Download Summary

Pharmacy Services and Psychotropic Medications: CMS SOM Appendix PP (F755, F756, F757, F605)

Pharmacy Services and Psychotropic Medications

What the CMS State Operations Manual (Appendix PP, 2025 revision) requires under F755, F756, F757, and the former F758 requirements now located at F605

This summary is written for nursing staff and for physicians, NPs, and PAs who practice in the nursing home. Each section gives the federal regulation, what the surveyor guidance says, and the practical points for each group. Blue underlined text is a clickable link.

How the links work

- **SOM guidance:** each tag heading links to the page where that tag begins in the final 2025 text, CMS Transmittal 229 (Rev. 229; issued April 25, 2025; implemented April 28, 2025). It is a 544-page PDF, so allow a moment for it to load. F755 was not revised in 2025 and is not in the transmittal, so its link opens the complete Appendix PP attached to memo QSO-25-14-NH.
- **Regulation text:** links open the exact paragraph of 42 CFR Part 483 on Cornell's Legal Information Institute, which mirrors the eCFR.
- **About F758:** F758 no longer contains requirements. The manual states that the requirements for §483.45(c)(3) and §483.45(e) have been relocated, and they are now surveyed under **F605**. The F605 section below summarizes that content where it now lives.
- **Printable version:** the PDF handout contains this summary plus the complete F605 text from the manual as an appendix.

At a glance

Tag	Title	Regulation	Covers
F755	Pharmacy Services / Procedures / Pharmacist / Records	§483.45(a), (b)(1)-(3)	Getting the right drug to the resident on time; pharmacist oversight; controlled drug records
F756	Drug Regimen Review, Report Irregularity, Act On	§483.45(c)(1), (2), (4), (5)	Monthly pharmacist review and the required response to it
F757	Drug Regimen Is Free from Unnecessary Drugs	§483.45(d)(1)-(6)	Unnecessary medications other than psychotropics
F605 (was F758)	Right to Be Free from Chemical Restraints; unnecessary psychotropics and PRN use	§483.12(a)(2); §483.45(c)(3), (d), (e)(1)-(5)	Psychotropic indications, GDR, PRN limits, chemical restraint

Regulation: , ,

What the regulation requires

- The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under agreement.
- Pharmaceutical services must include procedures that assure accurate **acquiring, receiving, dispensing, and administering** of all drugs and biologicals to meet each resident's needs.
- The facility must employ or obtain a **licensed pharmacist** who (1) consults on all aspects of pharmacy services, (2) establishes a system of records of receipt and disposition of all controlled drugs in enough detail for accurate reconciliation, and (3) determines that drug records are in order and that all controlled drugs are accounted for and periodically reconciled.
- Unlicensed personnel may administer drugs only if State law permits, and only under the general supervision of a licensed nurse.

What the surveyor guidance says

- **Timeliness is part of the requirement.** Medications must be available when needed: new admission orders, first doses, after-hours and emergency needs, and refills before supply runs out. Delays that leave a resident without an ordered medication are investigated here.
- **The pharmacist's role is broad.** Working with the facility and the medical director, the pharmacist helps develop and evaluate procedures for ordering, receiving, storing, labeling, administering, and disposing of medications; emergency supplies and automated dispensing; IV therapy; and staff education on recognizing adverse consequences.
- **Administration procedures** should address who is authorized to administer, timing of doses, correct technique (for example, medications that must not be crushed, and enteral tube administration), and documentation.
- **Controlled medications:** records must show receipt, access, usage, and disposition (including destruction, wastage, and return) in enough detail to reconcile. Reconciliation is periodic, as defined by facility procedure or whenever loss is identified, and should minimize the time between a loss and its detection. If diversion is suspected, reconciliation may need to be as frequent as daily. State or other federal requirements may set the frequency. Controlled drugs in the emergency supply must be reconciled too.
- **Loss and diversion:** discrepancies must be investigated and resolved, and suspected diversion acted on, including any required reporting. Diversion can also be cited as misappropriation of resident property.
- **Disposal** must follow State and federal requirements and prevent diversion and accidental exposure. The

guidance singles out fentanyl patches because of their boxed warnings and the substantial amount of drug remaining after removal; facility policy should specify the disposal method.

