F605

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.10(e) Respect and Dignity.
The resident has a right to be treated with respect and dignity, including:

§483.10(e)(1) 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, consistent with §483.12(a)(2).

§483.12
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.

§483.12(a) The facility must—

§483.12(a)(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are 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 person to attain and maintain his/her highest practicable well-being in an environment that prohibits the use of chemical restraints:

- For discipline or convenience; and
- Not required to treat a resident's medical symptoms.

When a medication is indicated to treat a medical symptom, the facility must:
- Use the least restrictive alternative for the least amount of time;
- Provide ongoing re-evaluation of the need for the medication; and
- Not use the medication for discipline or convenience.

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.

DEFINITIONS
"**Chemical restraint**" is defined as any drug that is used for discipline or staff convenience and not required to treat medical symptoms.

"**Convenience**" is defined as the result of any action that has the effect of altering a resident's behavior such that the resident requires a lesser amount of effort or care, and is not in the resident's best interest.

"**Discipline**" is defined as any action taken by facility staff for the purpose of punishing or penalizing residents.

"**Indication for use**" is defined as 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.

"**Medical symptom**" is defined as an indication or characteristic of a medical, physical or psychological condition.

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.

INVESTIGATIVE PROTOCOL FOR CHEMICAL RESTRAINTS USE

Use this protocol to investigate whether the facility is using a medication as a chemical restraint when:

- An allegation of use of a chemical restraint is received; or
- The survey team determines noncompliance with F757 and/or F758, and the resident was or is receiving an unnecessary medication that restricts movement, or sedates or subdues the resident

NOTE: If the survey team identifies an unnecessary medication that is acting as a chemical restraint (sedating or subduing a resident), the noncompliance is cited at F605 – Chemical Restraints and not cited at F757 – Unnecessary Medications. Both tags shall not be cited for the same noncompliance.

PROCEDURES

The survey team must first use the Interpretive Guidance (Refer to F757 and F758) and Critical Element Pathway for Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review (Form CMS-20082) to determine whether the medication is used to treat a medical symptom.

Review the assessment, care plan, practitioner orders, and consulting pharmacist reviews to identify facility interventions and to guide observations to be made. Corroborate observations by interview and record review.

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.

Observation
Record observations regarding any potential environmental causes of distress to the resident, such as staffing levels, over stimulating noise or activities, under stimulating activities, lighting, hunger/thirst, physical aggression leading to altercations, temperature of the environment, and crowding. In addition, observe for any alteration to the resident's customary location or daily routine.

Record any visible physical and psychosocial reaction to the potential use of a medication, such as:

- Drowsiness, somnolence, excessive sedation, and hallucinations;
- Neurologic consequences such as akathisia, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia; and/or
- Confusion, agitation, anxiety, nervousness;
- Social isolation, withdrawal, loss of self-esteem; and/or
- Lack of participation in individualized activities, according to the resident's care plan.

Interviews
Interview the resident, and/or resident representative, to the degree possible, to identify:

- Prior to administration of the medication:
    - Whether other interventions have been attempted; if so, what alternatives; and what the response was;
    - Whether staff provided information regarding why the medication was being used;
    - The risks and/or benefits of using the medication; and
    - When and for how long the medication was going to be used.
- Who requested the medication to be used and why;
- Describe the effect of the medication on the resident's functioning, participation in individual and/or group activities, and how it makes them feel; and
- Describe any changes in the resident's ability to understand, sleeping patterns, or social involvement since receiving the medication.

