The following is a condensed and sometimes edited version of the new regulations which take effect on November 28, 2017. This is intended to be a list of pertinent regulations which affect us as Consultants in long term care. Please see the full text for complete guidance and explanations that may not be included here.

TABLE OF CONTENTS

F554 Self-Administration of Medications
F600 Free from Abuse, Neglect, and Exploitation (Consultant to resident included here)
F604 Respect and Dignity (free from physical and chemical restraints)
F608 Reporting of Crimes
F609 Response to Allegations of Abuse, Neglect, Exploitation or Mistreatment (2 hour -vs- 24 reporting time frame can include up to notification of the Board of Pharmacy)
F675 Quality of Life
F684 Quality of Care (mentions hospice)
F690 Urinary Incontinence (including medication management)
F692 Assisted Nutrition and Hydration (mentions medications, includes feedings, hydration)
F693 Assisted Nutrition and Hydration (includes consent, technical and nutritional aspects of feeding tubes
F697 Pain Management
F698 Dialysis
F711 Physician Visits
F712 Frequency of Physician Visits
F740 Behavioral Health Services
F744 Dementia (patients receive appropriate treatment and services)
F755 Pharmacy Services (Consultant, Emergency Meds, Borrowing, Foreign Acquired Meds, Pharmacy Services and Procedures, Controlled meds)
F756 DRR
F757 Unnecessary Drug
F758 Psychotropic Medications
F759 Medication Errors
F761 Labeling of Drugs and Biologicals
F880 Infection Control
F881 Infection Prevention and Control Program (includes Antibiotic Stewardship)

F554 Self-Administration of Medications

If a resident requests to self-administer medication(s), it is the responsibility of the interdisciplinary team (IDT) (See F657, Comprehensive Care Plans) to determine that it is safe before the resident exercises that right. A resident may only self-administer medications after the IDT has determined which medications may be self-administered.

When determining if self-administration is clinically appropriate for a resident, the IDT should at a minimum consider the following:

- The medications appropriate and safe for self-administration;
- The resident's physical capacity to swallow without difficulty and to open medication bottles;
- The resident's cognitive status, including their ability to correctly name their medications and know what conditions they are taken for;
- The resident's capability to follow directions and tell time to know when medications need to be taken;
- The resident's comprehension of instructions for the medications they are taking, including the dose, timing, and signs of side effects, and when to report to facility staff.
- The resident's ability to understand what refusal of medication is, and appropriate steps taken by staff to educate when this occurs.
- The resident's ability to ensure that medication is stored safely and securely.

Appropriate notation of these determinations must be documented in the resident's medical record and care plan. If a resident is self-administering medication, review the resident's record to verify that this decision was made by the IDT, including the resident. The decision that a resident has the ability to self-administer medication is subject to periodic assessment by the IDT, based on changes in the resident's medical and decision-making status. If self-administration is determined not to be safe, the IDT should consider, based on the assessment of the resident's abilities, options that allow the resident to actively participate in the administration of their medications to the extent that is safe (i.e., the resident may be assessed as not able to self-administer their medications because they are not able to manage a locked box in their room, but they may be able to get the medications from the nurse at a designated location and then safely self-administer them).

Medication errors occurring with residents who self-administer should not be counted in the facility's medication error rate and should not be cited at §483.45(f)(1) F759 and §483.45(f)(2) F760, Medication Errors. However, this may call into question the judgment of facility staff in allowing self-administration of medication for that resident.

F600 Freedom from Abuse, Neglect, and Exploitation

The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or **chemical restraint not required to treat the resident's medical symptoms.**

INTENT: Each resident has the right to be free from abuse, neglect and corporal punishment of any type by anyone.

DEFINITIONS
"Abuse," is defined at §483.5 as "the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology."

"Neglect," as defined at *§483.5*, means "the failure of the facility, its employees or **service providers** to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or emotional distress."

"Sexual abuse," is defined at §483.5 as "non-consensual sexual contact of any type with a resident."

"Willful," as defined at §483.5 and as used in the definition of "abuse," "means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm."

GUIDANCE NOTE: For purposes of this guidance, "staff" includes employees, the medical director, **consultants**, contractors, and volunteers. Staff would also include caregivers who provide care and services to residents on behalf of the facility, students in the facility's nurse aide training program, and students from affiliated academic institutions, including therapy, social, and activity programs.

Staff to Resident Abuse of Any Type
Nursing homes have diverse populations including, among others, residents with dementia, mental disorders, intellectual disabilities, ethnic/cultural differences, speech/language challenges, and generational differences. When a nursing home accepts a resident for admission, the facility assumes the responsibility of ensuring the safety and well-being of the resident. It is the facility's responsibility to ensure that all staff are trained and are knowledgeable in how to react and respond appropriately to resident behavior. **All staff are expected to be in control of their own behavior, are to behave professionally, and should appropriately understand how to work with the nursing home population**. A facility cannot disown the acts of staff, since the facility relies on them to meet the Medicare and Medicaid requirements for participation by providing care in a safe environment. **CMS does not consider striking a combative resident an appropriate response in any situation. It is also not acceptable for an employee to claim his/her action was "reflexive" or a "knee-jerk reaction" and was not intended to cause harm**. **Retaliation by staff is abuse, regardless of whether harm was intended, and must be cited.**

NOTE: It should not be assumed that every accident or disagreement that occurs between an employee and a resident should be considered to be abuse. Accidents that may not be considered to be abuse include instances such as a staff member tripping and falling onto a resident; or a staff member quickly turning around or backing into a resident that they did not know was there.

F604 Respect and Dignity

Respect and Dignity. The resident has a right to be treated with respect and dignity, including:

The right to be free from any physical or **chemical restraints imposed for purposes of discipline or convenience,** and not required to treat the resident's medical symptoms.

When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

INTENT
The intent of this requirement is for each resident to attain and maintain his/her highest practicable well-being in an environment that:

- Prohibits the use of physical restraints for discipline or convenience;
- Prohibits the use of physical restraints to unnecessarily inhibit a resident's freedom of movement or activity; and
- Limits physical restraint use to circumstances in which the resident has medical symptoms that may warrant the use of restraints.

When a physical restraint is used, the facility must:

- Use the least restrictive restraint for the least amount of time; and
- Provide ongoing re-evaluation of the need for the physical restraint.

Assessment, Care Planning, and Documentation for the Use of a Physical Restraint
The regulation limits the use of any physical restraint to circumstances in which the resident has medical symptoms that warrant the use of restraints. There must be documentation identifying the medical symptom being treated and an order for the use of the specific type of restraint. However, the practitioner's order alone (without supporting clinical documentation) is not sufficient to warrant the use of the restraint. The facility is accountable for the process to meet the minimum requirements of the regulation including appropriate assessment, care planning by the interdisciplinary team, and documentation of the medical symptoms and use of the physical restraint for the least amount of time possible and provide ongoing re-evaluation.

The resident or resident representative may request the use of a physical restraint; however, the nursing home is responsible for evaluating the appropriateness of the request, and must determine if the resident has a medical symptom that must be treated and must include the practitioner in the review and discussion. If there are no medical symptoms identified that require treatment, the use of the restraint is prohibited. Also, a resident, or the resident representative, has the right to refuse treatment; however, he/she does not have the right to demand a restraint be used when it is not necessary to treat a medical symptom.

NOTE: Falls do not constitute self-injurious behavior or a medical symptom that warrants the use of a physical restraint. Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries. There is no evidence that the use of physical restraints, including, but not limited to, bed rails and position

change alarms, will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries (e.g., strangulation, entrapment).

GUIDANCE

The indication for use for any medication ordered for a resident must be identified and documented in the resident's record. (Also refer to F757 and/or F758.) When any medication restricts the resident's movement or cognition, or sedates or subdues the resident, and is not an accepted standard of practice for a resident's medical or psychiatric condition, the medication may be a chemical restraint. Even if use of the medication follows accepted standards of practice, it may be a chemical restraint if there was a less restrictive alternative treatment that could have been given that would meet the resident's needs and preferences or if the medical symptom justifying its use has subsided. The facility is accountable for the process to meet the minimum requirements of the regulation including appropriate assessment, care planning by the interdisciplinary team, and documentation of the medical symptoms and use of a less restrictive alternative for the least amount of time possible and provide ongoing re-evaluation.

NOTE: A medication may have been required to treat a medical symptom, and as a result, the medical symptom is no longer present. In some cases, the clinical goal of the continued use of the medication is to stabilize the symptoms of the disorder so that the resident can function at the highest level possible. In other words, the clinical goal is to have no symptoms of the disorder Although the symptom may no longer be present, the disease process is still present. For example, diseases may include:

- Chronic psychiatric illness such as schizophrenia or schizoaffective disorder, bipolar disorder, depression, or post-traumatic stress disorder;
- Neurological illness such as Huntington's disease or Tourette's syndrome; and
- Psychosis and psychotic episodes.

In such instances, if the medication is reduced or discontinued, the symptoms may return. Reducing or eliminating the use of the medication may be contraindicated and must be individualized. If the medication is still being used, the clinical record must reflect the rationale for the continued administration of the medication. If no rationale is documented, this may meet the criteria for a chemical restraint, such as for staff convenience (See also F758 for concerns related to unnecessary use of a psychotropic medication and lack of gradual dose reduction).

Determination of Medical Symptoms

The clinical record must reflect whether the staff and practitioner have identified, to the extent possible, and addressed the underlying cause(s) of distressed behavior, either before or while treating a medical symptom. Potential underlying causes for expressions and/or indications of distress may include, but are not limited to:

- Delirium;
- Pain;
- The presence of an adverse consequence associated with the resident's current medication regimen; and
- Environmental factors, such as staffing levels, over stimulating noise or activities, under stimulating activities, lighting, hunger/thirst, alteration in the resident's customary location or

daily routine, physical aggression leading to altercations, temperature of the environment, and crowding.

NOTE: If it is determined that the administration of a medication is being used to treat a medical symptom, the survey team should review to assure that the use of the medication is supported by adequate indication and rationale for use, and is used at the correct dose and duration, and with adequate monitoring. (See also F741, F757, and F758 for concerns related to non-pharmacological approaches of redirecting or addressing behavior)

Determination of Indication for Medication Use
The clinical record must reflect the following:

- Whether there is an adequate indication for use for the medication (e.g., a psychotropic medication is not administered unless the medication is used to treat a specific condition);
- Whether an excessive dose and/or duration of the medication was administered to the resident;
- Whether there is adequate monitoring for the effectiveness of the medication in treating the specific condition and for any adverse consequences resulting from the medication;
- Whether a resident who uses a psychotropic drug(s) is receiving gradual dose reduction and behavioral interventions, unless clinically contraindicated; and
- Whether a resident who receives a psychotropic drug(s) pursuant to a PRN (pro re nata, or as needed) order is not administered the medication unless the medication is necessary to treat a diagnosed specific symptom, as documented in the clinical record.

If the practitioner orders a medication to be administered on a PRN time-limited basis for the provision of medical treatment to address an emergency medical condition (e.g., delirium), this would not be considered to be a chemical restraint. The dosage cannot exceed what is prescribed by the practitioner, and if the resident does not respond to the initial administration of the PRN medication, the practitioner must be contacted, regarding re-assessment of the resident's medical condition and evaluation of interventions. The administration of a PRN medication must be discontinued when the resident does not need the medication for treatment of the medical condition (also see §483.45(e) F758 for limitations on psychotropic and antipsychotic medication PRN orders). **If staff continue to utilize a PRN medication that subdues or sedates a resident, and is not treating a medical condition, this would be considered to be a chemical restraint for staff convenience or discipline**.

Risks and Psychosocial Impacts Related to Use of Chemical Restraints
A medication that is used for discipline or convenience and is not required to treat medical symptoms, may cause the resident to be:

- Subdued, sedated, or withdrawn;
- Asleep during hours that he/she would not ordinarily be asleep; or
- Limited in his/her functional capacity.

Additional effects resulting from sedating or subduing a resident may include, but are not limited to, the following:

- Loss of autonomy, dignity, self-respect and orientation;
- Confusion, cognitive decline, withdrawal, depression;
- Decreased activity levels, including social activities;

- Decline in skin integrity;
- Decline in continence level;
- Decline in physical functioning including an increased dependence in activities of daily living (e.g., ability to walk), impaired muscle strength and balance, decline in range of motion, and risk for development of contractures, increased risk of falls; and
- Weight loss if missing meals.

Facilities are responsible for knowing the effects medications have on their residents. If a medication has a sedating or subduing effect on a resident, and is not administered to treat a medical symptom, the medication is acting as a chemical restraint. The sedating/subduing effects to the resident may have been caused intentionally or unintentionally by staff, and would indicate an action of discipline or convenience. In the case of an unintentional chemical restraint, the facility did not intend to sedate or subdue a resident, but a medication is being administered that has that effect, and is not the least restrictive alternative to treat the medical symptom. These effects may result in convenience for the staff, as the resident may require less effort than previously required. Even if a medication was initially administered for a medical symptom, the continued administration of a medication in the absence of a medical symptom, that sedates a resident or otherwise makes it easier to care for them, is a chemical restraint.

Other examples of facility practices that indicate that a medication (ordered by a practitioner) is being used as a chemical restraint for staff convenience or discipline include, but are not limited to:

- Staff indicate that a medication is being administered based on the resident's representative's request to administer a medication to "calm down" the resident;
- Staff have recommended to the practitioner that a resident be administered a medication in order to prevent a resident from displaying behaviors such as wandering into other resident's rooms:
- Staff administer a medication to quiet the resident because the resident continually calls out, without attempting alternative interventions;
- Staff become frustrated with a resident who continually requests staff assistance (such as for toileting), or continually puts on the call light, and administer a medication to sedate or subdue the resident);
- Staff administer a medication that subdues or sedates a resident when insufficient staffing levels do not allow for the resident's needs to be met;
- Staff administer a medication to sedate or subdue the resident, and/or to restrict the resident to a seated or lying position, since the resident continually wanders into other resident's rooms or attempts to leave the unit; and
- Staff become upset with a resident who resists receiving a bath and pinches staff. The staff had not re-assessed the resident nor revised interventions regarding how to provide bathing care in order to meet the resident's needs. Instead, staff administer a medication that is used to subdue the resident prior to providing the bath, but the medication is not used to treat an identified medical symptom.

Gather information regarding the resident's mental, physical, functional, and psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

Interview the practitioner regarding concerns identified during the investigation, including when the staff contacted him/her, what concerns they identified regarding the residents behavior, the response provided, including whether other interventions were attempted prior to the use of a medication, what medical symptom is being treated with the medication, whether the medication is considered to be the least restrictive (in type, dose, and duration) that may be used to treat the symptom, and the plan for discontinuing and/or revising interventions. **Interview the pharmacist to identify when he/she conducted the last medication regimen review for the resident; if the medication was administered prior to the last review and it was not identified as a concern, whether he/she can provide information regarding the indication for use of the medication; if the medication was administered prior to the last review and it was identified as a concern, , whether he/she notified the practitioner, Director of Nurses, and/or medical director and what was the response; and what is the facility's process for notifying the pharmacist when initiating a medication for a change in the resident's condition, such as when there are expressions or indications of distress, or other changes in a resident's psychosocial status.**

It may be necessary to interview the medical director regarding medications that are not required to treat the resident's medical symptoms result in the resident being subdued, sedated, or withdrawn or limited in his/her functional capacity.

Determine whether the Quality Assessment & Assurance committee is aware of psychotropic medication used to address resident behavioral symptoms, whether there is sufficient, qualified staff trained to provide interventions for behavioral symptoms, and supervision of staff to assure that medications are only used to treat a medical symptom and do not have the effect of convenience or discipline.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

During the investigation, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

- 42 CFR 483.10, 483.10(a)(1)-(2), 483.10(b)(1)-(2), F550-Resident Rights and Dignity
- 42 CFR 483.10(c)(2)-(3), F553 -Right to Participate Planning Care
- 42 CFR 483.21(b)(1), F656-Develop/Implement Comprehensive Care Plan
- 42 CFR 483.35, 483.35(a), and 483.35(c)-F725 and F726 – Sufficient and Competent Staff
- 42 CFR 483.40(b)-(b)(1), F742-Treatment/Svc for Mental/Psychosocial Concerns
- 42 CFR 483.45(c), F756-Drug Regimen Review, Report Irregular, Act On
- 42 CFR 483.45(d), F757-Drug Regimen is Free From Unnecessary Drugs
- 42 CFR 483.45, F758-Psychotropic Medications
- 42 CFR 483.70(h), F841-Responsibilities of Medical Director
- 42 CFR 483.75 (g)(2)(ii)-F867-QAA Activities

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F608 Reporting of Crimes

The facility must develop and implement written policies and procedures that ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act. The policies and procedures must include but are not limited to the following elements.

Annually notifying covered individuals, as defined at section 1150B(a)(3) of the Act, of that individual's obligation to comply with the following reporting requirements.

(A) Each covered individual shall report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility.

(B) Each covered individual shall report immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury.

(ii) Posting a conspicuous notice of employee rights, as defined at section 1150B(d)(3) of the Act.

(iii) Prohibiting and preventing retaliation, as defined at section 1150B(d)(1) and (2) of the Act.

INTENT

The intent is for the facility to develop and implement policies and procedures that:

- Ensure reporting of crimes against a resident or individual receiving care from the facility occurring in nursing homes within prescribed timeframes to the appropriate entities, consistent with Section 1150B of the Act;
- Ensure that all covered individuals, such as the owner, operator, employee, manager, agent or contractor report reasonable suspicion of crimes, as required by Section 1150B of the Act;
- Provide annual notification for covered individuals of these reporting requirements;
- Post a conspicuous notice of employee rights, including the right to file a complaint; and
- Assure that any covered individual who makes a report to be made, or is in the process of making a report, is not retaliated against.

DEFINITIONS "Covered individual" is anyone who is an owner, operator, employee, manager, agent or contractor of the facility (See section 1150B(a)(3) of the Act).

"Crime": Section 1150B(b)(1) of the Act provides that a "crime" is defined by law of the applicable political subdivision where the facility is located. A political subdivision would be a city, county, township or village, or any local unit of government created by or pursuant to State

F609 Response to allegations of abuse, neglect, exploitation, or mistreatment

Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law

provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

F675 Quality of life

Quality of life is a fundamental principle that applies to all care and services provided to facility residents. Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive assessment and plan of care.

The intent of this requirement is to specify the facility's responsibility to create and sustain an environment that humanizes and individualizes each resident's quality of life by:

- Ensuring all staff, across all shifts and departments, understand the principles of quality of life, and honor and support these principles for each resident; and
- Ensuring that the care and services provided are person-centered, and honor and support each resident's preferences, choices, values and beliefs.

