

# COMPLIANCE CUE

SOM

Pharmacy-Related Updates to State Operations Manual Appendix PP  
Effective 3.24.25

## BACKGROUND

On November 18, 2024, CMS released memo [QSO-25-07-NH](#), announcing major updates to surveyor guidance for multiple F-tags in the State Operations Manual (SOM) Appendix PP. These revisions reflect emerging trends in deficiency citations; most notably, the continued focus on **psychotropics**. Long-term care stakeholders will also note that the updated SOM Appendix PP revises language to align **pain management** regulations with current standards of practice and adds guidance around enhanced barrier precautions, as **infection prevention and control** measures continue to be scrutinized. It is crucial for facility leadership to familiarize themselves with these revisions, evaluate current policies and procedures for compliance with the regulatory updates, and educate staff on the changes before they go into effect on **March 24, 2025**.

## SUMMARY OF REVISIONS

### Chemical Restraints, Unnecessary Psychotropic Medications, Accuracy of Assessment, and Professional Standards

#### F757 (Free from Unnecessary Medications)

**F757** has been revised and reorganized to focus surveyor guidance on unnecessary medication use in residents and has moved language regarding unnecessary psychotropic use to be found under **F605 (Free from Chemical Restraints)**. CMS states this is to ensure each resident's medication regimen promotes mental, physical, and psychosocial well-being and to clear confusion surrounding unnecessary psychotropic use.

**F757 §483.45(d)** [The facility must ensure that] each resident's drug regimen must be free from unnecessary drugs.

An unnecessary drug is any drug when used:

- In excessive dose (including duplicate drug therapy)
- For excessive duration
- Without adequate monitoring
- Without adequate indications for its use
- In the presence of adverse consequences which indicate the dose should be reduced or discontinued
- Any combinations of the reasons listed above

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- 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 §483.12(a)(2), **F605**.
- Notably, this potentially qualifies instances of unnecessary psychotropic medication use as an abuse tag.

### **F758 (Free from Unnecessary Psychotropic Meds/PRN Use)**

**F758** has been removed from Appendix PP and previous regulations and guidance under this tag have been incorporated into and will now be cited under **F605** (Free from Chemical Restraints).

### **F605 (Free from Chemical Restraints)**

Regulations and guidance previously found under **F758** will now be cited under **F605**.

The intent of these guidance changes stems from the CMS initiative to streamline the survey process, increase consistency, and strengthen their message that facilities must prevent the unnecessary use of psychotropic medications. The guidance regarding “**convenience**” has been revised to include situations when medications are used to cause symptoms consistent with sedation and/or require less effort by facility staff to meet the resident’s needs.

Additional guidance has been added to emphasize requirements related to the right to be fully informed of and participate in or refuse treatment, noting that before initiating or increasing a psychotropic medication, the resident must be notified of and have the right to participate in their treatment, including the right to accept or decline the medication.

#### **F605**

§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.

(a)(2) [The facility must] ensure that the resident is free from chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident’s medical symptoms.

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A medication used for staff **convenience** or to discipline and is not required to treat medical symptoms, may cause:

- Sedation, such as sleeping during hours that he/she would not ordinarily sleep
- Withdrawal from activities and socializing
- Loss of autonomy and dignity
- Confusion, cognitive decline, and depression
- Weight loss, decline in skin integrity, or continence level
- Decline in physical functioning, including an increased dependence in activities of daily living.

If a medication has a sedating or subduing effect on a resident and is not being administered to treat a medical symptom, the medication is acting as a **chemical restraint**. These effects could indicate an intentional action to discipline or make care more convenient for staff or the facility did not intend to sedate or subdue a resident, but an unnecessary medication is being administered that has that effect.

Medication requirements within the Ftag apply to all four categories of traditionally held psychotropic drugs (**anti-psychotic, anti-depressant, anti-anxiety, and hypnotics**) without exception. Recognize too, that other medication classes with behavior-altering effects that are used in place of traditional psychotropic drugs (e.g., anticonvulsants) may be subject to applicable regulations by surveyors.

If psychotropic medication administration is warranted, guidance under **F605** reminds surveyors of resident's rights under **F552** (Right to be Informed/Make Treatment Decisions). Under regulations set forth through **F552**, prior to initiating or increasing doses of psychotropic medications, residents must be informed of the risks, benefits, and alternative medications. It is within the resident's rights to then either accept or decline the initiation or increase of a psychotropic medication.

To reflect the revisions made to **F605**, CMS has taken a further step by renaming the Critical Elements Pathway, which outlines investigative procedures for surveyors, to now be called the [Unnecessary Medications, Chemical Restraints/Psychotropic Medications, and Medication Regimen Review Critical Element Pathway](#) (Form CMS – 20082; pg 869).

### **F641 (Accuracy/Coordination/Certification)**

Guidance related to citing noncompliance when a concern related to documentation to support a diagnosed mental disorder, has been revised and expanded at **F605, F641** and **F658**.

**F642** has been removed from Appendix PP and previous regulations and guidance under this tag have been incorporated into and will now be cited under **F641**.

