

LABELING OF MEDICATIONS AND BIOLOGICALS

This section requires facility compliance with currently accepted labeling requirements, even though the pharmacies are responsible for the actual labeling. Labeling of medications and biologicals dispensed by the pharmacy must be consistent with applicable federal and State requirements and currently accepted pharmaceutical principles and practices. Although medication delivery and labeling systems may vary, the medication label at a minimum includes the medication name (generic and/or brand), *prescribed dose,* strength, the expiration date when applicable, the resident's name, and route of administration. The medication should also be labelled with *or accompanied by* appropriate instructions and precautions (such as shake well, *take* with meals, do not crush, special storage instructions).

For medications designed for multiple administrations (e.g., inhalers, eye drops), the label *identifies the specific* resident for whom it was prescribed.

When medications are prepared or compounded for intravenous infusion, the label contains the name and volume of the solution, resident's name, infusion rate, name and quantity of each additive, date of preparation, initials of compounder, date and time of administration, initials of person administering medication if different than compounder, ancillary precautions as applicable, and date after which the mixture must not be used. *The FDA and the Institute for Safe Medication Practices provide labelling guidance and recommendations aimed at preventing errors, https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf and https://www.ismp.org/tools/guidelines/labelFormats/comments/default.asp.*

For over-the-counter (OTC) medications in bulk containers (e.g., in states that permit bulk OTC medications to be stocked in the facility), the label contains the original manufacturer's or pharmacy-applied label indicating the medication name, strength, quantity, accessory instructions, lot number, and expiration date when applicable. The facility ensures that

medication labeling in response to order changes is accurate and consistent with applicable state requirements.

Additionally, to minimize contamination, facility staff should date the label of any multi-use vial when the vial is first accessed and access the vial in a dedicated medication preparation area:

- *If a multi-dose vial has been opened or accessed (e.g., needle-punctured), the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.*
- *If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.*

The Centers for Disease Control and Prevention website provides additional information regarding multi-use vials, http://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html.

MEDICATION ACCESS AND STORAGE

A facility is required to secure all medications in a locked storage area and to limit access to authorized personnel (for example, pharmacy technicians or assistants who have been delegated access to medications by the facility's pharmacist as a function of their jobs) consistent with state or federal requirements and professional standards of practice.

Storage areas may include, but are not limited to, drawers, cabinets, medication rooms, refrigerators, *and* carts. Depending on how the facility locks and stores medications, access to a medication room may not necessarily provide access to the medications (for example, medications stored in a locked cart, locked cabinets, a locked refrigerator, or locked drawers within the medication room). When medications are not stored in separately locked compartments within a storage area, only appropriately authorized staff may have access to the storage area.

Access to medications can be controlled by keys, security codes or cards, or other technology such as fingerprints. Schedule *II-V* medications must be maintained in separately locked, permanently affixed compartments. The access system (e.g. key, security codes) used to lock Schedule II-*V* medications and other medications subject to abuse, cannot be the same access system used to obtain the non-scheduled medications. The facility must have a system to limit who has security access and when access is used.

Exception: Controlled medications and those *medications* subject to abuse may be stored with non-controlled medications as part of a single unit package medication distribution system, if the supply of the medication(s) is minimal and a shortage is readily detectable.

During a medication pass, medications must be under the direct observation of the person administering the medications or locked in the medication storage area/cart. In addition, the facility should have procedures for the control and safe storage of medications for those residents who can self-administer medications. *(See F554, 483.10(c)(7) for guidance related to the right to self-administer medications).*

Safe medication storage includes the provision of appropriate environmental controls. Because many medications can be altered by exposure to improper temperature, light, or humidity, it is

important that the facility implement procedures that address and monitor the safe storage and handling of medications in accordance with manufacturers' specifications, State requirements and standards of practice (e.g., United States Pharmacopeia (USP) standards).

PROCEDURES

Use the Medication Administration Observation Facility Task and the Medication Storage and Labeling Critical Element pathway, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to, Medication Labeling and Storage.

KEY ELEMENTS OF NONCOMPLIANCE §*483.*45*(*g*) Labeling of Drugs and Biologicals *and §483.45(h) Storage of Drugs and Biologicals

To cite deficient practice at F761, the surveyor's investigation will generally show that the facility failed to:

- *Ensure that all drugs and biologicals used in the facility are labeled in accordance with professional standards,* including expiration dates and with appropriate accessory and cautionary instructions; or
- *Store all drugs and biologicals in locked compartments, including the storage of* schedule II-*V* medications in separately locked, permanently affixed compartments, *permitting only authorized personnel to have access* except when the facility uses single unit medication distribution systems in which the quantity stored is minimal and a missing dose can be readily detected, *or*
- Store medications at proper temperatures *and other appropriate environmental controls* to preserve their integrity.

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of noncompliance that demonstrate severity at Level 4 include, but are not limited to:

- The facility failed to *assure that medications were secure and inaccessible to unauthorized staff and residents. As a result, a resident accessed and ingested medications that caused clinically significant adverse consequences necessitating hospitalization to stabilize the resident*; or
- As a result of an incorrect label on the package, staff administered the wrong medication or wrong dose(s) of a medication (e.g., anticonvulsant, antihyperglycemic, benzodiazepine) with a potential for clinically significant adverse consequences, which resulted in, or had the potential for, serious harm or death (e.g., toxic levels of the medication, unresponsiveness, uncontrolled seizures).

An example of Level 3, Actual harm (physical or psychosocial) that is not immediate jeopardy, includes, but is not limited to:

- Medication labeling was incomplete and lacked instructions that the medication was not to be given with specific foods (e.g., milk or milk-based products) resulting in altered

effectiveness of the medication and worsening of the residents' symptoms, requiring medical intervention.

Examples of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include but are not limited to:

- The facility's medication cart was not kept locked or under direct observation of authorized staff *in an area where residents could access it. No medications were taken by residents but the potential for more than minimal harm exists*; or
- As a result of inaccurate labeling, the resident received the wrong medication or dose or the correct medication by the wrong route and experienced discomfort but did not require any interventions.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

- *Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to accurately label and safely secure storage of all medications places residents at risk for more than minimal harm.*

§483.50 Laboratory, radiology, and other diagnostic services
(Rev.)

This regulation is intended to ensure that laboratory, radiology, and other diagnostic services meet the needs of residents, that results are reported promptly to the ordering provider to address potential concerns and for disease prevention, provide for resident assessment, diagnosis, and treatment, and that the facility has established policies and procedures, and is responsible for the quality and timeliness of services whether services are provided by the facility or an outside resource.

There are clinical and physiological risks when laboratory, radiology, or other diagnostic services are not performed in a timely manner or the results of these services are not reported and acted upon quickly. These delays may adversely affect a resident's diagnosis, treatment, assessment, and interventions. If a resident has been adversely affected, refer as appropriate, to Quality of Care, Quality of Life, Abuse, or Neglect. Also refer to Physician Services and Nursing Services if test results were not acted upon timely as per the facility's policies or the prescribing practitioner orders.

There is no Tag for this section; refer to other Tags for concerns related to noncompliance.

F770
§483.50(a) **Laboratory Services.**
§483.50(a)**(1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.**

(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.