Defined: "Quality of Life" An individual's "sense of well-being, level of satisfaction with life and feeling of self-worth and self-esteem. For nursing home residents, this includes a basic sense of satisfaction with oneself, the environment, the care received, the accomplishments of desired goals, and control over one's life."

Facilities must create and sustain an environment that humanizes and promotes each resident's well-being, and feeling of self-worth and self-esteem. This requires nursing home leadership to establish a culture that treats each resident with respect and dignity as an individual, and addresses, supports and/or enhances his/her feelings of self-worth including personal control over choices, such as mealtimes, activities, clothing, and bedtime; privacy during visits, and treatments; and opportunities to engage in religious, political, civic, recreational or other social activities.

F684 Quality of care

Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. Based on the comprehensive assessment of a resident, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the residents' choices.

INTENT: To ensure facilities identify and provide needed care and services that are resident centered, in accordance with the resident's preferences, goals for care and professional standards of practice that will meet each resident's physical, mental, and psychosocial needs.

Nursing homes must place priority on identifying what each resident's highest practicable wellbeing is in each of the areas of physical, mental and psychosocial health. Each resident's care plan must reflect person-centered care, and include resident choices, preferences, goals, concerns/needs, and describe the services and care that is to be furnished to attain or maintain, or improve the resident's highest practicable physical, mental and psychosocial well-being. For concerns related to the resident's comprehensive care plan, see F656, 483.21(b) Comprehensive Care Plans.

The following sections describe some, but not all of the care needs that are not otherwise covered in the remaining tags of **§** 483.25, Quality of Care.

I. Review of a Resident with Non Pressure-Related Skin Ulcer/Wound. Residents may develop various types of skin ulceration. At the time of the assessment and diagnosis of a skin ulcer/wound, the clinician is expected to document the clinical basis (e.g., underlying condition contributing to the ulceration, ulcer edges and wound bed, location, shape, condition of surrounding tissues) which permit differentiating the ulcer type, especially if the ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one. This section differentiates some of the different types of skin ulcers/wounds that are not considered to be pressure ulcers. (not discussed here, see actual regulations for further detail).

II. Review of a Resident at or Approaching End of Life and/or Receiving Hospice Care and Services Assessment The resident must receive a comprehensive assessment to provide direction for the development of the resident's care plan to address the choices and preferences of the resident who is nearing the end of life. In addition, in order to promote the physical, mental, and psychosocial wellbeing of a resident who is approaching the end of life, the facility and the resident's attending physician/practitioner, should, to the extent possible:

- Identify the resident's prognosis and the basis for that prognosis; and
- Initiate discussions/considerations regarding advance care planning and resident choices.

The hospice retains primary responsibility for the provision of hospice care and services, based upon the resident's assessments, including but not limited to the following: providing medical direction and management of the resident; nursing,(including assigning a hospice aide as needed to support the resident's ongoing care); counseling (including spiritual, dietary, and bereavement); social work; providing medical supplies, durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions. See 42 C.F.R. § 418.112(c)(6).

F690 URINARY INCONTINENCE

Medication Therapy

Medications are often used to treat specific types of incontinence, including stress incontinence and those categories associated with an overactive bladder, which may involve symptoms including urge incontinence, urinary urgency, frequency and nocturia. The current literature identifies classifications and names of medications used for various types of incontinence. When using medications, potentially problematic anticholinergic and other side effects must be recognized. The use of medication therapy to treat urinary incontinence may not be appropriate for some residents because

of potential adverse interactions with their other medications or other co-morbid conditions. The resident/representative must be provided with the risks and benefits of using medications for continence management.

F692 Assisted Nutrition and Hydration

Assisted nutrition and hydration. (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). Based on a resident's comprehensive assessment, the facility must ensure that a resident—

§483.25(g)(1) Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;

§483.25(g)(2) Is offered sufficient fluid intake to maintain proper hydration and health;

§483.25(g)(3) Is offered a therapeutic diet when there is a nutritional problem and the health care provider orders a therapeutic diet.

"Tube feeding" refers to the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum. It is also referred to as an enteral feeding.

Medications: Medications may be helpful in improving a resident's nutritional status. Some ways medications may help a resident can be to increase appetite, reduce acid reflux, or reduce nausea. Some medications may have the unintended effect of impairing a resident's nutritional or hydration status and the resident may experience a lack of appetite, nausea, dry mouth, or other unintended effects. Interventions may be required to address these. For example, a resident may require frequent sips of a drink during a meal if they experience dry mouth. It may also be appropriate to consider changing, stopping, or reducing the doses of those medications as appropriate[17]. For additional guidance related to medications, refer to §483.45(d), F757, Unnecessary Drugs, or §483.45(e), F758, Psychotropic Drugs.

F693 Assisted Nutrition and Hydration

Nutrition and feeding issues and their underlying causes in the resident with advanced dementia or other chronic neurological disorders such as Parkinson's disease present a particular set of issues and considerations that are discussed in F692. The extended use of enteral feeding tubes in individuals with advanced dementia does not necessarily extend life and remains controversial. The literature regarding enteral feeding of these individuals suggests that there is little evidence that enteral feeding improves clinical outcomes (e.g., prevents aspiration or reduces mortality).

CONSENT: A feeding tube should not be placed unless consented to by the resident or if applicable, appropriately authorized resident representative. The resident has the right to make an informed decision about the treatment they receive. If a resident had a feeding tube placed prior to admission or in another care setting the physician and interdisciplinary care team must review the basis (e.g., precipitating illness or condition change) for the initial placement of the feeding tube and the resident's current condition. This is to determine if there is a continued rationale for its use and to ensure that its continued use is consistent with the resident's treatment goals and wishes. Decisions to continue or discontinue the use of a feeding tube are made through collaboration between the resident (or a representative for a resident who lacks capacity to make and communicate such decisions), the physician, and the interdisciplinary care team. This includes a discussion of the relevance of a feeding tube to attaining a resident's goals (e.g., whether the nutritional intervention is likely to have a significant impact on the individual's underlying condition or overall status).

TECHNICAL AND NUTRITIONAL ASPECTS OF FEEDING TUBES

It is important that staff providing care and services to the resident who has a feeding tube are aware of, competent in, and utilize facility protocols regarding feeding tube nutrition and care. These protocols are required to be developed with the medical director in order to assure staff implement and provide care and services according to resident needs and professional standards of practice.

Facility policies and procedures regarding the technical aspects of feeding tubes must be developed and implemented, which address:

- Monitoring the feeding tube
- How to verify that the tube is functioning before beginning a feeding and before administering medications, which may include:
- Checking gastric residual volume (GRV)
    - Not recommended for individuals who are alert and able to report symptoms that indicate a feeding is not well tolerated.
    - May be appropriate when initiating tube feedings or for individuals who are unable to report symptoms such as bloating, nausea, or abdominal pain.
    - Actions to take based upon the amount of GRV vary depending on the individual and the clinical condition.
    - pH of GRV may indicate correct placement i.e. pH < 5 generally indicates gastric contents versus intestinal contents but medications and feeding formulas can alter pH levels.
    - Changes in GRV appearance may also be helpful in confirming placement but should not be used in isolation.

      Observing changes in external length of tubing may indicate a change in position but can only be used if the exit site was marked upon initial placement; this method does not apply to low profile G tubes (tube that sits at skin level).

NOTE: Auscultation is no longer recommended for checking placement of the feeding tube. Movement of air would likely be heard whether the tube was in the correct or incorrect location. X-ray confirmation is the most accurate method for verification of tube placement when concerns arise regarding dislodgement or placement. Additional information regarding monitoring of feeding tubes may be found at, https://www.ismp.org/tools/articles/ASPEN.pdf

Care of the feeding tube

- Securing a feeding tube externally;
- Providing needed personal, skin, oral, and nasal care to the resident;
- Examining and cleaning the insertion site in order to identify, lessen or resolve possible skin irritation and local infection;
- Using infection control precautions and related techniques to minimize the risk of contamination; for example, in connecting the tube and the tube feeding; and
- Defining the frequency of and volume used for flushing, including flushing for medication administration, and when a prescriber's order does not specify.

F697 Pain Management

The facility must ensure that pain management is provided to residents who require such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

Based on the comprehensive assessment of a resident, the facility must ensure that residents receive the treatment and care in accordance with professional standards of practice, the comprehensive care plan, and the resident's choices, related to pain management.

Strategies for Pain Management

Strategies for the prevention and management of pain may include but are not limited to the following:

- Assessing the potential for pain, recognizing the onset, presence and duration of pain, and assessing the characteristics of the pain;
- Addressing/treating the underlying causes of the pain, to the extent possible;
- Developing and implementing both non-pharmacological and pharmacological interventions/approaches to pain management, depending on factors such as whether the pain is episodic, continuous, or both;
- Identifying and using specific strategies for preventing or minimizing different levels or sources of pain or pain-related symptoms based on the resident-specific assessment, preferences and choices, a pertinent clinical rationale, and the resident's goals and; using pain medications judiciously to balance the resident's desired level of pain relief with the avoidance of unacceptable adverse consequences;
- Monitoring appropriately for effectiveness and/or adverse consequences (e.g., constipation, sedation) including defining how and when to monitor the resident's symptoms and degree of pain relief; and
- Modifying the approaches, as necessary.

Pharmacological interventions

The interdisciplinary team (nurses, practitioner, pharmacists, etc.) is responsible for developing a pain management regimen that is specific to each resident who has pain or who has the potential for pain, such as during a treatment. The regimen considers factors such as the causes, location, and severity of the pain, the potential benefits, risks and adverse consequences of medications; and the resident's desired level of relief and tolerance for adverse consequences. The resident may accept partial pain relief in order to experience fewer significant adverse consequences (e.g., desire to stay

alert instead of experiencing drowsiness/confusion). The interdisciplinary team works with the resident to identify the most effective and acceptable route for the administration of analgesics, such as orally, rectally, topically, by injection, by infusion pump, and/or transdermally.

It is important to follow a systematic approach for selecting medications and doses to treat pain. Developing an effective pain management regimen may require repeated attempts to identify the right interventions. General guidelines for choosing appropriate categories of medications in various situations are widely available to the provider, pharmacist and nurses. Factors influencing the selection and doses of medications include the resident's medical condition, current medication regimen, nature, severity, and cause of the pain and the course of the illness. Analgesics may help manage pain; however, they often do not address the underlying cause of pain. Examples of different approaches may include, but are not limited to: administering lower doses of medication initially and titrating the dose slowly upward, administering medications "around the clock" rather than "on demand" (PRN); or combining longer acting medications with PRN medications for breakthrough pain. Recurrent use of or repeated requests for PRN medications may indicate the need to reevaluate the situation, including the current medication regimen. Some clinical conditions or situations may require using several analgesics and/or adjuvant medications (e.g., antidepressants or anticonvulsants) together. Documentation helps to clarify the rationale for a treatment regimen and to acknowledge associated risks.

Opioids or other potent analgesics have been used for residents who are actively dying, those with complex pain syndromes, and those with more severe acute or chronic pain that has not responded to non-opioid analgesics or other measures. Opioids should be selected and dosed in accordance with current professional standards of practice and manufacturers' guidelines in order to optimize their effectiveness and minimize their adverse consequences. Adverse consequences may be especially problematic when the resident is receiving other medications with significant effects on the cardiovascular and central nervous systems. Therefore, careful titration of dosages based on monitoring/evaluating the effectiveness of the medication and the occurrence of adverse consequences is necessary. The clinical record should reflect the ongoing communication between the prescriber and the staff is necessary for the optimal and judicious use of pain medications.

Other interventions have been used for some residents with more advanced, complex, or poorly controlled pain *such as* radiation therapy, neurostimulation, spinal delivery of analgesics (implanted catheters and pump systems), and neurolytic procedures (chemical or surgical) that are administered under the close supervision of expert practitioners. Referrals to pain management clinics and pain management specialists may also be appropriate in these situations.

Monitoring, Reassessment, and Care Plan Revision

Monitoring the resident over time helps identify the extent to which pain is controlled, relative to the individual's goals and the availability of effective treatment. The ongoing evaluation of the status (presence, increase or reduction) of a resident's pain is vital, including the status of underlying causes, the response to interventions to prevent or manage pain, and the possible presence of adverse consequences of treatment. Adverse consequences related to analgesics can often be anticipated and to some extent prevented or reduced. For example, opioids routinely cause constipation, which may be minimized by an appropriate bowel regimen.

Identifying target signs and symptoms (including verbal reports and non-verbal indicators from the resident) and using standardized assessment tools can help the interdisciplinary team evaluate the resident's pain and responses to interventions and determine whether the care plan should be revised, for example:

- If pain has not been adequately controlled, it may be necessary to reconsider the current approaches and revise or supplement them as indicated; or
- If pain has resolved or there is no longer an indication or need for pain medication, the facility works with the practitioner to discontinue or taper (as needed to prevent withdrawal symptoms) analgesics.

F698 *Dialysis*

The facility must ensure that residents who require dialysis receive such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

The intent of this requirement is that the facility assures that each resident receives care and services for the provision of hemodialysis and/or peritoneal dialysis consistent with professional standards of practice including the:

- Ongoing assessment of the resident's condition and monitoring for complications before and after dialysis treatments received at a certified dialysis facility;
- Safe administration of hemodialysis at the bedside and/or peritoneal dialysis in the nursing home provided by qualified trained staff/caregivers, in accordance with State and Federal laws and regulations;
- Ongoing assessment and oversight of the resident before, during and after dialysis treatments, including monitoring the resident's condition during treatments, monitoring for complications, implementing appropriate interventions, and using appropriate infection control practices; and
- Ongoing communication and collaboration with the dialysis facility regarding dialysis care and services.

Responsibilities for the Provision of Dialysis Care/Services

If the nursing home has made the decision to provide dialysis care and services according to the options above, there must be, in accordance with current standards of practice, coordination and collaboration between the nursing home and the dialysis facility to assure that:

- The resident's needs related to dialysis treatments are met;
- Only trained and qualified staff/caregivers administer the dialysis treatments;
- The provision of the dialysis treatments and care of the resident meets current standards of practice for the safe administration of the dialysis treatments;
- Documentation requirements are met to assure that treatments are provided as ordered by the nephrologist, attending practitioner and dialysis team; and
- There is ongoing communication and collaboration for the development and implementation of the dialysis care plan by nursing home and dialysis staff.

The nursing home remains responsible for the overall quality of care the resident receives and must provide the same services to a resident who is receiving dialysis as it furnishes to its residents who

are not. This includes the ongoing provision of assessment, care planning and provision of care. There must be a coordinated plan for dialysis treatments developed with input from both the nursing home and dialysis facility. The resident should not experience any lack of nursing home services or care because of his or her dialysis status. The nursing home staff must be aware and identify changes in resident's behavior, especially for a cognitively impaired resident, that may impact the safe administration of dialysis, including, resistance to care, and pulling on tubes/access sites and inform the attending practitioner and dialysis facility of the changes. This requires more frequent and increased observations and monitoring for this resident before, during (if dialysis is provided by nursing home staff/caregivers or the resident) and after dialysis treatments.

NOTE: The nursing home may wish to designate a staff person to coordinate activities and communications with each dialysis facility that they have arrangements with to provide dialysis services.

The dialysis facility is responsible for the medical management for the end stage renal disease including dialysis treatments, performed offsite or onsite. It is the responsibility of the dialysis facility to provide all necessary equipment and supplies for the provision of the dialysis treatments, including maintenance and repair as needed, testing/monitoring water and dialysate quality for the dialysis treatment, and for the training of individuals providing the HHD/PD.

Shared Communication between the Nursing Home and the Dialysis facility

It is essential that a communication process be established between the nursing home and the dialysis facility to be used 24-hours a day. The care of the resident receiving dialysis services must reflect ongoing communication, coordination and collaboration between the nursing home and the dialysis staff. The communication process should include how the communication will occur, who is responsible for communicating, and where the communication and responses will be documented in the medical record, including but not limited to:

- Timely medication administration (initiated, administered, held or discontinued) by the nursing home and/or dialysis facility; Physician/treatment orders, laboratory values, and vital signs;
- Advance Directives and code status; specific directives about treatment choices; and any changes or need for further discussion with the resident/representative, and practitioners;
- Nutritional/fluid management including documentation of weights, resident compliance with food/fluid restrictions or the provision of meals before, during and/or after dialysis and monitoring intake and output measurements as ordered;
- Dialysis treatment provided and resident's response, including declines in functional status, falls, the identification of symptoms such as anxiety, depression, confusion, and/or behavioral symptoms that interfere with treatments;
- Dialysis adverse reactions/complications and/or recommendations for follow up observations and monitoring, and/or concerns related to the vascular access site/PD catheter;
- Changes and/or decline in condition unrelated to dialysis. This would include communication related to care concerns such as a resident who is at risk for or who has a pressure ulcer, receiving appropriate interventions; and
- The occurrence or risk of falls and any concerns related to transportation to and from the dialysis facility.

Coordination of Physician Services between the Nursing Home and Dialysis facility
For a resident receiving dialysis, the nursing home staff must immediately contact and communicate with the attending physician/practitioner, resident/resident representative, and designated dialysis staff (i.e., nephrologist, registered nurse) regarding any significant changes in the resident's status related to clinical complications or emergent situations that may impact the dialysis portion of the care plan. (Refer to F580 – Notification of Changes in condition) These situations may include but are not limited to changes in cognition or sudden unexpected decline in condition, dialysis complications such as bleeding, hypotension, or adverse consequences to a medication or therapy, or other situations.

Any changes in the resident's care initiated by the dialysis facility must be communicated to the resident's nursing home attending physician/practitioner.

F711 Physician Visits

a) The physician must review the resident's total program of care, including medications and treatments, at each visit.
b) The physician must write, sign, and date progress notes at each visit; and
c) Sign and date all orders with the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications**.**

INTENT**:** The intent of this regulation is to have the physician take an active role in supervising the care of the residents. Physician visits should not be superficial visits, but must include an evaluation of the resident's condition and total program of care, including medications and treatments, and a decision about the continued appropriateness of the resident's current medical regimen.

Except where the regulation specifies the task must be completed **personally** by the physician, the term "attending physician" or "physician" also includes a non-physician practitioner (NPP) involved in the management of the resident's care, to the extent permitted by State law.

Total program of care includes all care the facility provides residents to maintain or improve their highest practicable physical, mental and psychosocial well-being, as defined by the comprehensive assessment and plan of care. Care includes medical services and medication management, physical, occupational, and speech/language therapy, nursing care, nutritional interventions, social work and activity services that maintain or improve psychosocial functioning.

During required visits, the physician must document a review of the resident's total program of care, including the resident's current condition, progress and problems in maintaining or improving their physical, mental and psychosocial well-being and decisions about the continued appropriateness of

the resident's current medical regimen. The physician need not review the total plan of care at each visit, but must review the total plan of care at visits required by §483.30(c), F712.