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The joining of these tags and increased surveyor focus has come after a 2022 OIG study – [Long-Term Trends of Psychotropic Drug Use in Nursing Homes](#) – found increasing numbers of unsupported schizophrenia diagnoses (residents reported as having schizophrenia per MDS but lacking corresponding diagnoses in Medicare claims and encounter data). Emphasis has been placed on providing supporting documentation of diagnoses and penalties for facilities found to be in noncompliance with these regulations.

### F658 (Services Provided Meet Professional Standards)

To further emphasize the importance of appropriate diagnosis documentation, CMS added guidance within F658 (Services Provided Meet Professional Standards) with instructions for investigating adherence to professional standards of practice when concerns arise regarding residents diagnosed with a condition without sufficient supporting documentation (for which antipsychotic medications are an approved indication). Guidance for citing noncompliance and examples were also included.

A large focus of additions within this tag are focused around supporting the DSM-5 criteria for a schizophrenia diagnosis, and what constitutes supporting documentation for treatment.

Examples of insufficient documentation to support a mental health diagnosis would include:

- A situation where schizophrenia or another diagnosis is only mentioned as an indication in medication orders without supporting documentation.
- The addition of, or request by the facility to a practitioner for, a diagnosis of schizophrenia or another diagnosis without documentation supporting the diagnosis.
- A practitioner's note or transfer summary from a previous provider stating, "history of schizophrenia," "schizophrenia," or another diagnosis without supporting documentation confirming the diagnosis with a previous practitioner or family, and the facility failed to provide evidence that a practitioner conducted a comprehensive evaluation after admission.
- A diagnosis list stating schizophrenia or another diagnosis without supporting documentation.
- A note of schizophrenia or another diagnosis in an electronic health record (EHR) without supporting documentation which populates throughout the EHR.
- A note of schizophrenia or another diagnosis in the medical record by a nurse without supporting documentation by the practitioner.

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## F841 (Responsibilities of a Medical Director)

**F841** has been revised to address the role of the medical director in the implementation of policies on diagnosing and prescribing medications, stating that the medical director is responsible for intervening when medical care is inconsistent with current accepted standards of care.

Specifically, ensuring physicians and other practitioners adhere to facility policies on diagnosing and prescribing medications and issues related to the coordination of medical care and implementation of resident care policies identified through the facility's quality assessment and assurance committee and other activities.

Medical director responsibilities must include:

- Implementation of resident care policies, such as ensuring physicians and other practitioners adhere to facility policies on diagnosing and prescribing medications and intervening with a health care practitioner regarding medical care that is inconsistent with current professional standards of care.
- Participation in the Quality Assessment and Assurance (QAA) committee or assign a designee to represent him/her. (Refer to **F868**).
- Addressing issues related to the coordination of medical care and implementation of resident care policies identified through the facility's quality assessment and assurance committee and other activities.

It is within the scope of the medical director's role to ensure facility's prescribers are adhering to clinical guidelines and are responsible for intervening when medical care is inconsistent with accepted standards of care. The addition of these amendments further highlights the CMS initiative to prevent inappropriate prescribing practices and reduce the incidences of falsified health record information.

## Pain Management

### F697 (Pain Management)

Updates to pain management guidance in the SOM Appendix PP fall under **F697**, with special attention paid to opioid use in response to the current opioid crisis, balanced against ensuring that resident pain is effectively managed.

Facilities are encouraged to conduct thorough assessments and create individualized care plans for residents prescribed opioids. Updated definitions of acute, chronic, and subacute pain from the CDC have been integrated. When initiating opioid therapy for these types of pain, clinicians are advised to initiate treatment with immediate-release opioids prior to extended-release or long-acting forms. The

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guidance also provides updated resources on opioid use and emphasizes the resident's right to be informed about the risks and benefits of the proposed treatment.

- **"Acute Pain"** refers to pain that is usually sudden in onset and time-limited with a duration of less than 1 month and often is caused by injury, trauma, or medical treatments such as surgery.
- **"Chronic Pain"** refers to pain that typically lasts greater than 3 months and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause.
- **"Subacute Pain"** refers to pain that has been present for 1–3 months.

[The Pain Recognition and Management Critical Element Pathway](#) (Form CMS – 20076; pg. 858) has been streamlined with the updated interpretive guidance. Within updated **F697** Pain Management guidance, CMS also emphasizes the importance of ensuring that residents' rights regarding pain management are upheld. Surveyors will confirm that residents are informed of the risks and benefits of their proposed treatments. If there are concerns related to informing the resident or their representative about the risks of opioid use for pain, the surveyor should refer to **F552**.

### F697

§483.25(k) 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.

## Infection Control

### F880 (Infection Prevention and Control)

**F880** has been revised to define Enhanced Barrier Precautions (EBP) and provide guidance on implementing these precautions as a preventative measure against Multidrug-resistant organisms (MDROs). MDRO transmission is common in long term care (LTC) facilities, contributing to substantial resident morbidity and mortality and increased healthcare costs. Many residents in nursing homes are at increased risk of becoming colonized and developing infections with MDROs.