Nursing focus

- If an ordered medication is not available, notify the prescriber and pharmacy the same shift and document what was done. Do not leave the dose blank.
- Know what is in the emergency kit and how to access it after hours.
- Count controlled drugs per policy, never pre-sign or co-sign a count you did not witness, and report any discrepancy immediately.
- Dispose of controlled drugs and fentanyl patches with the required witness and documentation.
- Check before crushing or giving a medication through a feeding tube.

Physician / prescriber focus

- Admission and after-hours orders drive most timeliness citations. Order what the pharmacy can deliver, and give staff an interim plan when there will be a gap.
- Controlled-substance prescriptions must meet DEA and State requirements so the pharmacy can dispense without delay.
- Medical directors: F755 expects your involvement in pharmacy policies and procedures, including the emergency drug supply and diversion response.

Regulation:

What the regulation requires

- A licensed pharmacist must review each resident's drug regimen **at least once a month**, and the review must include the **medical chart**.
- The pharmacist must report any **irregularities** to the **attending physician, the medical director, and the director of nursing**, and the reports must be acted upon. Irregularities include, but are not limited to, any drug that meets the unnecessary drug criteria in §483.45(d).
- Irregularities must be documented on a **separate written report** that lists, at a minimum, the resident's name, the relevant drug, and the irregularity identified.
- The **attending physician must document in the medical record** that the irregularity was reviewed and what action, if any, was taken. If there is no change to the medication, the physician should document the

rationale.

- The facility must have **policies and procedures** for the monthly review that include time frames for each step and the steps the pharmacist takes when an irregularity requires urgent action to protect the resident.

What the surveyor guidance says

- The medication regimen review (MRR) is a thorough evaluation of the regimen to promote positive outcomes and minimize adverse consequences, and medication-related problems must be considered whenever a resident has a change in condition.
- **Monthly is the minimum.** Some residents need review more often, even weekly, depending on condition. Policy should address residents expected to stay less than 30 days, and residents with an acute change of condition for whom an immediate review is requested.
- The pharmacist documents either that no irregularity was found (a signed and dated statement) or the nature of each irregularity, in a separate written report that may be paper or electronic. How fast the pharmacist notifies depends on the risk: immediate notification is expected for problems such as bleeding in a resident on an anticoagulant. The findings are part of the medical record and available to the resident or representative on request.
- **The prescriber's response must be in the resident's record.** The attending either accepts and acts on the recommendation or rejects it and documents why. The guidance states it is not acceptable to document only disagreement without giving a clinical basis.
- The facility should have a procedure for resolving situations where the attending does not concur with or does not act on an identified irregularity, and where **the attending physician is also the medical director** (see also F841, §483.70).
- When the attending has documented a valid clinical rationale for rejecting a recommendation, the pharmacist does not need to re-report the same irregularity each month unless a change in the resident's condition or other circumstances warrants it.
- Surveyors investigate F756 together with F605 and F757 using one Critical Element Pathway (form CMS-20082), found in the Survey Resources download on the CMS Nursing Homes page.

Nursing focus

- Route pharmacist recommendations to the prescriber promptly and track them to closure within the policy time frame.
- Escalate an unanswered recommendation to the DON and medical director; do not file it.
- Treat an urgent irregularity like a change in condition: call the prescriber.
- Give the pharmacist what the chart may not show, such as falls, sedation, poor intake, and new behaviors.
- Request an early review for short-stay residents and acute changes of condition.

Physician / prescriber focus

- Respond to every recommendation within the facility's time frame.
- Accept or decline in the medical record. If declining, give the clinical basis: the indication, what was tried, why benefit outweighs risk, and how you are monitoring.
- Medical directors: you receive every irregularity report. If you are also the attending, the facility needs a defined way to resolve your own declined or unanswered recommendations.