Progress notes must be written, signed and dated at each physician visit, which may be done in a physical chart or electronic record, in keeping with facility practices.

During visits, the physician must also sign and date all orders, with the exception of influenza and pneumococcal vaccinations, which may be administered per physician-approved facility policy after an assessment for contraindications. This includes co-signing orders written by NPPs, qualified dietitians, other clinically qualified nutrition professionals and qualified therapists, as required by state law.

In cases where facilities have created the option for a resident's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. See Guidelines for §483.70(i)(1), F842, for information on facility safeguards concerning electronic signatures.

Physician orders may be transmitted by facsimile machine if the following conditions are met:

a) The physician should have signed and retained the original order from which the facsimile was transmitted and be able to provide it upon request.
b) Alternatively, the original may be sent to the facility at a later time and substituted for the facsimile.
c) The facility should photocopy the faxed order, if the faxed order is subject to fading over time. The facsimile copy can be discarded after facility photocopies it.
d) It is not necessary for a physician to re-sign the facsimile order when he/she visits the facility. When rubber stamp signatures are authorized by the facility's management, the individual whose signature the stamp represents shall place in the administrative offices of the facility a signed statement to the effect that he/she is the only one who has the stamp and uses it. A list of computer codes, identification numbers and/or written signatures must be readily available and maintained under adequate safeguards. Adequate safeguards may include, but are not limited to, locked in a drawer; locked in a location that is accessible only by appropriate staff as defined by the facility; or available on a protected electronic site accessible by appropriate staff as defined by the facility.

PROBES §483.*30*(b)

- Are physician progress notes written, signed and dated during each physician visit?
- For visits required by §483.30(c), do physician progress notes reflect a review of the resident's total program of care and current condition, including medications and treatments?
- Do physician progress notes reflect the physician's decisions about the continued appropriateness of the resident's current medical regimen?
- Does the physician sign and date all physician orders, during visits, with the exception of influenza and pneumococcal vaccines as outlined above?
- If the physician has not met the requirements of physician visits, how has the facility worked with the physician or sought alternate physician participation to assure that the resident receives appropriate care and treatment?
- If facility management allows for the use of rubber stamp signatures, are adequate safeguards in place to ensure the security of the stamps?

F712 Frequency of physician visits

(1) The residents must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 thereafter.

(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

(3) Except as provided below, all required physician visits must be made by the physician personally.

(4) At the option of the physician, required visits in SNFs, after the initial visit, may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner or clinical nurse specialist.

DEFINITIONS "Must be seen", for purposes of the visits required means that the physician or NPP must make actual face-to-face contact with the resident, and at the same physical location, not via a telehealth arrangement. There is no requirement for this type of contact at the time of admission, since the decision to admit an individual to a nursing facility (whether from a hospital or from the individual's own residence) generally involves physician contact during the period immediately preceding the admission.

"Non-physician practitioner (NPP)" means a nurse practitioner (NP), clinical nurse specialist (CNS) or physician assistant (PA).

GUIDANCE: The timing of physician visits is based on the admission date of the resident.

In a SNF, the first physician visit (this includes the initial comprehensive visit) must be conducted within the first 30 days after admission, and then at 30 day intervals up until 90 days after the admission date. After the first 90 days, visits must be conducted at least once every 60 days thereafter.

Permitting up to 10 days' slippage of a due date will not affect the next due date. However, do not specifically look at the timetables for physician visits unless there is indication of inadequate medical care. The regulation states that the physician (or his/her delegate) must visit the resident at least every 30 or 60 days. There is no provision for physicians to use discretion in visiting at intervals longer than those specified. Although the physician may not delegate the responsibility for conducting the initial visit in a SNF, NPPs may perform other medically necessary visits prior to and after the physician's initial visit, as allowed by State law.

After the initial physician visit in SNFs, where States allow their use, a NPP may make every other required visit. (See §483.30(e), F714 Physician delegation of tasks in SNFs.) These alternate visits, as well as medically necessary visits, may be performed and signed by the NPP. (Physician co-signature is not required, unless required by State law). In a NF, the physician visit requirement

may be satisfied in accordance with State law by a NPP who is not an employee of the facility but who is working in collaboration with a physician and who is licensed by the State and performing within the state's scope of practice. (See §483.30(f)).

In a NF, medically necessary visits performed by NPPs employed by the facility, may not take the place of physician required visits, nor may the visit count towards meeting the physician visit schedule prescribed at §483.20(c)(1).

In SNFs and NFs, facility policy that allows NPPs to conduct required visits, and/or allows a 10-day slippage in the time of the required visit, does not relieve the physician of the obligation to visit a resident personally when the resident's medical condition makes that visit necessary.

Table 1: Authority for Non-physician Practitioners to Perform Visits, Sign Orders and Sign Medicare Part A Certifications/Re-certifications When Permitted by the State

	Initial Comprehensive Visit/Orders	**Other Required Visits**	**Other Medically Necessary Visits & Orders +**	**Certification/ Recertification +/-**
SNFs				
PA, NP & CNS employed by the facility	May not perform/ May not sign	May perform alternate visits	May perform and sign	May not sign
PA, NP & CNS not a facility employee	May not perform/ May not sign	May perform alternate visits	May perform and sign	May sign subject to State Requirements
NFs				
PA, NP, & CNS employed by the facility	May not perform/ May not sign	May not perform	May perform and sign	Not applicable
PA, NP, & CNS not a facility employee	May perform/ May sign*	May perform	May perform and sign	Not applicable

**A NPP may provide admission orders if a physician personally approved in writing a recommendation for admission to the facility prior to admission. For additional requirements on physician recommendation for admission and admission orders, see §483.30(a), F710. ^Other required visits are the physician visits required by 483.30(c)(1) other than the initial comprehensive visit.*
+Medically necessary visits are independent of required visits and may be performed prior to the initial comprehensive visit.
±Though not part of a compliance determination for this section, this requirement is provided for clarification and relates specifically to coverage of a Part A Medicare stay, which can take place only in a Medicare-certified SNF.

F740 Behavioral health services.

Each resident must receive and the facility must provide the necessary behavioral health care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders.

DEFINITIONS §483.40
Definitions are provided to clarify terminology related to behavioral health services and the attainment or maintenance of a resident's highest practicable well-being.

"Highest practicable physical, mental, and psychosocial well-being" is defined as the highest possible level of functioning and well-being, limited by the individual's recognized pathology and normal aging process. Highest practicable is determined through the comprehensive resident assessment and by recognizing and competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.

"Mental disorder" is a syndrome characterized by a clinically significant disturbance in an individual's cognition, emotion regulation, or behavior that reflects a dysfunction in the psychological, biological, or developmental processes underlying mental functioning (American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth edition. Arlington, VA: American Psychiatric Association Publishing, 2013.).

"Substance use disorder" is defined as recurrent use of alcohol and/or drugs that causes clinically and functionally significant impairment, such as health problems or disability (Adapted from: Substance Abuse and Mental Health Services Administration (SAMHSA) definition found at http://www.samhsa.gov/disorders/substance-use).

GUIDANCE §483.40
Providing behavioral health care and services is an integral part of the person-centered environment. This involves an interdisciplinary approach to care, with qualified staff that demonstrate the competencies and skills necessary to provide appropriate services to the resident. Individualized approaches to care (including direct care and activities) are provided as part of a supportive physical, mental, and psychosocial environment, and are directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities.

The facility must provide necessary behavioral health care and services which include:

- Ensuring that the necessary care and services are person-centered and reflect the resident's goals for care, while maximizing the resident's dignity, autonomy, privacy, socialization, independence, choice, and safety;
- Ensuring that direct care staff interact and communicate in a manner that promotes mental and psychosocial well-being.

- Providing meaningful activities which promote engagement, and positive meaningful relationships between residents and staff, families, other residents and the community. Meaningful activities are those that address the resident's customary routines, interests, preferences, etc. and enhance the resident's well-being;
- Providing an environment and atmosphere that is conducive to mental and psychosocial well-being;
- Ensuring that pharmacological interventions are only used when non-pharmacological interventions are ineffective or when clinically indicated. For concerns about the use of pharmacological interventions, see Pharmacy Services requirements at §483.45.

Individualized Assessment and Person-Centered Planning:
In addition to the facility-wide approaches that address residents' emotional and psychosocial well-being, facilities are expected to ensure that residents' individualized behavioral health needs are met, through the Resident Assessment Instrument (RAI) Process.

All areas are to be addressed through the:
- Minimum Data Set (MDS);
- Care Area Assessment Process;
- Care Plan Development;
- Care Plan Implementation; and
- Evaluation.

Sections of the MDS related to behavioral health needs that may be helpful include, but are not limited to:
- Section C. Cognitive Patterns;
- Section D. Mood;
- Section E. Behavior; and
- Section F. Activities.

Utilizing Care Areas such as Psychosocial Well-Being, Mood State, and Behavioral Symptoms will also help to ensure the assessment and care planning processes are accomplished. It is also important for the facility to use an interdisciplinary team (IDT) approach that includes the resident, their family, or resident representative.

The following section discusses general information pertaining to depression, anxiety, and anxiety disorders, conditions that are frequently seen in nursing home residents and may require facilities to provide specialized services and supports that vary, based upon residents' individual needs.

Depression
Although people experience losses, it does not necessarily mean that they will become depressed. Depression is not a natural part of aging, however, older adults are at an increased risk. Symptoms may include fatigue, sleep and appetite disturbances, agitation, expressions of guilt, difficulty concentrating, apathy, withdrawal, and suicidal ideation. Late life depression may be harder to identify due to a resident's cognitive impairment, loss of functional ability, the complexity of multiple chronic medical problems that compound the problem, and the loss of significant relationships and roles in their life. Depression presents differently in older adults and it is the responsibility of the facility to ensure that an accurate diagnosis is established.

Anxiety and Anxiety Disorders
Anxiety is a common reaction to stress that involves occasional worry about circumstantial events. Anxiety disorders, however, include symptoms such as excessive fear and intense anxiety and can cause significant distress. Anxiety disorders are prevalent among older adults and may cause debilitating symptoms. The distinction between general anxiety and an anxiety disorder is subtle and can be difficult to identify. Accurate diagnosis by a qualified professional is essential. Anxiety can be triggered by loss of function, changes in relationships, relocation, or medical illness. Importantly, anxiety may also be a symptom of other disorders, such as dementia, and care must be taken to ensure that other disorders are not inadvertently misdiagnosed as an anxiety disorder (or vice versa).

F744 A resident who displays or is diagnosed with dementia, receives the appropriate treatment and services to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.

Definitions are provided to clarify terminology related to dementia and the attainment or maintenance of a resident's highest practicable well-being.

"Dementia" is a general term to describe a group of symptoms related to loss of memory, judgment, language, complex motor skills, and other intellectual function, caused by the permanent damage or death of the brain's nerve cells, or neurons. However, dementia is not a specific disease. There are many types and causes of dementia with varying symptomology and rates of progression. (Adapted from: "About Dementia." Alzheimer's Foundation of America. 30 Nov 2016. Accessed at: https://www.alzfdn.org/AboutDementia/definition.html)

"Highest practicable physical, mental, and psychosocial well-being" is defined as the highest possible level of functioning and well-being, limited by the individual's recognized pathology and normal aging process. Highest practicable is determined through the comprehensive resident assessment and by recognizing and competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.

GUIDANCE §483.40(b)(3)
Providing care for residents living with dementia is an integral part of the person-centered environment, which is necessary to support a high quality of life with meaningful relationships and engagement. Fundamental principles of care for persons living with dementia involve an interdisciplinary approach that focuses holistically on the needs of the resident living with dementia, as well as the needs of the other residents in the nursing home. Additionally, it includes qualified staff that demonstrate the competencies and skills to support residents through the implementation of individualized approaches to care (including direct care and activities) that are directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities.

If there are staffing concerns related to the provision of behavioral health services, refer to §483.40(a) (F741), Sufficient and Competent Staff.

The facility must provide dementia treatment and services which may include, but are not limited to the following:

- Ensuring adequate medical care, diagnosis, and supports based on diagnosis;
- Ensuring that the necessary care and services are person-centered and reflect the resident's goals, while maximizing the resident's dignity, autonomy, privacy, socialization, independence, choice, and safety; and
- Utilizing individualized, non-pharmacological approaches to care (e.g., purposeful and meaningful activities). Meaningful activities are those that address the resident's customary routines, interests, preferences, and choices to enhance the resident's wellbeing.

It is expected that a facility's approach to care for a resident living with dementia follows a systematic care process. In order to ensure that residents' individualized dementia care needs are met, the facility is expected to assess, develop, and implement care plans through an interdisciplinary team (IDT) approach that includes the resident, their family, and/or resident representative, to the extent possible. Care plan goals must be achievable and the facility must provide those resources necessary for an individual resident to be successful in reaching those goals. Surveyors must determine whether the failure to attain or maintain the highest practicable physical, mental, and psychosocial well-being (in accordance with the comprehensive assessment and care plan) was avoidable or unavoidable. An unavoidable facility failure refers to a situation where the IDT has completed comprehensive assessments, developed and implemented individualized, person-centered approaches to care through the care-planning process, revised care plans accordingly, and residents are unable to attain or maintain their highest practicable physical, mental, and psychosocial well-being.

Residents living with dementia require specialized services and supports, (e.g., specialized activities, nutrition, and environmental modifications) that vary, based on the individual's abilities and challenges related to their condition. Dementia causes significant intellectual functioning impairments that interfere with life, including activities and relationships. People living with dementia may lose their ability to communicate, solve problems, and cope with stressors. They may also experience fear, confusion, sadness, and agitation. While memory loss is a common indication of dementia, memory loss by itself does not mean that a person has dementia.

Although it is common in very elderly individuals, dementia is not a normal part of the aging process. There are several diseases that can cause symptoms of dementia (e.g., Alzheimer's disease, vascular dementia, Lewy body dementia). Other conditions can also cause dementia or dementia-like symptoms (including, e.g., reactions to medications, metabolic problems and endocrine abnormalities, nutritional deficiencies, and heart and lung problems).

Some individuals living with dementia may have co-existing symptoms, such as paranoia, delusions or hallucinations or psychiatric conditions, such as depression or bipolar affective disorder. Progressive dementia may exacerbate these symptoms and conditions.

Behavioral or psychological expressions are occasionally related to the brain disease in dementia; however, they may also be caused or exacerbated by environmental triggers. Such expressions or indications of distress often represent a person's attempt to communicate an unmet need, discomfort, or thoughts that they can no longer articulate.

Medications may be unnecessary and are likely to cause harm when given without a clinical indication, at too high of a dose, for too long after the resident's distress has been resolved, or if the medications are not monitored. However, medications may be effective when the underlying cause of a resident's distress has been determined and non-pharmacologic approaches to care have been ineffective or for expressions of distress that have worsened. All approaches to care, non-pharmacological and pharmacological, need to be person-centered, monitored for efficacy, risks, benefits, and harm, and revised as necessary.

If there are concerns about medication use in dementia, refer to §483.45(d) (F757), Unnecessary Drugs and §483.45(e) (F758), Psychotropic Drugs.

Investigating Concerns Related to Dementia Care Treatment and Services
Use the Dementia Care Critical Element Pathway (CMS-20133), along with guidance, when determining if the facility meets the requirements pertaining to the treatment and services for a resident who displays or is diagnosed with dementia. Treatment and services must meet the resident's highest practicable physical, mental, and psychosocial well-being.

Review, as needed, all appropriate resident assessments, associated care planning and care plan revisions, along with physician's orders to identify initial concerns and guide the investigation. Review the Minimum Data Set (MDS) and other supporting documentation to help determine if the facility is in compliance. Observe for evidence that dementia care needs are met and related services are provided. Staff are expected to assess and provide appropriate care for residents with dementia. Interview the resident, their family, and/or representative(s) and the IDT, as needed to gather information about dementia care in the nursing home. Corroborate the information obtained and any concerns noted during the survey, by building upon the investigation through additional observations, interviews, and record review. In determining compliance, additionally refer to the Psychosocial Severity Outcome Guide.

F755 PHARMACY SERVICES

Facilities must provide pharmaceutical services to meet the needs of each resident that are consistent with state and federal requirements, and reflect current standards of practice. These procedures address, but are not limited to, acquiring; receiving; dispensing; administering; disposing; labeling and storage of medications; and personnel authorized to access or administer medications. To meet this requirement, facilities must employ or obtain the services of a consultant pharmacist.

PHARMACEUTICAL SERVICES – CONSULTANT PHARMACIST

Consultant Pharmacist Responsibilities: Provide consultation on all aspects of the provision of pharmacy services in the facility, including procedures to support resident quality of life; including those that support safe, individualized medication administration programs. The consultant pharmacist should collaborate with the facility to coordinate pharmacy services to identify, evaluate and resolve pharmaceutical concerns.

Providing pharmaceutical consultation is an ongoing, interactive process with prospective, concurrent, and retrospective components. To accomplish some of these consultative responsibilities, pharmacists can use various methods and resources, such as technology, additional personnel, and related policies and procedures from outside sources (such as ASCP, ASHP, AMDA, ASPEN, etc.)

Responsibilities include:

- Establishment of a process of receiving and interpreting (including documentation) of physician orders;
- Coordinate pharmaceutical services with multiple provider services (pharmacy, infusion, hospice, prescription drug plans);
- Develop IV procedures consistent with state requirements which include competency of staff;
- Determine the contents of the emergency supply of medications and monitor the use, replacement, and disposition of the supply;
- Develop mechanisms for communicating, addressing, and resolving issues related to pharmaceutical services;
- Establish/monitor procedures for acquiring, receiving, storing, controlling, reconciling, compounding, administering, and monitoring responses to and using and/or disposing of all medications.
- Provide medication related information to health care professionals and residents. (However, the pharmacist is not personally required to present education programs).
- Identify, evaluate and address medication related issues, including the prevention and reporting of medication errors; and
- The provision, monitoring and use of medication related devices.
- Assist in the development of medication-related documentation procedures, such as identification of abbreviations approved for use in the facility; and
- Guide the selection of medication in accordance with the prescribers' orders, applicable state and federal requirements; manufacturers' specifications, characteristics of the resident population and individual resident condition.

PROVISION OF ROUTINE AND/OR EMERGENCY MEDICATIONS

The facility is required to provide or obtain routine and emergency medications and biologicals to meet the needs of each resident. The facility may maintain a limited supply of medications in the facility for use during emergency or after hour situations. Whether routine, emergency or as needed, medications should be administered in a timely manner. Delayed acquisition of medications may impede timely administration and adversely affect a resident's condition. Factors that may help determine timeliness and guide acquisition procedures include:

1. Availability of medications for continuity of care for anticipated admissions or transfers from acute care or other institutional setting;

2. Condition of the resident including the severity or instability of their condition, significant change in condition, discomfort, risk factors, current signs and symptoms and the potential impact of any delay in acquiring the medication;
3. Category of the medication (antibiotics, analgesics);
4. Availability of medication in emergency supply; if applicable, and
5. Ordered start time/date for a medication.