Interview direct care staff and/or licensed personnel (e.g. nursing, social worker), as appropriate, on various shifts that provide care to the resident to determine:

- Why the medication is being administered and what effect (physical and/or psychosocial) it has on the resident;

- Depending on whether distressed behavior is expressed, how do staff respond and what individualized, person-centered interventions are attempted;
- Prior to administration of the medication, whether other interventions have been attempted; if so, what alternatives; and how the interventions met or failed to meet the resident's needs;
- How long the medication has been administered, and when it began;
- Prior to administration of the medication, what is determined to be the underlying cause(s) of the medical symptom that is being treated; how is the cause(s) treated;
- Who and how the facility monitors for adverse consequences related to the administration of the medication;
- How is it determined that the medical symptom is no longer present and who determines this;
- If the medication continues to be administered and the medical symptom is no longer present, what is the clinical rationale for continuing the use of the medication and where is this documented;
- How staff are assigned to monitor, care for, and be familiar with residents' behaviors (e.g., the number, location, and consistency of staff assigned across different shifts/units);
- Who supervises the overall delivery of care to the residents to assure care planned interventions are implemented and how supervision occurs (to assure that a chemical restraint is not used for staff convenience); and
- Whether staff have discussed concerns with the Director of Nurses and Administrator regarding the behavioral symptoms of specific residents and the monitoring of interventions, and whether staff have requested more resources or changes to resident assignments, and the response to the concerns.

Interview the practitioner regarding concerns identified during the investigation, including when the staff contacted him/her, what concerns they identified regarding the resident's 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.

Interview the social worker to determine any patterns of behaviors that may impact the resident's safety or care provided, whether he/she was aware of interventions attempted, how attempts met or did not meet the resident's needs, whether he/she was aware of what medications are administered to the resident, whether he/she has identified any changes in the

resident's behavior or activity level after administration of the medication, and why he/she believes the medication is being administered.

Interview the Director of Nurses to identify his/her knowledge regarding the behavioral symptoms of specific residents and the monitoring of interventions. Also, interview the Director of Nurses and Administrator to identify whether staff have requested more resources or changes to resident assignments, and the response to the concerns.

Record Review

Review the assessment, care plan, practitioner orders, progress notes, and consulting pharmacist reviews. Determine whether there was a decline in the resident's functional and/or psychosocial status related to the medication that was administered. If so, the surveyor must determine whether the decline can be attributed to disease progression or administration of an unnecessary medication. Determine if documentation in the resident's record reflects:

Prior to administration of the medication, whether other interventions have been attempted; if so, what alternatives; and how the interventions met or failed to meet the resident's needs;

- Prior to administration of the medication, whether the facility identified, to the extent possible, and addressed the underlying cause(s) of the medical symptom;
- Indication for use for the medication(s), including the medical symptom(s) being treated;
- Whether the record reflects any adverse consequences after administration of the medication;
- Whether the record reflects whether there was a change in functioning and/or activity after administration of the medication;
- If a medication used to treat medical symptoms was appropriate at one time, determine if it was discontinued once it was no longer necessary, or if a clinical rationale to continue the medication is documented; and
- Whether the medication is administered on a PRN basis on particular days or shifts or when certain staff is caring for the resident and the symptoms for which the medication is prescribed are not documented.

Facility Review

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.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F605, the surveyor's investigation will generally show that the facility has failed, in one or more areas, to do**any one**or more of the following:

- Assure that the resident is free from restraints imposed for discipline or staff convenience (convenience can be caused intentionally or unintentionally by staff);
- Identify medical symptoms that were being treated with the use of a chemical restraint;
- If a chemical restraint is in use, the facility:
  - Provides the least restrictive alternative for the least time possible, including and as appropriate, developing and implementing a plan for gradual dose reduction, in the absence of identified and documented clinical contraindications;
  - Monitors and evaluates the resident's response to the medication; and
  - Discontinues the use of the medication when the medical symptom is no longer being treated, unless reducing or eliminating the use of the medication may be clinically contraindicated.