Regulation: | Applies to medications other than psychotropics

What the regulation requires

Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug used (1) in **excessive dose**, including duplicate drug therapy; (2) for **excessive duration**; (3) without **adequate monitoring**; (4) without **adequate indications** for its use; (5) in the presence of **adverse consequences** which indicate the dose should be reduced or discontinued; or (6) any combination of these reasons.

What the surveyor guidance says

- **Scope:** F757 covers unnecessary medications excluding psychotropics. For concerns involving psychotropic medications, including the unnecessary-drug criteria as applied to them, surveyors are directed to F605.
- **When to re-evaluate the regimen:** at admission or re-admission, with any new or worsening change in condition, when the pharmacist identifies an irregularity, and after an emergency order once the acute problem has stabilized.
- **Indication:** the record should show why the resident is on each medication, consistent with the diagnosis, the resident's goals and preferences, and accepted standards of practice. Non-drug approaches should be considered where appropriate.
- **Dose and duplication:** doses should reflect age, renal and hepatic function, and interactions. Two drugs of the same class or effect need a documented reason. The guidance points prescribers to the AGS Beers Criteria.
- **Duration:** medications started for a time-limited problem should have a stop date or a planned reassessment. Unnecessary antibiotic prescribing is cited at F757, and the same findings may also support F881 (antibiotic stewardship).
- **Monitoring:** the facility must monitor for effectiveness and for adverse consequences using the clinical and laboratory parameters appropriate to the drug, for example INR with warfarin, glucose with insulin, renal function and electrolytes with diuretics, and pain, sedation, and bowel function with opioids.

- **Adverse consequences:** when a resident has a new or worsening problem such as falls, confusion, anorexia, weight loss, lethargy, or bleeding, the team is expected to consider medications as a possible cause before adding another drug.
- **Tapering:** residents should be monitored and re-evaluated for adverse consequences and for the need to taper or stop a medication.
- **Transitions:** the risk of polypharmacy and duplicate therapy is highest at transitions of care. Medications started in the hospital or community without a clear documented indication call for a comprehensive evaluation of whether to continue them.

Nursing focus

- Every order needs an indication the nurse can state. Ask if it is missing.
- Carry out ordered monitoring (labs, vital signs, pain and sedation scales, glucose) and report results outside parameters.
- When a resident changes, tell the prescriber which medications were started or changed recently.
- Question orders without a stop date for short-course drugs, and flag duplicates at admission reconciliation.

Physician / prescriber focus

- Document the indication for each medication and the reassessment plan for anything time limited.
- At admission and at the 30-day and annual comprehensive visits, decide for each drug: continue, reduce, or stop.
- Order the monitoring you need and document that you reviewed it.
- Before treating a new symptom with a new drug, document that you considered the current regimen as the cause.

Regulation: ; ; , , | F758 requirements relocated here |

What the regulation requires

- §483.12(a)(2): the resident must be free from chemical restraints imposed for discipline or convenience and not required to treat medical symptoms.
- §483.45(c)(3): a psychotropic drug is any drug that affects brain activities associated with mental processes and behavior, including but not limited to antipsychotics, antidepressants, anti-anxiety drugs, and hypnotics.
- §483.45(e)(1): residents who have not used psychotropic drugs are not given them unless necessary to treat a specific condition that is diagnosed and documented in the clinical record.

- §483.45(e)(2): residents who use psychotropic drugs receive **gradual dose reductions and behavioral interventions**, unless clinically contraindicated, in an effort to discontinue the drugs.
- §483.45(e)(3): no PRN psychotropic unless necessary to treat a diagnosed specific condition documented in the clinical record.
- §483.45(e)(4): PRN orders for psychotropic drugs are limited to **14 days**. If the prescriber believes a longer PRN order is appropriate, he or she should document the rationale in the medical record and indicate the duration.
- §483.45(e)(5): PRN orders for **antipsychotic** drugs are limited to 14 days and cannot be renewed unless the prescriber evaluates the resident for the appropriateness of that medication.
- The unnecessary drug criteria in §483.45(d) (dose, duration, monitoring, indication, adverse consequences) apply to psychotropics under this tag.