Borrowing: Note that the practice of borrowing medications from other residents' supplies is not consistent with professional standards and contributes to medication errors. (This will fall under F658 Services Provided Meet Professional Standards.)

Availability of an Emergency Supply:

1. Determine the medications, amounts, dosages/strengths to be provided;
2. Establish a location for storage of the emergency supply;
3. Determine access to the supply; and
4. Establish record keeping, monitoring for expiration dates and a procedure for replacement when medications are used.

Foreign Acquired Medications:

Medications obtained from foreign sources may present safety issues since they have been manufactured or held outside of the jurisdiction of the US regulatory system. The Federal Food, Drug, and Cosmetic Act strictly limits the types of drugs that may be imported into the U.S. Medications imported into the U.S. may violate the FFDCA if they are unapproved by the FDA, labeled incorrectly, or dispensed without a valid prescription. The facility should, in collaboration with the pharmacist, assure that medications are provided or obtained from approved sources and do not violate the FFDCA.

If it is determined that the facility is providing/obtaining foreign medications that are not FDA approved for use by the residents, the State Agency must make referrals to appropriate agencies, such as the FDA; depending on the medication classification, the DEA, State Board of Nursing; State Board of Pharmacy; and the State Licensure Board for Nursing Home Administrators.

PHARMACEUTICAL SERVICES AND PROCEDURES

Acquisition of Medications:

1. Procedure in place for obtaining medication for original or refills of routine medications.
2. Establish a procedure so that medications are available. This can be from the emergency supply or from a 24-hour pharmacy.
3. Monitor delivery and receipt of medications; and
4. Establish a procedure when delivery of a medication will be delayed or the medication is not or will not be available.

Receiving of Medications:

1. Determine a procedure for how the receipt of medication from the pharmacy (family members or others) will occur and how it will be reconciled with the prescriber's order and the requisition for the medication.
2. There should be a process identified for receipt of medications and how access to the medications will be controlled until the medications are delivered to the secured storage area.
3. Determine who will be responsible for assuring that medications are incorporated into the resident's specific allocation/storage area.

Administration of Medications:

1. Provide continuity of staff to ensure that medications are administered without unnecessary interruptions;
2. Reporting of medication errors, including how and to whom to report;
3. Assure that the correct medication is administered in the correct dose to the correct person via the correct route in the correct dosage form and at the correct time.
4. Define the medication administration to:
    a. Maximize effectiveness;
    b. Prevent potential drug-drug or drug-food interactions;
    c. Honor resident choice as much as possible, consistent with the person-centered comprehensive care plan;
5. Define general guidelines for specific monitoring related to medications when ordered or indicated, including specific items to monitor (blood pressure, pulse, blood sugar, weight, etc.), the frequency (daily, weekly), timing (before or after administering the med), and parameters for notifying the prescriber.
6. Define pertinent techniques and precautions that meet current standards of practice for administering meds through alternate routes such as eye, ear, buccal, injection, intravenous, atomizer/aerosol/inhalation therapy, or enteral tubes.
    a. For G-Tube this includes:
        i. Determine the types of meds that may be safely administered via the enteral tube
        ii. Appropriate dosage forms for tube administration
        iii. Techniques to monitor and verify that the feeding tube is in the right location before administering medications
        iv. Preparation of drugs for enteral administration, administering drugs separately, diluting drugs as appropriate and flushing the feeding tube before, between, and after drug administration, including the amount of water to be used for the flushing and administration of medications (and obtaining physician/practitioners order to address a resident with fluid restrictions.)
        v. Documenting the administration of medications:
            - The administration of routine meds and if not administered, an explanation of why not;
            - The administration of as needed (PRN) meds including the justification and response;

- The route, if other than oral (intended route may be preprinted on MAR/eMAR; and
- Location of administration sites such as transdermal patches and injections,
- Providing accessible current information about medications (side effect, contraindications, doses, etc.) and medication-related devices and equipment (user manuals);
- Reconciling med orders, including telephone orders, monthly or other periodic recap, including who may transcribe prescriber's orders and enter them onto the MAR/eMAR.

Disposition of Medications

1. Timely identification and removal from current supply any medications for disposition;
2. Identification of storage method for meds awaiting final disposition
3. Control and accountability of medications awaiting final disposition consistent with standards of practice;
4. Documentation of actual disposition of medications to include: resident name, medication name, strength, prescription number; quantity, date of disposition, and involved facility staff, consultant or other applicable individuals; and
5. Method of disposition (including controlled medications) should prevent diversion and/or accidental exposure and is consistent with applicable state and federal requirements, local ordinances, and standards of practice.
6. Authorized Personnel
    a. All persons administering meds are authorized according to state and federal requirements;
    b. Are oriented to the facilities medication-related procedures (competencies, training; knowledge of equipment use and cleaning); and
    c. Have access to current information regarding medications being administered.

Controlled Medications

Establish a system of receipt and disposition of all controlled drugs receipt and disposition in sufficient detail to enable an accurate reconciliation in sufficient detail to enable an accurate reconciliation, and that the facility conduct a periodic reconciliation.

This system should include:

1. Record of receipt of all controlled medications with sufficient detail to all for reconciliation: name, strength, quantity and date received, resident's name (if applicable) **NOTE**: If permitted by, and in accordance with, state requirements, the facility may store some controlled medications in an emergency medication supply. The facility's policies and procedures must address the reconciliation and monitoring of this supply.
2. Records of personnel access, usage, and disposition of all controlled medications with sufficient detail to allow reconciliation (e.g., the MAR, proof-of-use sheets, or declining inventory sheets), including destruction, wastage, return to the pharmacy/manufacturer, or disposal in accordance with applicable State requirements;

3. Periodic reconciliation of records of receipt, disposition, usage, and inventory for all controlled medications (as defined by facility procedures or when loss is identified). The reconciliation identifies loss or potential diversion of controlled medications so as to minimize the time between the actual loss or potential diversion and the time of detection and follow-up to determine the extent of loss. Because diversion can occur at any time, periodic reconciliation should accommodate actual facility experience, such that if there is any evidence or even suspicion that diversion may be occurring, then that may dictate conducting the periodic reconciliation as frequently as daily.. State or other federal requirements may specify the frequency of reconciliation.
    a. If discrepancies are identified during the reconciliation, the pharmacist and the facility develop and implement recommendations for resolving them, and make referrals to law enforcement agencies as appropriate.
    b. Data from injectable, scheduled drug tracking should be regularly reviewed and discrepancies or unusual access patterns are investigated including whether residents should be screened for exposure to blood borne pathogens. See §483.80 Infection Control, F880.
    c. Liquid controlled medications are often dispensed in multi-dose containers which indicate approximate volume. The containers may also be opaque to protect the medication from light. It should be noted that absolute accuracy in tracking volume and use of liquid controlled medications may not be possible. The actual volume in these containers may be slightly over or under the manufacturer's stated volume depending on the shape and material of the container and the formulation of the medication such as thick liquid suspensions. The opaque container, measurement markings, manufacturer fill volume variation, and method for recording usage all make detection of diversion for liquid controlled medications more difficult. The general standard of practice for documenting usage of liquid controlled medications is to record the starting volume from the label, record each dose administered, subtract the dose administered from the previously recorded volume, and record the remaining amount. Any observed discrepancy between the recorded amount and what appears to be remaining in the container should be reported according to facility policy. Manufacturer's instructions may list the estimated volume variance (e.g., 30 mL plus or minus 2.5 mL). For liquid controlled medications, signs of diversion may include: an observable discrepancy between the written balances of remaining medication compared to the remaining amount in the bottle upon visual inspection; changes in the viscosity or color of the medication; reports of spills; and, as with other controlled medications, statements from a resident that the medication is not working.
    d. Disposal methods for controlled medications must involve a secure and safe method to prevent diversion and/or accidental exposure.
    e. Fentanyl transdermal patches present a unique situation given the multiple boxed warnings, and the substantial amount of fentanyl remaining in the patch after removal, creating a potential for abuse, misuse, diversion, or accidental exposure. The Food and Drug Administration (FDA) and manufacturer instructions recommend that users dispose of used fentanyl patches by folding the patch in half with the sticky sides together and flushing the patch down the sink or toilet, due to the life threatening risks associated with exposure to or ingestion of the patch. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=e15a7e9b-8025-49dd-9a6d-bafcccf1959f&type=display, see section 2.4.

NOTE: The pharmacist is not required by these regulations to perform the reconciliation of medications, but rather to evaluate and determine that the facility maintains an accurate account of all controlled medications and completes the reconciliation according to its procedures, consistent with State and federal requirements.

PROCEDURES §483.45

Use the Medication Administration Observation and the Medication Storage and Labelling 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, the provision of Pharmacy Services.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F755, the surveyor's investigation will generally show that the facility failed to:

- Provide medications and/or biologicals, as ordered by the prescriber, to meet the needs of each resident; or
- Ensure that only appropriate personnel administer medications, consistent with applicable state law and regulations; or
- Provide pharmaceutical services to meet each resident's needs which includes: acquiring, receiving, dispensing, accurately administering, or disposing of medications; or
- Provide or arrange for a licensed pharmacist who consults on all aspects of pharmaceutical services; or
- Establish systems to accurately reconcile controlled medications using acceptable standards of practice; or
- Have safeguards and systems in place to control, account for, and periodically reconcile controlled medications in order to prevent loss, diversion, or accidental exposure.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Examples of some of the related requirements that should be considered when concerns have been identified include the following:

- 42 CFR 483.12, F602, Right to be Free from Misappropriation/Exploitation
  - o Determine if the facility diverted a resident's medication, including, but not limited to, controlled substances for staff use or personal gain. If it is determined that a resident's medications were diverted, the State Agency must make referrals to appropriate agencies, such as local law enforcement; Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; the state Medicaid Fraud Control Unit, and possibly the State licensure board for Nursing Home Administrators.
- 42 CFR 483.35, F725, Sufficient Staff and F726, Competent Staff
  - o Determine if the facility had competent staff in sufficient numbers available to provide medications on a 24-hour basis to meet the needs of the residents, based upon the comprehensive assessment and care plan.
- 42 CFR 483.70(h), F841, Medical Director
  - o Determine whether the medical director, in collaboration with the facility and the pharmacist, and based on current standards of practice, helped the facility develop procedures for the safe and accurate provision of medications to meet the needs of the residents.

- 42 CFR 483.75(g), F867, Quality Assessment and Assurance
  - o If concerns regarding pharmaceutical services have been identified, determine whether the quality assessment and assurance committee has identified and responded to those concerns, as appropriate, and has developed, implemented, and monitored appropriate plans of action to correct identified quality deficiencies.
- 42 CFR 483.70(i), F842, Medical Records
  - o Determine whether the facility has maintained clinical records, including medication administration, in accordance with accepted professional standards and practices that are complete, accurately documented, and readily

F756 DRR

The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. This review must include a review of the resident's medical chart.

The pharmacist must report any irregularities to the:

1. attending physician and;
2. the facility's medical director and;
3. the director of nursing

These reports must be acted upon.

Irregularities include, but are not limited to, any drug that meets the criteria for an unnecessary drug.

Any irregularities noted by the pharmacist during this review must be:

1. Documented on a separate, written report
2. This report must be sent to the attending physician, the facility's medical director and the director of nursing
3. The report lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.

Response by the attending physician: The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

Facility Policy for Review/Response to DRR: The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

The intent of this requirement is that the facility maintains the resident's highest practicable level of physical, mental and psychosocial well-being and prevents or minimizes adverse consequences related to medication therapy to the extent possible, by providing oversight by a licensed pharmacist, attending physician, medical director, and the director of nursing.

NOTE: Although the regulatory language refers to "drug regimen review," the guidance in this document generally will refer to "medication regimen review," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

DEFINITIONS: Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident's medication regimen for effectiveness and safety.

"Adverse consequence" is a broad term referring to unwanted, uncomfortable, or dangerous effects that a drug may have, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease) (adapted from The Merck Manual Professional Version, http://www.merckmanuals.com/professional/clinical-pharmacology/adverse-drugreactions/adverse-drug-reactions.)

NOTE: Adverse drug reaction (ADR) is a form of adverse consequence. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic and helpful effects of the medication or any response to a medication that is noxious and unintended and occurs in doses used for prophylaxis, diagnosis, or therapy. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories. The others are hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not rise to the level of being an adverse consequence.

"Clinically significant" means effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

"Dose" is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

"Irregularity" refers to use of medication that is inconsistent with accepted standards of practice for providing pharmaceutical services, not supported by medical evidence, and/or that impedes or interferes with achieving the intended outcomes of pharmaceutical services. An irregularity also includes, but is not limited to, use of medications without adequate indication, without adequate monitoring, in excessive doses, and/or in the presence of adverse consequences, as well as the identification of conditions that may warrant initiation of medication therapy. (See reference to F757 Unnecessary Drugs which defines unnecessary drugs in opening regulatory language.)

"Medication Interaction" is the impact of another substance (such as another medication, herbal product, food or substances used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

"Medication Regimen Review (MRR)" or Drug Regimen Review is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences and potential risks associated with medication. The MRR includes review of the medical record in order to prevent, identify, report, and resolve medication-related problems, medication errors, or other irregularities. The MRR also involves collaborating with other members of the IDT, including the resident, their family, and/or resident representative.

GUIDANCE

A. OVERVIEW

Many nursing home residents have been identified as being at high risk for adverse consequences related to medications. Some adverse consequences may mimic symptoms of chronic conditions, the aging process, or a newly emerging condition.

This guidance is not intended to imply that all adverse consequences related to medications are preventable, but rather to specify that a system exists to assure that medication usage is evaluated on an ongoing basis, that risks and problems are identified and acted upon, and that medication-related problems must be considered when the resident has a change in condition. This guidance will discuss the following aspects of the facility's MRR component of the pharmaceutical services systems:

- A pharmacist's review of the resident's medication regimen and medical record to identify and report irregularities; and
- Acting upon identified irregularities in order to minimize or prevent adverse consequences, to the extent possible.

NOTE: The surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents, including whether or not the resident, resident's family and/or representative were informed about risks, benefits and treatment options and involved in the decision-making process.

The review should take into account resident preferences and provide recommendations that assist facility staff in understanding and communicating to the resident any risks related to their preferences regarding medications or medication administration, as well as modifications that can be made to mitigate those risks.

Transitions in care such as a move from home or hospital to the nursing home, or vice versa, increase the risk of medication-related issues. Medications may be added, discontinued, omitted, or changed. It is important, therefore, to review the medications. Currently, safeguards to help identify medication issues around transitions in care and throughout a resident's stay include:

- The pharmacist performing the medication regimen review, which includes a review of the resident's medical record, at least monthly;

- The pharmacist reporting any irregularities in a separate written report to the attending physician, medical director, and director of nursing; and
- The attending physician reviewing and acting on any identified irregularities.

B. MEDICATION REGIMEN REVIEW (MRR)

The MRR is an important component of the overall management and monitoring of a resident's medication regimen. The pharmacist must review each resident's medication regimen at least once a month in order to identify irregularities and to identify clinically significant risks and/or actual or potential adverse consequences which may result from or be associated with medications. It may be necessary for the pharmacist to conduct the MRR more frequently, for example weekly, depending on the resident's condition and the risks for adverse consequences related to current medications. Regulations prohibit the pharmacist from delegating the medication regimen reviews to other staff. The requirement for the MRR applies to all residents (whether short or long-stay) without exceptions.

The pharmacist performing the monthly MRR must also review the resident's medical record to appropriately monitor the medication regimen and ensure that the medications each resident receives are clinically indicated. Certain circumstances which may include residents who have multiple medical conditions, concurrent administration of certain medications, administration of medications which require close monitoring through lab work, and transitions of care may also increase the risk of adverse consequences. Review of the medical record as part of the MRR may prevent errors due to drug-drug interactions, omissions, duplication of therapy, or miscommunication during the transition from one team of care providers to another.

Facilities must develop policies and procedures to address the MRR. The policies and procedures must specifically address:

- The appropriate time frames for the different steps in the MRR process; and
- The steps a pharmacist must follow when he or she identifies an irregularity that requires immediate action to protect the resident and prevent the occurrence of an adverse drug event.
- MRR policies and procedures should also address, but not be limited to:
- MRRs for residents who are anticipated to stay less than 30 days;
- MRRs for residents who experience an acute change of condition and for whom an immediate MRR is requested after appropriate staff have notified the resident's physician, the medical director, and the director of nursing about the acute change.

While conducting the MRR in the facility is not required for compliance, important information about indications for use, actual or potential medication irregularities or adverse consequences (such as symptoms of tardive dyskinesia, dizziness, anorexia, or falls) may be attainable only by talking to the staff, reviewing the medical record, and observing and speaking with the resident, the resident's family and/or representative. However, electronic health and medication records and other available technology may permit the pharmacist to conduct some components of the review outside the facility.

Electronic transmission of information may enable facilities to quickly communicate resident-specific information to an off-site pharmacy or pharmacist, however, electronic communication must remain secure to protect individually identifiable information as mandated by the Health Insurance

Portability and Accountability Act (HIPAA) of 1996. With secure electronic communication the pharmacist may promptly identify actual or potential medication-related problems before a medication is initiated or soon afterwards. However, brief communication via secure devices to address or prevent immediate or potential problems does not constitute a complete MRR. All information that is needed to perform an MRR may not be available electronically, for example, flow sheets that monitor a resident's pain or that document other observations or symptoms.

- Resources are available to facilitate evaluating medication concerns related to the performance of the MRR, such as:
- U.S. Department of Health and Human Services, Food and Drug Administration (FDA) http://www.fda.gov/medwatch/safety.htm.
- American Society of Consultant Pharmacists (ASCP) http://ascp.com/;
- American Medical Directors Association – The Society for Post-Acute and Long-Term Care Medicine (AMDA) http://www.paltc.org/;
- National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) http://www.nccmerp.org;
- American Geriatrics Society (AGS) http://www.americangeriatrics.org; and

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Identification of Irregularities

An objective of the MRR is to try to minimize or prevent adverse consequences by identifying irregularities including, for example: syndromes potentially related to medication therapy, emerging or existing adverse medication consequences (e.g., drug reactions or medication errors). The resident's record may contain information regarding possible and/or actual medication irregularities. Possible sources to obtain this information include: the medication administration records (MAR); prescribers' orders; progress, nursing and consultants' notes; the Resident Assessment Instrument (RAI); laboratory and diagnostic test results, and other sources of information about documented expressions or indications of distress and/or changes in condition. The pharmacist may also obtain information from the Quality Measures/Quality Indicator reports, the attending physician, facility staff, and (as appropriate) from interviewing, assessing, and/or observing the resident.