### F880

#### DEFINITIONS

Enhanced Barrier Precautions (EBP) refer to an infection control intervention designed to reduce transmission of multidrug-resistant organisms that employs targeted gown and glove use during high contact resident care activities.

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## GUIDANCE

### Enhanced Barrier Precautions (EBP)

EBP are used in conjunction with standard precautions and expands the use of PPE to donning of gown and gloves during high-contact resident care activities that provide opportunities for transfer of MDROs to staff hands and clothing.

EBP are indicated for residents with any of the following:

- Infection or colonization with a CDC-targeted MDRO when Contact Precautions do not otherwise apply; or
- Wounds and/or indwelling medical devices even if the resident is not known to be infected or colonized with a MDRO.

Wounds generally include chronic wounds, not shorter-lasting wounds, such as skin breaks or skin tears covered with an adhesive bandage (e.g., Band-Aid®) or similar dressing. Examples of chronic wounds include, but are not limited to, pressure ulcers, diabetic foot ulcers, unhealed surgical wounds, and venous stasis ulcers.

Indwelling medical device examples include central lines, urinary catheters, feeding tubes, and tracheostomies. A peripheral intravenous line (not a peripherally inserted central catheter) is not considered an indwelling medical device for the purpose of EBP.

EBP should be used for any residents who meet the above criteria, wherever they reside in the facility.

Facilities have **discretion** in using EBP for residents who do not have a chronic wound or indwelling medical device and are infected or colonized with an MDRO that is not currently targeted by CDC.

For residents whom EBP are indicated, EBP is employed when performing the following high-contact resident care activities:

- Dressing
- Bathing/showering
- Transferring
- Providing hygiene
- Changing briefs or assisting with toileting
- Device care or use: central line, urinary catheter, feeding tube,
- Wound care: any skin opening requiring a dressing

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Note: In general, gowns and gloves would not be recommended when performing transfers in common areas such as dining or activity rooms, where contact is anticipated to be shorter in duration. Outside the resident's room, EBP should be followed when performing transfers or assisting during bathing in a shared/common shower room and when working with residents in the therapy gym, specifically when anticipating close physical contact while assisting with transfers and mobility.

Residents are not restricted to their rooms or limited from participation in group activities. Because EBP do not impose the same activity and room placement restrictions as Contact Precautions, they are intended to be in place for the duration of a resident's stay in the facility or until resolution of the wound or discontinuation of the indwelling medical device that placed them at higher risk.

Facilities have discretion on how to communicate to staff which residents require the use of EBP. CMS supports facilities in using creative (e.g., subtle) ways to alert staff when EBP use is necessary to help maintain a home-like environment, as long as staff are aware of which residents require the use of EBP prior to providing high-contact care activities.

Facilities should ensure PPE and alcohol-based hand rub are readily accessible to staff. Discretion may be used in the placement of supplies which may include placement near or outside the resident's room. PPE for enhanced barrier precautions is only necessary when performing high-contact care activities and may not need to be donned prior to entering the resident's room. For example, staff entering the resident's room to answer a call light, converse with a resident or provide medications **and** who do **not** engage in a high-contact resident care activity would likely not need to employ EBP while interacting with the resident.

Information regarding CDC-targeted MDROs and current recommendations on Enhanced Barrier Precautions are available on the CDC's Implementation of Personal Protective Equipment (PPE) Use in Nursing Homes to Prevent Spread of Multi-Drug-Resistant Organisms (MDROs) webpage at <https://www.cdc.gov/long-term-care-facilities/hcp/prevent-mdro/PPE.html>.

**Surveyors will evaluate the use of EBP when reviewing sampled residents for whom EBP are indicated and focus their evaluation of EBP use as it relates to CDC-targeted MDROs.**

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## STEPS TO FACILITY COMPLIANCE

- ✓ Review current policies and procedures to align with updated SOM Appendix PP regulations.
- ✓ Educate staff on areas of surveyor focus, per regulatory changes as detailed above.
- ✓ Ensure accurate diagnoses are captured at resident admission, with emphasis on supporting documentation for use of psychotropics and 'other' medications used with psychotropic intent.
- ✓ Ensure approaches to pain management align with current best practices (e.g., per CDC guidelines).
- ✓ Update infection prevention and control policies to integrate enhanced barrier precautions per updated CMS guidance.
- ✓ View [PharMerica's Illuminate Webinar](#) on February 4, 2025, to learn more about these impending changes.

## HOW PHARMERICA CAN HELP

- ✓ Consultant pharmacists may attend behavior meetings and participate in collaborative discussions with facility IDT care team.
- ✓ Consultant pharmacists remain cognizant of warning signs for over sedation (e.g., unintentional weight loss, cognitive decline, lethargy, withdrawal) during routine MRRs and Nursing Note reviews – to report and provide corrective action plans when chemical restraint potential is identified.
- ✓ Consultant pharmacists respond timely to facility requests for retrospective audits to assess facility compliance with updated regulations and provide feedback on opportunities for improvement.