What the surveyor guidance says

- **One tag for both problems.** Because psychotropics can cause sedation that makes care more convenient for staff, CMS cites chemical restraint and unnecessary psychotropic use together at F605.
- **Chemical restraint is judged by effect.** "Convenience" means unnecessary administration of a medication that causes, intentionally or unintentionally, a change in behavior such as sedation, so that the resident is subdued or requires less effort from staff. "Discipline" means any action, including giving a medication, taken to punish or penalize a resident.
- **Severity:** if a medication has caused symptoms consistent with prolonged sedation that was not addressed (excessive sleeping, drowsiness, withdrawal, decreased participation in activities), noncompliance is cited at a minimum of severity level 3, actual harm.
- **Signs surveyors look for:** sleeping at times the resident would not ordinarily sleep, withdrawal from activities, confusion or cognitive decline, loss of function and greater ADL dependence, weight loss, skin breakdown, and new incontinence.
- **Other drug classes count.** Antihistamines, anticholinergics, and central nervous system agents used for conditions such as seizures, mood disorders, pseudobulbar affect, and muscle spasm are held to the psychotropic requirements when they are used in place of a psychotropic or for their effect on behavior or mental processes.
- **Indication and diagnosis:** without documentation that the practitioner has determined other treatments to be clinically contraindicated, the indication for a psychotropic is considered inadequate. Psychotropics started in the hospital or community without a clear documented indication, for example a history of schizophrenia without documentation supporting the diagnosis under DSM-5-TR, require a comprehensive evaluation of whether to continue.
- **Unsupported diagnoses and prescriber referral:** CMS states it is aware of residents given a schizophrenia diagnosis without sufficient supporting documentation. Where this causes actual harm or the likelihood of serious harm, or surveyors find a pattern (for example three or more) of the same practitioner prescribing antipsychotics for a new diagnosis lacking support, the survey team is told to consider referral to

the State Medical Board or Board of Nursing.

- **Non-pharmacological approaches first,** unless clinically contraindicated, and continued alongside any medication. The care plan should name the target behavior or symptom and the person-centered approaches being used.
- **Right to be informed:** before a psychotropic is started or increased, the resident, family, or representative must be told the benefits, risks, and alternatives, including any boxed warning for antipsychotics, and may accept or decline. The record must document this; if it does not, F552 is cited (§483.10(c)).
- **Gradual dose reduction:** time frames must be consistent with standards of practice, with reductions in modest increments over adequate periods. The guidance gives this example of compliance: within the first year after a resident is admitted on a psychotropic or after one is started, the facility attempts a GDR in **two separate quarters with at least one month between attempts**, unless clinically contraindicated. The record should show the date of each attempt, the outcome, and the plan for future attempts.
- **When GDR may be clinically contraindicated:** reasons include, but are not limited to, (1) continued use is in accordance with current standards of practice and the physician has documented why a dose reduction would likely impair function or exacerbate an underlying medical or psychiatric disorder; or (2) target symptoms returned or worsened after the most recent GDR attempt in the facility and the physician has documented why a further attempt at that time would likely impair function, exacerbate the disorder, or increase distressed behavior. Residents with enduring, progressive, or terminal conditions such as chronic depression, Parkinson's disease psychosis, or recurrent seizures may need these medications indefinitely.
- **Monitoring:** ongoing documentation of target symptoms, response, and adverse consequences such as sedation, falls, orthostasis, anticholinergic effects, movement disorders, and metabolic changes.
- **PRN use without the indication:** the guidance's deficiency examples include staff giving a PRN anxiolytic nightly to help a resident sleep without a documented indication, and a PRN psychotropic order left in place beyond 14 days.