The pharmacist's review considers factors such as:

1. Whether the physician and staff have documented objective findings, diagnoses, symptom(s), and/or resident goals and preferences to support indications for use;
2. Whether the physician and staff have identified and acted upon, or should be notified about, the resident's allergies and/or potential side effects and significant medication interactions;
3. Whether the medication dose, frequency, route of administration, and duration are consistent with the resident's condition, manufacturer's recommendations, and applicable standards of practice;
4. Whether the physician and staff have documented progress towards, decline from, or maintenance of the resident's goal(s) for the medication therapy;

5. Whether the physician and staff have documented any attempts for gradual dose reduction (GDR) or added any non-pharmacological approaches, in an effort to reduce or discontinue a drug;
6. Whether the physician and staff have obtained and acted upon laboratory results, diagnostic studies, or other measurements (such as bowel function, intake and output) as applicable;
7. Whether medication errors exist or circumstances exist that make them likely to occur; and
8. Whether the physician and staff have noted and acted upon possible medication-related causes of recent or persistent changes in the resident's condition such as worsening of an existing problem or the emergence of new signs or symptoms. Some examples of changes potentially related to medication use that could occur include:
    a. Anorexia and/or unplanned weight loss, or weight gain;
    b. Expressions or indications of distress, or other changes in a resident's psychosocial status;
    c. Bowel function changes including constipation, ileus, impaction;
    d. Confusion, cognitive decline, worsening of dementia (including delirium);
    e. Dehydration, fluid/electrolyte imbalance;
    f. Excessive sedation, insomnia, or sleep disturbance;
    g. Falls, dizziness, or evidence of impaired coordination;
    h. Headaches, muscle pain, generalized aching or pain;
    i. Rash, pruritus;
    j. Spontaneous or unexplained bleeding, bruising; and
    k. Urinary retention or incontinence.

Upon conducting the MRR, the pharmacist may identify and report irregularities in one or more of the following categories:

- The use of a medication without identifiable evidence of adequate indications for use, such as, the use of a medication to treat a clinical condition without identifiable evidence that safer alternatives or more clinically appropriate medications have been considered;
- The use of homeopathic or herbal options (e.g., St. John's Wort) that may interfere with the effectiveness of clinically appropriate medications;
- The use of an appropriate medication that is not helping attain the intended treatment or resident's goals because of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons;
- The use of a medication in an excessive dose (including duplicate therapy) or for excessive duration, thereby placing the resident at greater risk for adverse consequences or causing existing adverse consequences;
- The presence of an adverse consequence associated with the resident's current medication regimen;
- The use of a medication without evidence of adequate monitoring; i.e., either inadequate monitoring of the response to a medication or an inadequate response to the findings;
- Presence of medication errors or the risk for such errors;
- Presence of a clinical condition that might warrant initiation of medication therapy; and (NOTE: The presence of a diagnosis or symptom does not necessarily warrant medication, but often depends on the consideration of many factors simultaneously.)
- A medication interaction associated with the current medication regimen. (NOTE: Concomitant use of certain medication combinations is not necessarily inappropriate. Often, several medications with documented interactions can be given together

safely. However, concomitant use of certain medications warrants careful consideration of potential alternatives, possible need to modify doses, and diligent monitoring.)

Websites for organizations such as AMDA -The Society for Post-Acute and Long-Term Care Medicine (American Medical Directors Association) have made information available regarding problematic medication interactions in the long-term care population: https://www.amda.com/tools/clinical/m3/topten.cfm; and https://www.crediblemeds.org/healthcare-providers/drug-drug-interaction, Woosley, RL and Romero, KA, www.Crediblemeds.org, QTdrugs List, [Accessed March6, 2017], AZCERT, Inc. 1822 Innovation Park Dr., Oro Valley, AZ 85755.

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

Location and Notification of Medication Regimen Review Findings

1. The pharmacist is expected to document either that no irregularity was identified or the nature of any identified irregularities.
2. The pharmacist is responsible for reporting any identified irregularities to the attending physician, the facility's medical director, and director of nursing. The timeliness of notification of irregularities depends on factors including the potential for or presence of serious adverse consequences; for example, immediate notification is indicated in cases of bleeding in a resident who is receiving anticoagulants or in cases of possible allergic reactions to antibiotic therapy.
3. The pharmacist must document any identified irregularities in a separate, written report. The report may be in paper or electronic form.
4. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect.
5. The pharmacist does not need to document a continuing irregularity in the report each month **if** the attending physician has documented a valid clinical rationale for rejecting the pharmacist's recommendation unless warranted by a change in the resident's condition or other circumstances.

The pharmacist's findings are considered part of each resident's medical record and as such are available to the resident/representative upon request. If documentation of the findings is not in the active record, it is maintained within the facility and is readily available for review. Establishing a consistent location for the pharmacist's findings and recommendations can facilitate communication with the attending physician, the director of nursing, the remainder of the IDT, the medical director, the resident and his or her legal representative, the ombudsman, and surveyors.

Response to Irregularities Identified in the MRR

The medical record must show documentation that the attending physician reviewed any irregularities identified by the pharmacist. For those issues that require physician intervention, the attending physician either accepts and acts upon the report and recommendations or rejects all or some of the report and should document his or her rationale of why the recommendation is rejected

in the resident's medical record. It is not acceptable for an attending physician to document only that he/she disagrees with the report, without providing some clinical basis for disagreeing.
The facility should have a procedure for how to resolve situations where:

- The attending physician does not concur with or take action on identified irregularities, and;
- The attending physician is also the medical director.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F756, the surveyor's investigation will generally show that:

1. The MRR was not conducted by a licensed pharmacist; or
2. The pharmacist failed to conduct a complete MRR, at least monthly (or more frequently, as indicated by the resident's condition) for every resident of the facility; or
3. The pharmacist's findings in the MRR did not show evidence that the pharmacist also reviewed the resident's chart, for example, the pharmacist did not reference the resident response to a particular medication that was cited as an irregularity.; or
4. The pharmacist failed to identify or report the absence of or inadequate indications for use of a medication, or a medication or medication combination with significant potential for adverse consequences or medication interactions; or
5. The pharmacist failed to identify and/or report medications prescribed or administered in excessive dose (including but not limited to duplicate therapy); or
6. The pharmacist failed to identify and/or report medications prescribed or administered for excessive duration; or
7. The pharmacist failed to identify and/or report medications prescribed or administered without adequate monitoring; or
8. The pharmacist failed to identify or report medications in a resident's regimen that could (as of the review date) be causing or associated with new, worsening, or progressive signs and symptoms; or
9. The pharmacist failed to identify and report the absence of any explanation as to why or how the benefit of a medication(s) with potential for clinically significant adverse consequences outweighs the risk; or
10. The attending physician failed to document that he or she reviewed the pharmacist's identified irregularities and/or failed to document the action taken or not taken to address the irregularities; or
11. The facility failed to develop, maintain, and implement policies and procedures which address the time frames for the steps in the MRR process; or
12. The facility failed to develop and implement policies and procedures which address steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

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:

- Despite identifying irregularities with the potential for serious harm or death in a resident's medication regimen, the pharmacist did not report the irregularities to the attending physician, DON, and medical director or action was not taken on the irregularities reported.
- On the MRR, the pharmacist identified that a resident was prescribed an antipsychotic medication without a clinical indication. This placed the resident at likely risk for harm such as experiencing a fall, mental status changes, or sustained negative psychosocial outcomes. The medical record did not show evidence that the attending physician had reviewed and responded to the identified irregularity.

Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, include, but are not limited to:

- The pharmacist's MRR failed to identify the indication for continued use for opioid analgesics that had been prescribed for a resident's acute pain which had resolved. As a result of prolonged duration of use, the resident continued to be or became more lethargic and/or withdrawn.
- The pharmacist's MRR identified that the staff were crushing medications that should not be crushed. As a result of facility failure to act upon the notification, the resident experienced clinically significant adverse consequences such as hypoglycemia or hypotension that required medical intervention.
- The attending physician failed to act in response to the pharmacist's MRR which identified the indefinite continuation of an antidepressant in a resident who had no history of depression, who had been placed on the antidepressant without an evaluation to confirm presence of depression, and whose function and mood were not monitored while getting the medication for months. The resident experienced clinically significant adverse consequences such as falls without serious injury, constipation, or change in weight.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Examples of some of the related requirements that should be considered when concerns have been identified include the following:

- 42 CFR 483.10(g)(14), F580, Notification of Changes
  - Review whether a member of the IDT contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a different form of treatment).
- 42 CFR 483.45(d), F757, Unnecessary Drugs and 42 CFR 483.45(e), F758, Psychotropic Medications
  - Review whether the resident is receiving any medications without an indication for use, in excessive dose or duration, with inadequate monitoring, or in the presence of any adverse consequences that indicate that the dose should be reduced or discontinued.
- 42 CFR 483.30(a), F710, Physician Supervision
  - Review whether the attending physician supervised the resident's medical treatment, including assessing the resident's condition, identifying the need for and continuing use of medication to address the resident's needs, and identifying and addressing adverse consequences related to medications.

- 42 CFR 483.30(b), F711 Physician Visits and 42 CFR 483.30(c), F712, Frequency of Physician Visits
  - Review whether the attending physician or another designated practitioner reviewed the resident's total program of care including the beneficial and adverse effects of medications and treatment, and provided a relevant progress note at each visit.
- 42 CFR 483.45(a), (b)(1)-(3), F755, Pharmacy Services
  - Review whether the licensed pharmacist has provided consultation regarding all aspects of pharmaceutical services.
- 42 CFR 483.70(h), F841, Medical Director
  - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding an inadequate response to identified or reported potential medication irregularities and adverse consequences.

F757 Unnecessary Drug - Each resident's drug regimen must be free from unnecessary drugs.

An unnecessary drug is any drug when used**:**

1. In excessive dose (including duplicate drug therapy); or
2. For excessive duration; or
3. Without adequate monitoring; or
4. Without adequate indications for its use; or
5. In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
6. Any combinations of the above

F758 Psychotropic Drugs

A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

1. Anti-psychotic;
2. Anti-depressant;
3. Anti-anxiety; and
4. Hypnotic

Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that-

1. Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;
2. Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

3. Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and
4. **PRN** orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.
5. PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

INTENT: **UNECESSARY DRUGS**: The intent of this requirement is that:

1. each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial wellbeing;
2. the facility implements gradual dose reductions(GDR) and non-pharmacological interventions, unless contraindicated, prior to initiating or instead of continuing psychotropic medication; and
3. PRN orders for psychotropic medications are only used when the medication is necessary and PRN use is limited.

NOTE: WHICH TAG WILL BE CITED?

- For concerns related to unnecessary medications, excluding psychotropic medications, surveyors should assess compliance with §483.45(d), F757.

- For concerns related to psychotropic medications only, including the unnecessary medication requirements, surveyors should assess compliance with §483.45(c) and (e), F758.

The Guidance for these two tags is combined to avoid unnecessary duplication**.**

Although the regulatory language refers to "drugs," the guidance in this document generally will refer to "medications," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

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

The surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

DEFINITIONS §483.45 (d) Unnecessary drugs and 483.45(c)(3) and (e) Psychotropic Drugs
Definitions are provided to clarify terminology related to medications and to the evaluation and treatment of residents.

"Adverse consequence" is a broad term referring to unwanted, uncomfortable, or dangerous effects that a drug may have, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease) (adapted from The Merck Manual Professional Version, http://www.merckmanuals.com/professional/clinical-pharmacology/adverse-drugreactions/adverse-drug-reactions.)

> NOTE: Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

"Anticholinergic side effect" is an effect of a medication that opposes or inhibits the activity of the parasympathetic (cholinergic) nervous system to the point of causing symptoms such as dry mouth, blurred vision, tachycardia, urinary retention, constipation, confusion, delirium, hallucinations, flushing, and increased blood pressure. Types of medications that may produce anticholinergic side effects include:

- Antihistamines, antidepressants, anti-psychotics, antiemetics, muscle relaxants; and
- Certain medications used to treat cardiovascular conditions, Parkinson's disease, urinary incontinence, gastrointestinal issues and vertigo.

"Behavioral interventions" are individualized, non-pharmacological approaches to care that are provided as part of a supportive physical and psychosocial environment, directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities, as well as maintaining or improving a resident's mental, physical or psychosocial wellbeing.

"Clinically significant" refers to effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

"Expressions or indications of distress" refers to a person's attempt to communicate unmet needs, discomfort, or thoughts that he or she may not be able to articulate. The expressions may present as crying, apathy, or withdrawal, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others.

"Dose" is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

"Excessive dose" means the total amount of any medication (including duplicate therapy) given at one time or over a period of time that is greater than the amount recommended by the manufacturer's label, package insert, and accepted standards of practice for a resident's age and condition.

"Duplicate therapy" refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.

"Extrapyramidal symptoms (EPS)" are neurological side effects that can occur at any time from the first few days of treatment with antipsychotic medication to years later. EPS includes various syndromes such as:

- Akathisia, which refers to a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing, or rocking.
- Medication-induced Parkinsonism, which refers to a syndrome of Parkinson-like symptoms including tremors, shuffling gait, slowness of movement, expressionless face, drooling, postural unsteadiness and rigidity of muscles in the limbs, neck and trunk.
- Dystonia, which refers to an acute, painful, spastic contraction of muscle groups (commonly the neck, eyes and trunk) that often occurs soon after initiating treatment and is more common in younger individuals.

"Gradual Dose Reduction (GDR)" is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

"Indications for use" is the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals and is consistent with manufacturer's recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

"Neuroleptic Malignant Syndrome (NMS)" is a syndrome related to the use of medications, mainly antipsychotics, that typically presents with a sudden onset of diffuse muscle rigidity, high fever, labile blood pressure, tremor, and notable cognitive dysfunction. It is potentially fatal if not treated immediately, including stopping the offending medications.

"Psychotropic drug" is defined in the regulations at §483.45(c)(3), as "any drug that affects brain activities associated with mental processes and behavior." Psychotropic drugs include, but are not limited to the following categories: anti-psychotics, anti-depressants, anti-anxiety, and hypnotics.

"Serotonin Syndrome" is a potentially serious clinical condition resulting from overstimulation of serotonin receptors. It is commonly related to the use of multiple serotonin-stimulating medications (e.g., SSRIs, SNRIs, triptans, certain antibiotics). Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.

"Tardive dyskinesia" refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking, although the trunk or other parts of the body may also be affected.

GUIDANCE §483.45(d) Unnecessary drugs and §483.45(c)(3) and (e) Psychotropic Drugs

Medications are an integral part of the care provided to residents of nursing facilities. They are administered to try to achieve various outcomes, such as curing an illness, arresting or slowing a disease process, reducing or eliminating symptoms, or as part of diagnosing or preventing a disease or symptom.

Proper medication selection and prescribing (including dose, duration, and type of medication(s)) may help stabilize or improve a resident's outcome, quality of life and functional capacity. Any medication or combination of medications—or the use of a medication without adequate indications, in excessive dose, for an excessive duration, or without adequate monitoring—may increase the risk of a broad range of adverse consequences such as medication interactions, depression, confusion, immobility, falls, hip fractures, and death. **The Beers Criteria** for Potentially Inappropriate Medication Use in Older Adults provides information on safely prescribing medications for older adults, http://www.healthinaging.org/medications-olderadults/.

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

Intrinsic factors including physiological changes accompanying the aging process, multiple comorbidities, and certain medical conditions may affect the absorption, distribution, metabolism or elimination of medications from the body and may also increase an individual's risk of adverse consequences.

While assuring that only those medications required to treat the resident's assessed condition are being used, reducing the need for and maximizing the effectiveness of medications are important considerations for all residents. Therefore, as part of all medication management (especially psychotropic medications), it is important for the IDT to implement non-pharmacological approaches designed to meet the individual needs of each resident. Educating facility staff and providers about the importance of implementing individualized, non-pharmacological approaches to care prior to the use of medications may minimize the need for medications or reduce the dose and duration of those medications. Additional information as well as examples of non-pharmacological interventions may be found in other guidance for regulations at §483.40, Behavioral Health Services and §483.25, Quality of Care and Quality of Life.

The indications for initiating, withdrawing, or withholding medication(s), as well as the use of non-pharmacological approaches, are determined by assessing the resident's underlying condition, current signs, symptoms, and expressions, and preferences and goals for treatment. This includes, where possible, the identification of the underlying cause(s), since a diagnosis alone may not warrant treatment with medication. Orders from multiple prescribers or providers can increase the resident's chances of receiving unnecessary medications.

Staff and practitioner access to current medication references and pertinent clinical protocols helps to promote safe administration and monitoring of medications. One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include within the medication labeling warnings about adverse reactions and potential safety hazards identified both before and after approval of a medication, and what to do if they occur

(Visit:http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/. Manufacturers are required to update labels to warn about newly identified safety hazards—regardless of whether causation has been proven and whether the medication is prescribed for a disease or condition that is not included in the "Indications and Usage" section of the labeling (so-called "off-label" or unapproved use). Federal regulations at 21 CFR 201.57 (a)(4) and (c)(1) also require manufacturers to place statements about serious problems or contraindications in a prominently displayed box that appears on the medication labelling and in greater detail in the full prescribing information that accompanies the medication. The boxed warning is reserved for prescription drugs that pose a significant risk of serious or life-threatening adverse effects, based on medical studies.

The facility's pharmacist is a valuable source of information about medications. Listings or descriptions of most significant risks, recommended doses, medication interactions, cautions, etc. can be found in widely available, standard references, and computer software and systems that provide up-to-date information. It is important to note that some of the medication information found in many of these references is not specific to older adults or individuals residing in nursing homes. A list of resources and tools is provided at the end of this guidance.

MEDICATION MANAGEMENT

Medication management is based in the care process and includes recognition or identification of the problem/need, assessment, diagnosis/cause identification, management/treatment, monitoring, and revising interventions, as warranted as well as documenting medication management steps. The attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents, their families, and/or representative(s) and other professionals and direct care staff (the IDT).