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

DEFICIENCY CATEGORIZATION

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

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- The facility administered a medication to a resident for staff convenience without a medical symptom identified. The resident was admitted to a secured area of the facility two months prior to the survey. During observations the resident was observed lying in a reclining chair, sleeping and staff had difficulty arousing the resident for meals. The staff had to provide one to one assistance to assist the resident to eat. The resident was unable to hold the utensils, and was being fed a pureed meal. The resident required a two-person assist to transfer from bed to chair and required total assistance for activities of daily living. The resident's record revealed that on admission, the resident was independent in mobility and ambulation and did not require assistance to eat. Staff interviewed stated that they had difficulty monitoring the resident as they were taking care of other residents. They stated that there were no identified interventions or activities to address these behaviors. As a result, staff requested a medication from the physician for the wandering behavior. The physician was interviewed and stated that the medication was being administered for wandering, but that he was not aware that the resident was sedated and the resident's decline in walking and activities of daily living. There was no other evidence in the resident's record or from interviews with staff and the physician that indicate a medical reason for the decline and sedating effect.

- The facility failed to assure that a medication it administered to a resident was being used to treat a medical symptom and not for staff convenience. The resident was admitted for post-surgical rehabilitation of a fractured hip. During an interview, the resident's representative stated that prior to admission, the resident had been alert, was able to recognize her family members, was used to sitting with the family after the evening meal at home, and, although pleasantly confused, enjoyed a warm bath prior to bedtime and slept through the night. However, after admission, there had been a significant change in the resident's status. The resident's record reflected that the resident, after admission, was immediately put to bed after the evening meal every day; subsequently, the resident began yelling out for help, wanted to get out of bed, and disrupted other residents' sleep. During an interview with the practitioner, staff had contacted him and requested an antipsychotic medication to keep the resident quiet during the night hours as she was disruptive and agitated. The practitioner ordered an antipsychotic medication twice a day, but did not provide documentation of a medical symptom being treated with the medication. Observations throughout the survey revealed the resident seated in a wheelchair, subdued or sleeping, sucking on her hand, mumbling to self, and not aware of surroundings or visitors. Staff interviewed corroborated that there had been a decline in the resident's condition since the administration of the medication. Due to the significant change in the resident's status related to the initiation and use of a chemical restraint, serious harm occurred to the resident.

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include, but is not limited to:

- The facility administered a medication that was not being used to treat medical symptoms, the facility did not attempt any less restrictive interventions, and the medication was used for the convenience of staff. As a result of this noncompliance, the resident was sedated into the morning hours. The resident was unable to be aroused

sufficiently to eat breakfast in the dining room where he normally eats meals, and now required assistance by staff to eat breakfast. The resident was observed to attend and participate in his other meals and activities for the rest of the day. The record did not indicate any falls or any decline in other activities of daily living. The resident, diagnosed with Alzheimer's disease, had displayed night time behaviors that frustrated other residents and nursing staff, such as wandering into other resident's rooms, and rummaging through drawers and closets. To address the resident's behavior, staff contacted the attending physician to discuss the issue and request a long-acting anti-anxiety medication. No other attempts of non-pharmacological interventions were identified or implemented prior to the use of the chemical restraint. Staff stated that they did not have the time to implement other interventions. The resident's record did not indicate a medical symptom being treated, nor a reduction of the medication when the resident's functional status declined.

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

- The facility failed to assure that an antianxiety medication was being administered to treat a medical symptom and not for the convenience of staff. Although the resident has not experienced falls or other adverse consequences in relation to the administration of the medication, the potential exists for more than minimal harm with the continued use of the anti-anxiety medication in the absence of a medical symptom. Interviews and record review revealed that the facility was giving a resident anti-anxiety medication prior to the resident taking showers occasionally on weekends. Staff indicated that the resident had occasionally declined showers not because she was anxious, but because she found bed baths to be more relaxing than the shower environment. The staff interviewed stated that the nurse aides, who worked the daytime weekend shift, were upset about the resident refusing the shower as they did not have time to come back and shower the resident at another time not realizing that this was not the resident's preference. The weekend nurse contacted the physician for a medication to alleviate the resident's "anxiety to taking a shower." A nursing assistant who was assigned to provide the resident's care during the week, stated that sometimes the resident does not want to take a shower and on those occasions, she would give the resident a bed bath. The nursing assistant said the resident is not resistive or combative.

Severity Level 1: No Actual Harm with Potential for Minimal Harm
The failure of the facility to assure residents are free from chemical restraints is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.