PRN psychotropic orders: the 14-day rules

PRN order for	Time limit	To continue beyond 14 days	What must be documented
Psychotropics **other than** antipsychotics (for example lorazepam, trazodone, zolpidem, hydroxyzine for anxiety)	14 days	The order may be extended beyond 14 days.	The prescriber's rationale for the extension **and a specific duration**, in the medical record. An open-ended PRN does not comply.

PRN order for	Time limit	To continue beyond 14 days	What must be documented
Antipsychotics (for example haloperidol, quetiapine, olanzapine, risperidone)	14 days, no exceptions	The order cannot be extended. A **new** order may be written for up to 14 days only after the prescriber evaluates the resident.	The prescriber **directly examines the resident** and documents, at a minimum: Is the antipsychotic still needed on a PRN basis? What is the benefit to the resident? Have the resident's expressions or indications of distress improved because of the PRN medication?

Nursing focus

- Every PRN psychotropic order needs a diagnosis, a specific target symptom, and a stop date no later than day 14. Clarify any order that lacks one.
- Before giving a PRN: document the specific behavior or symptom and the non-drug approaches tried. Afterward: document the response.
- Track day 14. Notify the prescriber ahead of time so the order is either stopped or properly renewed.
- A PRN antipsychotic cannot be renewed on a nursing report alone. The guidance requires the prescriber to directly examine the resident.
- Report sedation, falls, reduced intake, withdrawal from activities, and new movement problems.
- Make sure the resident or representative was informed before a psychotropic was started or increased, and that it is documented.

Physician / prescriber focus

- Document the diagnosis with the clinical basis for it, the target symptoms, and the non-drug approaches tried or why they are contraindicated.
- Write PRN psychotropic orders with a duration. For non-antipsychotics beyond 14 days, document the rationale and the specific duration.
- For a PRN antipsychotic, directly examine the resident before each new 14-day order and document need, benefit, and symptom response.
- Re-evaluate hospital-started psychotropics at admission. Do not carry forward a delirium-era antipsychotic or an unsupported psychiatric diagnosis.
- Attempt GDR or document a resident-specific contraindication; record the date, outcome, and future plan. Support any new psychiatric diagnosis with DSM-based documentation.
- Document the risk, benefit, and alternatives discussion and the resident's or representative's decision.

Read the full F605 text

The complete F605 section runs 20 pages: regulation text, intent, definitions, guidance, investigative procedures, deficiency categorization examples, and resources.

- Download the PDF handout, which reproduces F605 from Transmittal 229 as Appendix A.
- Open F605 in CMS Transmittal 229 (PDF page 32).

In the CMS document, red italic text marks language that is new or revised in Rev. 229. The State Operations Manual is a U.S. Government publication and is in the public domain.

Sources

- CMS Transmittal R229SOMA, Revisions to State Operations Manual, Appendix PP (Rev. 229), issued April 25, 2025, implemented April 28, 2025 (PDF). This is the final text of the revised tags: F605 begins on page 32, F756 on 354, and F757 on 368.
- CMS memo QSO-25-14-NH (revised March 10, 2025), with the advance copy of the complete Appendix PP (918 pages); used here for F755, which begins on page 548. A later transmittal, R232SOMA (July 23, 2025), was not reviewed for this summary.
- 42 CFR §483.45, Pharmacy services; §483.12, Freedom from abuse, neglect, and exploitation; §483.10, Resident rights; §483.70, Administration.

The “What the regulation requires” and “What the surveyor guidance says” sections paraphrase CMS text. The “Nursing focus” and “Physician / prescriber focus” boxes are practical teaching points written for this handout and are not CMS language. State requirements, including Colorado 6 CCR 1011-1 Chapter 5, apply in addition to these federal requirements.

Educational summary of CMS SOM Appendix PP (2025 revision). Not a substitute for the source text. Prepared September 2026 by David Shepherd, DO, CMD, DCS Internal Medicine, LLC.