When selecting medications and non-pharmacological approaches, members of the IDT, including the resident, his or her family, and/or representative(s), participate in the care process to identify, assess, address, advocate for, monitor, and communicate the resident's needs and changes in condition. This guidance is intended to help the surveyor determine whether the facility's medication management supports and promotes:

- Involvement of the resident, his or her family, and/or the resident representative in the medication management process.
- Selection of medications(s) based on assessing relative benefits and risks to the individual resident;
- Evaluation of a resident's physical, behavioral, mental, and psychosocial signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;
- Selection and use of medications in doses and for the duration appropriate to each resident's clinical conditions, age, and underlying causes of symptoms and based on assessing relative benefit and risks to, and preferences and goals of, the individual resident;
- The use of non-pharmacological approaches, unless contraindicated, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued; and
- The monitoring of medications for efficacy and adverse consequences.
- Resident Choice –If a resident declines treatment, the facility staff and physician should inform the resident about the risks related to the lack of the medication, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach.
- Advance Directives – A resident's advance directives may include withdrawing or withholding medications. Whether or not a resident has an advance directive, the facility is responsible for giving treatment, support, and other care that is consistent with the resident's condition and applicable care instructions, according to the resident's care plan. If there are concerns regarding Resident Choice or Advance Directives, consider investigating the requirements at §483.10, Resident Rights and §483.21, Care Planning.

The resident's medical record documents and communicates to the entire team the basic elements of the care process and the resident's goals and preferences. Information about aspects of the care process related to medications may be found in various locations within the record, such as: hospital discharge summaries and transfer notes, progress notes and interdisciplinary notes, history and physical examination, Resident Assessment Instrument (RAI), plan of care, laboratory reports, professional consults, medication orders, Medication Regimen Review (MRR) reports, and Medication Administration Records (MAR).

The regulations associated with medication management include consideration of:

1. Indication and clinical need for medication;
2. Dose (including duplicate therapy);
3. Duration;
4. Adequate monitoring for efficacy and adverse consequences; and
5. Preventing, identifying, and responding to adverse consequences.

With regard to psychotropic medications, the regulations additionally require:

1. Giving psychotropic medications only when necessary to treat a specific diagnosed and documented condition;
2. Implementing GDR and other non-pharmacologic interventions for residents who receive psychotropic medications, unless contraindicated; and

3. Limiting the timeframe for PRN psychotropic medications, which **are not** antipsychotic medications, to 14 days, unless a longer timeframe is deemed appropriate by the attending physician or the prescribing practitioner.
4. Limiting PRN psychotropic medications, which **are** antipsychotic medications, to 14 days and not entering a new order without first evaluating the resident.

NOTE: While there may be isolated situations where a pharmacological intervention is required first, these situations do not negate the obligation of the facility to develop and implement non-pharmacological interventions. For additional information related to situations where a non-pharmacological intervention may be contraindicated, refer to §483.40(a)(2), Implementing non-pharmacological interventions.

Indication for Use

The resident's medical record must show documentation of adequate indications for a medication's use and the diagnosed condition for which a medication is prescribed. An evaluation of the resident by the IDT helps to identify his/her needs, goals, comorbid conditions, and prognosis to determine factors (including medications and new or worsening medical conditions) that are affecting signs, symptoms, and test results. This evaluation process is important when selecting initial medications and/or non-pharmacological approaches and when deciding whether to modify or discontinue a current medication. The evaluation also clarifies:

- Whether other causes for the symptoms (including expressions or indications of distress that could mimic a psychiatric disorder) have been ruled out;
- Whether the physical, mental, behavioral, and/or psychosocial signs, symptoms, or related causes are persistent or clinically significant enough (e.g., causing functional decline) to warrant the initiation or continuation of medication therapy;
- Whether non-pharmacological approaches are implemented, unless clinically contraindicated for the resident or declined by the resident;
- Whether a particular medication is clinically indicated to manage the symptom or condition; and
- Whether the intended or actual benefit is understood by the resident and, if appropriate, his/her family and/or representative(s) and is sufficient to justify the potential risk(s) or adverse consequences associated with the selected medication, dose, and duration.

The content and extent of the evaluation may vary with the situation and may employ various assessment instruments and diagnostic tools. Examples of information to be considered and evaluated may include, but are not limited to, the following:

- An appropriately detailed evaluation of mental, physical, psychosocial, and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of resident complaints, symptoms, and signs (including the onset, scope, frequency, intensity, precipitating factors, and other important features);
- Each resident's goals and preferences;
- Allergies to medications and foods and potential for medication interactions;
- A history of prior and current medications and non-pharmacological interventions (including therapeutic effectiveness and any adverse consequences);
- Recognition of the need for end-of-life or palliative care; and
- The basis for declining care, medication, and treatment and the identification of pertinent alternatives.
- Documentation of indications of distress, delirium, or other changes in functional status.

Circumstances that warrant evaluation of the resident and medication(s) include:

- Admission or re-admission;
- A clinically significant change in condition/status;
- A new, persistent, or recurrent clinically significant symptom or problem;
- A worsening of an existing problem or condition;
- An unexplained decline in function or cognition;
- A new medication order or renewal of orders; and
- An irregularity identified in the pharmacist's medication regimen review. See F756 for guidance related to the medication regimen review.
- Orders for PRN psychotropic and/or antipsychotic medications which are not prescribed to treat a diagnosed specific condition or do not meet the PRN requirements for psychotropic and antipsychotic medications.

Specific considerations related to these circumstances may include the following:

- Admission (or Readmission) – Some residents may be admitted on medications for an undocumented chronic condition or without a clear indication as to why a medication was begun or should be continued. It is expected that the attending physician, pharmacist, and staff subsequently determine if continuing the medication is justified by evaluating the resident's clinical condition, risks, existing medication regimen, preferences, goals, and related factors.
- Multiple prescribers – Regardless of who the prescribers are, the continuation of a medication needs to be evaluated to determine if the medication is still warranted in the context of the resident's other medications and comorbidities. Medications prescribed by a specialist or begun in another care setting, such as the hospital, need to have a clinically pertinent documented rationale in the resident's medical record.
- New medication order as an emergency measure – When a resident is experiencing an acute medical problem or psychiatric emergency (e.g., the resident's expression or action poses an immediate risk to the resident or others), medications may be required. In these situations, it is important to identify and address the underlying causes of the problem or symptoms. Once the acute phase has stabilized, the staff and prescriber consider whether medications are still relevant. Subsequently, the medication is reduced or discontinued as soon as possible or the clinical rationale for continuing the medication is documented. If the new medication is a psychotropic or antipsychotic medication ordered on a PRN basis, the PRN order(s) must be consistent with the requirements for PRN use of psychotropic and antipsychotic medications at §483.45(e)(3), (4), and (5). When psychopharmacological medications are used as an emergency measure, adjunctive approaches, such as individualized, non-pharmacological approaches and techniques must be implemented. Longer term management options should be discussed with the resident, their family, and/or representative(s). Psychiatric disorders or expressions and/or indications of distress – As with all symptoms, it is important to seek the underlying cause of the distress. Some examples of potential causes include delirium, pain, psychiatric or neurological illness, environmental or psychological stressors, dementia, or substance intoxication or withdrawal. Non-pharmacologic approaches, unless clinically contraindicated, must be implemented to address expressions or indications of distress. However, medications may be effective when the underlying cause of a resident's distress has been determined, non-pharmacologic approaches to care have been ineffective, or expressions of distress have worsened. Medications may be unnecessary and are likely to

cause harm when given without a clinical indication, at too high of a dose, for too long after the resident's distress has been resolved, or if the medications are not monitored. All approaches to care, including medications, need to be monitored for efficacy, risks, benefits, and harm and revised as necessary.

NOTE: Permission given by or a request made by the resident and/or representative does not serve as a sole justification for the medication itself.

Dose

Medications are prescribed based on a variety of factors including the resident's diagnoses, signs and symptoms, current condition, age, coexisting medication regimen, review of lab and other test results, input from the IDT about the resident, including the resident's preferences and goals, the type of medication(s), and therapeutic goals being considered or used.

The route of administration influences a medication's absorption and ultimately the dose received. Examples of factors that can affect the absorption of medications delivered by transdermal patches include skin temperature and moisture, and the integrity of the patch. Similarly, the flow rate of intravenous solutions affects the amount received at a given time.

Duplicate therapy is generally not indicated, unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effects. Some examples of potentially problematic duplicate therapy include, use of more than one product containing the same medication, concomitant use of drugs within the same class, or medications from different therapeutic categories with similar effects or properties. Additionally, the risk for duplication is particularly high during transitions of care, especially if medications are not tracked closely between locations or within the care settings. Documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences.

Duration

Periodic re-evaluation of the medication regimen is necessary to determine whether prolonged or indefinite use of a medication is indicated. The clinical rationale for continued use of a medication(s) may have been demonstrated in the clinical record, or the staff and prescriber may present pertinent clinical reasons for the duration of use. Regarding PRN medications, it is important that the medical record include documentation related to the attending physician's or other prescriber's evaluation of the resident and of indication(s), specific circumstance(s) for use, and the desired frequency of administration for each medication. As part of the evaluation, gathering and analyzing information helps define clinical indications and provide baseline data for subsequent monitoring. Common considerations for appropriate duration may include:

- A medication initiated as a result of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching) is then discontinued when the condition has resolved, or there is documentation indicating why continued use is still relevant. Failure to review whether the underlying cause has resolved may lead to excessive duration.

- A medication administered beyond the stop date established *by* the prescriber, without evidence of clinical justification for continued use of the medication, may be considered excessive duration.
- A medication, which is prescribed on a PRN basis, is requested by the resident and/ or/administered by staff on a regular basis, indicating a more regular schedule may be needed.

Monitoring for Efficacy and Adverse Consequences

The information gathered during the initial and ongoing evaluations and through conversations with the resident and, as appropriate, his or her family or representative is essential to:

- Verify or differentiate the underlying diagnoses or other underlying causes of signs and symptoms.
- Incorporate into a comprehensive care plan that reflects person-centered medication related goals and parameters for monitoring the resident's condition, including the likely medication effects and potential for adverse consequences. Examples of this information may include the FDA boxed warnings or warnings of adverse consequences that may be rare, but have sudden onset, or that may be irreversible. If the facility has established protocols for monitoring specific medications and the protocols are accessible for staff use, the care plan may refer staff to these protocols;
- Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences;
- Establish parameters for evaluating the ongoing need for the medication; and
- Track progress and/or decline towards the therapeutic goal.

Sources of information to facilitate defining the monitoring criteria or parameters may include cautions, warnings, and identified adverse consequences from:

- Manufacturers' package inserts and boxed warnings;
- Facility policies and procedures;
- Pharmacists;
- Clinical practice guidelines or clinical standards of practice;
- Medication references; and
- Clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

Monitoring and accurate documentation of the resident's response to any medication(s) is essential to evaluate the ongoing benefits as well as risks of various medications. Monitoring should also include evaluation of the effectiveness of non-pharmacological approaches, such as prior to administering PRN medications.

Monitoring involves several steps, including:

- Identifying the essential information and how it will be obtained and reported--It is important to consider who is responsible for obtaining the information, which information should be collected, and how the information will be documented. The information that is collected depends on therapeutic goals, detection of potential or actual adverse consequences, and consideration of risk factors, such as:
  - Medication-medication, medication-food interactions;
  - Clinical condition (for example renal disease);

  - Properties of the medication;
  - Boxed warnings; and
  - Resident's history of adverse consequences related to a similar medication.
- Determining the frequency of monitoring--The frequency and duration of monitoring needed to identify therapeutic effectiveness, achievement of resident goals, and adverse consequences will depend on factors such as clinical standards of practice, facility policies and procedures, manufacturer's specifications, and the resident's clinical condition and choices. Monitoring involves three aspects:
  - Periodic planned evaluation of progress toward the therapeutic goals;
  - Continued vigilance for adverse consequences; and
  - Evaluation of identified adverse consequences.
- Defining the methods for communicating, analyzing, and acting upon relevant information--The monitoring process needs to identify who is to communicate with the prescriber, what information is to be conveyed, and when to ask the prescriber to evaluate and consider modifying the medication regimen.
- If the therapeutic goals are not being met or the resident is experiencing adverse consequences, it is essential for the prescriber in collaboration with facility staff, the pharmacist, and the resident to consider whether current medications and doses continue to be appropriate or should be reduced, changed, or discontinued. Serum concentration monitoring may be necessary for some medications. Abnormal or toxic serum concentrations must be evaluated for dosage adjustments. If serum concentrations are within normal ranges, each resident should still be evaluated for effectiveness and side effects.
- Re-evaluating and updating monitoring approaches--Modification of monitoring may be necessary when the resident experiences changes, such as:
  o Acute onset of signs or symptoms or worsening of chronic disease;
  o Addition or discontinuation of medications and/or non-pharmacological approaches, for example, a resident who takes warfarin regularly starts on a medication that interacts with warfarin, therefore more frequent blood work may be needed;
  o Addition or discontinuation of care and services such as enteral feedings; and
  o Significant changes in diet that may affect medication absorption or effectiveness or increase adverse consequences.

Additional examples of circumstances that may indicate a need to modify the monitoring include: changes in manufacturer's specifications, FDA warnings, pertinent clinical practice guidelines, or other literature about how and what to monitor.

Adverse consequences related to medications are common enough to warrant serious attention and close monitoring. An HHS Office of the Inspector General (OIG) report released in February 2014 found approximately one in five SNF residents experienced at least one adverse even during their SNF stay. Thirty-seven percent of these events were related to medications and were often preventable, See the full report, Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries at http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.

Some adverse consequences may be avoided by:

- Following relevant clinical guidelines and manufacturer's specifications for use, dose, administration, duration, and monitoring of the medication;
- Defining appropriate indications for use; and
- Determining that the resident:
    - Has no known allergies to the medication;
    - Is not taking other medications, nutritional supplements including herbal products, or foods that would be incompatible with the prescribed medication; and
    - Has no condition, history, or sensitivities that would preclude use of that medication
- Responding to the resident's reported experience with medications and treatments they have received.

The risk for adverse consequences increases with both the number of medications being taken regularly and with medications from specific pharmacological classes, such as anticoagulants, diuretics, psychotropic medications, anti-infectives, and anticonvulsants.[32] Adverse consequences can range from minimal harm to functional decline, hospitalization, permanent injury, and death. Use of a tool, such as the CMS Adverse Drug Event Trigger Tool may assist in identifying resident risk factors and triggers for adverse drug events as well as determine whether a facility has systems and processes in place to minimize risk factors and mitigate harm to residents. The tool is available on the CMS Nursing Home Quality Assurance and Performance Improvement website, https://www.cms.gov/Medicare/Provider-Enrollment-andCertification/QAPI/Downloads/Adverse-Drug-Event-Trigger-Tool.pdf.

One common adverse consequence is delirium, which presents as an alteration in attention and awareness associated with a change in cognition not explained by a current or emerging neurocognitive disorder. Delirium may result from medications as well as other factors including electrolyte imbalances or infections. While delirium is not always preventable, identifying and addressing risk factors may reduce the occurrence. In many facilities, a majority of the residents have dementia. Individuals who have dementia may be more sensitive to medication effects and may be at greater risk for delirium.

Delirium may go undiagnosed, be misinterpreted as dementia, or misdiagnosed as a psychiatric disorder, such as bipolar disorder. Delirium develops rapidly over a short period of time, such as hours or days, and usually follows a fluctuating course throughout the day. Additionally, the resident may have difficulty paying attention and be less aware of his or her surroundings. Delirium can be characterized as hyperactive (e.g., extreme restlessness, climbing out of bed), hypoactive (e.g., sluggish and lethargic), or mixed (e.g., normal level of activity with lowered awareness). Delirium is particularly common post-hospitalization; signs and symptoms may be subtle and therefore are often missed. Although generally thought to be short lived, delirium can persist for months. Recognizing delirium is critical, as failure to act quickly to identify and treat the underlying causes may result in poor health outcomes or death.

Negative psychosocial outcomes can also occur in relation to unnecessary medications, including psychotropic medications. These adverse consequences may include: suicidal ideation, recurrent debilitating anxiety, extreme aggression or agitation, significant decline in former social patterns, social withdrawal, psychomotor agitation or retardation, inability to think or concentrate, and apathy.

Psychotropic Medications and Antipsychotic Medications (F758 Only Guidance) As clarified in the section on Indication for Use, residents must not receive any medications which are not clinically indicated to treat a specific condition. The medical record must show documentation of the diagnosed condition for which a medication is prescribed. This requirement is especially important when prescribing psychotropic medications which, as defined in this guidance, include, but are not limited to, the categories of anti-psychotic, anti-depressant, anti-anxiety, and hypnotic medications. All medications included in the psychotropic medication definition may affect brain activities associated with mental processes and behavior. Use of psychotropic medications, other than antipsychotics, should not increase when efforts to decrease antipsychotic medications are being implemented, unless the other types of psychotropic medications are clinically indicated. Other medications which may affect brain activity such as central nervous system agents, mood stabilizers, anticonvulsants, muscle relaxants, anticholinergic medications, antihistamines, NMDA receptor modulators, and over the counter natural or herbal products must also only be given with a documented clinical indication consistent with accepted clinical standards of practice. Residents who take these medications must be monitored for any adverse consequences, specifically increased confusion or over-sedation. The regulations and guidance concerning psychotropic medications are not intended to to supplant the judgment of a physician or prescribing practitioner in consultation with facility staff, the resident and his/her representatives and in accordance with appropriate standards of practice. Rather, the regulations and guidance are intended to ensure psychotropic medications are used only when the medication(s) is appropriate to treat a resident's specific, diagnosed, and documented condition and the medication(s) is beneficial to the resident, as demonstrated by monitoring and documentation of the resident's response to the medication(s).

Use of Psychotropic Medications in Specific Circumstances Acute or Emergency Situations: When a psychotropic medication is being initiated or used to treat an emergency situation (i.e., acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others) related to a documented condition or diagnosis, a clinician in conjunction with the IDT must evaluate and document the situation to identify and address any contributing and underlying causes of the acute condition and verify the need for a psychotropic medication. Use of psychotropic medication to treat an emergency situation must be consistent with the requirements regarding PRN orders for psychotropic and antipsychotic medications and any continued use must be consistent with the requirements for gradual dose reduction (GDR).

Enduring Conditions: Psychotropic medications may be used to treat an enduring (i.e., non-acute; chronic or prolonged) condition. Before initiating or increasing a psychotropic medication for enduring conditions, the resident's symptoms and therapeutic goals must be clearly and specifically identified and documented. Additionally, the facility must ensure that the resident's expressions or indications of distress are:

- Not due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or poly-pharmacy) that can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) are discontinued;
- Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response), that can be addressed to improve the symptoms or maintain safety;

- Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed; and
- Persistent--The medical record must contain clear documentation that the resident's distress persists and his or her quality of life is negatively affected and, unless contraindicated, that multiple, non-pharmacological approaches have been attempted and evaluated in any attempts to discontinue the psychotropic medication.

New Admissions: Many residents are admitted to a SNF/NF already on a psychotropic medication. The medication may have been started in the hospital or the community, which can make it challenging for the IDT to identify the indication for use. However, the attending physician in collaboration with the consultant pharmacist must re-evaluate the use of the psychotropic medication and consider whether or not the medication can be reduced or discontinued upon admission or soon after admission. Additionally, the facility is responsible for:

- Preadmission screening for mental illness and intellectual disabilities, see §483.20(k), F645 and F646; and
- Obtaining physician's orders for the resident's immediate care, see§483.20(a), F635.

Monitoring of Psychotropic Medications: When monitoring a resident receiving psychotropic medications, the facility must evaluate the effectiveness of the medications as well as look for potential adverse consequences. After initiating or increasing the dose of a psychotropic medication, the behavioral symptoms must be reevaluated periodically (at least during quarterly care plan review, if not more often) to determine the potential for reducing or discontinuing the dose based on therapeutic goals and any adverse effects or functional impairment.

If the record shows evidence of adding other psychotropic medications or switching from one type of psychotropic medication to another category of psychotropic medication, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale.

Potential Adverse Consequences: The facility assures that residents are being adequately monitored for adverse consequences such as:

- **General**: anticholinergic effects which may include flushing, blurred vision, dry mouth, altered mental status, difficulty urinating, falls, excessive sedation, constipation
- **Cardiovascular:** signs and symptoms of cardiac arrhythmias such as irregular heart beat or pulse, palpitations,lightheadedness, shortness of breath, diaphoresis, chest or arm pain, increased blood pressure, orthostatic hypotension
- **Metabolic:** increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain
- **Neurologic:** agitation, distress, EPS, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA).

If the psychotropic medication is identified as possibly causing or contributing to adverse consequences as identified above, the facility and prescriber must determine whether the medication

should be continued and document the rationale for the decision. Additionally, the medical record should show evidence that the resident, family member or representative is aware of and involved in the decision. In some cases, the benefits of treatment may outweigh the risks or burdens of treatment, so the medication may be continued.

Antipsychotic Medications

As with all medications, the indication for any prescribed first generation (also referred to as typical or conventional antipsychotic medication) or second generation (also referred to as atypical antipsychotic medication) antipsychotic medication must be thoroughly documented in the medical record. While antipsychotic medication may be prescribed for expressions or indications of distress, the IDT must first identify and address any medical, physical, psychological causes, and/or social/environmental triggers. Any prescribed antipsychotic medication must be administered at the lowest possible dosage for the shortest period of time and is subject to the GDR requirements for psychotropic medications.

Antipsychotic medications (both first and second generation) have serious side effects and can be especially dangerous for elderly residents. When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling expressions or indications of distress without first identifying the cause, there is little chance that they will be effective, and they commonly cause complications such as movement disorders, falls with injury, cerebrovascular adverse events (cerebrovascular accidents (CVA, commonly referred to as stroke), and transient ischemic events) and increased risk of death. The FDA Boxed Warning which accompanies second generation anti-psychotics states, "Elderly patients with dementia-related psychosis treated with atypical anti-psychotic drugs are at an increased risk of death," https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm. The FDA issued a similar Boxed Warning for first generation antipsychotic drugs, https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm. .

Diagnoses alone do not necessarily warrant the use of an antipsychotic medication. Antipsychotic medications may be indicated if:

- behavioral symptoms present a danger to the resident or others;
- expressions or indications of distress that are significant distress to the resident;
- If not clinically contraindicated, multiple non-pharmacological approaches have been attempted, but did not relieve the symptoms which are presenting a danger or significant distress; and/or
- GDR was attempted, but clinical symptoms returned.

If antipsychotic medications are prescribed, documentation must clearly show the indication for the antipsychotic medication, the multiple attempts to implement care-planned, non-pharmacological approaches, and ongoing evaluation of the effectiveness of these interventions.

Gradual Dose Reduction for Psychotropic Medications

The requirements underlying this guidance emphasize the importance of seeking an appropriate dose and duration for each medication and minimizing the risk of adverse consequences. The

purpose of tapering a medication is to find an optimal dose or to determine whether continued use of the medication is benefiting the resident. Tapering may be indicated when the resident's clinical condition has improved or stabilized, the underlying causes of the original target symptoms have resolved, and/or non-pharmacological approaches have been effective in reducing the symptoms.

There are various opportunities during the care process to evaluate the effects of medications on a resident's physical, mental, and psychosocial well-being, and to consider whether the medications should be continued, reduced, discontinued, or otherwise modified. Examples of these opportunities include:

- During the monthly medication regimen review, the pharmacist evaluates resident-related information for dose, duration, continued need, and the emergence of adverse consequences for all medications;
- When evaluating the resident's progress, the attending physician or prescribing practitioner reviews the total plan of care, orders, the resident's response to medication(s), and determines whether to continue, modify, or stop a medication; and
- During the quarterly MDS review, the facility evaluates mood, function, behavior, and other domains that may be affected by medications.

The time frames and duration of attempts to taper any medication must be consistent with accepted standards of practice and depend on factors including the coexisting medication regimen, the underlying causes of symptoms, individual risk factors, and pharmacologic characteristics of the medications. Some medications (e.g., antidepressants, sedative/hypnotics, opioids) require more gradual tapering so as to minimize or prevent withdrawal symptoms or other adverse consequences. Close monitoring while medications are tapered will enable facility staff to determine whether a resident is experiencing side effects, changes in behavior, or withdrawal symptoms that originally prompted prescribing of the drug. However, some residents with specific, enduring, progressive, or terminal conditions such chronic depression, Parkinson's disease psychosis, or recurrent seizures may need specific types of psychotropic medications or other medications which affect brain activity indefinitely.

NOTE: If the resident's condition has not responded to treatment or has declined despite treatment, it is important to evaluate both the medication and the dose to determine whether the medication should be discontinued or the dosing should be altered, whether or not the facility has implemented GDR as required, or tapering.

The regulation addressing the use of psychotropic medications identifies the process of tapering as a GDR and requires a GDR, unless clinically contraindicated.

Within the first year in which a resident is admitted on a psychotropic medication or after the prescribing practitioner has initiated a psychotropic medication, the facility must attempt a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a GDR must be attempted annually, unless clinically contraindicated.

For any individual who is receiving a psychotropic medication to treat expressions or indications of distress related to dementia, the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; and
- The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or increase distressed behavior.

For any individual who is receiving a psychotropic medication to treat a disorder other than expressions or indications of distress related to dementia (for example, schizophrenia, bipolar mania, depression with psychotic features, or another medical condition, other than dementia, which may cause psychosis), the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder.

PRN Orders for Psychotropic and Antipsychotic Medications

In certain situations, psychotropic medications may be prescribed on a PRN basis, such as while the dose is adjusted, to address acute or intermittent symptoms, or in an emergency. However, residents must not have PRN orders for psychotropic medications unless the medication is necessary to treat a diagnosed specific condition. The attending physician or prescribing practitioner must document the diagnosed specific condition and indication for the PRN medication in the medical record.

The table below explains additional limitations for PRN psychotropic (other than antipsychotic medications) and PRN antipsychotic medications.

Type of PRN order	Time Limitation	Exception	Required items
PRN orders for psychotroic medications, excluding antipsychotics	14 days	Order may be extended beyond 14 days if the attending physician or prescribing practicitioner believes it is appropriate to extend the order	Attending physician or prescribing practitioner should document the rationale for the extended time period in the medical record and indicate a specific duration

PRN orders for antipsychotic medications only	14 days	None	If the attending physician or prescribing practitioner wishes to write a new order for the PRN antipsychotic, the attending physician or prescribing practitioner must first evaluate the resident to determine if the new order for the PRN antipsychotic is appropriate

The required evaluation of a resident before writing a new PRN order for an antipsychotic entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident's current condition and progress to determine if the PRN antipsychotic medication is still needed. As part of the evaluation, the attending physician or prescribing practitioner should, at a minimum, determine and document the following in the resident's medical record:

- Is the antipsychotic medication still needed on a PRN basis?
- What is the benefit of the medication to the resident?
- Have the resident's expressions or indications of distress improved as a result of the PRN medication?

NOTE: Report of the resident's condition from facility staff to the attending physician or prescribing practitioner does not constitute an evaluation.

If any of the elements the sections below involve psychotropic medications, investigate F758. For all other medications, investigate F757.

To cite deficient practice at F757and/or F758, the surveyor's investigation will generally show:

Inadequate Indications for Use

NOTE: For concerns related to a medication that involves an inadequate indication for use and evidence shows the medication is also being used for the purpose of discipline or staff convenience rather than to treat the resident's medical symptoms, surveyors should evaluate whether evidence shows the medication is being used to sedate the resident or restrict the resident's movement or cognition and assess compliance with §483.10(e)(1) and §483.12(a)(2), F605, Right to Be Free From Chemical Restraints instead of citing both at F605 and F757 or F758 for the same evidence.

- Failure to document a clinical reason or a clinically pertinent rationale, for using medication(s) for a specific resident or for continuing medication(s) that may be causing an adverse consequence; or

- Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed; or
- Failure to consider relative risks and benefits or potentially lower risk medications before initiating medication(s) that present clinically significant risks; or
- Failure to provide a clinically pertinent explanation for concomitant use of two or more medications in the same pharmacological class; or
- Failure to consider other factors that may be causing expressions or indications of distress before initiating a psychotropic medication, such as an underlying medical condition (e.g., urinary tract infection, dehydration, delirium), environmental (lighting, noise) or psychosocial stressors; or
- Administering a psychotropic medication(s), which the resident has not previously received, when it is not necessary to treat a specific condition that has been diagnosed and documented in the clinical record; or
- Failure to attempt non-pharmacological approaches, unless clinically contraindicated, in efforts to discontinue psychotropic medications.

Inadequate Monitoring –

- Failure to monitor the responses to or effects of a medication, or
- Failure to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., relief of pain or normalization of thyroid function) or the emergence of an adverse consequence; or
- Failure to monitor for changes in psychosocial engagement resulting from adverse consequences of medications, (e.g., resident no longer participates in activities because medication causes confusion or lethargy); or
- Failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines; or
- Failure to carry out the monitoring that was ordered or failure to monitor for potential adverse consequences; or
- Failure to consider whether the onset or worsening of symptoms, or a change of condition, may be related to a medication; or
- Failure to monitor effectiveness of non-pharmacological approaches, unless clinically contraindicated, before prescribing and administering medications.

NOTE: Additional information as well as examples of non-pharmacological approaches may be found in other guidance for regulations at §483.40, Behavioral Health Services and §483.25, Quality of Care and Quality of Life.

Excessive Dose (including duplicate therapy) –

- Giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident's age and condition, without a documented clinically pertinent rationale; or
- Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication; or
- Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.

- Failure to consider each resident's clinical condition as a factor in determining an appropriate dose, as adverse consequences may occur even when medication serum concentration levels are in the therapeutic range.

Excessive Duration –

- Continuation beyond the manufacturer's recommended time frames, the stop date or duration indicated on the medication order, facility-established stop order policies, or clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or current standards of practice, without documented clinical justification; or
- Continuation of a medication after the desired therapeutic goal has been achieved, without evaluating whether there is a continued need for the medication, for example, use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment and evaluation of the resident.

Adverse Consequences

- Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) or report the presence of adverse consequence(s); or
- Failure to monitor for the presence of adverse consequences related to the use of medications (particularly high risk medications, such as warfarin, insulin, opioids, or medications requiring monitoring of blood work); or
- Failure to respond to the presence of adverse consequences related to the use of medications (particularly high risk medications, such as warfarin, insulin, or opioids).

Psychotropic Medications

- Failure to present to the attending physician or prescribing practitioner the need to attempt GDR in the absence of identified and documented clinical contraindications; or
- Use of psychotropic medication(s) without documentation of the need for the medication(s) to treat a specific diagnosed condition; or
- PRN psychotropic medication ordered for longer than 14 days, without a documented rationale for continued use; or
- Failure to implement person-centered, non-pharmacological approaches in the attempt to reduce or discontinue a psychotropic medication; or
- Administering a new PRN antipsychotic medication for which the resident had a previous PRN order (for 14 days) but the medical record does not show that the attending physician or prescribing practitioner evaluated the resident for the appropriateness of the new order for the medication.

PROCEDURES: §483.45(d) Unnecessary drugs and §§483.45(c)(3) and (e) Psychotropic Drugs Investigating Concerns Related to Medication Regimen Review, Unnecessary Medications, and Psychotropic Medications

Use the Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element (CE) Pathway along with the interpretive guidelines when determining if the facility meets the requirements for, and when investigating concerns related to, Medication Regimen Review, Unnecessary Medications, and Psychotropic Medications.

Review the medications (prescription, over-the-counter medications, and nutritional supplements such as herbal products) currently ordered and/or discontinued by the prescriber at least back to the most recent signed recapitulation of all medications. Obtain a copy of the current orders if necessary. Gather information regarding the resident's mental, physical, functional, and psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. Symptoms and signs described in the table may also be related to a resident's condition or disease. The surveyor may seek clarification about the basis of specific signs and symptoms from the attending physician and/or pharmacist

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	**REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT**
Determine if the resident has been transferred to acute care since the last survey and/or has recently (e.g., the previous 3 months) experienced a change in condition or currently has signs and symptoms, such as: • Anorexia and/or unplanned weight loss, or weight gain • Apathy • Behavioral changes, unusual patterns (including increased *expressions or indications of distress*, social isolation or withdrawal) • Bleeding or bruising, spontaneous or unexplained • Bowel dysfunction including diarrhea, constipation and impaction • Dehydration, fluid/electrolyte imbalance • Depression, mood disturbance	Review the record (including the care plan, comprehensive assessment, and other parts of the record as appropriate) to determine whether it reflects the following elements related to medication management for the resident: • Clinical indications for use of the medication • *Implementation* of *person-centered*, non-pharmacological *approaches to care* • Dose, including excessive dose and duplicate therapy • Duration, including excessive duration • Consideration of potential for tapering/GDR or rationale for clinical contraindication

Interview the resident, his or her family, and representative(s) and the IDT, as needed to gather information about use of medications in the nursing home.

NOTE: This review is not intended to direct medication therapy. However, surveyors are expected to review factors related to the implementation, use, monitoring, and documentation of medications.

The surveyor is not expected to prove that an adverse consequence was directly caused by a medication or combination of medications, but rather that there was a failure in the care process related to considering and acting upon such possibilities.

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the medication regimen, it is recommended that the facility's staff

have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Examples of some of the related requirements that may be considered when *concerns have* been identified include the following:

- 42 CFR 483.*10(g)(14), F580,* Notification of Changes
  - Review whether the facility contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or if the resident has not responded to medication therapy as anticipated and/or indicated.
- 42 CFR 483.10 (*c*), *F552, Planning and Implementing Care*
  - Determine whether the resident was advised of her/his medical condition and therapy and was informed about her/his treatment including medications and the right to refuse treatments.
- 42 CFR 483.24(c), F679, Activities
  - Review whether the facility provides activities that address a resident's needs and may permit discontinuation or reduction of psychotropic medications. Review also whether adverse consequences of medications interfere with a resident's ability to participate in activities.
- 42 CFR 483.24(*a*), *F676, Activities of Daily Living*
  - Review whether the facility had identified, evaluated, and responded to a new or rapidly progressive decline in function, development or worsening of movement disorders, increased fatigue and activity intolerance that affected the resident's ADL ability in relation to potential medication adverse consequences.
- 42 CFR 483.*40, F740, Behavioral Health Services*
  - Review whether the facility had identified, evaluated, and responded to a change in behavior and/or psychosocial changes, including depression or other mood disturbance, distress, restlessness, increasing confusion, or delirium in relation to potential medication adverse consequences.
- 42 CFR 483.*30(a), F710,* Physician Supervision
  - Review if the attending physician supervised the resident's medical treatment, including assessing the resident's condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.
- 42 CFR 483.*30(b), F711,* Physician Visits *and 42 CFR 483.30(c), F712, Frequency of Physician Visits*
  - Review if the attending physician or designee reviewed the resident's total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.
- 42 CFR 483.*70(h), F841,* Medical Director
  - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.

F759 Medication Errors.

The facility must ensure that its—

(1) Medication error rates are not 5 percent or greater; and

(2) Residents are free of any significant medication errors**.**

DEFINITIONS "Medication Error" means the observed or identified 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; or
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 below. Significance may be subjective or relative depending on the individual situation and duration, e.g., constipation that is unrelieved because an ordered laxative is omitted for one day, resulting in a medication error, may cause a resident slight discomfort or perhaps no discomfort at all. However, if this omission leads to constipation that persists for greater than three days, the medication error may be deemed significant since constipation that causes an obstruction or fecal impaction can directly 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 F759. 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 systemic problems exist. The survey team should consider investigating additional potential noncompliance issues, such as F755– Pharmacy Services, related to the facility's medication distribution system.

NOTE: Significant and non-significant medication errors observed at 5% or greater during the Medication Administration Observation task should be cited at F759. However, any

significant medication error, whether or not the error rate is 5% or greater, should be cited at F760.

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 diuretic (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, such as with strict intake and output measurement, daily weights, or monitoring of lab values, 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 include: phenytoin (Dilantin), carbamazepine (Tegretol); warfarin (Coumadin); digoxin (Lanoxin); theophylline (TheoDur); lithium salts (Eskalith, Lithobid); and
- Frequency of Error -If an error is occurring repeatedly, there may be more reason to classify the error as significant. For example, if a resident's medication was omitted several times, it may be appropriate, depending on consideration of resident condition and medication categor, to classify that error as significant. (See Dose Reconciliation Technique to the Observation Technique below).

Significant medication errors are cited at F760 in the following circumstances:

- When the surveyor observes a significant medication error during a medication preparation and/or administration (regardless of whether the overall facility error rate is 5% or greater);
- When the surveyor identifies a significant medication error(s) during the course of a resident record review.

While observation is the preferred method for citing medication errors, the surveyor may identify medication errors based on evidence from other sources, such as documentation of a change in the resident's condition determined to be due to medication errors, reports from family members that medication was given incorrectly and investigation supports that a medication error occurred, or discrepancies in the MAR that lead to identification of a medication error. The surveyor 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 review other relevant documents. Surveyors should evaluate whether past non-compliance exists using the survey protocol.

Medication errors identified through methods other than observation are not counted in the medication pass observation and not cited at F759, but, any significant medication errors would be cited at F760 if evidence supports the citation.

Examples of Significant and Non-Significant Medication Errors

Some of the error examples are identified as significant. This designation is based on accepted clinical standards of practice without regard to the status of the resident because these error examples show 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, actual or potential resident response to the error, and frequency of error could cause such errors to be classified as significant.

Medication error examples include (see regulations for more detail):Omission of medication administration

1. Medication administered without an order
2. Incorrect medication administered
3. Medication given in the wrong
    a. Dose
    b. Time
    c. Route
    d. Dosage form
4. Failure to follow manufacturers specifications or accepted professional standards
5. Failure to shake well or mix a suspension

Crushing Medications and Administering Medications via Feeding Tube
The crushing of tablets or capsules for which the manufacturer instructs to "do not crush" requires further investigation by the surveyor. 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 peer-reviewed health journal to justify why modification of the dosage form will not compromise resident care.

The standard of practice is that crushed medications should not be combined and given all at once, either orally (e.g., in pudding or other similar food) or via feeding tube. Crushing and combining medications may result in physical and chemical incompatibilities leading to an altered therapeutic response, or cause feeding tube occlusions when the medications are administered via feeding tube. Additionally, a resident may not want or may be unable to finish eating the food into which combined crushed medications were added or the resident's feeding tube could malfunction, all of which could prevent complete administration of the crushed medications. In these situations, staff would not know which medications the resident actually received because they were crushed and combined but not fully administered.

If the surveyor observes medications being crushed and combined, then the number of errors would be equal to the number of medications crushed whether the medications are to be administered orally or via feeding tube. For example, if four medications were crushed and added altogether to

applesauce or combined to be administered all at once via feeding tube, then four errors have occurred before the medications have been administered.

Flushing between each medication is also standard of practice and the lack of flushing between each medication is equivalent to combining medications, regardless of whether the medication is in crushed or liquid form, as it may result in physical and chemical incompatibilities leading to an altered therapeutic response, or cause feeding tube occlusions. If the surveyor observes that the nurse did not flush a feeding tube between each crushed or liquid medication, then the number of errors would be equal to the number of medications administered without the lack of appropriate flushing.

A facility is not required to flush the tubing between each medication 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 between crushed medications and administration of medications.

Before giving medications via feeding tube, the placement of the feeding tube should be confirmed in accordance with the facility's policy based on current standards of practice. Concerns related to placement and function of the feeding tube should be evaluated under the requirements at §483.25(g)(4)-(5), F693, Enteral Nutrition.

Lastly, the administration of enteral nutrition formula and administration of phenytoin (Dilantin) must be separated to minimize interaction, according to drug and enteral formula manufacturer recommendations. The surveyor should consider the simultaneous administration of phenytoin and enteral nutrition formula as a medication error.

NOTE: Additional information related to administering medications via feeding tube may be found in ASPEN Safe Practices for Enteral Nutrition Therapy at https://www.ismp.org/tools/articles/ASPEN.pdf (2009) and http://pen.sagepub.com/content/early/2016/11/09/0148607116673053.full.pdf (2016). References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

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. Taking medications with inadequate fluid may interfere with the medication working properly. Most medications can be taken with water, but there are exceptions, as further explained below. If the resident declines to take adequate fluid, the facility is not 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. Additionally, the surveyor should look for evidence that the IDT considered other medication options or routes of administration for residents who decline to take adequate fluids or who are fluid restricted. For example, the surveyor would 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); Alendronate—should be taken with 6-8 ounces of plain water only.
- 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.

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 older individuals living with multiple diagnoses are at greater risk of gastritis and GI bleeds. Determine if the time of administration takes into account the need to give the medication with food.

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 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. The exception to this would be vitamins and minerals which are generally considered a category of dietary supplements. Medication errors involving vitamins and/or minerals should be documented at F759 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 F760 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 Administered into the Eye

Facility staff must follow the manufacturer's product information for administration instructions. Facility staff must verify the eye(s) into which eye medication will be administered. When observing

the administration of eye drops, confirm that the medication makes full contact with the lower conjunctival sac, so that the medication is washed over the eye when the resident closes eyelid; the eye drop(s) should not fall onto the cornea and the tip of the eye drop bottle should not touch any portion of the eye. The eye drop must contact the eye for a sufficient period of time before the next eye drop is administered. The time for optimal eye drop absorption is approximately 3 to 5 minutes. Systemic effects of eye medications may be reduced if the nurse or resident presses the tear duct for one minute after eye drop administration or gently closes the eye for approximately three minutes after the administration. For additional information related to administration of eye drops, see http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Libraries/NEWWEBSITE-LOGOeyedropinstruction_orig_HI.pdf and http://journals.lww.com/nursing/Citation/2007/05000/Administering_eyedrops.14.aspx

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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.

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*(s)* 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 an isolated failure to administer the medication because the resident is unable to understand the procedure (for example, a resident with dementia), this should not be counted as a medication error. The surveyor would evaluate the facility's responsibility to assess the resident's circumstance, and possibly attempt other dosage forms such as oral dosage forms or nebulizers. If the facility staff repeatedly fail to administer the inhaler due to circumstances related to the resident's condition, then the surveyor would cite a medication error. The surveyor should look for evidence of staff communication with the prescriber and/or the **consultant pharmacist** to address inability to administer a resident's medication(s) as prescribed. The surveyor should also investigate appropriate tags related to the circumstances which prevent the administration of an inhaler or other medication(s), such as care of residents with dementia.

For concerns related to care of residents with dementia, the surveyor should also consider the requirements at §483.40 Behavioral Health Services.

Determining Medication Errors

Timing Errors

If a medication is prescribed before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a medication is prescribed PC and is given AC, count as a medication error. Count a wrong time error if the medication is administered 60 or more 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.

Residents have the right to choose health care schedules consistent with their interests and preferences, and the nursing home should gather this information in order to be proactive in assisting residents to fulfill their choices. The adjustment of medication administration times, to meet the individual needs and preferences of residents, must be considered by the nursing home. However, medication administration scheduling must still consider physician prescription, manufacturer's guidelines, and the types of medication, including time-critical medications. Some medications require administration within a narrow window of time to ensure resident safety or achieve a therapeutic effect while other medications are not affected by a more flexible schedule. Additionally, a facility may, for example, set up a medication ordered twice a day (BID) on a different schedule for one resident than for another resident, based upon individual preferences.

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 a dose of medication that is ordered but not given *(omitted)*. If a surveyor detects an omitted dose, *investigate the omission further through interviews with the responsible person(s) (and/or his/her supervisor) and all relevant individuals if a medication cart is shared.* 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.

F761 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.

Storage of Drugs and Biologicals

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.
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 : The intent of this requirement is that the facility, in coordination with the licensed pharmacist, provides for:

1. Accurate labeling to facilitate consideration of precautions and safe administration, of medications; and
2. 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.

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).

F880 Infection Control

This section is highly abbreviated for our purposes. See regulations for specific details.

INFECTION CONTROL POLICIES AND PROCEDURES
The facility must develop and implement written policies and procedures for the provision of infection prevention and control. The facility administration and medical director should ensure that current standards of practice based on recognized guidelines are incorporated in the resident care policies and procedures. These IPCP policies and procedures must include, at a minimum:

1. As necessary, and at least annually, review and revision of the IPCP based upon the facility assessment (according to 483.70(e)) which includes any facility and community risk;
2. An ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;
3. When and to whom possible incidents of communicable disease or infections should be reported within the facility;
4. Which communicable diseases are reportable to local/state public health authorities;
5. How to use standard precautions and how and when to use transmission-based precautions (i.e., contact precautions, droplet precautions, airborne isolation precautions). The areas described below are part of standard and transmission-based precautions40 which are further described under their respective sections. For example:
    a. Hand hygiene (HH) (e.g., hand washing and/or ABHR): consistent with accepted standards of practice such as the use of ABHR instead of soap and water in all clinical situations except when hands are visibly soiled (e.g., blood, body fluids), or after caring for a resident with known or suspected Clostridium (C.) difficile or norovirus infection during an outbreak, or if infection rates of C. difficile infection (CDI) are high; in these circumstances, soap and water should be used;

       NOTE: According to the CDC, strict adherence to glove use is the most effective means of preventing hand contamination with C. difficile spores as spores are not killed by ABHR and may be difficult to remove even with thorough hand washing.

For further information on appropriate hand hygiene practices see the following CDC website: http://www.cdc.gov/handhygiene/providers/index.html

b. The selection and use of PPE (e.g., indications, donning/doffing procedures) and the clinical conditions for which specific PPE should be used (e.g., CDI, influenza);
c. Addressing the provision of facemasks for residents with new respiratory symptoms;

6. Addressing resident room assignment (e.g. single/private room/cohorted) as appropriate and/or available, based on a case by case analysis of the presence of risk factors for increased likelihood of transmission (e.g., uncontained drainage, stool incontinence);
7. The process to manage a resident on transmission-based precautions when a single/private room is not available;
8. Limiting the movement of a resident with a highly infectious disease (e.g., norovirus, CDI) who is on transmission-based precautions with active symptoms (e.g., resident has diarrhea, vomiting, draining wounds, or other uncontained excretions or secretions) while outside of his/her room for medically necessary purposes only; and
9. Respiratory Hygiene/Cough Etiquette[40]: Implementing policies and procedures would include providing resources and instructions for performing HH in or near lobby areas or entrances; provide conveniently-located dispensers of ABHR and supplies for hand washing where sinks are available. During times of increased prevalence of respiratory infections in the community, facilities must have facemasks available and should offer facemasks to coughing or sneezing visitors and other symptomatic persons (e.g., family who accompany ill residents upon entry to the facility). Symptomatic (e.g., coughing) visitors should wear a facemask or maintain at least a three foot separation from others in common areas (e.g., admitting office). In addition, the facility should consider posting signs in the facility with instructions to family/visitors with symptoms of respiratory infection to cover their mouth/nose when coughing or sneezing; use and dispose of tissues; perform hand hygiene after contact with respiratory secretions; and to take appropriate precautions if they are having symptoms of respiratory infection or other communicable diseases.

• Resident Care Activities:

1. The use and care of urinary catheters, which must include a written rationale for the use, consistent with evidence-based guidelines (e.g., acute urinary retention, bladder outlet obstruction, neurogenic bladder or terminally ill for comfort measures) (Refer to §483.25(e)(2)(i)(ii)&(iii) Incontinence, F690, for further information.);
2. Wound care, fecal/urinary incontinence care, and skin care. Since the IPCP must be based on the facility assessment, the presence of certain resident conditions would require that the facility have policies and procedures related to other specific services such as mechanical ventilation, infusion therapy, and/or dialysis either onsite or at an offsite dialysis facility;
3. Performing fingersticks and point-of-care testing (e.g., assisted blood glucose monitoring) to the extent identified as a resident need based on the facility assessment;
4. Preparation, administration, and care for medications administered by injection or peripheral and central venous catheters, if performed by the facility; and
5. Use and care of peripheral and central venous catheters, if performed by the facility.

STANDARD PRECAUTIONS

Standard precautions represent the infection prevention measures that apply to all resident care, regardless of suspected or confirmed infection status of the resident, in any setting where healthcare

is being delivered. These evidence-based practices are designed to protect healthcare staff and residents by preventing the spread of infections among residents and ensuring staff do not carry infectious pathogens on their hands or via equipment during resident care. As mentioned in the definitions section, standard precautions include hand hygiene, use of PPE (e.g., gloves, gowns, facemasks), respiratory hygiene and cough etiquette, safe injection practices, and safe handling of equipment or items that are likely contaminated with infectious body fluids, as well as cleaning and disinfecting or sterilizing of potentially contaminated equipment.

In order to perform hand hygiene appropriately, soap, water, ABHR, and a sink should be readily accessible in appropriate locations including but not limited to resident care areas, and food and medication preparation areas. Staff must perform hand hygiene (even if gloves are used):

1. Before and after contact with the resident;
2. Before performing an aseptic task;
3. After contact with blood, body fluids, visibly contaminated surfaces or after contact with objects in the resident's room;
4. After removing personal protective equipment (e.g., gloves, gown, facemask);
5. After using the restroom; and
6. Before meals.

The facility must prevent infections through indirect contact transmission. This requires the decontamination(i.e., cleaning and/or disinfecting an object to render it safe for handling) of resident equipment, medical devices, and the environment. Alternatively, the facility may also consider using single-use disposable devices or designating reusable equipment for only an individual resident. **NOTE**: Refer to the CDC website for information on environmental cleaning -https://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

The facility must identify the decontamination method based upon the risk of infection to the resident coming into contact with equipment or medical devices. Equipment or items in the resident environment likely to have been contaminated with infectious fluids or other potentially infectious matter must be handled in a manner so as to prevent transmission of infectious agents, (e.g., wear gloves for handling soiled equipment and properly clean and disinfect or sterilize reusable equipment before use on another resident).

F881 Prevention and Control program.

The facility must establish an infection prevention and control program (IPCP) that includes antibiotic use protocols and a system to monitor antibiotic use.

INTENT
The intent of this regulation is to ensure that the facility:

1. Develops and implements protocols to optimize the treatment of infections by ensuring that residents who require an antibiotic, are prescribed the appropriate antibiotic;
2. Reduces the risk of adverse events, including the development of antibiotic-resistant organisms, from unnecessary or inappropriate antibiotic use; and
3. Develops, promotes, and implements a facility-wide system to monitor the use of antibiotics.

GUIDANCE
As part of their IPCP programs, facilities must develop an antibiotic stewardship program that promotes the appropriate use of antibiotics and includes a system of monitoring to improve resident outcomes and reduce antibiotic resistance. This means that the antibiotic is prescribed for the correct indication, dose, and duration to appropriately treat the resident while also attempting to reduce the development of antibiotic-resistant organisms.

Nursing home residents are at risk for adverse outcomes associated with the inappropriate use of antibiotics that may include but are not limited to the following:

1. Increased adverse drug events and drug interactions (e.g., allergic rash, anaphylaxis or death);
2. Serious diarrheal infections from C. difficile;
3. Disruption of normal flora (e.g., this can result in overgrowth of Candida such as oral thrush); and/or
4. Colonization and/or infection with antibiotic-resistant organisms such as MRSA, VRE, and multidrug-resistant GNB.

NOTE: The Centers for Disease Control and Prevention (CDC) has identified core actions to prevent antibiotic resistance within the control of the nursing home. For more information, refer to CDC NH Core Elements at: http://www.cdc.gov/longtermcare/pdfs/core-elements-antibiotic-stewardship-appendix-a.pdf

NOTE: For examples of antibiotic use protocols, policies and practices developed by the Agency for Healthcare Research and Quality, see: http://www.ahrq.gov/nhguide/index.html

NOTE: References to non-U. S. Department of Health and Human Services (HHS) sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Antibiotic Stewardship Program
As summarized by the CDC, the core elements for antibiotic stewardship in nursing homes include:

1. Facility leadership commitment to safe and appropriate antibiotic use;
2. Appropriate facility staff accountable for promoting and overseeing antibiotic stewardship;
3. Accessing pharmacists and others with experience or training in antibiotic stewardship;
4. Implement policy(ies) or practice to improve antibiotic use;
5. Track measures of antibiotic use in the facility (i.e., one process and one outcome measure);
6. Regular reporting on antibiotic use and resistance to relevant staff such as prescribing clinicians and nursing staff; and
7. Educate staff and residents about antibiotic stewardship.

The facility must develop an antibiotic stewardship program which includes the development of protocols and a system to monitor antibiotic use. This development should include leadership support and accountability via the participation of the medical director, consulting pharmacist, nursing and administrative leadership, and individual with designated responsibility for the infection control program if different.

The antibiotic stewardship program protocols shall describe how the program will be implemented and antibiotic use will be monitored, consequently protocols must:

1. Be incorporated in the overall infection prevention and control program;
2. Be reviewed on an annual basis and as needed;
3. Contain a system of reports related to monitoring antibiotic usage and resistance data. Examples may include the following:
    a. antibiotic use from pharmacy data, such as the rate of new starts, types of antibiotics prescribed, or days of antibiotic treatment per 1,000 resident days;
    b. Summarizing antibiotic resistance (e.g., antibiogram) based on laboratory data from, for example, the last 18 months; and/or
    c. Tracking measures of outcome surveillance related to antibiotic use (e.g., C. difficile, MRSA, and/or CRE).
    d. Incorporate monitoring of antibiotic use, including the frequency of monitoring/review. Monitor/review when the resident is new to the facility; when a prior resident returns or is transferred from a hospital or other facility [63]; during each monthly medication regimen review when the resident has been prescribed or is taking an antibiotic, or any antibiotic regimen review as requested by the QAA committee. In addition, establish the frequency and mode or mechanism of feedback (e.g., verbal, written note in record) to prescribing practitioners regarding antibiotic resistance data, their antibiotic use and their compliance with facility antibiotic use protocols. [63] Feedback on prescribing practices and compliance with facility antibiotic use protocols may include information from medical record reviews for new antibiotic starts to determine whether the resident had signs or symptoms of an infection; laboratory tests ordered and the results; prescription documentation including the indication for use (i.e., whether or not an infection or communicable disease has been documented), dosage and duration; and clinical justification for the use of an antibiotic beyond the initial duration ordered such as a review of laboratory reports/cultures in order to determine if the antibiotic remains indicated or if adjustments to therapy should be made (e.g., more narrow spectrum antibiotic);
    e. Assess residents for any infection using standardized tools and criteria (e.g., SBAR tool for urinary tract infection (UTI) assessment [67], Loeb minimum criteria for initiation of antibiotics); and
    f. Include the mode (e.g., verbal, written, online) and frequency (as determined by the facility) of education for prescribing practicitioners and nursing staff on antibiotic use (stewardship) and the facility's antibiotic use protocols. **NOTE:** Prescribing practitioners can include attending

physicians and non-physician practitioners (NPP) (i.e., nurse practitioners, clinical nurse specialists, and physician assistants).

The Antibiotic Stewardship Program in Relation to Pharmacy Services
The assessment, monitoring, and communication of antibiotic use shall occur by a licensed pharmacist in accordance with §483.45(c), F756, Drug Regimen Review. A pharmacist must perform a medication regimen review (MRR) at least monthly, including review of the medical record and identify any irregularities, including unnecessary drugs.

INVESTIGATIVE SUMMARY
Surveyors should use the Infection Control Facility Task to assess for compliance with the antibiotic stewardship program during the standard survey.

Antibiotic Stewardship Review
Determine whether the facility's antibiotic stewardship program includes antibiotic use protocol(s) addressing antibiotic prescribing practices (i.e., documentation of the indication, dose, and duration of the antibiotic; review of laboratory reports to determine if the antibiotic is indicated or needs to be adjusted; an infection assessment tool or management algorithm is used when prescribing) and a system to monitor antibiotic use (i.e., antibiotic use reports, antibiotic resistance reports).

Specific Concerns That May Warrant Further Investigation
If concerns have been identified, it may be necessary to conduct record reviews of one (or more) residents receiving antibiotics to identify whether the documented indication for the use of the antibiotic, dosage, and duration is appropriate. It may also be necessary to interview the appropriate person, (e.g., director of nursing, medical director, consulting pharmacist, administrator, or infection preventionist) to verify how antibiotic use is monitored in the facility. Furthermore, review records including evidence of actions taken by the QAA committee related to antibiotic use and stewardship.